Weight Loss During the Intensive Intervention Phase of the Weight-Loss Maintenance Trial

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Background: To improve methods for long-term weight management, the Weight Loss Maintenance (WLM) trial, a four-center randomized trial, was conducted to compare alternative strategies for maintaining weight loss over a 30-month period. This paper describes methods and results for the initial 6-month weight-loss program (Phase I).

Methods: Eligible adults were aged ≥25, overweight or obese (BMI=25–45 kg/m^2), and on medications for hypertension and/or dyslipidemia. Anthropomorphic, demographic, and psychosocial measures were collected at baseline and 6 months. Participants (n=1685) attended 20 weekly group sessions to encourage calorie restriction, moderate-intensity physical activity, and the DASH (dietary approaches to stop hypertension) dietary pattern. Weight-loss predictors with missing data were replaced by multiple imputation.

Results: Participants were 44% African American and 67% women; 79% were obese (BMI≥30), 87% were taking anti-hypertensive medications, and 38% were taking antidyslipidemia medications. Participants attended an average of 72% of 20 group sessions. They self-reported 117 minutes of moderate-intensity physical activity per week, kept 3.7 daily food records per week, and consumed 2.9 servings of fruits and vegetables per day. The Phase-I follow-up rate was 92%. Mean (SD) weight change was −5.8 kg (4.4), and 69% lost at least 4 kg. All race–gender subgroups lost substantial weight: African-American men (−5.4 kg ± 7.7); African-American women (−4.1 kg ± 2.9); non–African-American men (−8.5 kg ± 12.9); and non–African-American women (−5.8 kg ± 6.1). Behavioral measures (e.g., diet records and physical activity) accounted for most of the weight-loss variation, although the association between behavioral measures and weight loss differed by race and gender groups.

Conclusions: The WLM behavioral intervention successfully achieved clinically significant short-term weight loss in a diverse population of high-risk patients.
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Introduction

The U.S. Surgeon General's recent call to action has highlighted the epidemic rise in obesity, as overweight and obesity affect about 65% of adults in the U.S.[1,2] Obesity increases cardiovascular disease (CVD) risk factors[3–5] and overall mortality.[6–8] The prevalence of these risk factors—hypertension, dyslipidemia, and type 2 diabetes—is generally 1.5–2.9 times higher among overweight adults than normal-weight adults.[9] Modest weight loss significantly improves CVD risk factors, including lowering blood pressure (BP)[10,11] and hypertension risk[12]; reducing total cholesterol, low-density lipoprotein (LDL) cholesterol, and total triglycerides; and raising high-density lipoprotein (HDL) cholesterol.[13] Similarly, weight loss lowers blood glucose in both diabetic and nondiabetic individuals and reduces risk of type 2 diabetes.[14,15] In

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response to this overwhelming evidence, clinical treatment guidelines for hypertension, dyslipidemia, and type 2 diabetes include weight control as a core component.[2,16–19]

A combined emphasis on dietary intake and physical activity is important to both short- and long-term weight-loss goals.[3,20–23] Behavioral strategies to modify these health behaviors are important components of weight-loss interventions because they emphasize the individual's ability to monitor and regulate behavior,[24–26] and target the barriers to both initial weight loss[20] and long-term maintenance. Weight loss is difficult, however, and in the Trials of Hypertension Prevention (TOHP-II)[12] only 43% of participants lost ≥4 kg during a 6-month intensive behavioral intervention. Unfortunately, regain following weight loss is also common, and few trials have implemented interventions for longer than 18 months or have explicitly tested alternative strategies to sustain weight loss.[27–30]

This paper describes results from the 6-month Phase I of the Weight-Loss Maintenance (WLM) trial. This controlled trial examined three approaches for maintaining weight loss for 30 months following initial weight loss in a large, diverse adult population at high risk for CVD. Phase I of the WLM provided a nonrandomized intensive behavioral intervention[10,11,31–35] to all participants to help them reduce caloric intake, promote a DASH (dietary approaches to stop hypertension) dietary pattern, and increase moderate-intensity physical activity to lose ≥4 kg of weight. Those who lost ≥4 kg during Phase I were eligible for Phase II and were randomized to a self-directed control group, a personal contact intervention providing brief monthly phone or face-to-face contacts, or an interactive technology intervention. The technology intervention provided support almost exclusively through an interactive website with self-monitoring tools, a bulletin board, problem-solving modules, up-to-date information, and other resources. Given the high prevalence of overweight in African Americans,[9] and the burden of CVD in that population,[36] a major trial goal was to recruit about 40% African Americans. Adequate representation of both men and women was also an important recruitment goal.

Described here are the overall Phase-I weight-loss results and demographic and behavioral measures associated with weight loss in this large and diverse cohort. Race- and gender-specific weight-loss outcomes are presented, along with other demographic and behavioral modifiers of outcome.

Research Methods and Procedures

Overview of the WLM Design

The WLM trial was an investigator-initiated trial sponsored by the National Heart, Lung, and Blood Institute (NHLBI). It was reviewed and approved by IRBs at the participating institutions and by an NHLBI-appointed protocol review committee. NHLBI collaborated in the design and oversight of the trial, the analysis and interpretation of the data, and reviewed this manuscript. All participants provided written informed consent.

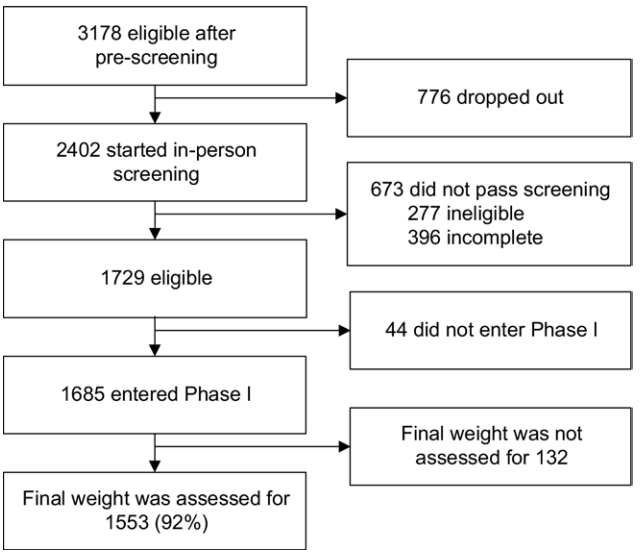

Figure 1. Flow diagram

The overall study design for Phase I of the WLM trial is illustrated in Figure 1. During Phase I, overweight or obese adults (n=1685) were offered 20 group weight-loss sessions over about 6 months. Those who lost ≥4 kg were eligible for Phase II and were randomized to one of three 30-month maintenance interventions. This paper presents only the Phase-I methods and results. A complete description of the rationale, design, and methods for Phase II of the trial is available elsewhere.[37]

Phase-I Eligibility

Participants were eligible for Phase I if they were: aged ≥25 years; BMI 25–45 kg/m^2; currently taking prescription medication for hypertension and/or dyslipidemia; willing to follow a healthy eating pattern; and willing not to use weight-loss medications for the duration of the trial. Participants also had to provide informed consent, keep a 5-day food record during screening, participate in the Phase-I weight-loss program, and try to lose at least 4 kg of weight. Because of the web- and phone-based nature of the Phase-II interventions, participants also had to have telephone and Internet access and were asked to demonstrate their ability to respond to e-mail and go to a specific website.

Participants were excluded if they had contraindications to weight loss; a cancer diagnosis (except for nonmelanoma skin cancer) in the past 2 years; medicated or poorly controlled diabetes (HbA1c≥8%); or a cardiovascular event within the past 12 months. Those with unmedicated, controlled diabetes (with a HbA1c<8%), a positive Rose angina questionnaire,[38] or a prior CVD event that occurred more than 12 months before screening could participate with the permission of their physician plus a negative stress test or other diagnostic test for CVD. Other exclusion criteria were self-reported history of renal disease (other than kidney stones);

Table 1. Phase-I goals and lifestyle guidelines given to participants

Lose weight
- Individually negotiated with a minimum of 4 kg to be eligible for Phase II

Eat fewer calories
- Consume about 500 fewer calories each day

Exercise regularly
- Exercise a total of 180 minutes each week (e.g., 30 minutes on 6 days per week)
- Add this moderate-intensity physical activity in addition to daily routine

Record daily food intake and physical activity
- Keep daily records of food and beverages consumed
- Keep daily records of exercise minutes

Be an active study participant
- Attend intervention group sessions and clinic visits

Move more! Lose more!
- In addition to regular exercise, find at least 5 "extra" opportunities to move more each day

Follow the DASH eating style
- Eat 9 to 12 servings fruits and vegetables every day
- Eat 2 to 3 servings of low-fat dairy foods every day
- Eat 25% or less of total calories from fat

Eat a low-sodium diet
- Eat 2400 mg or less of sodium each day

Limit alcohol consumption
- Women: Drink no more than 1 drink per day
- Men: Drink no more than 2 drinks per day (1 drink = 12 ounces beer, 5 ounces wine, or 1 jigger [½ ounce]of 80-proof liquor)

DASH, dietary approaches to stop hypertension

psychiatric hospitalization within the last 2 years; consumption of more than 21 alcoholic drinks per week or binge drinking; and weight loss of >9.09 kg ("20 lbs" in recruiting material) in the last 3 months. Also excluded were those with histories of gastric bypass surgery or fundoplication for obesity, or scheduled surgery for this purpose; liposuction in the past 12 months or use of prescription weight-loss medications in the 3 months prior to screening; using medications for treatment of psychosis or manic–depressive illness; planning to leave the area within 3 years; currently or planning pregnancy or breast feeding; and WLM trial staff or their household members.

Recruitment and Screening

Participants were recruited at four clinical research centers (Duke University, Johns Hopkins University, Pennington Biomedical Research Center in Baton Rouge LA, and Kaiser Permanente's Center for Health Research in Portland OR), with oversight from a Coordinating Center (also at Kaiser Permanente's Center for Health Research) and the NHLBI. Recruitment relied primarily on mass mailings of brochures, coupons, flyers, and print media. After telephone or face-to-face prescreening of respondents to assess preliminary eligibility and interest, potential participants attended two 60-minute screening visits to confirm eligibility and to collect weight, height, accelerometry, fasting blood samples, self-reported minutes of 28 moderate-intensity physical activities per week, and a battery of questionnaires and interview items. Enrollment into Phase I occurred between August 2003 and July 2004 and final analyses were completed in 2007.

Phase-I Initial Weight-Loss Intervention

The Phase-I intervention included 20, typically weekly, group sessions led by nutrition and behavioral counselors to help participants achieve initial weight loss through moderate calorie reduction and increased physical activity. The specific intervention targets for participants (Table 1) included reducing weight by at least 4 kg, engaging in 180 minutes per week of moderate-intensity physical activity (e.g., 6 × 30 minutes per day), and reducing calories while following a healthy (i.e., DASH) dietary pattern designed to reduce CVD risk factors.[39]

Intervention design and implementation. The approach was derived from social cognitive theory[24] and techniques of behavioral self-management,[25] and used the transtheoretical, or stages-of-change model,[26,40] and motivational enhancement.[24,41–43] The trial protocol and manual of operations are available at www.wlmtrial.org. Intervention was delivered primarily in the group sessions, although participants occasionally had individual contacts by phone or in person to help with specific behavior change needs. The group sessions were 90–120 minutes long with about 18–25 participants per group. Each center convened from 14 to 25 groups. Sessions were participatory and interactive, rather than didactic. Small-group activities fostered problem solving, social support, and program ownership. Many sessions included guided physical activity or food demonstrations. The intervention was tailored to the participants' preferences and readiness to change. The intervention included group interactions and social support, goal setting, nutrition and physical activity information modules, skill development, and problem solving, with careful attention to cultural appropriateness for minority populations.

While the minimum weight loss needed for Phase II was 4 kg, interventionists negotiated individualized weight-loss goals with participants, encouraging as much loss as possible at a safe rate of 0.5 to 2 lbs per week. Each week, participants set reasonable short-term goals and developed specific short-term behavioral action plans to reinforce, support, and monitor their progress[25] toward moderate caloric reduction (500 kcal less per day) and >180 minutes per week of moderate-intensity physical activity (3–6 METS), which was the national recommendation at the time. Participants aimed to do the following: (1) maintain daily food and physical activity records; (2) reduce portion sizes; (3) reduce foods high in calories, fat, and sodium; (4) increase consumption of fruits, vegetables, and low-fat dairy products; and (5) weigh themselves frequently and at least weekly. To promote accountability, participants weighed in at the beginning of each session and reported their minutes of physical activity and the number of daily diet records kept that week. (For analyses, those with no reports were assumed to have zero physical activity and food records for the week.) Participants worked together in small groups to identify threats to their plans and goals and to develop and rehearse coping strategies.

Intervention standardization, training, and quality control. Intervention staff received both centralized and local training throughout the study and used standardized program content, activities, materials, and data-collection forms for each session. A Minority Implementation Committee organized and conducted special trialwide training programs for all staff to highlight the cultural context for both African Americans and non–African Americans. Interventionists held monthly teleconference calls to monitor and refine intervention activities, clarify procedures, and share best practices. Local intervention directors continually monitored intervention quality, and the Coordinating Center conducted annual quality-control site visits during which intervention sessions were observed and critiqued.

Clinical Assessments

To maximize follow-up rates, staff made strong efforts to (1) select committed participants initially; (2) build a strong sense of teamwork and commitment during the groups; and (3) meet participants' needs at follow-up, including doing home visits, if needed. Staff measured participant height once at entry to the nearest 0.1 cm using a calibrated, wall-mounted stadiometer, and weight using high-quality, calibrated digital scales while participants wore light indoor clothes without shoes. BMI was calculated as the Quetelet index (kg/m^2). The first of two "entry" weights taken during screening was used to compute BMI for eligibility. A second entry weight, typically measured within the 2 weeks before the Phase-I intervention started, was the starting point for measuring Phase-I weight loss. Relevant baseline measures were repeated at 6 months, although blood samples were collected only for those entering Phase II, and are not presented here. For participants randomized into Phase II, the final Phase-I weight was the Phase-II randomization weight, which was generally taken within 7 days of Phase-II randomization. For other participants, the final Phase-I weight was the last measured weight on or after the 16th group session. When no measured weight was available (8% of participants), the final Phase-I weight was imputed using the method described below.

Statistical Analysis

Missing data. A multiple imputation procedure[44,45] was applied to replace the 132 missing weights at the end of Phase I and to replace other measures with missing values at entry. Five separate imputation samples were generated using Markov Chain Monte Carlo sampling in SAS® PROC MI, each with 1000 burn-in iterations and 500 iterations between data draws. Separate data analyses were then performed on each of these five complete data sets. Parameter estimates were then averaged, standard errors were adjusted with a function of the between-imputation variation, and the degrees of freedom were adjusted to obtain unbiased *p*-values. Most analyses were combined using SAS PROC MIANALYZE, but a SAS macro was used to implement Rubin's rules for combining results. The resulting standard errors account for the added variability of the imputation process itself and hence are typically inflated relative to what would be seen using only a single imputation sample.

Regression model. The association of three sets of variables on weight change during Phase I was examined: (1) **demographic:** race, gender, and race–gender interaction; (2) **behaviors:** number of sessions attended, number of daily diet records kept, minutes of moderate-intensity physical activity; and (3) **SES:** income and education. In addition, the models were adjusted for the entry-level weight or BMI-for-weight change and BMI change, respectively. To simplify the modeling process, a model comparisons approach was used to evaluate the significance of second- and third-order interactions among the three sets of variables.[46] This approach evaluates the significance of change in the model R^2 between a starting ("full") model and a nested ("reduced") model using the multiple-partial F test. For instance, the cluster of 3-way interactions among variables from the three sets was dropped because it did not significantly improve the fit of the model. Two-way interactions between variables in a different cluster were then evaluated and dropped if not significant. After evaluating all interactions, nonsignificant ($p>0.10$) individual terms that were not in an interaction were stepped out to arrive at the final models.

Results

Baseline Characteristics

Among 1729 eligible participants, 1685 consented to the study and attended at least one Phase-I group intervention session, which constitutes the Phase-I analysis sample. Table 2 shows that, at entry, participants had a mean age of 55 years, 67% were women, and 44% were African American. Most (91%) attended at least some college, and 45% had an annual household income of <$60,000. By design, all participants were taking medications for high blood pressure (87%) or elevated lipids (38%), all were overweight, and most (79%) were obese (BMI ≥30 kg/m^2).

Attendance, Adherence, and Follow-Up

Participants attended an average of 14 of the 20 possible intervention sessions (Table 3), and 61% attended 16 or more sessions. Attendance declined over time, but remained at 73% even during the last month of Phase I (data not shown). Over the 6-month intervention, participants self-reported a mean of 117 minutes of moderate-intensity physical activity per week (goal was 180) and 2.9 servings of fruits and vegetables per day (goal was 9–12). Unadjusted subgroup comparisons showed that men, compared to women, reported more physical activity per week ($p<0.0001$) and more food records per week ($p<0.0038$). Non–African Americans, relative to African Americans, attended more sessions, reported more physical activity, and kept more food records ($p<0.0001$ for each test).

Weight Change

Among participants with at least one weight measurement in each month, mean weight decreased steadily over time in all race–gender subgroups, and was still on a downward trajectory at the end of Phase I (Figure 2).

Table 2. Baseline characteristics

		African American		Non–African American	
	Total	**Men**	**Women**	**Men**	**Women**
n	1685	196	540	355	594
Age, mean (SD)	54.8 (9.1)	52.3 (10.1)	52.3 (8.9)	57.5 (8.9)	56.2 (8.2)
Women, %	67.3	0	100	0	100
Hispanic, %	1.4	0.5	0.4	2.3	2.0
Education, %					
High school	9.0	6.6	7.5	5.7	13.1
Some college	33.7	29.7	39.8	23.4	35.7
College degree	22.2	29.9	21.8	22.6	19.8
Post college	35.1	33.8	30.9	48.2	31.4
Income, $, %					
<30,000	9.4	4.6	16.2	3.7	8.1
30,000–59,000	35.2	27.3	41.8	24.9	37.9
60,000–89,999	30.7	36.5	28.6	31.9	30.0
≥90K	24.7	31.5	13.4	39.4	24.0
On BP medications, %	87.5	89.3	94.4	82.0	83.8
On lipid-lowering medications, %	38.3	38.3	23.1	54.4	42.6
Weight, kg mean (SD)	96.5 (16.5)	107.3 (16.2)	95.1 (15.1)	104.7 (15.2)	89.2 (14.5)
BMI, mean (SD)	34.3 (4.8)	34.1 (4.5)	35.6 (4.9)	33.6 (4.3)	33.6 (4.9)
Obese (BMI≥30), %	78.8	80.6	84.4	78.3	73.4
# Alcohol beverages/day, mean (SD)	0.2 (0.4)	0.2 (0.3)	0.1 (0.2)	0.4 (0.6)	0.2 (0.4)
Current tobacco use, %	6.3	8.2	7.0	6.5	4.9

With imputed missing data (after excluding one participant who died), mean (SD) weight decreased by 5.8 kg (4.4) during Phase I, and 69% of participants lost at least 4 kg (Table 3). Among the 1553 with follow-up data (i.e., no imputation), mean (SD) weight loss was 6.2 kg (5.1). This weight loss corresponded to a mean (SD) change in BMI of −2.0 (1.5) kg/m^2 and a mean percentage decrease in initial weight of 6.0% (4.1).

Predictors of Phase-I Weight Loss

Table 4 shows the results for final multiple regression models on absolute weight change that include both entry characteristics and measures of intervention adherence. Significant predictors included higher initial weight, more sessions attended, more food records kept per week, and more minutes of reported moderate-intensity physical activity per week. Model 1 (R^2=0.48) shows the direct effect of race, gender, race-by-gender interaction, and behavioral measures (food records and physical activities) with weight loss. Model 2 (R^2=0.49) is the outcome of model comparisons evaluating interactions among race, gender, and behavioral measures. In contrast to Model 1, race and gender moderated the effects of food records and physical activities on weight loss (i.e., race by number of food records kept per week and gender by minutes of exercise per week). The difference in R^2 between these models is significant (F[2,1673]=18.19,

Table 3. Attendance, adherence, and weight loss by race and gender

		African American		Non–African American	
	Total	**Men**	**Women**	**Men**	**Women**
n	1685	196	540	594	
Number of sessions attended, mean (SD)	14.4 (5.8)	13.8 (6.4)	13.5 (6.0)	15.4 (5.3)	15.0 (5.4)
Number of sessions attended, %					
<11	24	29	30	16	21
11–15	15	14	19	15	12
16–20	61	57	51	69	67
Moderate physical activity/week, minutes, mean (SD)	117.1 (111.7)	112.9 (115.4)	90.0 (95.8)	159.4 (135.1)	117.7 (100.4)
Number of food records/week, mean (SD)	3.7 (2.3)	3.4 (2.4)	3.1 (2.2)	4.2 (2.2)	3.9 (2.1)
Fruit and vegetable servings/day, mean (SD)	2.9 (2.7)	2.5 (2.6)	2.1 (2.3)	3.6 (3.1)	3.3 (2.6)
Weight change,[a] kg, mean (SD)	−5.8 (4.4)	−5.4 (7.7)	−4.1 (2.9)	−8.5 (12.9)	−5.8 (6.1)
BMI change,[a] mean (SD)	−2.0 (1.5)	−1.7 (2.4)	−1.5 (1.2)	−2.7 (4.0)	−2.2 (2.1)
Percent weight change,[a] mean (SD)	−6.0 (4.1)	−5.1 (7.2)	−4.4 (3.1)	−8.1 (11.8)	−6.5 (6.9)
Weight loss ≥ 4 kg,[a] N (%)	1167 (69)	135 (69)	316 (59)	281 (79)	435 (73)
Randomized to Phase II (%)	1032 (61)	121 (62)	267 (49)	257 (72)	387 (65)

[a]With missing data imputed using multiple imputation procedures after excluding one deceased participant (n = 1684)

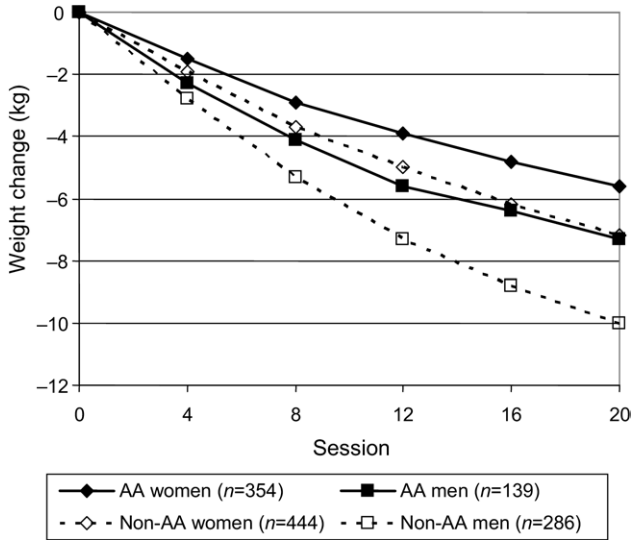

Figure 2. Mean weight loss during Phase I by race–gender subgroups for participants with at least one weight measurement in every month
AA, African American

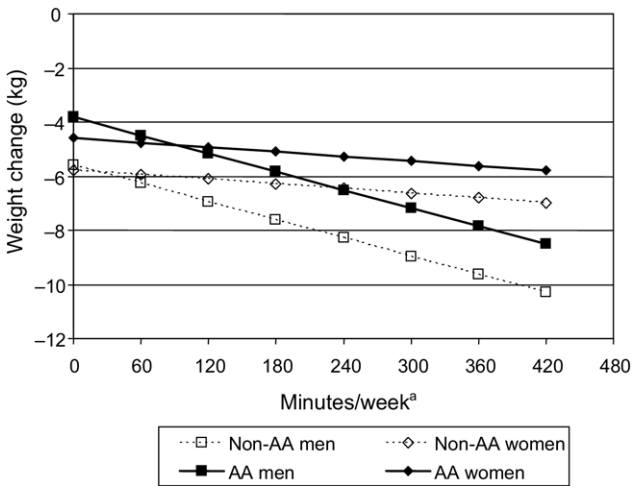

Figure 3. Estimated effect of physical activity on weight change, by gender and race [a] Model evaluated at the overall mean of 3.7 food records per week
AA, African American

$p<0.0001$). Figure 3 illustrates how, based on Model 2, a given increase in physical activity per week is estimated to have a greater effect on weight loss for men than for women, regardless of race. A sensitivity analysis that dropped outlying activity values (>420 min, $n=27$) gave virtually identical results. Similarly, Figure 4 illustrates the greater estimated impact of keeping more food records on weight loss for non–African Americans than for African Americans, regardless of gender. Other potential predictors, including income, education, and other 2- and 3-way interactions, were considered but rejected as nonsignificant from the final model. The same model comparisons approach was used for BMI change and percent weight change with similar results.

Discussion

The WLM trial's Phase-I behavioral weight-loss program resulted in a substantial 5.8 kg mean weight loss (BMI decrease of 2.0 kg/m^2) over about 20 weeks in a population of overweight and obese adults who were being treated for cardiovascular risk factors. Two thirds (69%) of all participants who started the program lost a clinically relevant[12,47,48] 4 kg or more of weight by the end of Phase I. While other studies have shown similar amounts of weight loss,[32,33,47] these findings are particularly noteworthy given the highly diverse nature of the

Table 4. Baseline measures and adherence indicators as predictors of change in weight

	Model 1 without behavior interactions					Model 2 with behavior interactions				
Effect	Parameter estimate[a]	SE	95% CIs		p	Parameter estimate[a]	SE	95% CIs		p
Intercept	6.71	0.78	5.17	8.25	<0.0001	7.84	0.81	6.23	9.44	<0.0001
Weight at entry (kg)	−0.07	0.01	−0.08	−0.06	<0.0001	−0.07	0.01	−0.08	−0.05	<0.0001
African American race (AA=1)	2.02	0.37	1.30	2.74	<0.0001	0.79	0.54	−0.28	1.87	0.1447
Gender (female=1)	0.98	0.29	0.42	1.54	0.0006	−0.17	0.38	−0.92	0.57	0.6479
Race[a] × gender	−0.98	0.43	−1.83	−0.13	0.0240	−0.59	0.43	−1.44	0.25	0.1699
Sessions attended	−0.29	0.03	−0.35	−0.24	<0.0001	−0.30	0.03	−0.35	−0.25	<0.0001
Diet records per week	−0.52	0.08	−0.67	−0.37	<0.0001	−0.69	0.09	−0.86	−0.52	<0.0001
Moderate-intensity physical activity (MPA) per week (100 min)	−0.76	0.12	−1.00	−0.51	<0.0001	−1.12	0.15	−1.41	−0.83	<0.0001
Race × diet records per week						0.27	0.09	0.08	0.45	0.0052
Gender × MPA per week (100 min)						0.83	0.18	0.48	1.18	<0.0001

[a]A negative parameter estimate indicates that increase in the measure predicts greater weight loss (weight loss is a negative change score).

participants, which included 44% African Americans. This group has been generally under-represented in weight-control studies and has typically achieved less weight loss.[12,49] In this study, a majority of African American men (69%) and women (59%) lost at least 4 kg of weight. While African Americans lost somewhat less weight than non–African Americans on average, racial differences in weight loss in WLM were less pronounced than in previous studies. This improvement may be attributable to the extensive trialwide efforts to make the intervention culturally appropriate. African Americans were also well represented among investigators, interventionists, and other staff. The higher proportion of African-American participants in the intervention group meetings may also have created a more comfortable and supportive environment.

After adjusting for race, gender, and initial weight, greater weight loss was associated with more frequent attendance at the group sessions, number of food records kept per week, and minutes of moderate-intensity physical activity per week. These findings provide additional evidence[50] that these standard behavioral strategies are key for successful weight loss. Further, even more weight loss would be expected if more participants had achieved the recommended minimum of 180 minutes of exercise per week. Race and gender, however, also affected the associations among weight loss, reported activity, and food record adherence. The adjusted association between activity and weight loss was stronger for men than for women. On average, men weigh more and have greater muscle mass and might therefore burn more calories in a given period of exercise. Several previous studies in both humans and animals have shown that a given increase in physical activity leads to greater weight loss in males than females, and this relationship may have a biological basis.[51–53] Another possibility is that WLM men may have exercised at higher intensity levels than did women. It is less clear why the association between the number of food records kept per week and weight loss was greater for non–African Americans than for African Americans, regardless of gender. More research is needed on this differential effect of food records to refine intervention approaches and possibly develop alternative methods for tracking dietary intake in African Americans.

Even though the 20-session intervention in this study was a bit shorter than the 6-month series of weekly meetings commonly recommended,[54,55] a greater percentage of WLM's racially diverse participants lost at least 4 kg during the first 6 months than in the TOHP-II trial (69% vs 43%).[12] Weights were still declining at meeting 20 and, had the intervention continued for another 6 weeks or longer, it is likely that the mean weight loss and the proportion of participants with at least 4 kg weight loss would have been even greater.

Even a modest weight loss of at least 4 kg has been associated with health benefits in studies of the prevention and/or treatment of hypertension,[10–12,33,56] diabetes,[14,15,47,57,58] and lipid management.[13] These health benefits occur contemporaneously with weight loss and persist as long as weight loss is maintained.[59,60] For example, Stevens and colleagues[12] reported that a net mean weight loss of only 2 kg led to a 20% relative risk reduction in incident hypertension. Meta-analyses by Neter and colleagues[61] and Staessen and colleagues[48] suggest that systolic BP decreases 1.0–2.4 mmHg per kg of weight loss. This reduction in systolic BP, in turn, has been estimated to reduce stroke mortality by 6%–8% and CHD mortality by 4%–5%.[62] Based on these meta-analyses, the mean weight loss in Phase I of WLM (5.8 kg) would be predicted to reduce systolic BP by 5.8–13.9 mmHg. The weight loss is comparable to the effect of a single antihypertensive medication.[63] Because the amount of achieved weight loss varies by initial weight, the preceding discussion may over-simplify the likely observed effects.[64]

A limitation of Phase I of WLM was that it was an uncontrolled observational study. Compared to other large weight-loss studies, however, a higher proportion of both African-American and non–African American participants achieved clinically important weight loss. Another limitation is the use of self-reported adherence measures of physical activity and diet. Finally, Phase I was relatively short and, in the absence of additional intervention, regain would be expected over longer periods of time.[50] Research specifically comparing various maintenance strategies is limited[50,65,66] and badly needed. Phase II of the WLM trial will help address this need.[37]

In summary, as part of a study comparing alternative strategies for maintaining weight loss, the WLM trial enrolled a large and heterogeneous sample into an

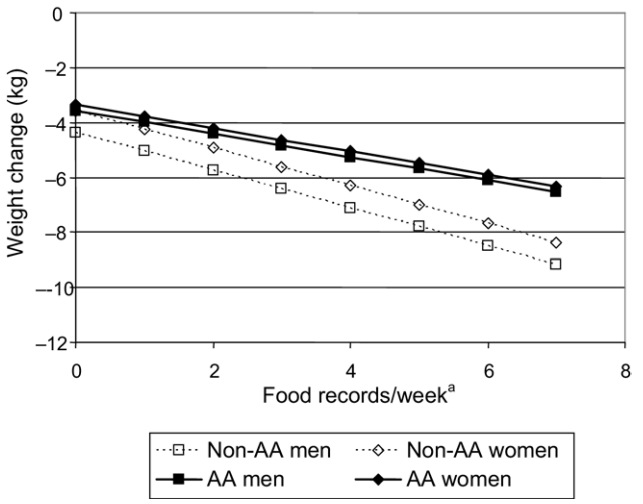

Figure 4. Estimated effect of number of food records kept per week on weight change, by gender and race [a] Evaluated at the overall mean of 117 minutes per week of moderate-intensity physical activity
AA, African American

intensive 6-month behavioral intervention to achieve weight loss. Two thirds of all participants achieved clinically significant weight loss of 4 kg or more. Although some racial and gender differences were noted, all subgroups achieved clinically meaningful weight loss. Differences in attendance, food records adherence, and physical activity accounted for most of the weight-loss variation by race and gender groups. These results suggest that the WLM Phase-I intervention successfully achieved clinically significant short-term weight loss in an unusually diverse high-risk population, including 44% African Americans. Long-term maintenance results are presented elsewhere.[67]

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