

RECRUITMENT OF BLACK WOMEN WITH TYPE 2 DIABETES INTO A SELF-MANAGEMENT INTERVENTION TRIAL

The purpose of this study was to evaluate the relationship of recruitment methods to enrollment status in Black women with type 2 diabetes screened for entry into a randomized clinical trial (RCT). Using a cross-sectional study design with convenience sampling procedures, data were collected on recruitment methods to which the women responded ($N=236$). Results demonstrated that the RCT had a moderate overall recruitment rate of 46% and achieved only 84% of its projected accrual goal ($N=109$). Chi-square analysis demonstrated that enrollment outcomes varied significantly according to recruitment methods ($P=.05$). Recruitment methods such as community health fairs (77.8%), private practice referrals (75.0%), participant referrals (61.5%), community clinic referrals (44.6%), community advertising and marketing (40.9%), and chart review (40.4%) demonstrated variable enrollment yields. Results confirm previous findings that indicate that Black Americans may be successfully recruited into research studies at moderate rates when traditional recruitment methods are enhanced and integrated with more culturally sensitive methods. Lessons learned are considered. (*Ethn Dis.* 2006;16:956–962)

Key Words: Black Women, Clinical Trial, Recruitment, Sampling, Type 2 Diabetes

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INTRODUCTION

With passage of the National Institutes of Health (NIH) Revitalization Act of 1993, all federally funded research, with limited exceptions, is mandated to include ethnic minority populations. Passage of the NIH Revitalization Act reflected recognition of the scientific importance of including minorities in clinical research in order to decrease escalating rates of morbidity and mortality despite unprecedented advances in medical diagnoses and treatment of diseases. The NIH Revitalization Act generated considerable concern regarding the feasibility of recruiting sufficient numbers of minority participants into clinical studies.

Following enactment of the NIH Revitalization Act, Ness, Nelson, and Kumanyika¹ assessed the actual degree of success in recruiting ethnic minorities vs Whites into clinical studies. The authors performed a meta-analysis, abstracting articles that documented detailed results of participant recruitment for US studies. Findings indicated that the published literature contains insufficient data to determine the presence or absence of differential recruitment rates among varying racial/ethnic populations. A limited number of studies reported data on the ethnic/racial characteristics of potential or screened subjects—data that are essential in calculating recruitment rates.¹

Over the past decade, an increasing number of sampling reports have addressed ethnic minority recruitment into clinical treatment trials, prevention trials, and descriptive studies with

published data on screened and enrolled Black Americans. Review of sampling report data indicate that, for Blacks, recruitment rates into treatment trials may range, for example, from 14%–40%, into prevention trials from 4%–15%, and into descriptive studies from 42%–57%.^{2–10} Indeed, differing study sampling criteria, protocols, incentives, and disincentives likely contribute to these variable figures. However, sampling studies that document a strong reliance on traditional recruitment methods—such as mass mailings, media, and referrals—tended to report lower recruitment rates of Black Americans (4%–19%).^{3–5,7} Studies that reported a more pronounced use of culturally sensitive methods—such as ethnically matched recruiters, community advisory boards, and church endorsements or presentations—tended to demonstrate relatively higher recruitment rates (38%–60%).^{2,6–10} However, while the use of culturally sensitive methods may result in a higher rate of recruitment, they may not translate into attainment of accrual goals. Studies suggest that the use of culturally sensitive methods may not sufficiently increase Black American research participation despite their apparent recruitment efficiency.^{6,11}

The purpose of the study was to evaluate the relationship of recruitment methods to enrollment status in a population of Black American women with type 2 diabetes. With consideration of its projected and actual accrual goals, the present study contributes to the growing sampling literature, detailing the effectiveness of recruitment methods in this understudied population.

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METHODS

The Self-Management Intervention of Education and Care for Black Women with Type 2 Diabetes Mellitus study took place in an urban community in southern New England. The randomized clinical trial (RCT), in partnership with local community health clinics, was implemented to test the effect of a culturally competent intervention designed to empower women with diabetes-related knowledge and skills necessary for effective disease self-management to improve metabolic control and quality of life. The trial randomized eligible participants to experimental or control conditions, which took place over a 10- to 12-week period with a two-year follow-up.

Sampling

The study aimed at enrolling 129 participants. Black women were eligible to participate if they met the study's inclusion criteria of current diabetes treatment from a primary care provider; age 18–65 years; and having a diagnosis of type 2 diabetes. Exclusion criteria were pregnant or lactating; body mass index (BMI) <25 or >36; report of receiving insulin therapy; untreated anxiety, depression, or major psychiatric disorder; comorbidities that would interfere with metabolic indices or completion of the study; serious diabetes-related complications; or participation

in the RCT's pilot study. The exclusion criteria were liberalized because of a slow pace of participant enrollment. Based on preliminary evaluation of recruitment data, exclusion criteria were modified so that potential participants with BMI <46 or receiving insulin therapy in combination with oral anti-diabetic agents, as opposed to insulin therapy alone, would be included.

Recruitment

To achieve the sample of 129, the RCT used a recruitment process consisting of four overlapping components: 1) planning recruitment; 2) initiating recruitment; 3) conducting recruitment; and 4) reviewing progress. Planning recruitment involved establishing a reasonable timeline for sample accrual. Informed by pilot work, an average enrollment goal of 10–15 participants per month over a 12-month period was established. To achieve this goal, barriers to entry into the RCT were considered. Documented in the literature, barriers to ethnic minority participation in clinical trials include lack of awareness, mistrust, economic factors, and communication, among others.^{12–14}

Culturally Competent Recruitment Strategies

Culturally competent approaches that involve the actual integration of consistent behaviors, attitudes, practices, and protocols in the delivery of health care in cross-cultural situations is necessary when working with ethnic minority populations, particularly in the context of recruitment for clinical investigations. Based on this premise, special attention was paid to the context of culture in the development of our recruitment methods. Culturally specific materials were used to supplement generic inclusive materials. The trial partnered with two local community health clinics providing care for a large volume of Black Americans to inform and educate potential enrollees about the study.

Addressing potential distrust of the RCT, dedicated Black research team members were hired for screening and assistance with implementation of the study protocol. The ethnically matched staff, an advisory board representative of community leaders and Black women, provided critical input throughout the recruitment process and study. To minimize possible economic barriers, the two community health clinics were designated as primary screening sites to promote accessibility for potential enrollees. Flexible hours, child care, and transportation or travel reimbursement were provided. Study brochures were designed to be culturally sensitive and reviewed for relevance and appropriateness by the community advisory board. The screening survey, consent form, and study measures were also designed or selected to promote ease of comprehension. Individuals with low literacy levels were provided extended contact time to ensure that they understood written materials.

Recruitment Process and Procedures

Recruitment was formally initiated with the two community health clinics as key resources. Primary modes of recruitment were computerized chart review and community clinic-based referrals. Computerized chart review involved generation of clinical lists with a diagnostic code of diabetes (ICD-250.00) at the community sites. Chart review allowed for identification of potential candidates for enrollment. Potential candidates were contacted by telephone and invited to a face-to-face screening contact. These strategies were employed before the enactment of the Health Insurance Portability and Accountability Act (HIPAA). As a recruitment resource, the health clinics disseminated study-related brochures and provided patient referrals. Direct referrals were facilitated by the delivery of presentations to clinic staff about the study's sampling requirements and protocol.

Conducting recruitment was challenging despite the community-based approach through partnerships with the local health clinics and community advisory board. Recruitment moved slowly, and we did not achieve the monthly accrual goal. In April of 2003, HIPAA was introduced, which eliminated computerized chart review as recruitment method. As a result, recruitment methods were diversified.

Review of the RCT's recruitment progress was ongoing. Bimonthly research team meetings evaluated enrollment yields and considered strategies to enhance recruitment efforts. The community advisory board, community diabetes clinicians, and participants from our pilot study were consulted to assess barriers to and devise strategies for facilitating entry into the RCT. Barriers were identified as lack of current care from a diabetes care provider, use of insulin therapy, elevated BMI, competing life demands of the targeted population, and inadequate community awareness of the trial. To overcome these barriers, exclusion criteria were liberalized (see Sampling), while additional recruitment methods were introduced.

Direct referrals from private medical practices caring for a high volume of the targeted population were solicited. Letters were sent to the medical practices and to pastors involved in the coalition of community Black churches with a detailed description of the study purpose and its sampling requirements along with related brochures. Women participating in the trial were also encouraged to provide referrals, including family members, friends, and/or co-workers.

Moreover, a wide range of community advertising and marketing strategies were introduced, including the use of both mainstream media in addition to more culturally targeted approaches. Reaching a broad audience, the RCT was advertised in the major local newspaper for two days and was

advertised through a local hospital through its advancing care hotline. More ethnic and culturally targeted advertising approaches included mass mailings to local Black churches, providing local Black hair salons with study brochures, and marketing the study on a local Black radio station during a Sunday gospel hour.

To further increase community awareness of the RCT, study personnel participated in community health fairs to inform attendees about the trial. Study personnel participated in health fairs sponsored by local Black churches and the National Association for the Advancement of Colored People (NAACP), among others.

Screening

Screening contacts initially took place at the two community health clinics exclusively. However, as recruitment methods became more diversified, screening contacts were made more flexible by providing additional sites at a university research center, health fair locations (eg, churches), and other accessible sites. Screened women were entered into a tracking registry with identification of the recruitment effort to which they had responded. The tracking registry was periodically evaluated to monitor the productivity of each recruitment method. Those women who were screened and identified as eligible for participation in the RCT were subsequently randomized to either the experimental or control condition.

Data Collection and Screening Measures

A screening self-report survey was administered to all potential participants to obtain data on ethnicity, diabetes diagnosis, pregnancy status, insulin therapy, use of medications, treatment for mental health disorders, and participation in the RCT's pilot study. Categorical data were collected on comorbidities: 1) cancer; 2) multiple sclerosis; 3) hepatitis C; and 4) HIV/

AIDS. Data were collected on mental health disorders and also on diabetes-related complications: 1) amputations; 2) kidney disease; and 3) vision loss from diabetes. Continuous data on age and age at diabetes diagnosis in calendar years were obtained.

Interviewer-observed measures were obtained and recorded by the research associate. Interviewer-observed, continuous measures included weight and height. Weight was measured to the nearest quarter pound by using a standardized balance beam scale. Height was measured in inches, to the closest quarter inch barefoot, with the same standardized scale. Body mass index (BMI) was then computed from weight (kilograms) and height (meters squared).

Based on self-report and interview-observed data, in accordance with the study's sampling criteria, the research associate then recorded data on eligibility and enrollment status for each potential enrollee. Categorical data on recruitment source, as identified by the potential study participant, were also recorded: 1) computerized chart review, 2) community clinic referrals, 3) private practice referrals, 4) community advertising and marketing, 5) community health fairs, and 6) participant referrals.

Data Analysis

Data were double entered, with checks for accuracy, directly into Statistical Analysis Software (SAS, SAS Institute, Cary, NC) for analysis. Univariate statistics were used to describe the screening outcomes, enrolled population, and frequency of exclusion criteria met by those not enrolled. Bivariate statistics were used to compare the sample in terms of enrollment status. More specifically, the sample was dichotomized according to enrollment status (enrolled vs not enrolled) to determine if significant differences existed on recruitment source between the two groups according to the chi-square test.

RESULTS

Descriptive Findings

A total of 236 women were screened; 117 were identified as ineligible, 119 were eligible, and 109 consented to enrollment in the study with subsequent randomization, thereby indicating that the RCT had an overall recruitment rate of 46% and achieved 84% of its projected accrual goal of 129 participants. Enrolled women reported a mean age of 48.5 (SD=9.2) years and a mean age of 44.8 (SD=9.9) years for diabetes onset. Enrolled women also had a mean BMI of 34.3 (SD=6.0), and >10% reported use of insulin therapy (14%) or treatment for anxiety or depression (12%). The most common exclusion criteria met by non-enrolled women were BMI>36 (20%), BMI<25 (1%), insulin therapy (19%), untreated mental health disorder (13%), and age >65 (5%). Less frequently, women were excluded based on serious chronic medical condition (4%), diabetes-related complications (2%), pregnancy (2%), or participation in the RCT's pilot study (2%). Non-enrolled women reported a mean age of 46.7 years (SD=12.2) and 39.2 years (SD=13.2) for diabetes onset.

Recruitment Methods Outcomes

Chi-square tests demonstrated that enrollment and non-enrollment yields significantly varied according to recruitment methods ($P=.05$). Computerized chart review accounted for the largest number of screening contacts (46.0%), generating an enrollment yield of 40.4%. Community clinic referrals likewise resulted in a substantial proportion of screening contacts (29.0%), with a slightly higher enrollment yield of 44.6%. Community advertising and marketing accounted for a 9.8% of screenings while demonstrating a similar recruitment yield at 40.9% (Table 1). Mainstream advertising/marketing—local newspaper and hospital—generated

a low recruitment yield (14.3%). Conversely, culturally targeted advertising—particularly, mass mailings to churches, radio ads during the gospel hour, and brochures to Black salons—demonstrated a high yield (77.7%).

Private practice referrals (5.4%), participant referrals (5.8%), and community health fairs (4.0%) resulted in the smallest numbers of screenings. At the same time, private practice referrals (75.0%), participant referrals (61.5%), and community health fairs (77.8%) demonstrated exceptionally high enrollment yields (Table 1).

DISCUSSION

Limited data exist on recruitment of Black women with diabetes into clinical trials. The present study addressed recruitment of this population into a trial requiring substantial time commitment from study volunteers; however, we were successful in enrolling Black women with diabetes into a clinical trial. Over an almost three-year period, the RCT obtained 84% of its projected accrual goal, with an actual accrual of 109 participants. We cannot determine the actual level of success this accrual yield reflects because we do not have an estimate of the eligible sampling pool in the trial's geographic location to serve as a baseline from which comparisons may be made.¹ Consistent with research trials incorporating culturally sensitive recruitment strategies, the RCT generated a high recruitment yield of 46.2% with the use of diverse recruitment methods, both traditional and more ethnically and culturally sensitive methods.^{2,6-10}

As often reported by studies targeting Black women with or at risk for diabetes, this particular trial attracted the participation of middle-aged women.¹⁵⁻¹⁷ Elevated BMI was the most frequently identified reason for exclusion from the study. The second most common reason was use of insulin therapy, which in addition to diabetes-

related complications, may be related to age of diabetes onset. Relative to their enrolled counterparts, the non-enrolled women reported a lower mean age at diabetes onset, predisposing them to oral antidiabetic treatment failure that necessitated insulin therapy alone and/or diabetes-related complications, particularly in the context of uncontrolled diabetes.¹⁸

Despite redefined exclusion criteria during the recruitment process, elevated BMI and use of insulin therapy accounted for the greatest proportion of the study's sampling exclusions. This finding may be attributed, at least in part, to self-referrals and/or community clinic and private practice referrals that were based on inadequate knowledge of the study's explicit criteria regarding BMIs and insulin therapy.

An untreated mental health disorder was the third most common reason for exclusion. Although women were excluded on the basis of not receiving treatment for a mental health disorder of anxiety or depression, both those enrolled (11%) and not enrolled (12%) reported fairly comparable rates of these mental health disorders, which indicates that >20% of the screened population suffered from anxiety and/or depression. This finding is similar to those of other studies that indicate diabetes populations, including Blacks, tend to have ratios of anxiety and depression at 20%–30%, two to three times higher than in the general population.¹⁹⁻²³ Less frequently, age, diabetes-related complications, comorbidities, pregnancy, and participation in the RCT's pilot study were reasons for exclusion.

Findings indicated that, among the screened population, enrollment status varied significantly according to recruitment method. Computerized chart review accounted for the greatest proportion of screening contacts but had a lower enrollment yield than other methods. In use for ≈50% of the recruitment process because of the introduction of HIPAA guidelines,

Table 1. Chi-square analysis enrollment status and recruitment methods*

Enrollment	Enrolled/Randomized	Not Enrolled	Total Screened	P†
Recruitment Methods	n=119 Frequency (Percentage)	n=117 Frequency (Percentage)	N=236 Frequency (Percentage)	.05
Chart review	n=41 (40.4%)	n=62 (60.1%)	n=103 (46.0%)	
Community clinics	n=29 (44.6%)	n=36 (55.4%)	n=65 (29.0%)	
Private practices	n=9 (75.0%)	n=3 (25.0%)	n=12 (5.4%)	
Community advertising	n=9 (40.9%)	n=13 (59.0%)	n=22 (9.8%)	
Community fairs	n=7 (77.8%)	n=2 (22.2%)	n=9 (4.0%)	
Participant referrals	n=8 (61.5%)	n=5 (38.4%)	n=12 (5.8%)	

* Numbers may not equal 236 because of missing data; percentages may not equal 100% because of rounding.

† P value for chi-square test.

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computerized chart review proved to be a productive recruitment method, despite its high yield of ineligible women, as it provided easy access to the greatest number of potential enrollees. The African American Study of Kidney Disease and Hypertension pilot study (N=97) similarly reported clinic-based chart review as a successful method of recruitment that yielded the study's greatest number of randomizations.³

Community clinic referrals generated the second highest number of screening contacts. Private practice referrals, although producing a relatively smaller number of screening contacts, yielded a high ratio of enrolled women. The literature indicates that private practice referrals demonstrate varying levels of success across studies.^{2,3,8,24} Reports suggest that healthcare providers may feel uncomfortable introducing studies to their patients and, by extension, generating study referrals.^{25,26} However, data indicate that Blacks may be more likely to enroll in a research program if it is recommended by their

healthcare provider.²⁷⁻³⁰ In the current study, specific efforts such as clinic presentations were made to increase clinician knowledge of the RCT to enhance comfort or confidence in presenting the trial to potential participants. These factors likely facilitated the enrollment yields from community clinic and private practice referrals.

Although generating a greater number of screening contacts than private practice referrals, community advertising and marketing demonstrated a lower enrollment yield. Further analysis of community advertising and marketing strategies indicated that more mainstream media (newspaper and hospital) approaches were considerably less effective than culturally targeted approaches (Black American salons, radio, and mass mailings to churches). Mainstream media is a frequently used method of recruitment and has varying levels of effectiveness reported in the sampling literature.^{2-4,9,31} More ethnically targeted marketing strategies are reported as being particularly effective in recruiting Blacks into research studies.^{2,5,10}

Participant referrals, followed by community health fairs, produced the smallest numbers of screening contacts but produced relatively high rates of enrollment. The sampling literature reports that both participant referrals and community-based health fairs may be highly productive methods for recruiting Black study participants.^{2,5,9,31} As a method of participant recruitment,

community health fairs—including those sponsored by the NAACP and local churches—were introduced during the latter portion of the recruitment process, after the introduction of HIPAA guidelines. Community health fairs or diabetes screenings sponsored or supported by Black churches or organizations such as the NAACP may help alleviate any concern about enrolling in a research trial. Past experiences in clinical research trials, such as the Tuskegee Trial, continue to cause suspicion in the minds of ethnic minority individuals, particularly Black Americans. The NIH reported that from 1997 to 2001, the number of ethnic minorities volunteering for clinical research trials decreased from 41.3% to 29.5%, which underscores the need to employ multiple strategies in order to reach the given target population.³²

LIMITATIONS

The clinical trial described in this paper considered multiple barriers for participation when developing recruitment procedures, such as lack of awareness, mistrust, economic factors, and communication. While conducting recruitment, these barriers were addressed, integrating traditional recruitment methods with more culturally sensitive methods. Ongoing review of recruitment progress informed liber-

alization of exclusion criteria, diversification of recruitment methods, and extension of the recruitment period. As the result, the RCT demonstrated a high overall recruitment rate of 46.2%. Still, the RCT achieved only 84% of its projected accrual goal.

Sampling limitations may have contributed to the RCT's inability to achieve the projected accrual goal. Exclusion criteria, particularly an elevated BMI, may have limited inclusion of otherwise eligible women. As previously discussed, exclusion criteria were modified to enhance enrollment, which suggests that future studies that sample Black women with diabetes may consider including those women who are severely obese and/or require insulin therapy alone for diabetes management. These factors must be accounted for and factored into sample size calculations to ensure adequate power when controlling for their effect on outcome variable(s).

Additionally, the recruitment screening survey did not measure socioeconomic status with indices of income, educational status, marital status, and other demographic variables. Such data may have provided insight on sampling bias and may have informed further diversification of recruitment methods to reach untapped or underrepresented segments of the targeted population.

During the first year of recruitment, computerized chart review and clinic-based referrals served as the primary methods of recruitment. Because of the slow pace of enrollment as well as effective introduction of HIPAA guidelines, a pronounced focus was placed on varying recruitment methods, such as private practice referrals, community health fairs, and community advertising/marketing targeting Black women with diabetes. These methods demonstrated exceptional efficiency in terms of recruitment yields. A greater reliance on these methods from the initiation of the recruitment process may have generated a higher overall accrual yield.

CONCLUSION

Findings from the present sampling study demonstrate that Black women with diabetes may be recruited into clinical trials when multiple and culturally sensitive strategies are employed. Findings further indicate that integrating traditional with culturally sensitive recruitment methods is an effective strategy for enrolling this population and results in a high overall recruitment ratio. In particular, community clinic and private practice referrals appear to be productive traditional methods, especially when referring clinicians have been well informed about the study. More culturally targeted methods, such as community health fairs, participant referrals, and advertising/marketing aimed at reaching Blacks, also demonstrate high recruitment yields.

Future sampling studies, involving qualitative and/or quantitative methods, targeting Black women with diabetes are indicated. Little qualitative research has addressed Black women's willingness to participate in clinical trials, and even less research addresses those women with diabetes. Additional quantitative sampling research targeting this population is also needed to validate the present findings. Moreover, little is known quantitatively about the costs associated with recruitment of this ethnic minority population. Although several studies indicate that the use of culturally sensitive recruitment methods are costly, both in terms of staff and time, systematic cost-analyses of recruitment methods have not been conducted and warrant investigation.

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