Recruitment of Obese Black Women Into a Physical Activity and Nutrition Intervention Trial

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Background: Despite the increased health risks for obese Black women, relatively little research has explored physical activity and nutrition interventions for these women. This article describes the recruitment strategies used in a program designed specifically for obese Black women. Methods: Recruitment of Black women age 30 to 65 years with body mass indices between 30 kg/m² and 50 kg/m² was completed using in-person recruitment and flyers within 2 miles of the intervention site along with mass e-mails within the sponsoring university system. Medical clearance from a physician was an eligibility requirement because of Institutional Review Board safety concerns. Results: Of the 690 women who were screened, 213 (31%) were eligible and randomized. The most common reason for exclusion was failure to return a medical clearance form (n = 167, 39% of ineligible). Different rates of efficiency were noted across recruitment approaches. Conclusions: Black women were successfully recruited using in-person community recruitment, e-mail, and community flyers within close proximity to the intervention site. Careful consideration should be given to the advantages and disadvantages of various recruitment strategies that might not generalize across studies.

Keywords: minority, recruitment, physical activity, health promotion

Increased efforts have recently been put forth to enhance the representation of historically underserved subgroups of the US population in research studies.1 This has been driven partly by regulatory changes that now require an increase in minority participation in clinical trials.2,3 In 1993, the National Institutes of Health (NIH) Revitalization Act mandated that minorities be included in randomized trials.4 In this act, underrepresented minorities were defined as African Americans, Latinos, and American Indians. Nonetheless, in a recent review of the obesity treatment literature conducted on behalf of the US Preventive Services Task Force, more than 75% of the studies did not report an ethnic breakdown or failed to recruit a substantial number of Black participants.5 In addition, in a recent overview of the literature assessing the effects of diet and physical activity on weight and fitness, 86% of the 231 articles reviewed did not report the ethnic composition...
of the samples.\textsuperscript{6} Thus, it is difficult to assess how the recruitment of various ethnic minorities into a study might be impacted by recruitment strategies.

Considering that approximately 50\% of Black women are obese, weight loss and maintenance programs that effectively target Black women are warranted.\textsuperscript{7} More generally, there is a need for an increased understanding of the complex factors that influence physical activity and the overall health status of Black women. Creating an energy imbalance whereby a woman’s energy expenditure exceeds her energy intake might require specialized attention to cognitive, psychological, spiritual, and/or cultural factors.\textsuperscript{8–10} It has been difficult to study these factors because ethnic minorities are less likely than Whites to participate in health risk reduction research.\textsuperscript{11}

The purpose of this article is to describe the methods used in recruiting Black women into the Obesity Reduction Black Intervention Trial (ORBIT) and final yield of participants. Although virtually all of the physical activity and nutrition weight loss intervention trials with Black women have included obese women, to our knowledge ORBIT is the first weight loss and maintenance intervention that includes only obese Black women.\textsuperscript{12–17}

\section*{Methods}

\subsection*{Intervention Group}

ORBIT is a randomized controlled trial of a culturally adapted 6-month physical activity and nutrition weight loss intervention followed by a 1-year weight loss maintenance intervention in a sample of 213 Black women between the ages of 30 and 65 years with a body mass index (BMI) between 30 kg/m\textsuperscript{2} and 50 kg/m\textsuperscript{2}. The physical activity and nutrition weight loss period for the intervention group is conducted in small groups that meet twice weekly on a university campus. Each week, 1 weekly 90-minute meeting consists of a weigh-in, a didactic health education session, and a physical activity session. The health education topics address the broad areas of preventive health, physical activity, nutrition, food label reading, self-monitoring, lifestyle change, barriers to change, culturally specific barriers to behavior change, social support, and breast cancer. A dietician presents all classes related to nutrition such as energy balance, portion control, label reading, food self-monitoring, recommendations for fruits and vegetables, and physical activity guidelines among other topics. Individualized guidance for adopting a low-fat, high-fiber diet with increased fruit and vegetable consumption is offered based on food diaries in one-to-one meetings. Additional focus on the importance of physical activity and group discussion of successes and challenges are facilitated by a group leader with experience in physical fitness and motivational interviewing. The 30- to 40-minute educational session is followed by group physical activity with a certified exercise specialist. The second weekly meeting includes 40 minutes of physical activity and 20 minutes of discussion on increasing regular physical activity. Exercise specialists lead all the group physical activity sessions, which incorporate aerobic activity along with strength and flexibility training. To increase the cultural acceptability of the physical activity, Black exercise specialists are used as much as possible and a range of aerobic activities are offered to expose women to diverse types of physical activity. The aerobic activities include
traditional dance aerobics, salsa dancing, African dancing, belly dancing, yoga, and Pilates. Water-based aerobics has been added at the women’s request. In addition to the 2 weekly classes, opportunities to exercise on weekends with the group leader are offered to women. Activities include participating in a local breast cancer walk, walking to a museum with an African-themed exhibit, and gymnasium machine-based activity in the university facility. Physical activity monitoring forms are returned weekly. Women are expected to exercise at least 1 additional day of the week for 30 minutes and/or increase their walking to reach the recommended 10,000 steps per day. Pedometers are provided.

**Control Group**

The control group receives a general health newsletter once a week during the 6 months of the research period that coincides with the active weight loss period for the intervention group. During the 1-year maintenance period in the intervention group, the control group receives a general health newsletter monthly. The newsletters cover general health issues and safety topics relevant to adult women. At the end of the study, all control participants will receive the 6-month health education curriculum used in the intervention group, a pedometer, and a total of 6 weekly group sessions with an exercise specialist.

The primary research outcomes of weight change, weight maintenance, energy intake, and energy expenditure will be addressed in future manuscripts given that the trial is currently ongoing. Full Institutional Review Board (IRB) approval was obtained from the University of Illinois at Chicago where the study is being conducted. Women were eligible only if they passed the screening and were medically cleared by their physician. The IRB stipulated that a written physician’s approval was necessary for eligibility in the research study.

**Recruitment Procedure**

The success of ORBIT initially relied on the recruitment and randomization of Black women who met the inclusion criteria (Table 1) and then participated in a 6-month physical activity and nutrition weight loss intervention followed by a 1-year weight loss maintenance intervention.

A sample size of 200 was determined by conducting a power analysis with 0.90 power to detect a difference of 1.1 to 1.25 kg/m² change in BMI between the intervention and control groups at 18 months, assuming a 2-sided test at the 5% level. This standard deviation of change in BMI was based on the results of a pilot intervention for this larger project.¹⁸

Ultimately, 213 women between the ages of 30 and 65 years were recruited in 2 cohorts. Recruitment for cohort 1 began May 2005 and ended August 2005. Recruitment for cohort 2 began in July 2006 and ended in September 2006. During each recruitment period (ie, 4 months for cohort 1 and 3 months for cohort 2), an average of 20 hours each week was committed to recruitment out in the community. Four research assistants with extensive experience conducting community- and minority-based health studies conducted the recruitment typically in 2-hour intervals at different times of the day and on different weekdays. Research assistants recruited potential participants with flyers using several active and passive techniques.¹⁹
Active and Passive Recruitment Approaches

Active recruitment involves direct contact between study staff and potential participants. ORBIT recruiters approached women that they encountered who appeared to meet the inclusion criteria (ie, appeared to be Black, overweight, not obviously pregnant) to offer them a flyer that explained the study. In this process, recruiters explained all of the inclusion and exclusion criteria. In many cases, women took the flyer but did not stop to talk at length. The flyer was designed with feedback from the targeted audience and included a colorful logo of a large Black woman exercising. Materials clearly stated that the study was a weight loss research project specifically developed for African American or Black women. Aside from stating that the program was for weight loss, no details on BMI were listed because we have found in previous research that women do not know their BMI. Recruiters were prepared to screen women for initial eligibility at the time of contact based on their self-reported height and weight; however, most potential participants preferred a reactive response, which involved taking a flyer and contacting the study coordinator at a later date by telephone.

Recruiters systematically canvassed a 2-square-mile area centered on the intervention site by car and on foot. Within this specified area, recruiters went door to door, approaching businesses, stores, healthcare facilities, parking structures, churches, and local colleges to gain permission to recruit on-site. In many cases, follow-up telephone calls or repeated visits were required before the recruiters could identify the proper procedures for gaining approval to recruit. In other cases, recruiters stood on public space where foot traffic was heavy and no prior approval was required such as near hospital parking structures, bus stops, etc. Active recruitment was limited at some locations because recruiters were not able

<table>
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<tr>
<th>Inclusion criteria</th>
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<tr>
<td>• African American/Black (self-identified)</td>
<td>• Planning to move out of the area during the course of the study</td>
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<tr>
<td>• Female</td>
<td>• Pregnant, nursing, or planning a pregnancy</td>
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<td>• Age 30–65 y</td>
<td>• Consumes more than 2 alcoholic drinks per day on a daily basis</td>
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<td>• Body mass index 30–50 kg/m²</td>
<td>• Currently using illegal drugs</td>
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<td>• Able to participate in a program that requires 30 min of uninterrupted walking or ongoing activity</td>
<td>• Treated for cancer in the past 5 y, excluding skin cancer other than melanoma</td>
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<td>• Able to attend classes at scheduled times</td>
<td>• Unable to exercise because of emphysema, chronic bronchitis, or asthma</td>
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<tr>
<td>• Returned medical approval form signed by physician</td>
<td>• Uses a cane, walker, wheelchair, or other device to move around (cohort 2 only)</td>
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<td></td>
<td>• Taking weight loss medications prescribed by a doctor</td>
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to obtain permission to approach women on the premises. For example, large stores typically did not allow recruiters inside the store or near the entry/exit locations. Within healthcare settings and colleges/universities, recruiters were more likely to be allowed to set up a table in heavily trafficked areas such as the cafeteria. Within neighborhood churches, the recruiters met with church administrators to explain the research and answer questions. Subsequently, the church administrators recruited members of the church by handing out brochures and verbally endorsing the study.

Passive recruitment refers to approaches that prompt the potential participant to contact project staff without having direct contact with them. Strategies used in this study included sending mass e-mail announcements within the University of Illinois at Chicago (UIC) campus and placing flyers in high traffic areas within the community recruitment area. The e-mail distribution reached approximately 36,000 faculty, staff, and students of whom most were not eligible. The flyer was distributed by e-mail 3 times during the study—once for cohort 1 and twice for cohort 2. Barber shops, nail salons, beauty shops, dry cleaners, restaurants, and a community college were examples of locations where brochures were left for women to pick up. Recruiters periodically returned to these locations and replenished the stack of flyers.

A total of 5000 flyers were distributed during the entire project. Approximately 40% of the flyers were passed out directly to potential participants and 60% were placed in community locations.

**Screening Process and Eligibility Criteria**

Women were screened for inclusion and exclusion criteria as shown in Table 1. Medical clearance was required by the university IRB based on the potential health risk involved in having sedentary women initiate physical activity without a physician’s approval. Potential participants were asked to obtain a physician’s medical clearance to exercise only if they met all other criteria. The physician was asked to sign the medical form and indicate whether the woman was “healthy enough to participate in a diet and physical activity program designed to produce weight loss.” To facilitate this process, study staff offered to fax a copy of the form to the woman’s physician if the woman provided a fax number and notified the physician. In addition, study staff made follow-up telephone calls to physicians’ offices when a woman reported that she had dropped off the form. Women provided written informed consent when they arrived for the baseline interview. Randomization was conducted following the baseline interview.

**Results**

A total of 690 women were screened for participation. At the time of screening, the mode of recruitment was assessed by asking, “How did you learn about the program?” Of the women who provided a response, 312 (45.8%) learned about the research from a brochure, which was either handed to them by a research assistant or picked up from a community location. Another 189 (27.8%) learned
about the study from a family member or friend who shared information with them, and 180 (26.4%) responded to mass e-mails sent throughout the university system.

As shown in Figure 1, 690 women were screened for participation. Of those, 208 (30%) were identified as ineligible, and no medical clearance was requested. Four hundred eighty-two women were asked to obtain medical clearance. However, 216 (45%) of those 482 women were ineligible for various reasons (see Figure 1 for details); as a result, 424 (61%) of the 690 women screened were ineligible. The most common exclusion factor was the requirement to obtain medical clearance from a physician, accounting for 167 (39%) ineligible women. Seven women (2%) had significant health problems, leading their physicians to decline medical release. After obtaining medical release, 6 additional women were excluded as a result of worsening health while waiting for the study to begin. The second most common exclusion factor was having a BMI outside the range of 30 to 50 kg/m². In addition to the 130 (31%) who reported an out-of-range BMI over the telephone, an additional 14 were found to be outside the range when they were measured in person at the baseline interview. Twelve of these women had a BMI $> 50$ kg/m², and 2 had a BMI $< 30$ kg/m².

A $2 \times 3$ chi-square analysis was conducted grouping the 206 women who were ineligible without any request for medical clearance against the remainder of the sample by mode of recruitment. There was a statistically significant relationship ($P < .05$) between the respondent’s eligibility status after the telephone screening and mode of recruitment. Among e-mail responders, 37% were ineligible after the telephone screening; among brochure responders, 28% were ineligible; and among those referred by family or friends, 26% were ineligible.

For women who passed the telephone screening, a second chi-square analysis was conducted to determine if ability to obtain a medical clearance form was related to mode of recruitment. This $2 \times 3$ analysis was statistically significant ($P < .05$), revealing that 61% of women recruited by e-mail returned a medical clearance form, as did 60% of women referred by family members or friends. However, only 49% of women responding to brochures returned a medical clearance form.

Two hundred thirteen women were randomized, representing 31% of the 690 women who were screened. There was no statistically significant difference ($P = .06$) in the percentage of women who were randomized by mode of recruitment. Overall, 31% of 180 women who responded to the e-mail were randomized, compared with 37% of the 189 who learned of the study from family members or friends and 27% of the 312 women who responded to a brochure (Table 2). Of the 210 randomized women from whom recruitment data were collected, there was a statistically significant ($P < .05$) difference in mode of recruitment, with 56 (27%) recruited by e-mail, 70 (33%) through referrals from friends and a family member, and 84 (40%) through brochures. The demographic characteristics of the sample are shown in Table 3. Although 22% of the sample reported an income less than $25,000, most of the sample came from a middle socioeconomic background. As such, ORBIT is slightly different from much of the research on weight loss in Black women, which has tended to focus on lower income women.$^{21,22}$
Figure 1 — Study design of the ORBIT project and participant flow through randomization.
Although previous randomized controlled trials have addressed health promotion and weight loss/maintenance among Black women, ORBIT is distinguished in 2 ways. Only obese Black women were included in the study, and the physical activity intervention slowly conditioned obese women to tolerate moderately intense physical activity. Most weight loss research to date has mixed women with various body sizes or used low-intensity activities such as walking programs. As noted by Yancey, overweight Black women might be
hesitant to join physical activity programs unless they have assurance that the program will work for “women of their size.” Similarly, obese women might hesitate to engage in more intense physical activity programs. These concerns might have prevented some obese women from participating in previous research.

ORB1T was successful in randomizing 213 of 690 (31%) women who were screened. Recruitment goals were met using several strategies. Mixed recruitment approaches yielded different rates of efficiency and important insights for future research.

The ORBIT flyers were designed with assistance from our targeted audience, despite the fact that research on tailoring recruitment flyers has been mixed. For example, the Women’s Health Initiative showed that recruitment yields for Latina and Black women increased significantly following the use of a culturally tailored flyer rather than a general audience flyer. However, Satia et al failed to find any benefit in terms of recruitment when flyers were personalized in a cancer-prevention survey.

Our recruitment staff was ethnically diverse, with experience in recruiting minorities into health risk reduction trials. Although ethnic matching of recruitment staff and participants has been suggested as a necessary component of successful recruitment, the experience and sensitivity of the recruiter has been suggested as the more salient factor. Part of this sensitivity in recruiting minorities, particularly older women, extends to flexibility in scheduling interviews. Mis-trust of scientific investigators and of academic institutions in general has been shown to be a barrier to recruitment, particularly among Blacks. Recruiting women within the university through university e-mail might have diminished some of these trust-related barriers. Moreover, the University of Illinois at Chicago is an urban, very diverse institution. It serves predominantly underserved populations and is trusted by many people within the surrounding communities. Some issues voiced in previous research (ie, concerns that data would be used to advance academic careers rather than address health problems) might have been less of an issue given the positive history between the institution and the surrounding communities. Nonetheless, because ORBIT recruited exclusively Black obese women, we cannot evaluate the impact of these factors on recruitment rates.

As we have noted, our university IRB required medical clearance related to safety concerns. Whereas 7 women were excluded because their doctors said they should not participate, 167 women were excluded because they never returned a medical clearance form. Many of these women might have otherwise been eligible. Furthermore, women who picked up a flyer in the community were more likely to be excluded because they did not return a medical clearance form than women recruited by e-mail or referred by family and friends. This was an unexpected finding with important implications for our future studies. The most obvious explanations are that compared with women recruited by other modes, these women were either more likely to be uninsured, more likely to have financial strains (ie, could not afford copay), or less motivated so that the additional effort posed a barrier. Regardless of the causes, it is important that we work with our IRB to identify methods that balance safety concerns with the need to more fully represent communities that we study. In sum, a limitation to this study is that
Effectiveness of Recruiting

Medical clearance contributed bias to our recruitment. As a result, the generalizability of our results is limited.

Cost of the Recruitment Approaches

A formal economic analysis of recruitment approaches was beyond the scope of our project. Nonetheless, recruitment is an expensive and important aspect of research that deserves comment. Active in-person recruitment for this study typically occurred as the recruiters were walking to a location to place flyers for passive recruitment. As a result of the dynamic nature of these 2 recruitment approaches, we are unable to estimate the specific costs in staff time for in-person recruitment versus placement of flyers. On average, 20 hours each week were dedicated to recruitment activities in the community (ie, in-person and placement of flyers). Over the 7 months of recruitment, staff spent approximately 600 hours recruiting. Most of the time was focused on in-person recruitment, but the exact percentage of time was not documented. By virtue of staff time alone, active in-person recruitment was the most expensive approach. Locating sites to place flyers in the community for passive recruitment was the second most expensive recruitment mode. E-mail recruitment was the least expensive approach, despite yielding the highest percentage of ineligible participants. Excluding staff time to screen women, the cost of e-mail recruitment was approximately $14 per woman randomized.

The relative merits or cost and benefit of each recruitment approach vary across studies. Although typically the most expensive approach, active, in-person recruitment might be preferred when mistrust of institutions is higher, literacy or reliance on written material is lower, and/or personal contact is valued. Active recruitment conducted within the targeted community might also facilitate participation by breaking down attitudinal barriers. The uptake of flyers by passive recruitment might be impacted by the individual’s feelings toward the organization or institution where the flyers are placed. Community-based recruitment can be enhanced through endorsements or support from trusted sources such as pastors, barbers, or community leaders. Finally, e-mail recruitment typically results in low participation rates with associated response bias that can be difficult to assess. Depending on the source of the e-mail recruitment list, response bias can be decreased to varying degrees. We were unable to limit the e-mail distribution to individuals with specific demographic characteristics and had no idea what number of potentially eligible nonresponders we had in the pool of e-mails. Nonetheless, the close proximity of the university participant pool to the intervention site made e-mail recruitment attractive. It is also likely that because the e-mail recipients were employed by the same university that supported the study, women trusted the source, were familiar with previous research recruitment via e-mail, and felt comfortable making contact to inquire about the study or complete screening.

In conclusion, ORBIT was successful in meeting recruitment goals and attracting obese Black women interested in a physical activity and nutrition program by integrating a range of strategies and recruitment approaches. Although the ORBIT cohort was not representative of all obese Black women, the results suggest that various recruitment approaches reached different subgroups of
women. Our challenge in future physical activity interventions with obese women is to identify creative ways to balance the need for physical safety with the ability to maximize the representation of all Black women.

Acknowledgments

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References


