

RECRUITMENT AND ENROLLMENT OF AFRICAN AMERICANS AND CAUCASIANS IN A HEALTH PROMOTION TRIAL FOR PERSONS WITH SERIOUS MENTAL ILLNESS

African Americans with serious mental illness (SMI) continue to experience inadequate representation in clinical trials. Persons with SMI, regardless of race, have an increased burden of all cardiovascular disease (CVD) risk factors including obesity, hypertension, diabetes mellitus, dyslipidemia, metabolic syndrome and tobacco smoking. Having SMI and being African American, however, is each associated with an increased risk of CVD mortality compared to the general population. There is a critical need, therefore, to adapt health promotion interventions for African Americans with SMI. We sought to examine overall recruitment into a randomized clinical trial of CVD prevention among persons with SMI, and to examine racial differences in interest, enrollment, and potential barriers to participation. Although similar levels of interest in participation were seen between African Americans and Caucasians in signing screening consent, 9.6% fewer African Americans enrolled due to inability to complete initial data collection. Further work is needed to better understand the nature of the barriers encountered by African Americans with SMI who otherwise may be interested in participating within clinical trials. (*Ethn Dis.* 2015;25[1]:72–77)

Key Words: Recruitment, African Americans, Serious Mental Illness, Cardiovascular Disease, Clinical Trial

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INTRODUCTION

African Americans and individuals with serious mental illness (SMI) are populations that continue to experience inadequate representation in clinical trials.¹ Studies that target increased African American recruitment are most common among cancer clinical trials followed by those that examine recruitment in trials of cardiovascular disease (CVD) and diabetes.^{2–5} Few studies, however, have examined enrollment of African Americans into clinical trials of interventions for patients with SMI or substance use disorders.⁶ Although African Americans have similar rates of mental illness as Caucasians, nearly 60% do not receive needed care.⁷ Greater stigma associated with mental illness in this community and overall poor access to health care often leads to misdiagnosis, higher rates of untreated mental illness, and higher rates of hospitalizations.⁸

Persons with SMI such as schizophrenia and bipolar disorder also have an increased burden of all CVD risk factors including obesity, hypertension, diabetes mellitus, dyslipidemia, metabolic syndrome and cigarette smoking.^{9,10} Although African Americans and Caucasians have similar CVD risk, having SMI and being African American are each,

separately, associated with increased risk of CVD mortality compared to the general population.^{11,12} Recruiting persons with SMI into a CVD prevention trial, and specifically enrolling African Americans with SMI into such a trial, therefore, could be critical in improving CVD health outcomes.

Health promotion interventions to improve CVD risk factors have shown to be effective in the general population.^{13–21} However, the vast majority of clinical trials of interventions to reduce CVD risk systematically exclude individuals with SMI.⁶ There is a critical need to adapt health promotion interventions for a population with SMI, especially African Americans, who face lower socioeconomic status with resultant decreased access to healthy foods and pharmacotherapy regimens that are often unsustainable and exacerbate weight gain.¹⁰ Most of the few health promotion trials to reduce CVD risk factors conducted in persons with SMI have been limited by short study periods as well as small sample sizes and little is known regarding the interest, enrollment and potential barriers to enrollment experienced by African Americans with SMI.^{22,23}

We sought to examine overall recruitment into a trial of CVD prevention among persons with SMI, and to examine racial differences in interest, enrollment, and potential barriers to participation in a large randomized clinical trial of a behavioral weight loss intervention targeted to adults with SMI. Participant recruitment for this health promotion trial was focused on

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psychiatric rehabilitation programs (PRPs). As all PRP attendees were known, the denominator of potential trial participants could be established. Thus, we had the unique opportunity to assess potential participant interest in the trial and trial enrollment by race.

METHODS

The ACHIEVE Trial was a randomized clinical trial of an 18-month behavioral weight loss intervention in adults with SMI.²⁴ The study population consisted of overweight or obese attendees aged ≥ 18 years in one of 10 PRPs in Maryland. The programs serve individuals with SMI and offer skills training, case management and other services. Enrollees often attend multiple times per week. Trial eligibility criteria were minimal and aimed to enroll a broad SMI population. We excluded participants with a medical contraindication to weight loss, cardiovascular events within 6 months, impaired mobility, or inability to complete data collection. Before trial recruitment, investigators obtained oral consent for pre-screening of weight eligibility and measured height and weight on program attendees to assess overweight and obesity prevalence. Race was self-reported. Institutional Review

Boards at Johns Hopkins University and Sheppard Pratt Health System and an independent data safety and monitoring board approved the trial. Attendees receiving only BMI measurements provided oral consent; screened and enrolled participants provided written informed consent. Participants were recruited from September 2008 through February 2011.

Trial Recruitment Strategy

After BMI measurements for pre-screening for weight eligibility were completed, recruitment occurred with direct consumer contact with study staff. Presentations were given to both consumers and PRP staff and included the exercise component of the intervention. Study staff was available to answer questions and discuss the study. Study fliers and brochures, written to meet the low literacy criterion of grade 5 level of readability, were distributed. To promote representative enrollment, the brochure included images of individuals of diverse backgrounds. Study recruiters similarly represented a diverse ethnic background. The recruitment aim was to have 40% of study participants be African American.

Interested participants signed consent for screening. Data collection visits included measurement of fasting lipids and glucose, blood pressure, waist circumference, cycle ergometry and standardized questionnaires for mental and physical health status. These visits were conducted over several weeks between screening and enrollment. Once baseline data collection was completed and eligibility was assured, participants signed enrollment consent and were randomized to the active or control arms.

Statistical Analysis

We compared the proportion of African Americans and Caucasians among PRP consumers who met study weight criteria ($BMI \geq 25$ mg/kg²). We similarly compared the proportion signing screening consent and the proportion enrolling. For each race, we further stratified the analysis by sex and age. We also compared

reasons for exclusion after signing screening consent between African Americans and Caucasians. Bivariate analysis was performed using chi-square tests.

RESULTS

Nine hundred individuals gave oral consent to be weighed. Of these, 57 were neither African-American nor Caucasian and were excluded from this analysis. There was no significant difference between African Americans and Caucasians in the proportion with an eligible BMI of ≥ 25 kg/m² (322/379 and 396/464, respectively, both 85%) (Table 1).

We next evaluated the number in each race group that signed the screening consent first as a proportion of the total population and also as a proportion of those with an eligible BMI. No significant differences were noted in the proportions of consent for screening between African Americans (46% overall and 54% with BMI ≥ 25) and Caucasians (48% overall and 56% with BMI ≥ 25).

We then examined those in each race group that were enrolled and randomized first as a proportion of the total population and next as a proportion of those who signed screening consents. There was no significant difference in the proportion of the total population that enrolled and was randomized (African Americans 29%, Caucasians 35%); however, there was a significant difference in the proportion of individuals with screening consents who signed randomization consents ($P < .05$) with 64.2% of African Americans enrolling in the trial compared to 73.8% of Caucasians. We also noted a significantly lower proportion of African Americans age 36–50 enrolled, 29.2% as compared to 39.1% Caucasians ($P < .05$).

We next examined reasons for exclusion after signing screening consent. A total of 173 African Americans

Table 1. Eligibility, interest and enrollment of African Americans vs Caucasians in a behavioral weight loss clinical trial

	African Americans					Caucasians				
	Total	Males	Age			Total	Males	Age		
			18-35	36-50	>50			18-35	36-50	>50
Population, <i>n</i>	379	230	76	185	118	464	274	76	174	214
BMI ≥25, <i>n</i>	322	189	64	159	99	396	234	61	159	176
% with BMI ≥25	85.0	82.2	84.2	85.9	83.9	85.3	85.4	80.3	91.4	82.2
Signed screening consent, <i>n</i>	173	91	34	86	53	221	114	40	92	89
% of total population who signed screening consents	45.6	39.6	44.7	46.5	44.9	47.6	41.6	52.6	52.8	41.6
% with BMI ≥25 who signed screening consents	53.7	48.1	53.1	54.1	53.5	55.8	48.7	65.6	57.8	50.6
Randomized, <i>n</i>	111	55	23	54	34	163	81	31	68	64
% of total population who were randomized	29.3	23.9	30.3	29.2 ^a	28.8	35.1	29.6	40.8	39.1 ^a	29.9
% of those who signed screening consents who were randomized	64.2 ^b	60.4	67.7	62.8	64.2	73.8 ^b	71.1	77.5	73.9	71.9

^a *P*<.05, compares the proportion of the total population of African Americans versus Caucasians aged 36-50 who were randomized.

^b *P*<.05, compares the proportion of African Americans versus Caucasians who signed screening consents who were then randomized.

and 221 Caucasians signed screening consents after which, 62 African Americans (35.8%) and 58 Caucasians (26%) were excluded. Of these, 23% of African Americans vs 40% of Caucasians declined to participate (*P*<.05). A further 65% of African Americans vs 36% of Caucasians were excluded due to inability to complete the initial data collection (*P*<.01), commonly due to absences. In addition, 5% of African Americans versus 14% of Caucasians were excluded due to a medical contraindication (*P*<.01).

We explored lack of regular attendance at the rehabilitation programs as a reason for not enrolling in the trial after signing screening consent. Of the 15 African Americans with attendance at the rehabilitation program as a main reason for not being able to complete data collection and enroll in the study, four had disenrolled from the rehabilitation program during study screening, two had health reasons that were not medical exclusions for the study but prevented them from attending regularly (eg, chronic pain), and one became homeless and was not able to attend the rehabilitation center. In contrast, 9 Caucasians had attendance issues as a main reason for not enrolling in the

study, with one disenrolling from the psychiatric rehabilitation program during study screening.

DISCUSSION

In this clinical trial of a behavioral weight loss intervention at PRPs across Maryland, although similar levels of interest in participation were seen between African Americans and Caucasians in signing screening consent, 9.6% fewer African Americans enrolled. When reasons for not enrolling were examined, a higher proportion of Caucasians declined to participate due to lack of interest. A higher proportion of African Americans, however, were excluded from enrollment due to an inability to complete data collection. While the trial did not have a formal run-in period, the process of data collection over several weeks served this purpose and inconsistent attendance often resulted in more African Americans being excluded.⁸

Little research describes optimal recruitment strategies in populations with SMI, particularly African Americans. One prior study showed no significant differences between African

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Americans and Caucasians with SMI in enrolling in a community based trial to assist patients in managing physical health conditions.⁶ Lower rates of attendance at PRPs during data collection among African Americans in this study may reflect lower mental health treatment participation in this population, which has been attributed to several factors including patient preferences for treatment engagement and type of treatment, and cultural insensitivity among health professionals and institutions.²⁵⁻²⁹ In addition, the legacy of discriminatory treatment in clinical research is well known, and previous

research in the general population shows lower levels of trust in research by minorities.^{25,26} Although fewer African Americans than Caucasians specifically declined enrollment in the trial after screening consent, lack of attendance at the rehabilitation program, requisite to complete screening visits, could be consistent with disinterest in the study.

Our study has some limitations. First, the study took place in PRPs; these results may not be generalizable to all SMI populations. Second, while detailed sociodemographic data was collected for trial enrollees, this was unavailable for those who only provided oral consent for BMI. However, we do know that the vast majority of PRP attendees have Medicaid, which reduces the likelihood of confounding of our results by insurance coverage.³⁰ Third, the analysis was funded by a NIMH Request for Applications for competitive supplements of existing studies, and was awarded after study enrollment had already occurred. While we used recruitment techniques with demonstrated acceptability in other trials, we were unable to systematically collect data on impressions regarding cultural sensitivity on those who did and did not enroll in this trial, or examine how minority recruitment may have been impacted by our recruitment strategies. We were similarly limited in our ability to describe in depth reasons underlying individual participant behavior related to not enrolling in the study such as irregular attendance at the PRPs. Furthermore, although we endeavored to enhance the cultural sensitivity of the trial for African Americans, we addressed only what previous researchers refer to as surface structures, by using diverse staff, face to face recruitment, in person presentations and materials reflecting diverse images.³¹ Experts have suggested that to achieve true cultural sensitivity, it is necessary to incorporate deep structures such as the cultural, historical, and political factors that have shaped the beliefs of the targeted

population, in recruitment methods and materials, to motivate behavior such as trial enrollment.^{1,31}

An understanding of factors that impact differential recruitment and enrollment by race among a population with SMI is critical in designing successful health promotion interventions that can be implemented into practice for this vulnerable population. African Americans face significant barriers to participation in trials along the continuum from awareness to acceptance. For example, studies of barriers to full participation in research by ethnic minorities suggest that a variety of participant, research, institutional and funder characteristics may contribute to participation.³²⁻³⁴ Research characteristics such as study design and intervention factors interact with participants' backgrounds, including sociodemographic characteristics, cultural and health beliefs and prior experiences in health care. These in turn contribute to an individual's awareness of a trial, and in combination with opportunity, encompass the key determinants of participation.^{35,36}

Our study presented a unique opportunity. Given that the denominator of eligible PRP participants was known, we were able to examine study interest through the proportion of potential participants signing screening consent. Further, the large study sample of African Americans and Caucasians allowed for documentation of reasons for exclusion at enrollment. While trial interest was equivalent by race, disparities in enrollment remained. Potential barriers related to awareness and opportunities, such as age and health status, were not significant factors. Study recruiters were from diverse backgrounds, which likely minimized study-related barriers.³⁷ The lack of resources directed towards PRPs predominantly attended by African Americans further underscores the challenges faced by this group in accessing appropriate care.³⁸ In addition, unmeasured deep structures may not have been adequately addressed and

whether participants of both races felt similarly comfortable with staff members based on perceived similarity in other domains (eg, shared experiences with SMI, familiarity with other issues faced by participants) is unknown. Thus, it is unclear whether cultural barriers played a role in lower data completion rates among African Americans.

Health care organizational factors can impact disparities between African Americans and Caucasians in treatment quality and may have contributed to differentials in regular attendance and ability to successfully enroll participants in this study. Health organization location, resources, staff and staff turnover all have been shown to be related to quality of care.³⁹⁻⁴⁵ Two study sites served primarily African Americans and contributed almost half of the African Americans who were screened but unable to complete data collection for the trial. These locations were noted to be particularly under-resourced with a large number of ongoing mental health and addiction treatment programs in addition to the psychiatric rehabilitation program, and hundreds of individuals on site at any given time. The number of staff may have been inadequate to serve all attendees' needs. This environment may have contributed to less regular attendance for mental health consumers at the psychiatric rehabilitation program.

Our study is one of the first to describe recruitment and enrollment by race in a health promotion clinical trial for a population with SMI. Given the high mortality associated with CVD-related risk factors among African Americans with SMI, modification of these risk factors long term requires adequate enrollment of this group in health promotion trials to enable the design of sustainable interventions. Our study demonstrates that 9.6% fewer African Americans with SMI enrolled, not because of a lack of initial willingness to participate in the trial, but because of additional barriers leading

to difficulty completing data collection. This has important implications for future health promotion trials in addressing recruitment and enrollment among this vulnerable group. Continued evaluation within health promotion trials is needed to characterize the prevalence of racial disparities in awareness, opportunity, and participation among persons with SMI. Further efforts are also needed to more fully understand the nature of the challenges encountered by African Americans with SMI who otherwise may be interested in participating in clinical trials, including barriers to participating in regular treatment and health care organizational factors.

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