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Obesity Reduction Black Intervention Trial (ORBIT): Design and Baseline Characteristics

Marian L. Fitzgibbon, Ph.D.,[1,2,3] Melinda Stolley, Ph.D.,[1,3] Linda Schiffer, M.S., M.P.H.,[1] Lisa Sharp, Ph.D.,[1] Vicky Singh, Ph.D.,[1] Linda Van Horn, Ph.D., R.D.,[4] and Alan Dyer, Ph.D.[4]

Abstract

Background: Obesity is associated with many chronic diseases, and weight loss can reduce the risk of developing these diseases. Obesity is highly prevalent among Black women, but weight loss treatment for black women has been understudied until recently. The Obesity Reduction black Intervention Trial (ORBIT) is a randomized controlled trial designed to assess the efficacy of a culturally proficient weight loss and weight loss maintenance program for black women. This paper describes the design of the trial, the intervention, and baseline characteristics of the participants.

Methods: Two hundred thirteen obese black women aged 30–65 years were randomized to the intervention group or a general health control group. The intervention consists of a 6-month weight loss program followed by a 1-year maintenance program. Weight, dietary intake, and energy expenditure are measured at baseline, 6 months, and 18 months.

Results: More than 40% of participants had a baseline body mass index (BMI) >40 kg/m^2 (class III obesity). Intake of fat and saturated fat was higher and consumption of fruit, vegetables, and fiber was lower than currently recommended guidelines. Self-reported moderate to vigorous physical activity was high (median 85 min/day). However, objectively measured physical activity among a subgroup of participants was lower (median 15 min/day).

Conclusions: Weight loss among obese black women has received inadequate attention in relation to the magnitude of the problem. Factors that contribute to successful weight loss and more importantly, weight loss maintenance need to be identified.

Introduction

The prevalence of obesity has increased dramatically over the past 30 years, and about 32% of adults in the United States are now obese.[1,2] Obesity is associated with a variety of chronic conditions, including cardiovascular disease, type 2 diabetes, postmenopausal breast cancer, and colon cancer.[3,4] The prevalence of obesity is particularly high among black women (54%), and morbidity and mortality from diseases associated with obesity are higher among black women than among white women.[5–8] Weight loss is associated with numerous benefits, including reduced blood pressure, improved lipid profiles, prevention or delay of type 2 diabetes onset, and reduced risk of postmenopausal breast cancer.[9–11]

Overall, weight loss treatment among blacks has been studied less extensively than it has in white populations.[12] On behalf of the U.S. Preventive Services Task Force, McTigue et al.[13] recently conducted a review of the obesity treatment literature. They searched MEDLINE and the Cochrane Library for reports of randomized controlled trials of obesity treatment interventions published in English between January 1994 and February 2003. Strikingly, more than 75% of the studies either did not report an ethnic breakdown or did not include a substantial number of black participants. Similarly, in a recent randomized trial comparing four weight loss diets, only 6% of the participants were black.[14] Even when black women have been well-represented, however, they are often less successful at losing weight than white women.[15–17] For example, in the Diabetes Prevention

[1]Department of Medicine and [2]School of Public Health, University of Illinois at Chicago, Chicago, Illinois.
[3]Jesse Brown VA Medical Center, Center for the Management of Complex Chronic Care, Chicago, Illinois.
[4]Feinberg School of Medicine, Northwestern University, Chicago, Illinois.
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Program (DPP), approximately half as many black participants as white participants achieved the 7% weight loss goal at 6 months.[18] The black participants did show better weight loss maintenance in the DPP, but they lost less weight than white participants overall because of their lower initial weight loss.[18]

Weight loss studies that focused specifically on black populations have shown mixed results.[17] The Black American Lifestyle Intervention (BALI) weight loss program was developed specifically for black women, and results of a pilot study ($n = 67$) showed that participants lost 3.5% of body weight over a 10-week period.[19] McNabb et al.[20] also reported positive results from a 14-week church-based program ($n = 39$), with a loss of 4.5 kg in the intervention group vs. a gain of 0.9 kg in the control group. Pounds Off with Empowerment (POWER) was a 12-month randomized trial ($n = 152$) of an intensive lifestyle intervention that was modeled after the DPP.[21,22] Eighty-two percent of participants were black. Participants in the intensive lifestyle group lost significantly more weight in 6 months than those in the control group (2.6 kg vs. 0.4 kg, $p < 0.01$).[22] In a trial of a primary care weight management program designed for low-income, obese black women, women in the intervention group lost 2.0 kg in 6 months, compared with a gain of 0.2 kg in the control group ($p = 0.03$).[23] Finally, the small randomized trial that served as a pilot study for the Obesity Reduction Black Intervention Trial (ORBIT) was conducted in two cohorts.[24] In the first cohort ($n = 27$), women received a less intensive weight loss intervention, and there was no difference in weight loss between women in the intervention and control groups. However, the weight loss intervention was intensified for the second cohort ($n = 37$), and women in the intervention group lost 3.4 kg, whereas those in the control group gained 0.9 kg ($p = 0.002$).[24]

Other studies have shown less positive results. For example, the Healthy Eating and Lifestyle Program (HELP) study tested a culturally adapted two-phase weight loss program ($n = 237$).[25] The initial 10-week intervention resulted in modest weight loss (1.7 kg) among the 134 participants who completed phase 1, but there was no treatment effect after phase 2, which lasted 8–18 months.[25]

Considerably less information is available on maintenance of weight loss among black women.[26] The Life Enhancement Awareness Program (LEAP) was a study designed to assess factors associated with both weight loss and weight loss maintenance among black women.[27] Although the women who completed the study ($n = 10$) lost weight (10.7 lb, SD = 10.1, $p < 0.01$), the study reported an attrition rate of >50% over the course of the 32-week intervention, and there was no control group.[27] Another study reported feedback from two small focus groups of black women who had lost at least 10 pounds in the past.[28] The women in the first group ($n = 6$) had maintained the weight loss for at least 1 year, and the women in the second group ($n = 6$) had regained the weight. Successful women reported that improved energy and physical appearance motivated them to maintain their weight loss, and women who were unsuccessful reported being too "busy" or too "lazy" to maintain the new diet and exercise habits. Factors that facilitated or impeded weight loss and maintenance were not discussed in depth.[28]

ORBIT is a randomized controlled trial designed to assess the efficacy of a culturally proficient weight loss and maintenance intervention among 213 obese black women between the ages of 30 and 65 years. The aim of this paper is to outline the overall design of ORBIT, describe the intervention, and present baseline characteristics of the randomized women. The primary outcomes (i.e., weight change, weight loss maintenance, and changes in energy intake and energy expenditure) will be described in future publications, as the trial is ongoing.

Materials and Methods

Study design

ORBIT is a randomized controlled trial of a culturally adapted 6-month weight loss intervention followed by a 1-year weight loss maintenance intervention. The study design is shown in Figure 1. Eligible women who gave informed consent and completed a baseline interview were randomized to either the intervention group or the control group Data will be collected after the weight loss intervention (6 months) and the maintenance intervention (18 months). Full Institutional Review Board approval was obtained from the University of Illinois at Chicago (UIC), where the trial is being conducted.

Sample size. The sample size of 100 per group was selected to provide 90% power to detect a difference of 1.1–1.25 kg/m^2 in change in body mass index (BMI) between the intervention and control groups at 18 months, assuming a two-sided test at the 5% level. Power calculations also assumed that at least 85% of the women would provide data at 18 months and that the SD in change in BMI would be between 2.2 and 2.5 kg/m^2.

Recruitment/screening for eligibility. Because of resource limitations, the study is being conducted in two cohorts of approximately 100 women each. Recruitment for cohort 1 began in May 2005 and ended in August 2005. Recruitment for cohort 2 began in July 2006 and ended in September 2006. Recruitment strategies included a mass e-mail that was sent to all UIC faculty, staff, and students (approximately 36,000 recipients), and face-to-face recruitment from nearby neighborhoods, local grocery stores, churches, nearby healthcare centers, and the UIC Hospital primary care clinics. All recruitment was done within a 2-mile radius of the intervention site.

Women who were interested in the program were asked to complete a short eligibility interview either by telephone (86%) or in person (14%). The eligibility criteria are shown in Table 1. Consistent with principles for conducting a randomized controlled efficacy trial, exclusion criteria were kept to a minimum.[29,30] However, because the intervention was not designed for pregnant women, women <30 years old and women who were planning a pregnancy in the next 18 months were excluded. Women > age 65 were excluded because of concerns that obese older women would be less able than younger women to participate safely in the physical activity component of the intervention.

Eligible women were given a medical approval form to be signed by their healthcare provider. By signing the form, the provider indicated that the individual was healthy enough to participate safely in a weight loss program including moderate exercise geared toward women with low levels of physical fitness.

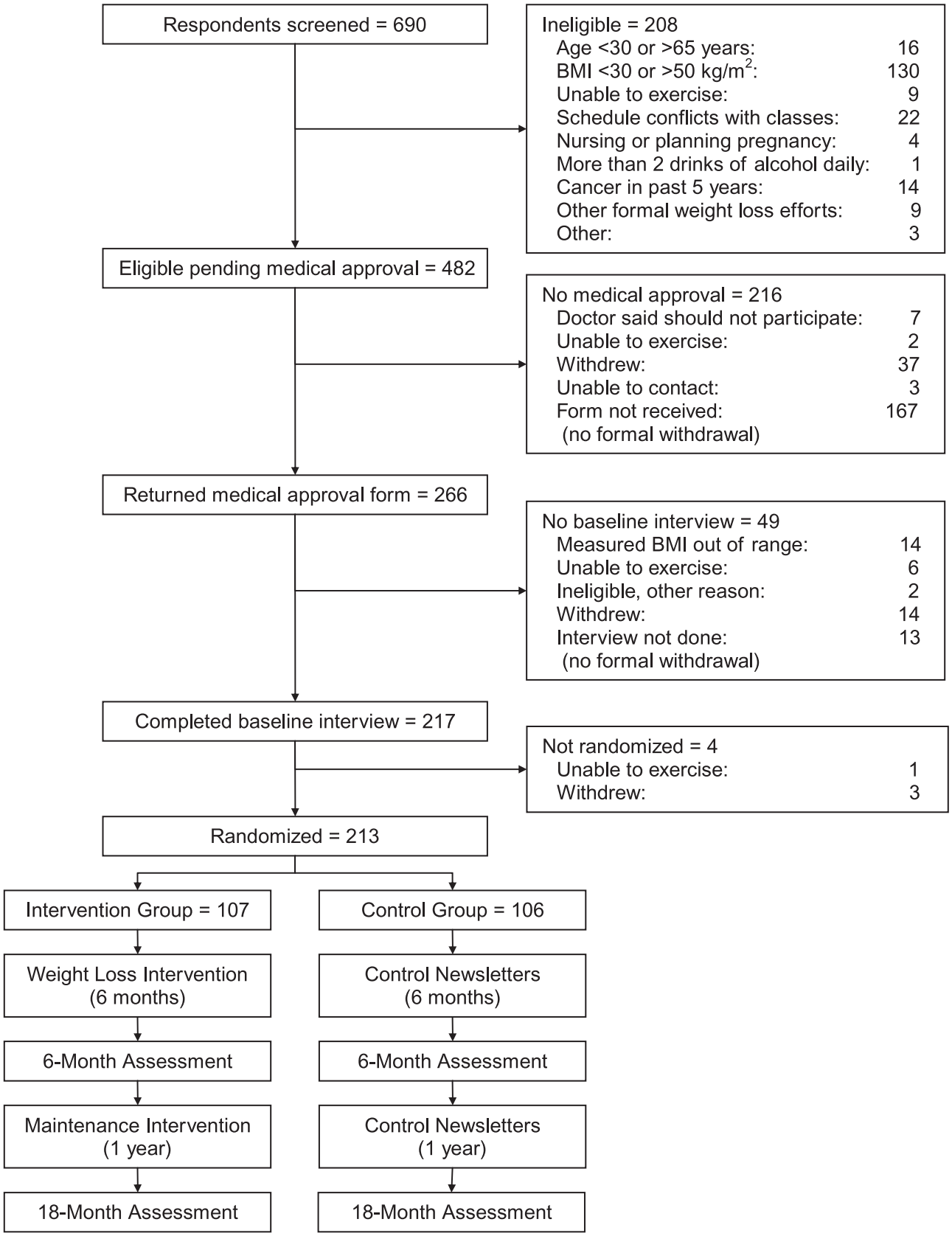

FIG. 1. Study design of the ORBIT project and participant flow through randomization.

Table 1. Eligibility Criteria for Participation in ORBIT

Inclusion Criteria	*Exclusion Criteria*
African American/Black (self-identified)	Planning to move out of the area during the course of the study
Female	Pregnant, nursing, or planning a pregnancy
Age 30–65 years	Consumes more than 2 alcoholic drinks per day on a daily basis
BMI 30–50 kg/m^2	Currently using illegal drugs
Able to participate in a program that requires 30 minutes of uninterrupted walking or ongoing activity	Treated for cancer in the past five years, excluding skin cancer other than melanoma
Able to attend classes at scheduled times	Unable to exercise because of emphysema, chronic bronchitis, or asthma
Returned medical approval form signed by physician	Uses a cane, walker, wheelchair, or other device to move around (cohort 2 only)
	Taking weight loss medications prescribed by a doctor
	Currently participating in an organized weight loss program

Measures

All data collectors were trained and certified by a master trainer in both interviewing and anthropometry. All questionnaires were interviewer administered.

Sociodemographic data. This information included date of birth, education, income, occupation, employment status, and marital status.

Anthropometrics. Height was measured using a Seca 214 portable stadiometer (Seca, Hanover, MD), and weight was measured using a Tanita BWB-800 digital scale (Tanita Corporation of America, Inc., Arlington Heights, IL). Participants removed their shoes and any heavy outer clothing for the anthropometric measurements. Height and weight were measured twice during the baseline interview, to the nearest 0.1 cm and 0.1 kg, respectively. If the two height measurements were more than 0.5 cm apart or if the two weight measurements were more than 0.2 kg apart, a third measurement was taken. The mean of the two closest measurements was used for analysis. BMI was computed from height and weight.

Block '98 Food Frequency Questionnaire (FFQ).[31,32] The Block FFQ asks about frequency of consumption in the past year and usual portion size for 110 different food items. The food list was developed using food intake data from the National Health and Nutrition Examination Survey III (NHANES III). Separate lists were developed using data from blacks, non-Hispanic whites, and Hispanics in order to ensure that the final food list would include foods that are frequently consumed among blacks and Hispanics. In addition, the Block '98 includes low-fat items that an individual could adopt in attempting to change dietary patterns. Reliability and validity have been established for the measure in a wide range of age, gender, income, and ethnic groups.[31,32] Data from the FFQ can be used to calculate nutrient intake, food group intake, and other dietary variables, including the Healthy Eating Index (HEI).[33–35] The HEI is a measure of overall diet quality developed by United States Department of Agriculture's (USDA) Center for Nutrition Policy and Promotion. Components of the index include servings of the five food groups in the USDA's Food Guide Pyramid, total fat and saturated fat as a percentage of energy, sodium, cholesterol, and variety. Scores range from 0 to 100, with a higher score reflecting a healthier diet.[33]

International Physical Activity Questionnaire, Long Last 7 Days Telephone Format (IPAQ).[36] The long IPAQ is designed to assess physical activity during the last 7 days. The IPAQ was developed by a multinational working group and can be interviewer-administered or self-administered. Items assess physical activity across a diverse set of domains, including leisure time physical activity, domestic and yard physical activity, work-related physical activity, and transport-related physical activity. Participants are asked only to report activity that they engaged in for at least 10 minutes at a time. Separate scores are calculated for walking, moderate-intensity activity, and vigorous-intensity activity for each of the domains. Participants are also asked about time spent sitting on weekdays and weekends. The psychometric properties of the IPAQ compare favorably to other commonly used self-reported physical activity measures.[36] To our knowledge, however, this measure has not been validated in obese individuals.

ActiGraph Activity Monitor (cohort 2 only). An objective measurement of physical activity was obtained for cohort 2 participants using the ActiGraph GT1M activity monitor (ActiGraph, LLC, Pensacola, FL). The ActiGraph is a small, lightweight ($3.8 \times 3.7 \times 1.8$ cm, 27 g), uniaxial accelerometer designed to detect normal body motion and filter out motion from other sources.[37] The acceleration signal is sampled 30 times per second, and signals are summed at the end of a specified period (1 minute for this study) and stored in nonvolatile flash memory. Participants were asked to wear

the ActiGraph during waking hours for 7 days. Study staff called participants several times during the 7 days to remind them to wear the accelerometer and to answer any questions. Activity counts were downloaded from the accelerometers using ActiLife Lifestyle Monitoring System Software (ActiGraph, LLC), and the resulting text files were read and analyzed using SAS for Windows v 9.1 (SAS Institute Inc., Cary, NC). Only days on which the participant wore the accelerometer for at least 10 hours were included in the analysis, and participants who had fewer than 4 valid days were excluded. When the ActiGraph registered 0 counts for at least 20 minutes at a time, it was assumed that the participant was not wearing the accelerometer. A number of prediction equations have been proposed for translating raw accelerometer counts into measures of energy expenditure.[38] In the absence of a clear consensus, we chose the widely used thresholds suggested by Freedson et al.[39]: 1952 counts for moderate activity (≥3 METs) and 5725 counts for vigorous activity (≥6 METs). These thresholds were used to calculate the amount of time spent in moderate, vigorous, and moderate/vigorous physical activity (MVPA), as well as the amount of time spent in bouts of MVPA lasting at least 10 minutes.

Body image. The Figure Rating Scale contains nine schematic figures (silhouettes) of women, displayed in order from underweight to obese (Fig. 2).[40] Women in this study were asked to indicate which figure looked most like them and which figure they would like to look like. We derived a body discrepancy (BD) rating by subtracting the ideal body image from the current body image. The BD rating can range from −8 to 8. A BD rating >0 indicates that the participant's current body image is larger than her ideal body image. A BD rating <0 indicates that the participant's current body image is lighter than her ideal body image. A score of 0 indicates that the same figure was chosen for the current and ideal image.

Data analysis

The Block '98 FFQs were sent to NutritionQuest (Berkeley, CA) for scoring. Participants with total energy < 500 kcal/day or > 5000 kcal/day were excluded from the analysis. The IPAQ was scored according to the November 2005 long-form scoring protocol.[41] As recommended in the scoring protocol, medians are reported for the physical activity data because the data are not normally distributed. Descriptive statistics were calculated using SAS for Windows v. 9.1. Two-sample *t* tests, chi-square tests, and Wilcoxon rank sum tests were used to test for differences between the intervention and control group at baseline. All analyses were repeated excluding all women who had any missing data.

Interventions

Weight loss intervention. Table 2 shows the topics covered in the 6-month weight loss intervention curriculum and the first 6 months of control newsletters. To produce and maintain weight loss, it is necessary to create an energy imbalance through a decrease in energy intake and an increase in energy expenditure.[42] However, for weight loss programs to be successful among black women, there must be a recognition and incorporation of the practices, attitudes, and beliefs of this particular subgroup.[43,44] For example, dietary changes must target foods that are typically reported by black women as being part of their usual dietary patterns. We were cognizant of the importance of offering alternatives that reduce caloric content without sacrificing flavor. Goals for increased physical activity need to account for potential barriers, such as child care, hair styling, and family and work responsibilities.[45–47] In addition to eating and exercise behaviors, culturally proficient weight loss programs must also incorporate body image, the meaning of weight, and reasons for weight loss.[48–50]

The conceptual framework guiding the development and delivery of the intervention was based on social cognitive theory (SCT)[51] and, thus, focused on changes in cognitions, behaviors, and social support related to weight loss. According to SCT, modeling or observational learning is a powerful contributor to behavioral change.[51] Individuals are more likely to model behavior that has a positive outcome, as well as the behavior of someone similar to themselves. The intervention provided ample opportunity for observa-

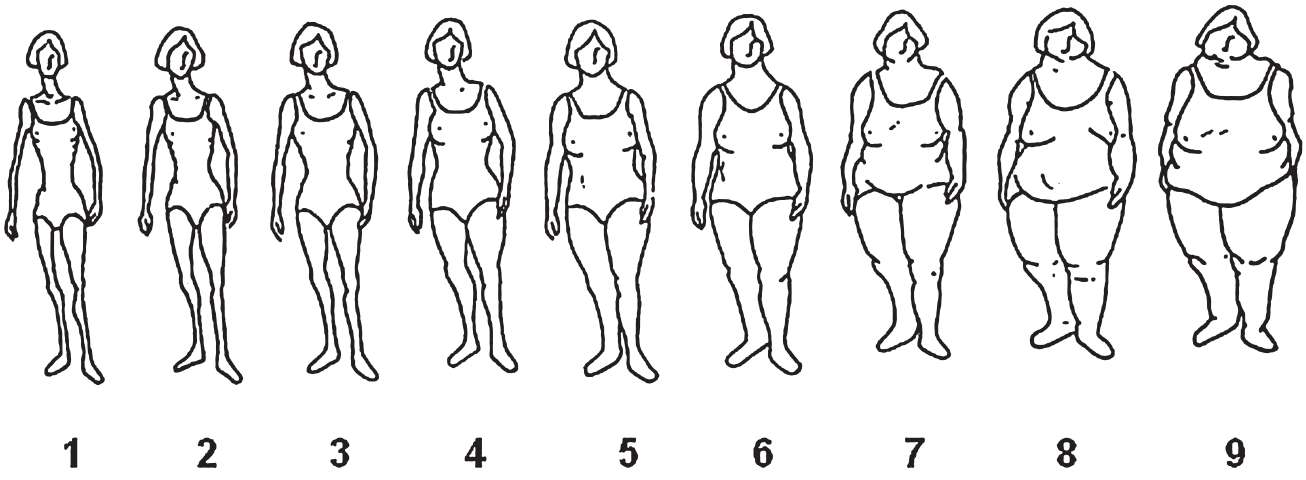

FIG. 2. Figure Rating Scale showing nine silhouettes of women displayed in order from underweight to obese. (Reprinted with permission from reference 40.)

Table 2. Topics Covered in the 6-Month Weight Loss Intervention Curriculum and Control Newsletters, ORBIT

Week	*Intervention Topic*	*Control Newsletter*
1	Introduction to the program	First aid
2	Tools for effective weight loss	Molds
3	Tools for effective weight loss, part 2	AIDS
4	Portion size, food labels	Healthy teeth
5	Food labels, part 2	De-stress, not distress
6	Physical activity	Immunizations
7	Meal planning	Carpal tunnel syndrome
8	Program review, goal setting	Flu season
9	Motivation	Prevent back pain
10	Holiday planning for Thanksgiving	Winter safety
11	Barriers to a healthy lifestyle	Menopause
12	Physical activity	Cataracts
13	African American fitness role models	Are you poison proof?
14	Stimulus control	Ankle sprains
15	Fast food	Headaches
16	Program review	Heart disease
17	Holiday planning for Christmas, Kwanzaa, and New Year's Eve	Lupus
18	Barriers to and motivators for physical activity	Osteoporosis
19	Ask the experts	Uterine fibroids
20	Breast cancer facts and prevention	Epilepsy
21	Benefits of exercise and healthy eating	Depression
22	Emotional eating	Domestic violence
23	Weight loss success stories	Mammograms
24	Conclusion/celebration	Complementary medicine

tional learning to occur. For example, although not all of our interventionists were black, our intervention team did include black women who served as potential role models to group members.

All intervention participants were encouraged to adopt a low-fat, high-fiber diet with increased fruit and vegetable consumption and to increase their overall physical activity. Exercise objectives included exercising at a moderate to vigorous level a minimum of 3–4 times per week for at least 30 minutes. Participants also received pedometers and were asked to increase their physical activity to a level equivalent to 10,000 steps per day.

The weight loss intervention was conducted in a small group format and met twice weekly on the university campus. One meeting each week was 90 minutes long and consisted of a weekly weigh-in, a didactic session, and a physical activity session. During the didactic session, the group leaders led discussions related to diet, physical activity, and weight loss for approximately 30–40 minutes. The didactic session was followed by a physical activity session that incorporated aerobic activity as well as strength and flexibility training. To increase the variety, some physical activity sessions included salsa dancing, African dancing, belly dancing, yoga, and Pilates. The second meeting of each week was 60 minutes in length and included a 30–40 minute physical activity class and discussion of topics related to increasing regular physical activity.

Weight loss maintenance intervention. The ability to maintain diet and physical activity patterns that affect long-term weight control requires permanent adoption of healthful behaviors.[52,53] During the 1-year ORBIT maintenance phase, the frequency of meetings decreased and emphasis was placed on structuring one's life in a way that supports maintenance of weight loss behaviors. In months 7–12, the group met twice weekly for 45–60 minutes, and each member received monthly motivational interviewing (MI) sessions.[54] During the group meetings, the didactic sessions were replaced with a support group conducted by the participants. The topic of each support group session was chosen by a participant, which allowed for tailoring of the material to fit the needs of members of the group. Participants discussed such topics as weight loss myths and how to care for oneself without using food. In months 13–15, the group met once weekly for an exercise class, and women continued to receive monthly MI. Finally, in months 16–18, there were no face-to face group meetings, but women continued to receive MI. Newsletters were sent to intervention participants every other month during the maintenance period.

Motivational interviewing (MI). As part of our conceptual model based on SCT, we sought multiple avenues to enhance self-efficacy. As a component of the intervention, we provided participants with the opportunity for individual problem solving through MI.[54] Participants received monthly MI sessions throughout the 6-month weight loss intervention and the 1-year maintenance intervention. Each MI session addressed either diet or physical activity. Sessions were conducted face-to face or over the phone, and each session lasted approximately 20–30 minutes.

General health intervention control group. Newsletters were sent to control group participants weekly throughout the 6 months of the weight loss intervention and monthly

Table 3. Participant Characteristics at Baseline, ORBIT

	Intervention		*Control*		
	n	*Mean (SD)*	n	*Mean (SD)*	p[a]
Age, years	107	46.4 (8.4)	106	45.5 (8.4)	0.42
Education, years	107	14.6 (2.0)	106	15.1 (1.9)	0.10
College graduate or graduate/professional degree, %		39.3		49.1	
Income, $, median	102	42,500	106	42,500	0.52
Employed full-time, (%)	107	72.0	106	71.7	0.97
Married/living with partner, %	107	34.6	106	34.0	0.92
Children under 18 in household	107	0.6 (0.9)	106	0.9 (1.3)	0.08
Other adults in household	107	1.2 (0.9)	106	1.1 (0.9)	0.61
BMI, kg/m^2	107	38.7 (5.5)	106	39.8 (5.8)	0.17
30–<35, %		33.6		25.5	
35–<40, %		29.0		24.5	
≥40, %		37.4		50.0	
Weight, kg	107	103.9 (15.7)	106	105.9 (17.4)	0.38
Current body image[b]	107	6.2 (1.1)	105	6.1 (1.1)	0.77
Ideal body image[b]	106	3.6 (0.7)	105	3.7 (0.8)	0.34
Body Discrepancy Current–ideal	106	2.6 (1.0)	105	2.4 (1.0)	0.24

[a]From chi-square tests for categorical variables, Wilcoxon rank sum test for income, and two-sample *t*-tests for other continuous variables.
[b]From Figure Rating Scale.[40]

during the 1-year maintenance phase. Control newsletters covered general health and safety topics relevant to adult women. The control group will receive the entire written curriculum at the end of the trial.

Results

As shown in Figure 1, the target recruitment goal of 200 obese black women was met. Two hundred thirteen women were randomized, 107 to the intervention group and 106 to the control group. As shown in Table 3, the mean age was 46.0 years (SD 8.4 years). Participants were well educated, with 44% reporting a college or graduate/professional degree. A majority of the women were employed full-time (72%). About a third of the women were married or living with a partner, and their median income was approximately $42,500. The average BMI was 39.2 (5.7) kg/m^2, and more than 40% of participants had a BMI ≥ 40 kg/m^2. On the body image rating scale,[40] all participants reported a discrepancy of at least 1 between their current and ideal body image, with their current body image being larger than their ideal body image. (See silhouettes in Fig. 2.)

Table 4. Diet at Baseline from Food Frequency Questionnaire[a]: Nutrients and Food Groups[b], ORBIT

	Intervention (n = 103) Mean (SD)	*Control (n = 96) Mean (SD)*	p[c]
Energy, kcal	2458 (1088)	2374 (984)	0.57
Protein, % kcal	15.1 (3.3)	15.7 (3.3)	0.25
Fat, % kcal	41.8 (6.6)	40.9 (5.9)	0.30
Saturated fat, % kcal	12.1 (2.4)	11.6 (1.9)	0.14
Carbohydrates, % kcal	44.5 (8.3)	45.1 (7.3)	0.57
Alcohol, % kcal	1.0 (2.0)	0.5 (1.1)	0.04
Fiber, g/1000 kcal	8.7 (3.5)	8.5 (2.9)	0.65
Food groups[b]			
Grains (bread, cereal, rice, and pasta), servings/day	4.8 (2.9)	4.9 (3.0)	0.84
Vegetables (includes salad and potatoes), servings/day	3.4 (2.0)	3.4 (2.1)	0.84
Fruits (includes juices), servings/day	1.3 (1.0)	1.3 (1.0)	0.81
Meat (meat, poultry, fish, dry beans, eggs, and nuts), servings/day	3.2 (1.9)	3.3 (2.0)	0.60
Dairy (milk, yogurt, and cheese), servings/day	1.0 (0.8)	1.1 (0.9)	0.63
Fats, oils, and sweets, servings/day	3.7 (2.0)	3.6 (1.8)	0.64

[a]Food frequency questionnaires with energy <500 kcal or >5000 kcal were excluded.
[b]Categories and approximate serving sizes were based on the 1992 Food Guide Pyramid.[34]
[c]From two-sample *t*-tests.

Table 5. Self-Reported Physical Activity in the Last 7 Days at Baseline, ORBIT

	Intervention (n = 107) Median (25th, 75th percentiles)	*Control (n = 106) Median (25th, 75th percentiles)*	p[a]
Walking, min/day	23.1 (8.6, 52.9)	26.1 (10.7, 57.1)	0.36
Moderate activity, excluding walking, min/day	34.3 (8.6, 77.1)	41.1 (17.1, 77.1)	0.15
Moderate activity, including walking, min/day	72.1 (30.7, 144.3)	80.4 (47.1, 147.1)	0.22
Vigorous activity, min/day	0.0 (0.0, 12.9)	0.0 (0.0, 12.9)	0.56
Moderate or vigorous activity, including walking, min/day	84.3 (31.4, 190.7)	86.4 (51.4, 175.7)	0.35
Sitting, weekday, min/day	420.0 (240.0, 600.0)	465.0 (360.0, 600.0)	0.15
Sitting, weekend day, min/day	300.0 (180.0, 480.0)	300.0 (180.0, 480.0)	0.87

[a]From Wilcoxon two-sample tests.

Table 4 shows estimated total energy and nutrient intake and servings per day of foods from each food group: grains, vegetables, fruits, meat, dairy, and fats, oils, and sweets. The average intake of energy was 2418 (1037) kcal, and mean percentage of energy from fat was 41.3 (6.3)%. Participants reported 3.4 (2.1) servings of vegetables and 1.3 (1.0) servings of fruits per day. The mean HEI score was 53.9 (11.7) out of a possible 100, which falls into the "needs improvement" category; 54% of the women scored in the needs improvement range (51–80), 43% scored in the poor range (< 51), and only 3% scored in the good range (> 80).

Table 5 shows self-reported physical activity for all participants, and Table 6 shows self-reported and objectively measured physical activity for the subgroup of women who wore an accelerometer for 4–7 days. Ninety-four of the 96 cohort 2 participants agreed to wear an accelerometer, but only 70 wore the accelerometer for at least 10 hours per day on at least 4 days. Among these 70 women, median self-reported time spent walking was 24.6 min/day, and median time spent in moderate activity, excluding walking, was 45.0 min/day. In contrast, as measured by the accelerometer, the median time spent in moderate activity (3–<6 METs) was only 15.2 min/day. Also, participants spent essentially no time, on average, in bouts of moderate or vigorous activity that lasted for at least 10 minutes (median 0 min/day). On the IPAQ, participants reported sitting for 420 minutes on weekdays and 300 minutes on weekends.

There were no significant differences between women in the intervention group and women in the control group, except for a difference in percentage of calories from alcohol, which is almost certainly not biologically meaningful (1% vs. 0.5%, $p = 0.04$). When the analyses were repeated including only the 193 women with no missing data, the results were similar to those shown in Tables 3, 4, and 5.

Discussion

Obesity is a major cause of morbidity and mortality and is a clear public health concern.[55] The high prevalence of obesity among black women places them at increased risk for a number of chronic diseases,[12] yet until recently, the experience of black women in weight loss and maintenance trials has been less studied than the experience of white women.[12] Most maintenance studies have not reported the ethnic composition of their samples.[56–58]

Lifestyle behaviors, such as dietary and physical activity preferences, are fundamentally linked to individual, familial, cultural, and environmental variables.[59] Nonetheless, there is currently no clear consensus as to the basic behavioral mechanisms that underlie individual dietary and phys-

Table 6. Self-Reported and Objectively Measured Physical Activity at Baseline in Participants with Valid Accelerometer Records, ORBIT

	Median (25th, 75th percentiles)
IPAQ, activities in last 7 days ($N = 70$)	
Walking, min/day	24.6 (10.7, 47.9)
Moderate activity, excluding walking, min/day	45.0 (20.7, 85.7)
Moderate activity, including walking, min/day	80.4 (47.1, 150.7)
Vigorous activity, min/day	0.0 (0.0, 12.9)
Moderate or vigorous activity, including walking, min/day	84.3 (47.9, 183.6)
Accelerometer, 4–7 days ($N = 70$)	
Moderate activity, 3–<6 METs, min/day	15.2 (7.8, 25.8)
Vigorous activity, ≥6 METs, min/day	0.0 (0.0, 0.0)
Moderate or vigorous activity, ≥3 METs, min/day	15.3 (7.8, 25.8)
Moderate or vigorous activity in bouts of at least 10 min, min/day	0.0 (0.0, 2.2)

ical activity choices.[43,60] Therefore, we face a challenge in developing the most salient lifestyle interventions for black women.

In the ORBIT study, 213 obese African American women were randomized either to a 6-month weight loss intervention followed by a 1-year maintenance intervention or to a general health control group. As reported on the Block '98 FFQ, participants consumed more than the recommended amount of fat and saturated fat and consumed less than the recommended amount of fruits, vegetables, and fiber.[61] Dietary factors that appear to affect the accumulation of body fat include foods that are high in energy density and foods that are low in fiber.[62] Moreover, data suggest that a high-fiber diet may protect against the development of obesity.[63] Women in ORBIT had a baseline HEI score of 53.9, which is lower than the overall score reported for a representative sample of non-Hispanic blacks in the United States (61.1).[64] This difference was not unexpected, as obese participants scored significantly lower on the HEI than normal weight participants in a large (n = 10,930) study based on data from the NHANES III.[65]

Weight reduction can occur only if energy expenditure is elevated above energy intake.[66] Overall, studies show that energy expenditure is particularly low among black women,[67,68] and NHANES III data suggest that black women have significantly higher odds of physical inactivity than white women.[69] In a cross-sectional study of U.S. women aged ≥40, 37.2% of the 745 black participants reported no leisure time physical activity, and only 8.4% reported regular activity, defined as participation in leisure time physical activity ≥ 5 times per week and ≥ 30 minutes per session.[70] Women in ORBIT reported a median of 85 min/day of MVPA, including walking, on the IPAQ. This level of activity would be higher than the current recommendations of the Institute of Medicine: approximately 60 min/day of moderate-intensity physical activity (e.g., walking /jogging at 4–5 mph).[71] By contrast, data from the subgroup of women who wore accelerometers reflected a median of only 15 min/day of MVPA, with no time, on average, spent in bouts of 10 minutes or longer. Jakicic et al.[72] observed a similar discrepancy between self-reported exercise and accelometer data in a study of overweight women participating in a behavioral weight loss program. Comparisons between accelerometer data and daily physical activity logs showed that approximately 45% of the women overreported the amount of physical activity they performed.

Research suggests that black women are more tolerant of being overweight and that their social environment is more accepting of larger body sizes.[49,73] Considerable evidence shows that normal weight black women are generally more satisfied with their body size than are white women of comparable body weight.[49] Among obese black women, however, there is a definite discrepancy between their current and ideal body image.[74] This was also the case for ORBIT participants, as would be expected among volunteers for a weight loss program. It is noteworthy that the mean current body image chosen by the women (6.1) does not necessarily reflect their current body size. Also, their choice of an ideal body image is smaller (3.6) than might be expected given the available literature on body image ideals among black women[49,74,75] (Fig. 2).

The ORBIT baseline data should be interpreted with the limitations of the study in mind. For example, dietary intake is frequently underreported on self-reported diet measures, and this has been shown to be a particular problem among obese individuals.[76,77] This potential limitation may be even more pronounced when obese participants enter a weight loss study, where the desire for weight change is one reason for entering the trial. Studies have shown that obese individuals who underreport their dietary intake are more apt to estimate lower intake of foods that are often considered unhealthful and overreport foods that are considered healthful.[78–80] Therefore, a social desirability bias in the diet data cannot be ruled out. Given that self-reported dietary intake is prone to error, more precise assessment tools are needed. Currently, however, biological markers that precisely reflect nutritional intake are not available for most nutrients.[81] Some data suggest that food diaries are a more precise method of measuring dietary intake than food frequency measures,[82,83] but all self-reported measures are vulnerable to underreporting and social desirability bias.

Just as dietary intake is often underreported, physical activity is often overreported when assessed by self-report.[72,84] Moreover, there is evidence to support the hypothesis that overweight and obese individuals have a greater tendency than normal weight individuals to overestimate physical activity.[85] This study was not designed to compare self-reported and objectively measured physical activity, so participants did not wear the accelerometer during the 7-day period covered by the IPAQ. Nonetheless, the large discrepancy between the two measures of physical activity is striking. We speculate that many of the participants, especially those who had very sedentary office jobs, overestimated the amount of time spent walking or performing other moderate activity over the course of a day. Also, some participants may have ignored the instructions asking them to report only activity that they engaged in for at least 10 minutes at a time. Accurate self-monitoring of physical activity can be difficult, and some people might require training to become proficient.[72]

We also recognize that individuals volunteer to participate in randomized trials for a variety of reasons, including altruism, curiosity, or interest in the study area. As the study was voluntary and asked for an 18-month commitment, we expect that participants were more highly motivated than average, reducing generalizability. Additionally, in an effort to recruit women who would not be harmed by weight loss but who were not necessarily candidates for or receptive to more aggressive forms of intervention (e.g., gastric bypass), we enrolled participants with a BMI between 30 and 50 kg/m^2. Just under half (44%) of our participants had a BMI ≥40 kg/m^2 (class III obesity); 30% were in the 30–<35 kg/m^2 range (class I obesity) and 27% were in the 35–<40 range (class II obesity). Although approximately 54% of black women in the United States are obese, only about 15% have a BMI ≥ 40 kg/m^2.[2] Finally, although BMI is correlated with percentage of body fat, it does not directly measure body composition. Therefore, at any BMI point, women could vary in their specific amount of body fat.[86,87] Future studies should include measures of body composition as well as waist circumference and other physiological changes that occur as a function of weight loss.

The ORBIT baseline data show that it is possible to recruit a group of black women into an 18-month weight loss and weight maintenance trial. It also suggests that this group of

obese, middle-aged, and educated women could benefit from reductions in dietary fat and saturated fat and increases in fruit, vegetable, and fiber intake. Our data also highlight the importance of obtaining objective physical activity data as well as self-reported physical activity, given the large discrepancy between these two methodologies. In subsequent papers, we will report on the effect of the intervention on weight loss and weight loss maintenance, as well as on changes in energy intake and energy expenditure.

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Address reprint requests to:
Marian L. Fitzgibbon, Ph.D.
Section of Health Promotion Research
Department of Medicine
University of Illinois at Chicago
1747 West Roosevelt Road, Room 558
M/C 275
Chicago, IL 60608

E-mail: mlf@uic.edu