Comparison of Strategies for Sustaining Weight Loss
The Weight Loss Maintenance Randomized Controlled Trial

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Context Behavioral weight loss interventions achieve short-term success, but regain is common.

Objective To compare 2 weight loss maintenance interventions with a self-directed control group.

Design, Setting, and Participants Two-phase trial in which 1032 overweight or obese adults (38% African American, 63% women) with hypertension, dyslipidemia, or both who had lost at least 4 kg during a 6-month weight loss program (phase 1) were randomized to a weight-loss maintenance intervention (phase 2). Enrollment at 4 academic centers occurred August 2003-July 2004 and randomization, February-December 2004. Data collection was completed in June 2007.

Interventions After the phase 1 weight-loss program, participants were randomized to one of the following groups for 30 months: monthly personal contact, unlimited access to an interactive technology–based intervention, or self-directed control.

Main Outcome Changes in weight from randomization.

Results Mean entry weight was 96.7 kg. During the initial 6-month program, mean weight loss was 8.5 kg. After randomization, weight regain occurred. Participants in the personal-contact group regained less weight (4.0 kg) than those in the self-directed group (5.5 kg; mean difference at 30 months, −1.5 kg; 95% confidence interval [CI], −2.4 to −0.6 kg; $P=.001$). At 30 months, weight regain did not differ between the interactive technology–based (5.2 kg) and self-directed groups (5.5 kg; mean difference −0.3 kg; 95% CI, −1.2 to 0.6 kg; $P=.51$); however, weight regain was lower in the interactive technology–based than in the self-directed group at 18 months (mean difference, −1.1 kg; 95% CI, −1.9 to −0.4 kg; $P=.003$) and at 24 months (mean difference, −0.9 kg; 95% CI, −1.7 to −0.02 kg; $P=.04$). At 30 months, the difference between the personal-contact and interactive technology–based group was −1.2 kg (95% CI −2.1 to −0.3; $P=.008$). Effects did not differ significantly by sex, race, age, and body mass index subgroups. Overall, 71% of study participants remained below entry weight.

Conclusions The majority of individuals who successfully completed an initial behavioral weight loss program maintained a weight below their initial level. Monthly brief personal contact provided modest benefit in sustaining weight loss, whereas an interactive techonology–based intervention provided early but transient benefit.

NEARLY TWO-THIRDS OF US adults are overweight or obese.[1] Together overweight and obesity are the second leading cause of preventable death, primarily through effects on cardiovascular disease (CVD) risk factors (hypertension, dyslipidemia, and type 2 diabetes).[2] Weight loss improves these risk factors, and evidence suggests that benefits persist as long as weight loss is maintained.[3-8] Relatively short-term (ie, 4-6 months) behavioral interventions for adults result in clinically significant weight loss, but regain is an intractable problem.[9-11] Given the vast scope of the over-

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weight and obesity epidemic, there is a critical need for practical, affordable, and scalable intervention strategies that effectively maintain weight loss. Such strategies may also play an important role in preventing weight gain among normal-weight individuals, thereby reducing the incidence of overweight and obesity.[12]

Despite the potential for health benefits of weight loss maintenance, there is little evidence, particularly from clinical trials, on how to accomplish this objective. Observational studies suggest that continued intervention contacts[9,13]; self-monitoring of dietary intake, physical activity, and weight[14-16]; accountability[10,14]; and regular physical activity[17] lead to sustained weight loss. However, very few trials have explicitly tested alternative strategies to sustain weight loss, and few weight loss studies have implemented interventions for longer than 18 months.[13,14,18-20]

Although effective weight management is an important goal for everyone, it is especially important for segments of the population at highest risk for future CVD. Minority populations in general and African Americans in particular are affected disproportionately by the obesity epidemic, with greater prevalence and incidence of overweight and obesity and greater severity of obesity-related CVD risk factors.[21-23] For individuals with known CVD risk factors, weight management is a priority because of the beneficial effect of weight loss on blood pressure, lipid profile, and insulin resistance. Even though African Americans and individuals with CVD risk factors may benefit the most from effective weight loss maintenance strategies, large weight loss trials historically have had limited inclusion of minorities and other high-risk groups, thereby limiting generalizability.

In this context, we report the main results of the Weight Loss Maintenance (WLM) trial, a controlled trial of 2 practical strategies for maintaining weight loss for 30 months following initial weight loss in a large, diverse, adult population at high risk for CVD.

METHODS

Participants were enrolled in 2 phases of the clinical trial: phase 1 was a 6-month nonrandomized initial weight loss intervention for all participants; phase 2 was a randomized 30-month trial comparing 2 weight-maintenance strategies (personal contact and interactive technology) vs a self-directed control condition.

Participating institutions included 4 clinical centers—Duke University, Johns Hopkins University, Pennington Biomedical Research Center, and the Kaiser Permanente Center for Health Research. The study was approved by an institutional review board at each participating site and by a protocol review committee appointed by the National Heart, Lung, and Blood Institute. All participants provided written informed consent, and a data and safety monitoring board provided trial oversight. A detailed description of trial methods is available at http://www.kpchr.org/wlmpublic.[24,25]

Participants

To be included into phase 1 of the study, participants were required to have a body mass index (BMI), calculated as weight in kilograms divided by height in meters squared, of between 25 and 45; to be taking medication for hypertension, dyslipidemia, or both; to have no active CVD (those with a positive Rose angina questionnaire or a CVD event no less than 12 months before study entry and a negative stress test result could join the study with permission from their physician); access to a telephone and to the Internet; and to keep a food diary for 5 days during the screening.

Major exclusion criteria for phase 1 were medication-treated diabetes mellitus, a recent cardiovascular event or other medical or psychiatric conditions that would preclude full participation in the study, weight loss of more than 9 kg in the last 3 months, recent use of weight loss medications, or prior weight loss surgery. The primary criterion for randomization into the study's second phase was weight

loss of at least 4 kg during the first phase.

Recognizing that weight loss studies often lack large numbers of male participants, we sought to enroll 40% men. In addition, a major trial goal was to recruit a study population that was approximately 40% African American. Participants self-identified their race categories.

Participant Flow

Recruitment relied on mass mailings, posted flyers, radio advertisements, and print media. Individuals meeting prescreening criteria attended a series of screening visits, after which eligible participants began the 6-month group-based, phase 1 behavioral weight-loss program, for which enrollment occurred from August 2003 through July 2004. Those who completed phase 1 and met criteria for phase 2 were randomized from February through December 2004 to one of the 3 interventions. Data collection was completed in June 2007.

Randomization assignments were stratified by clinic, race (ie, African American or non–African American), and amount of weight loss during phase 1 and were allocated in blocks of varying sizes to provide a balance in treatment assignments over time. The actual allocation assignments were generated using a password-restricted, Web-based application developed by the coordinating center and were accessible only to authorized unblinded personnel.

Measurements

Data collection visits occurred at study entry and at the end of phase 1 (ie, at randomization, also referred to as *baseline*) and every 6 months after randomization for 30 months (2½ years). Measurements were obtained by trained, certified staff members who were masked to treatment assignment.

Weight was measured in duplicate with the participant wearing light indoor clothes without shoes and using a high-quality, calibrated digital scale. At baseline and at 12 and 30 months after randomization, weight was measured on

2 separate days, and values were averaged. At other times, weight was measured at a single clinic visit. Height was measured once at entry using a calibrated, wall-mounted stadiometer.
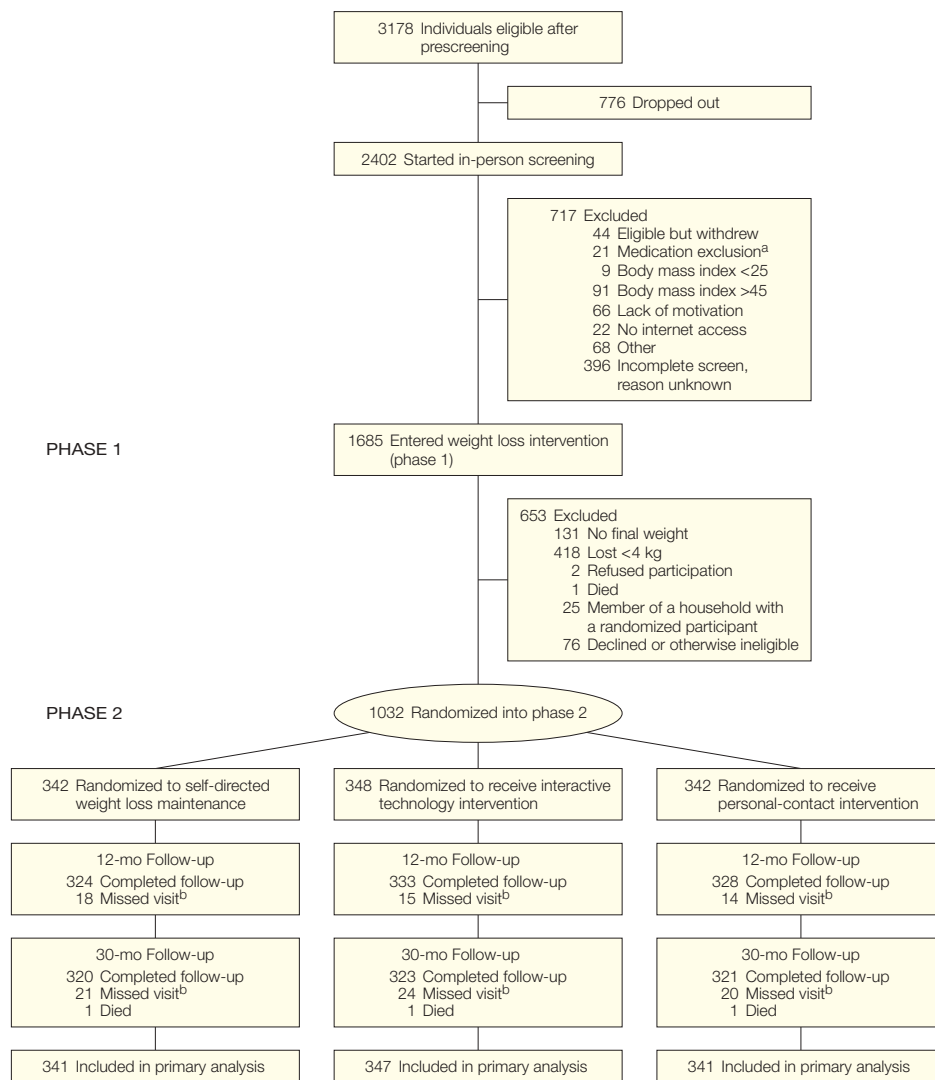
Dietary intake and physical activity were measured at entry, randomization, and the 12- and 30-month follow-up visits. Diet was assessed by the Block food frequency questionnaire.[26] Physical activity was measured by accelerometry. Participants were asked to wear a calibrated, triaxial accelerom-

eter (RT3, Stayhealthy Inc, Monrovia, California) for at least 10 hours per day for at least 4 days, including 1 weekend day. Accelerometry results that comprised at least 1 weekday and 1 weekend day were used to estimate total weekly minutes of moderate to vigorous physical activity (MVPA). Total MVPA reflects both leisure time exercise and daily activity patterns (such as climbing stairs) and thus provides a measure of total MVPA-related energy expenditure.

Initial Weight Loss Intervention

The phase 1 intervention was a group-based behavioral intervention. A trained interventionist led 20 weekly group sessions over approximately 6 months. Intervention goals were for participants to reach 180 minutes per week of moderate physical activity (typically walking); reduce caloric intake; adopt the Dietary Approaches to Stop Hypertension dietary pattern, which has been shown to reduce CVD risk factors[27-32]; and lose approximately 1 to 2 lb per week. Par-

Figure 1. Flow Chart of Enrollment, Randomization, and Follow-up

[a] Medications included antipsychotic agents and those that treat diabetes and overweight and obesity.
[b] Outcome data imputed for participants with missed visit; therefore, excluding 3 deaths, all 1029 randomized participants are included in this analysis.

ticipants were taught to keep food and physical activity self-monitoring records and to calculate caloric intake.

Maintenance Interventions

Participants included in the study's second phase were randomly assigned to 1 of 3 groups: a self-directed comparison condition in which participants received minimal intervention, an interactive technology–based intervention in which participants were encouraged to regularly log on to an interactive Web site; and a personal-contact intervention in which participants had monthly

individual contact with an interventionist. The goals of the interactive technology–based and personal-contact interventions were maintenance of the phase 1 weight loss or loss of additional weight if desired, continued adherence to the recommended dietary pattern, and increasing moderate physical activity to at least 225 minutes per week.[33,34]

Both personal-contact and interactive technology–based interventions reinforced the key theoretical constructs (motivation, support, problem solving, and relapse prevention) that

had been incorporated in phase 1. In addition, both active interventions incorporated features found to be associated with maintenance of behavior change in previous studies, such as continual intervention contacts, self-monitoring, accountability, prolonged continuous contact, and motivational interviewing. The counseling strategies and dietary and physical activity recommendations were the same in the personal-contact and interactive technology–based groups. Both maintenance interventions were designed to be easily disseminated and practical to implement.

At randomization, participants in the self-directed group received printed lifestyle guidelines with diet and physical activity recommendations, and they met briefly with a study interventionist again after the 12-month data collection visit.

The interactive technology–based intervention included unlimited access to a Web site designed to support weight loss maintenance.[25] Interactive features allowed participants to set personal goals and action plans for the next week and to graph personal data over time. Modules addressed problem solving and motivation, and a bulletin board facilitated social support but did not provide in-person counseling.

When participants logged on, they were required to enter their current weight and were encouraged to use the Web site for self-monitoring of physical activity and caloric intake. Participants were encouraged to log on at least once a week. If they missed a self-scheduled contact, they were sent an e-mail reminder that was repeated after another week of no contact. If there was no response to 2 e-mail prompts, participants received 2 weekly automated telephone calls. If there was no subsequent log-on, study staff contacted the participant and encouraged him/her to return to the Web site.

The personal-contact intervention consisted of a case management approach with monthly person-to-person guidance and support. Participants had telephone contact with an interventionist for 5 to 15 minutes each month, ex-

Table 1. Characteristics of Participants Randomized to Phase 2[a]

	Range	Self-directed (n = 342)	Internet Technology (n = 348)	Personal Contact (n = 342)	Total Randomized Population (n = 1032)
Age, mean (SD), y	28 to 83	55.8 (8.5)	55.7 (8.5)	55.4 (9.1)	55.6 (8.7)
Race/ethnicity and sex distribution, No. (%)					
African American					
Women		90 (26)	90 (26)	87 (25)	267 (26)
Men		35 (11)	41 (12)	45 (13)	121 (12)
Non–African American					
Women		131 (38)	130 (37)	126 (37)	387 (37)
Men		86 (25)	87 (25)	84 (25)	257 (25)
Weight, mean (SD), kg	59.2 to 158.0	95.9 (16.2)	97.2 (16.2)	97.1 (17.5)	96.7 (16.6)
BMI, mean (SD)	25.1 to 46.7	34.0 (4.8)	34.2 (4.9)	34.2 (4.8)	34.1 (4.8)
BMI weight category, No. (%)					
Overweight,	25 to 29.9	76 (22)	76 (22)	78 (23)	230 (22)
Obesity					
Stage 1	30 to 34.9	139 (41)	131 (38)	129 (38)	399 (39)
Stage 2	≥35	127 (37)	141 (40)	135 (39)	403 (39)
Medications, No. (%)					
Hypertension		294 (86)	301 (86)	302 (88)	897 (87)
Lipid		136 (40)	137 (39)	138 (40)	411 (40)
Education, No (%)					
Some college or less		135 (39.5)	132 (37.9)	130 (37.9)	396 (38.4)
College degree		207 (60.5)	216 (62.1)	212 (62.1)	636 (61.6)
Household income/y, $					
<60 000		147 (43.0)	137 (39.3)	155 (45.5)	440 (42.6)
≥60 000		195 (57.0)	211 (60.7)	186 (54.5)	592 (57.4)
Phase 1 weight change, mean (SD), kg	−4.0 to −30.3	−8.5 (4.0)	−8.6 (4.5)	−8.3 (4.2)	−8.5 (4.2)
Weight at randomization, mean (SD), kg	53.7 to 148.3	87.4 (15.3)	88.6 (15.4)	88.7 (16.9)	88.2 (15.8)
Energy intake at randomization, mean (SD), kcal/d		1608.4 (532.9)	1582.6 (520.7)	1599.8 (511.1)	1596.8 (461.1)
Physical activity at randomization, mean (SD), min MVPA/wk		158.8 (141.8)	159.1 (136.6)	172.0 (173.3)	163.3 (153.2)

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; MVPA, moderate to vigorous physical activity.
[a] All values are at start of phase 1 unless otherwise specified. Some actual numbers may not sum to 1032 due to missing data.

cept for every 4th month when they had a 45- to 60-minute individual face-to-face contact. This frequency of contact was based on previous trials[9,10,35] and on disease management programs[36] and is consistent with recommendations of the Medicare Medical Nutrition Therapy Amendment Act of 2001.[37] The personal-contact intervention did not involve Internet contacts.

Each personal-contact session began with a self-reported weight (or measured weight at face-to-face contacts) and a review of progress since the last contact, including number of days on which a food diary was kept, frequency of weighing, average number of minutes of exercise, and progress on additional goals and action plans. Each contact provided support from the interventionist, accountability for commitments made at the previous contact, and opportunities to discuss the individual's barriers to weight loss maintenance and plans to overcome those barriers.

Outcomes

The primary outcome was change in weight from randomization (the start of phase 2) to the end of the study, 30 months after randomization. We also present data on the change in weight from entry (the start of phase 1) to the end of the study, as well as dichotomous measures of weight change: maintenance of at least a 4-kg weight loss relative to entry weight, no net weight gain from entry, at least 5% loss from entry, and no more than a 3% gain from randomization. Additional outcomes were total energy intake (kcal/d) and MVPA (min/wk).

Statistical Methods

The primary between-group comparisons in weight change after randomization were adjusted for entry weight, change in weight during phase 1, age, sex, race, a race $\times$ sex interaction, and clinical center (site). Each active-treatment was compared with the self-directed control condition. To correct for multiple comparisons and thereby preserve the experiment-wide type I error

rate at .05 for the 2 tests in the primary outcome analysis, the smaller of these 2 *P* values was evaluated against an α level of .025, and, if significant, the larger *P* value was evaluated against an α level of .05.[38-40] The question of whether weight change differed between personal-contact and interactive technology–based groups was tested (at the .05 level, in a similarly adjusted model) only if 1 of the 2 primary contrasts was significant.

The model for the secondary outcome of change in weight from entry (ie, from the start of phase 1 to the end of the study) was similar, but did not include change in weight during phase 1 as a covariate. The analyses of change in total energy intake and MVPA paralleled those for the primary outcome analysis, except that they adjusted for entry-level and phase 1 change of the outcome of interest (energy intake or MVPA) rather than weight. To preserve power for secondary outcomes, the protocol stipulated a priori that no multiple comparisons correction would be made for these analyses. We also used similar models to test for interactions with prespecified subgroups. In the case of race-sex subgroups, clinical interest in these subgroups led to an analysis of treatment effects separately in each stratum despite the absence of significant interaction.

We used multiple imputation[41,42] to replace missing end-of-study weights (for 68 individuals), missing interim weights, and other measures. Only weights missing due to participant death (n=3) were not imputed. Consequently, all 1029 randomized participants who survived are included in the primary outcome analysis. To derive imputed end-of-study weights, we used interim weights and variables related to phase 1 weight loss to estimate the parameters of a multivariate distribution from which imputed values were drawn, creating 5 separate imputation samples. Results presented herein are the average of separate, identical analyses performed on each of these 5 complete data sets, with appropriate adjustment of standard errors[43] to incorporate the added variability over

imputations. Hence, the standard errors are somewhat inflated relative to what would be observed using only a single-imputation sample.

The originally anticipated phase 2 sample size of 800 was designed to provide 90% power to detect a 2.0-kg difference in weight change between either of the active interventions (personal contact or interactive technology) vs the self-directed strategy and 80% power to detect treatment differences of about 2.9 kg in an expected subset of 320 African Americans. All analyses were conducted using SAS, version 9.1 (SAS Institute Inc, Cary, North Carolina), and all *P* values are 2 sided.
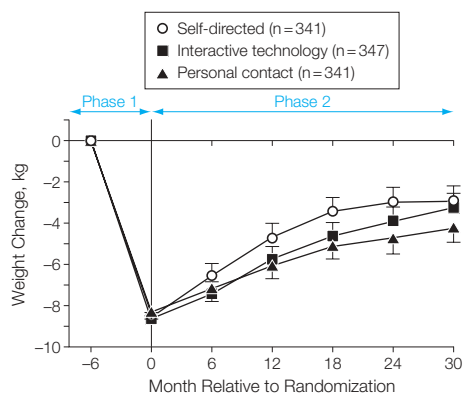
RESULTS

A total of 1685 individuals participated in phase 1, the initial weight loss intervention, of whom 1032 (61%) met phase 2 entry criteria (**FIGURE 1**). **TABLE 1** shows that 63% of those randomized were women and 38%, African American, with a mean age of 55.6 years (range, 28-83 years) and a mean initial weight loss of 8.5 kg (range, 4.0-30.3 kg).

Follow-up rates were 93% to 96% at each major data collection visit (Figure 1). There were no notable differences in participant characteristics at entry into the study between those who completed the final data-collection visit and the 68 individuals who did not (data not shown). Three participants (1 in each treatment group) died after randomization and are not included in the intention-to-treat analysis, which is therefore based on 1029 participants.

Participants in the interactive technology group logged onto the Web site an average of once a week and had at least 1 Web site contact for 77% of the months of the maintenance phase. Participants in the personal-contact group completed an average of 91% of monthly intervention contacts.

Change in Energy Intake and Expenditure

Self-reported energy intake decreased by approximately 325 kcal/d during phase 1 but increased slightly but not

Figure 2. Adjusted Weight Change by Treatment Group

Error bars indicate 95% confidence intervals.

Additional analyses reported in Table 3 demonstrate that participants in both the interactive technology–based and personal-contact groups experienced significantly less weight regain than those in the self-directed group at each follow-up visit for 24 months following randomization.

At the end of follow-up, there were no significant interactions with baseline BMI, age, or race. Nevertheless, given the strong clinical and public health interest in the impact of obesity in African Americans, we report weight changes in race-sex subgroups. **TABLE 4** shows that the magnitude of the observed treatment effects was generally consistent across these groups; in the absence of significant interaction, any apparent differences must be interpreted cautiously.

Post hoc sensitivity analyses removing 2 outliers (a participant in the interactive technology–based group who lost 30 kg and a participant in the self-directed group who gained 60 kg in phase 2) did not substantively change the results. Even without these outliers (both of whom were verified) the range of weight change after randomization was large in each group (self-directed range, –12 to 26 kg; interactive technology–based range, –12 to 24 kg; and personal-contact range, –17 to 25 kg).

A sizeable proportion of participants in each treatment group sustained clinically significant weight loss (**TABLE 5**). Overall, 41.8% of participants maintained at least 4 kg of weight loss compared with entry weight, with no significant differences between treatment groups; 70.9% remained at or below their entry weight. The proportion maintaining this much weight loss was significantly higher in the personal-contact group than in the self-directed group (*P* = .003), as was the difference between the personal-contact and interactive technology–based groups (*P* = .03). Also, 37.1% overall remained 5% or more below entry weight. The difference between the self-directed and personal-contact groups was significant (*P* = .02). Finally, 31.5% regained no more than 3% higher than their randomization weight. These percentages do not differ between treatment groups.

significantly during phase 2: 88 kcal/d in the self-directed group, 16 kcal/d in the interactive technology–based group, and 55 kcal/d in the personal-contact group. At the end of follow-up, caloric intake remained lower than entry levels by 231, 326, and 272 kcal/d, respectively. Changes in energy intake did not differ significantly between treatment groups: –33 kcal/d (95% confidence interval [CI], –117 to 51 kcal/d) for the personal-contact vs the self-directed, –72 kcal/d (95% CI, –168 to 24 kcal/d) for the interactive technology vs the self-directed, and 39 kcal/d (95% CI, –45 to 123 kcal/d) for the personal-contact vs the interactive technology groups.

During phase 1, participants increased their MVPA by about 48 minutes, but that decreased significantly in all 3 groups after randomization to the maintenance phase of the study by 32 minutes in the self-directed, 35 minutes in the interactive technology, and 33 in the personal-contact groups. By the end of follow-up, participants' exercise levels were not significantly higher than the amount of time they exercised at study entry. Changes in MVPA in phase 2 did not differ significantly between groups: –5 min/wk (95% CI, –24 to 14 min/wk) for personal-contact vs self-directed, –8 min/wk (95% CI, –27 to 12 min/wk) for the interactive technology–based vs the self-directed group, and 4 min/wk (95%

CI, –11 to 18 min/wk) for the personal-contact vs the interactive technology–based groups).

Weight Outcomes

All groups regained weight after randomization by a mean of 5.5 kg in the self-directed, 5.2 kg in the interactive technology–based, and 4.0 kg in the personal-contact group (**FIGURE 2**, **TABLE 2**). However, the mean weight at 30 months remained lower in each group than mean weight at entry into the study (Figure 2, Table 2). As shown in **TABLE 3**, at 30 months after randomization on average, those in the personal-contact group regained 1.5 kg less weight than those in the self-directed group (95% CI, 2.4-0.6 kg; *P* = .001), whereas those in the interactive technology–based group regained only 0.3 kg less than those in the self-directed group (95% CI, 1.2-0.6 kg; *P* = .51). Those in the personal-contact group regained a mean of 1.2 kg less than those in the interactive technology–based group (95% CI, 2.1-0.3 kg; *P* = .008). As expected, the pattern of results is similar when the outcome is expressed as percentage weight change (personal-contact vs self-directed group difference, –1.8%; *P* < .001; interactive technology–based vs self-directed group difference, –0.4%; *P* = .5; personal-contact vs interactive technology–based group difference, –1.5%; *P* = .003, data not shown).

COMMENT

In this study of overweight and obese adults, who are at high risk of CVD, those who were randomly assigned to the personal-contact intervention regained significantly less weight over a 30-month period than those assigned to the self-directed and interactive technology–based interventions. The personal-contact intervention was effective across all subgroups—men and women, African Americans and non-African Americans, and younger and older adults—suggesting the potential for broad public health impact. Because most personal-contact intervention contacts consisted of monthly 10- to 15-minute telephone conversations, this is an efficient and practical mode of delivery.

Although weight regain with the personal-contact intervention was statistically less than weight regain in the self-directed control group, the mean effect was a modest 1.5 kg at the end of the study. However, even modest weight loss can improve cardiovascular risk factors.[3,4,7,8,44] Each kilogram of weight loss is associated with an average decrease in systolic blood pressure of 1.0 to 2.4 mm Hg[44] and a reduction in incident diabetes of 16%.[45] Nevertheless, it is clear that preventing weight regain is extremely challenging. In fact, some observers have asserted that long-term success rates are so low that providing long-term behavioral weight loss treatments may ultimately be futile.[46,47] However, our results suggest that clinically relevant weight loss maintenance is feasible. At the end of the study, more than 45% of those in the personal-contact intervention were still maintaining at least 4 kg of weight loss, an amount with clear clinical benefits.

Our study results compare favorably with previous trials, including Trials of Hypertension Prevention Phase II (TOHP-II)[7] and STOP Regain.[18] In TOHP-II, an intensive behavioral weight loss intervention was followed by less intensive intervention for a total of 3 years. Only 43% of study participants lost 4 kg or more during the initial intervention compared with more than 60% in our study. Among TOHP-II participants who lost at least 4 kg in the first 6 months of intervention, their mean change in weight at 3 years was −2.3 kg[7] (Nancy Cook, ScD, TOHP Coordinating Center, written communication, November 19, 2007) compared with −4.2 kg in the WLM personal-contact group.

In STOP Regain, 319 adults who reported losing at least 10% of body weight within the previous 2 years were randomly assigned to one of three 18-month maintenance interventions: face-to-face contact, Internet intervention, and control.[18] Despite substantial study differences that might favor weight-loss maintenance (including shorter duration of maintenance intervention, more tailored intervention, and minimal enrollment of minorities), STOP Regain's findings were similar to those of our study: there was a 2.5-kg weight regain at 18 months in the STOP Regain face-to-face intervention compared with a 3.1-kg regain in the personal-contact intervention of WLM.

An important key to progress in combating the obesity epidemic is the extent to which effective intervention can be widely disseminated. In this regard, interactive technology–based interventions remain promising because of their potential for low-cost dissemination and the extent to which technology is rapidly becoming integrated into communication, learning, and health care. The effect of the WLM interactive technology–based intervention and the STOP Regain Internet intervention were similar: there was no significant difference in long-term regain between the Internet intervention and the control group. At 18 months, participants in the WLM Internet-based group had regained 3.8 kg compared with 4.7 kg in the STOP-Regain Internet group.[18] However, in the WLM interactive technology–based group, weight regain was significantly less than in the self-directed group through 24 months of follow-up. Participants in the interactive technology–based intervention remained

Table 2. Adjusted Weight Change at 30 Months by Treatment Group (N = 1029)[a]

	Initial Weight	Self-Directed	Interactive Technology	Personal Contact
Change from entry, mean (SE), kg[b]	96.7 (16.6)	−2.9 (0.4)[d]	−3.3 (0.4)[d]	−4.2 (0.4)[d]
Change from randomization, mean (SE), kg[c]	88.2 (15.8)	5.5 (0.3)[d]	5.2 (0.3)[d]	4.0 (0.3)[d]

[a] Analysis includes all randomized participants except 1 death in each treatment group. Final weight imputed for 65 individuals (21 in self-directed, 24 in interactive technology, and 20 in personal contact) who missed final data collection visit.
[b] Least-squares mean (SE) adjusted for entry weight, site, age, race, sex, race-by-gender interaction.
[c] Least-squares mean (SE) adjusted for entry weight, site, age, race, sex, race-by-gender interaction, and change in weight in the phase 1.
[d] $P < .001$ for change within treatment group.

Table 3. Between Group Difference in Weight Change From Randomization, Over Time in Phase 2[a]

	Months Since Randomization									
	6		12		18		24		30	
	Δ, kg	P Value	Δ, kg	P Value	Δ, kg	P Value	Δ, kg	P Value	Δ, kg	P Value
Interactive technology vs self-directed	−0.8	.003	−1.0	.005	−1.1	.003	−0.9	.045	−0.3	.51
Personal contact vs self-directed	−0.9	.001	−1.6	<.001	−1.8	<.001	−2.0	<.001	−1.5	.001
Interactive technology vs personal contact	−0.1	.73	−0.6	.11	−0.7	.08	−1.1	.01	−1.2	.008

[a] P values from these models adjust for site, race, sex, race×sex, and weight change during phase 1; a separate model was used for each time point.

Table 4. Adjusted Weight Change at 30 Months Within Race-Sex Subgroups[a]

Group	No. of Participants	At Entry, Mean (SD)[b]	Change From Entry, Mean (SE), kg[c]			At Randomization, Mean (SD)[b]	Change From Randomization, Mean (SE), kg[c]		
			Self-directed	Interactive Technology	Personal Contact		Self-directed	Interactive Technology	Personal Contact
African American									
Men	121	108.3 (16.2)	−4.8 (1.3)	−3.0 (1.1)	−4.9 (1.0)	100.2 (16.6)	4.1 (1.2)	6.1 (1.1)	3.7 (1.0)
Women	267	94.8 (15.2)	−1.8 (0.6)	−1.3 (0.6)	−2.2 (0.6)	87.7 (14.7)	5.5 (0.5)	5.7 (0.5)	4.7 (0.6)
Non-African American									
Men	255	104.0 (15.2)	−3.5 (0.8)	−5.1 (0.8)	−5.7 (0.8)	93.2 (14.2)	7.1 (0.7)	5.8 (0.7)	4.9 (0.7)
Women	386	89.5 (14.5)	−2.2 (0.6)	−3.0 (0.6)	−3.9 (0.6)	81.5 (13.9)	5.7 (0.5)	5.1 (0.5)	3.9 (0.5)

[a] $P < .001$ for all within-treatment-group changes except for African American women in whom $P = .03$.
[b] Unadjusted mean (SD).
[c] Least-squares mean (SE) adjusted for age, site, race, sex, race × sex, entry weight, and (for change from randomization only) for change in weight in phase 1.

Table 5. Percentage of Participants Who Met Various Criteria for Weight Loss, Overall and by Treatment Group

Group	No. (%) of Participants			
	Overall (n = 1029)	Self-directed (n = 341)	Interactive Technology (n = 347)	Personal Contact (n = 341)
Maintained at least 4 kg weight loss from entry	430 (41.8)	135 (39.5)	142 (40.8)	154 (45.2)
At or below entry weight	730 (70.9)	227 (66.6)	240 (69.3)	262 (76.7)[a]
No more than 3% above randomization weight	324 (31.5)	100 (29.3)	101 (29.2)	122 (35.9)
At least 5% below entry weight	382 (37.1)	116 (33.9)	122 (35.3)	144 (42.2)[b]

[a] $P = .003$ when comparing personal-contact with self-directed groups, and $P = .03$ when comparing personal-contact groups with interactive technology groups.
[b] $P = .02$ when comparing personal-contact with self-directed groups.

engaged with the Web site, continuing to log-on at least once a week throughout the study, and a large proportion maintained clinically significant weight loss. Given the potential for widespread dissemination at relatively low cost per participant, continued development of interactive technology–based intervention should be a high priority for obesity research.

For both the personal-contact and interactive technology–based interventions, future studies must determine how these maintenance interventions can be improved. It is possible that greater effects may be achieved by providing more tailored intervention. For example, individuals may benefit from different levels of intervention intensity at different times. The personal-contact approach may be superior for some individuals and the interactive technology–based approach for others, or combining elements from both interventions may have additive effects. In addition people attempting to maintain weight loss over the long-term may need to be reenergized, motivation may need to be re-engaged, and social support may need to be reinvigorated. In the interactive technology–based intervention, participants may also need technological enhancements and additional media resources, and they may need occasional personal contacts. Further development of these interventions is needed to increase the proportion of initial weight loss that is maintained and the duration over which it is maintained.

Future intervention development should also consider the fact that weight loss maintenance occurred in a substantial proportion of those in the control group. Similar effects have been seen in control groups in other lifestyle trials,[48] and may simply reflect the fact that the study population is highly selected, highly motivated, and successfully lost weight in phase 1. In addition, there may be an intervention effect associated with the semi-annual data collection visits. However, beyond these factors, identification of predictors of successful weight loss maintenance, regardless of randomized treatment group, may reveal factors that can be emphasized or added to future interventions to improve long-term weight loss maintenance.

The effect of both the personal-contact and interactive technology–based interventions was modest. Future consideration of implementation of these interventions must take into account the cost relative to benefit. But it is important to recognize that to date, there has been little research specifically addressing strategies for maintenance of weight loss, despite the fact that maintenance is the main impediment to long-term weight control. Clearly, these treatment modalities are at the early stages of development. The results of our study lay the groundwork for the development of even more effective approaches to combating and reversing the obesity epidemic, and the results represent significant forward progress.

There were several limitations of the WLM study. First, only individuals who had successfully lost weight in phase 1 were randomized into phase 2. The consequence of this design feature is that the results can only be generalized to the population of successful weight losers. However, this feature was the intent of the study: to compare strategies for maintaining weight loss. Second, there were very few Hispanic participants, another group disproportionately affected by the obesity epi-

demic. Third, our dietary and physical activity measures may not accurately reflect energy intake and expenditure. Food frequency questionnaires tend to underestimate caloric intake[49] while accelerometers may underestimate or overestimate energy expenditure, depending on the kind of physical activity.[50] More accurate measurements are necessary to determine the relative contribution of changes in energy intake and expenditure to weight loss maintenance. Fourth, the duration of intervention was only 3 years. The National Heart, Lung, and Blood Institute has recommended that truly long-term benefit be assessed over at least 5 years.[51] Few previous trials have continued intervention beyond 18 months,[7,18,48] but even longer trials are needed. Fifth, the outcome of WLM was weight loss maintenance, not CVD events. The number of participants and time that would be required for a true outcome study preclude such a design, but improvement in CVD risk factors with weight loss can be reasonably expected to reduce CVD risk.

To our knowledge, this is the longest, largest randomized controlled study that specifically tested alternative strategies for maintenance of weight loss. An important feature of the WLM study was the unusually high proportion of African American participants (38% in WLM vs 18% in TOHP-II[52] and 4% in STOP-Regain [Rena Wing, MD, Brown University Medical Center, written communication, February 2, 2008]). Previous trials suggest that weight loss in African Americans may be particularly challenging.[7,53-55] African Americans in our study achieved more weight loss than in other large studies,[7,55] and there were no significant race-sex interactions with treatment effects. In addition, the rates of adherence and follow-up were high, with 94% of participants attending the final data collection visit. These factors as well as the evaluation of participants prior to initial weight loss and the standardized initial weight loss intervention contribute to the strength of the study.

In conclusion, the majority of individuals who successfully completed an initial 6-month behavioral weight loss program maintained weight below their entry level after 30 additional months. Monthly brief personal-contact sessions provided modest benefit in sustaining weight loss, whereas an Internet-based intervention provided early but transient benefit. Future research should focus on longer intervention and follow-up, understanding predictors of successful maintenance and further refinement of both personal-contact and interactive technology–based interventions.

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REFERENCES

1. Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999-2004. *JAMA*. 2006; 958(13):1549-1555.
2. Flegal KM, Graubard BI, Williamson DF, Gail MH. Excess deaths associated with underweight, overweight, and obesity. *JAMA*. 2005;293(15):1861-1867.
3. Knowler WC, Barrett-Connor E, Fowler SE, et al; Diabetes Prevention Program Research Group. Reduction of the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002; 346(6):393-403.

4. Wood PD, Stefanick ML, Dreon DM, et al. Changes in plasma lipids and lipoproteins in overweight men during weight loss through dieting as compared with exercise. *N Engl J Med*. 1988;319(18):1173-1179.

5. Elmer PJ, Grimm R Jr, Laing B, et al. Lifestyle intervention: results of the Treatment of Mild Hypertension Study (TOMHS). *Prev Med*. 1995;24(4):378-388.

6. Whelton PK, Appel LJ, Espeland MA, et al; TONE Collaborative Research Group. Sodium reduction and weight loss in the treatment of hypertension in older persons: a randomized controlled Trial of Nonpharmacologic Interventions in the Elderly (TONE). *JAMA*. 1998;279(11):839-846.

7. Stevens VJ, Obarzanek E, Cook NR, et al. Long-term weight loss and changes in blood pressure: results of the trials of hypertension prevention, phase II. *Ann Intern Med*. 2001;134(1):1-11.

8. Tuomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med*. 2001;344(18):1343-1350.

9. Jeffery RW, Drewnowski A, Epstein LH, et al. Long-term maintenance of weight loss: current status. *Health Psychol*. 2000;19(1)(suppl):5-16.

10. Wadden TA, Crerand CE, Brock J. Behavioral treatment of obesity. *Psychiatr Clin North Am*. 2005;28(1):151-170.

11. Dansinger ML, Tabsioni A, Wong JB, Chung M, Balk EA. Meta-analysis: the effect of dietary counseling for weight loss. *Ann Intern Med*. 2007;147(1):41-50.

12. Kumanyika S, Brownson RC, eds. *Handbook of Obesity Prevention: A Resource for Health Professionals.* New York, NY: Springer; 2007.

13. Phelan S, Wing RR. Prevalence of successful weight loss. *Arch Intern Med*. 2005;165(20):2430.

14. Wadden TA, Butryn ML, Wilson C. Lifestyle modification for the management of obesity. *Gastroenterology*. 2007;132(6):2226-2238.

15. Wing RR, Phelan S. Long-term weight loss maintenance. *Am J Clin Nutr*. 2005;82(1)(suppl):222S-225S.

16. Wing RR, Tate DF, Gorin AA, Raynor HA, Fava JL, Machan J. "Stop Regain": are there negative effects of daily weighing? *J Consult Clin Psychol*. 2007;75(4):652-656.

17. Hill JO, Wyatt H, Phelan S, Wing R. The National Weight Control Registry: is it useful in helping deal with our obesity epidemic? *J Nutr Educ Behav*. 2005;37(4):206-210.

18. Wing RR, Tate DF. A self-regulation program for maintenance of weight loss. *N Engl J Med*. 2006;355(15):1563-1571.

19. Wing RR, Tate DF, Gorin AA, Raynor HA, Fava JL. Can we stop weight regain? results of a randomized trial. *J Counsult Clin Psychol*. 2007;75(4):652-656.

20. Orleans CT. Promoting the maintenance of health behavior change: recommendations for the next generation of research and practice. *Health Psychol*. 2000;19(1)(suppl):76-83.

21. Mokdad AH. The continuing epidemics of obesity and diabetes in the United States. *JAMA*. 2001;286(10):1195-1200.

22. National Heart, Lung, and Blood Institute. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.*

Washington, DC: US Dept of Health and Human Services; 1998. NIH publication 98-4083.

23. The surgeon general's call to action to prevent and decrease overweight and obesity. http://www.surgeongeneral.gov/topics/obesity. Accessed February 13, 2008.

24. Brantley PJ, Appel LJ, Hollis JF, et al. Weight Loss Maintenance (WLM): design and rationale of a multicenter trial to sustain weight loss. *J Soc Clin Trials*. In press.

25. Stevens VJ, Funk KL, Brantley PJ, et al. Design and implementation of an interactive website to support long-term maintenance of weight loss. *J Med Internet Res*. 2008;10(1):e1.

26. Harlan LC, Block G. Use of adjustment factors with a brief food frequency questionnaire to obtain nutrient values. *Epidemiology*. 1990;1(3):224-231.

27. Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group [see comments]. *N Engl J Med*. 1997;336(16):1117-1124.

28. Svetkey LP, Simons-Morton D, Vollmer WM, et al. Effects of dietary patterns on blood pressure: subgroup analysis of the Dietary Approaches to Stop Hypertension (DASH) randomized clinical trial. *Arch Intern Med*. 1999;159(3):285-293.

29. Obarzanek E, Sacks FM, Vollmer WM, et al; DASH Research Group. Effects on blood lipids of a blood pressure-lowering diet: the Dietary Approaches to Stop Hypertension (DASH) Trial. *Am J Clin Nutr*. 2001;74(1):1-89.

30. Miller ER III, Appel LJ, Risby TH. Effect of dietary patterns on measures of lipid peroxidation: results from a randomized clinical trial. *Circulation*. 1998;98(22):2390-2395.

31. Appel LJ, Miller ER III, Jee SH, et al. Effect of dietary patterns on serum homocysteine: results of a randomized, controlled feeding study. *Circulation*. 2000;102(8):852-857.

32. Sacks FM, Svetkey LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *N Engl J Med*. 2001;344(1):3-10.

33. Jakicic JM, Winters C, Lang W, Wing RR. Effects of intermittent exercise and use of home exercise equipment on adherence, weight loss, and fitness in overweight women: a randomized trial. *JAMA*. 1999;282(16):1554-1560.

34. Jakicic JM, Marcus BH, Gallagher KI, Napolitano M, Lang W. Effect of exercise duration and intensity on weight loss in overweight, sedentary women: a randomized trial. *JAMA*. 2003;290(10):1323-1330.

35. Wadden TA, Butryn ML, Byrne KJ. Efficacy of lifestyle modification for long-term weight control. *Obes Res*. 2004;12(suppl):151S-162S.

36. Wagner EH, Glasgow RE, Davis C, et al. Quality improvement in chronic illness care: a collaborative approach. *Jt Comm J Qual Improv*. 2001;27(2):63-80.

37. Medicare Medical Nutrition Therapy Amendment Act of 2001, HR 107th Cong, 1st Sess (2001).

38. Holm S. A simple sequentially rejective multiple test procedure. *Scand J Stat*. 1979;6:65-70.

39. Aickin M, Gensler H. Adjusting for multiple testing when reporting research results: the Bonferroni vs Holm methods. *Am J Public Health*. 1996;86(5):726-728.

40. Proschan MA, Waclawiw MA. Practical guidelines for multiplicity adjustment in clinical trials. *Control Clin Trials*. 2000;21(6):527-539.

41. Collins LM, Schafer JL, Kam CM. A comparison of inclusive and restrictive strategies in modern missing data procedures. *Psychol Methods*. 2001;6(4):330-351.

42. Schafer JL, Graham JW. Missing data: our view of the state of the art. *Psychol Methods*. 2002;7(2):147-177.

43. Rubin DB. *Multiple Imputation for Nonresponse in Surveys.* New York, NY: John Wiley & Sons Inc; 1987.

44. Neter JE, Stam BE, Kok FJ, Grobbee DE, Geleijnse JM. Influence of weight reduction on blood pressure: a meta-analysis of randomized controlled trials. *Hypertension*. 2003;42(5):878-884.

45. Hamman RF, Wing RR, Edelstein SL, et al; for the Diabetes Prevention Program Research Group. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care*. 2006;29(9):2102-2107.

46. Eddy DM, Schlessinger L, Kahn R. Clinical outcomes and cost-effectiveness of strategies for managing people at high risk for diabetes. *Ann Intern Med*. 2005;143(4):251-264.

47. Ikeda J, Amy NK, Ernsberger P, et al. The National Weight Loss Control Registry: a critique. *J Nutr Educ Behav*. 2005;37(4):203-205.

48. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *JAMA*. 2003;289(16):2083-2093.

49. Subar AF, Kipnis V, Troiano RP, et al. Using intake biomarkers to evaluate the extent of dietary misreporting in a large sample of adults: the OPEN study. *Am J Epidemiol*. 2003;158(1):1-13.

50. Bassett DR Jr, Ainsworth BE, Swartz AM, Strath SJ, O'Brien WL, King GA. Validity of four motion sensors in measuring moderate intensity physical activity. *Med Sci Sports Exerc*. 2000;32(9)(suppl):S471-S480.

51. National Heart, Lung, and Blood Institute. *Think Tank on Enhancing Obesity Research at the National Heart, Lung, and Blood Institute.* Washington, DC: Dept of Health and Human Services; 2004. NIH publication 04-5249.

52. Appel LJ, Hebert PR, Cohen JD, et al; for the Trials of Hypertension Prevention (TOHP) Collaborative Research Group. Baseline characteristics of participants in phase II of the Trials of Hypertension Preventions (TOHP-II). *Ann Epidemiol*. 1995;5(2):149-155.

53. Ard JD, Rosati R, Oddone EZ. Culturally-sensitive weight loss program produces significant reduction in weight, blood pressure, and cholesterol in eight weeks. *J Natl Med Assoc*. 2000;92(11):515-523.

54. Kumanyika SK, Obarzanek E, Stevens VJ, Hebert PR, Whelton PK. Weight-loss experience of black and white participants in NHLBI-sponsored clinical trials [published correction appears in *Am J Clin Nutr*. 2003;77(5):1342]. *Am J Clin Nutr*. 1991;53(6)(suppl):1631S-1638S.

55. Svetkey LP, Erlinger TP, Vollmer WM, et al. Effect of lifestyle modifications on blood pressure by race, sex, hypertension status, and age. *J Hum Hypertens*. 2005;19(1):21-31.