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## Comparative Effectiveness of Weight-Loss Interventions in Clinical Practice

Lawrence J. Appel, M.D., M.P.H., Jeanne M. Clark, M.D., M.P.H., Hsin-Chieh Yeh, Ph.D., Nae-Yuh Wang, Ph.D., Janelle W. Coughlin, Ph.D., Gail Daumit, M.D., M.H.S., Edgar R. Miller III, M.D., Ph.D., Arlene Dalcin, R.D., Gerald J. Jerome, Ph.D., Steven Geller, M.D., Gary Noronha, M.D., Thomas Pozefsky, M.D., Jeanne Charleston, R.N., Jeffrey B. Reynolds, M.S., Nowella Durkin, Richard R. Rubin, Ph.D., Thomas A. Louis, Ph.D., and Frederick L. Brancati, M.D., M.H.S.

### ABSTRACT

#### BACKGROUND

Obesity and its cardiovascular complications are extremely common medical problems, but evidence on how to accomplish weight loss in clinical practice is sparse.

#### METHODS

We conducted a randomized, controlled trial to examine the effects of two behavioral weight-loss interventions in 415 obese patients with at least one cardiovascular risk factor. Participants were recruited from six primary care practices; 63.6% were women, 41.0% were black, and the mean age was 54.0 years. One intervention provided patients with weight-loss support remotely — through the telephone, a study-specific Web site, and e-mail. The other intervention provided in-person support during group and individual sessions, along with the three remote means of support. There was also a control group in which weight loss was self-directed. Outcomes were compared between each intervention group and the control group and between the two intervention groups. For both interventions, primary care providers reinforced participation at routinely scheduled visits. The trial duration was 24 months.

#### RESULTS

At baseline, the mean body-mass index (the weight in kilograms divided by the square of the height in meters) for all participants was 36.6, and the mean weight was 103.8 kg. At 24 months, the mean change in weight from baseline was  $-0.8$  kg in the control group,  $-4.6$  kg in the group receiving remote support only ( $P < 0.001$  for the comparison with the control group), and  $-5.1$  kg in the group receiving in-person support ( $P < 0.001$  for the comparison with the control group). The percentage of participants who lost 5% or more of their initial weight was 18.8% in the control group, 38.2% in the group receiving remote support only, and 41.4% in the group receiving in-person support. The change in weight from baseline did not differ significantly between the two intervention groups.

#### CONCLUSIONS

In two behavioral interventions, one delivered with in-person support and the other delivered remotely, without face-to-face contact between participants and weight-loss coaches, obese patients achieved and sustained clinically significant weight loss over a period of 24 months. (Funded by the National Heart, Lung, and Blood Institute and others; ClinicalTrials.gov number, NCT00783315.)

From the Welch Center for Prevention, Epidemiology, and Clinical Research, Johns Hopkins University (L.J.A., J.M.C., H.-C.Y., N.-Y.W., G.D., E.R.M., F.L.B.); the Divisions of General Internal Medicine (L.J.A., J.M.C., H.-C.Y., N.-Y.W., G.D., E.R.M., A.D., G.J.J., G.N., T.P., J.B.R., N.D., F.L.B.) and Endocrinology (T.P.) and the Departments of Psychiatry and Behavioral Sciences (J.W.C.) and Pediatrics (R.R.R.), Johns Hopkins University School of Medicine; the Departments of Epidemiology (L.J.A., J.M.C., H.-C.Y., J.C., F.L.B.) and Biostatistics (N.-Y.W., T.A.L.), Johns Hopkins Bloomberg School of Public Health; and Johns Hopkins Community Physicians (G.N.) — all in Baltimore; and the Department of Kinesiology, Towson University, Towson (G.J.J.); the Centennial Medical Group, Elkridge (S.G.); and Park Medical Associates, Timonium (T.P.) — all in Maryland. Address reprint requests to Dr. Appel at [lappel@jhmi.edu](mailto:lappel@jhmi.edu).

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**O**BESITY IS AN IMPORTANT AND GROWING public health problem around the world. In the United States, approximately one third of adults are obese.<sup>1</sup> Obesity adversely affects each of the major cardiovascular risk factors — blood pressure, lipid profile, and diabetes. As a consequence, obese persons have an increased risk of death, especially from cardiovascular disease.<sup>2,3</sup> The economic burden of the obesity epidemic is enormous; the estimated direct and indirect costs related to obesity exceed \$110 billion annually in the United States.<sup>4</sup>

An extensive body of evidence from efficacy trials has shown that weight loss is achievable and that modest weight loss has beneficial effects on cardiovascular risk factors.<sup>5-7</sup> However, virtually all these trials tested intensive in-person interventions in highly selected participants. Typically, primary care providers (PCPs) were not directly involved in the intervention. Few weight-loss trials have examined the effect of behavioral interventions in clinical practice,<sup>8</sup> and the results of these trials have been inconsistent. Consequently, even though it is recommended that clinicians offer intensive counseling and behavioral support to their obese patients,<sup>9</sup> practicing physicians lack effective, empirically supported models of treatment to guide their efforts in helping obese patients lose weight.

To address the need for treatment models, we conducted a randomized, controlled trial to determine the effectiveness of two behavioral weight-loss interventions — including one without in-person contact — in obese patients with at least one cardiovascular risk factor. The intervention without in-person contact provided patients with support by means of the telephone, the Internet, and e-mail. The other intervention offered these remote sources of support but reflected common practice in efficacy trials by also providing face-to-face group and individual sessions conducted by health coaches. Participants in the control group received brief advice but none of the above resources. We hypothesized that patients assigned to both active interventions would achieve greater weight loss than those in the control group. We further hypothesized that patients in the group receiving in-person support would achieve greater weight loss than those in the group receiving only remote support.

## METHODS

### OVERSIGHT

This trial is one of three independent trials in the Practice-based Opportunities for Weight Reduction (POWER) trials, each supported by a grant from the National Heart, Lung, and Blood Institute.<sup>10,11</sup> For this trial, Healthways, a disease-management company, also provided support. The Prevention and Control Core of the Baltimore Diabetes Research and Training Center contributed to the data analysis. An institutional review board approved the trial, as did an independent data and safety monitoring board. All participants provided written informed consent. Healthways employees contributed to the study design, particularly on technical matters related to the design of the study-specific Web site. The first author wrote the article and vouches for the accuracy of the data and the analyses. The National Heart, Lung, and Blood Institute and Healthways had opportunities to comment on the manuscript. The final decisions regarding the content and composition of the manuscript and the decision to submit it for publication were made by the academic investigators. The study was conducted according to the protocol (available with the full text of this article at NEJM.org).

### STUDY POPULATION

The study population consisted of obese adults who were at least 21 years of age and had one or more cardiovascular risk factors (hypertension, hypercholesterolemia, or diabetes). To be eligible for the trial, potential participants had to be a patient at one of the participating primary care practices, have regular access to a computer, and have basic computer skills (i.e., could enter data into a Web site and send and receive e-mail). We excluded patients who had recently lost 5% or more of their body weight or were taking medications that cause weight gain or prevent weight loss (e.g., glucocorticoids or second-generation antipsychotic medications). In general, the eligibility criteria for the trial were less stringent than those typically used in efficacy trials.<sup>6,12-14</sup> There was no run-in period, no test given before randomization to determine adherence to study procedures, and no requirement that participants attend group sessions. Our approach to enrollment was to accept a person for

study participation even if there were doubts about the likelihood that the person would adhere to the study protocol or be available for follow-up. (See the protocol for a complete list of enrollment criteria.)

Participants were recruited from primary care practices in the Baltimore metropolitan area between February 2008 and February 2009 through physician referral, brochures, and targeted mailings. Eight clinics were invited to participate in the study, and six accepted. At the participating clinics, 46 PCPs enrolled participants; only 1 physician declined.

#### STUDY GROUPS

Randomization was stratified according to sex and was generated in blocks of 3 and 6 with the use of a Web-based program. The research staff who notified participants of their assignment were not involved in the collection of follow-up data.

Participants had an equal chance of being assigned to any one of the three study groups. The theoretical framework for the two active interventions was based on social cognitive theory and incorporated behavioral self-management approaches designed to help participants set weight-related goals, self-monitor weight and weight-related behaviors (exercise and reduced calorie intake), increase self-efficacy and social support, and solve problems. These approaches were modeled on those tested in previous trials.<sup>15-17</sup> Motivational interviewing was the primary approach to interactions with participants. Participants in the two intervention groups were encouraged to lose 5% of their baseline weight within 6 months and to maintain the reduced weight until the end of the study. Table 1 shows the key features of the two intervention groups. (For more information on the interventions, see the protocol and the Supplementary Appendix, available at NEJM.org.)

Participants in both intervention groups were encouraged to log on to the study-specific Web site weekly. The Web site contained learning modules; opportunities for self-monitoring of weight, calorie intake, and exercise; and feedback on progress in these key behaviors. Each participant who was assigned to an active intervention received automated monthly e-mail messages summarizing his or her progress. Automated re-engagement e-mail messages were sent to participants who had not logged on to the Web site in the preceding 7 days.

**Table 1. Features of Both Interventions.\***

#### Coaches

- Delivered the interventions in collaboration with the PCP to promote weight loss
- Focused on key weight-management behaviors (reduced calorie intake as part of the DASH diet, increased exercise, regular log-in to the study Web site, and use of food records)
- Used motivational interviewing techniques (e.g., asking open-ended questions, exploring participants' feelings of ambivalence, supporting their optimism regarding change, and directing conversations toward the desired behavioral goals)
- Followed re-engagement procedures when participants did not log in to the study Web site (automated e-mail message sent after 7 to 10 days without log-in and telephone call made after 14 days without log-in)
- Received case-management support

#### Web-based support

- Provided learning modules consisting of objectives, educational content, quizzes, and worksheets
- Provided self-monitoring tools and graphs (to record weight, minutes of exercise per day, and calories consumed per day), with a recommendation to record weight at least weekly on the study Web site
- Provided feedback regarding weight-loss progress (e.g., change in weight since last log-in and weight trend)

#### PCPs

- Reviewed one-page report on patient's weight-loss progress at each routine office visit
- Encouraged participation in the intervention
- Reported events that might affect patient's ability to participate in the intervention
- Sent letters to participants as part of the re-engagement strategy after prolonged periods with no participant contact
- For patients with diabetes, provided assistance with self-monitoring of glucose levels and medication adjustment

\* DASH denotes Dietary Approaches to Stop Hypertension, and PCP primary care provider.

Weight-loss coaches encouraged participants to complete the learning modules and provided positive reinforcement of key behaviors, with an emphasis on self-monitoring of weight, calorie intake, and exercise. Individual sessions (in person or by telephone) were approximately 20 minutes long; group sessions conducted for the group receiving in-person support typically lasted 90 minutes. Participants in both intervention groups were offered weekly contact with coaches during the first 3 months (nine group sessions and three individual sessions for participants receiving in-person support, and 12 weekly calls for those receiving only remote support). During the next

3 months, participants receiving in-person support were offered three monthly contacts (one group session and two individual sessions), whereas the group receiving only remote support were offered 1 call each month. For the remainder of the study, participants in the group receiving in-person support were offered two monthly contacts (one group session and one individual session, with the latter conducted either in person or by telephone), and the group receiving only remote support continued to be offered monthly calls.

The coaches for the group receiving in-person support were employees of Johns Hopkins University, and the coaches for the group receiving only remote support were employees of Healthways. Coaches were trained before enrollment of the first participant and on a quarterly basis thereafter. The topics covered included behavioral theory and strategies, basic nutritional and exercise guidelines, motivational interviewing techniques, and study procedures, including use of the intervention Web site. To assess fidelity to the protocol and to promote motivational interviewing techniques, a case-management team observed the coaches and provided feedback monthly for the first 3 months of the study and quarterly thereafter.

Participants in the control group met with a weight-loss coach at the time of randomization and, if desired, after the final data-collection visit, at 24 months. They also received brochures and a list of recommended Web sites promoting weight loss.

#### ROLE OF THE PCP

PCPs played a supportive role in the study. At routinely scheduled visits, each PCP received and reviewed a progress report on any of their patients who had been assigned to an intervention group (see the sample report in the Supplementary Appendix). PCPs used this report to provide patients with basic guidance (i.e., reduce calorie intake and increase exercise) and to motivate their patients. The report included a graph from the Web site showing the patient's baseline, target, and self-reported weights. If patients were not actively participating in their assigned intervention, the coaches sent re-engagement letters on behalf of the PCP.

#### DATA COLLECTION

Eligibility, baseline, and follow-up data were collected by telephone, through the Web, and through in-person visits. The enrollment process involved a

Web-based contact, an in-person visit during which baseline data were collected, and a second in-person visit at which participants were notified of their assigned group. Participants were asked to make in-person follow-up visits 6, 12, and 24 months after randomization. At each of these visits, weight was measured on a high-quality, calibrated digital scale, with the participant wearing light, indoor clothes and no shoes. Height was measured once, at study entry. Blood pressure was recorded at each of the three visits; waist circumference and fasting levels of blood glucose and lipids were measured at baseline and 6 and 24 months after randomization. Trained research staff who were not informed of the group assignment performed the measurements.

#### STATISTICAL ANALYSIS

The primary outcome was change in weight from baseline to 24 months. Other weight-related outcomes were percentage of weight change from baseline, percentage of participants without weight gain, percentage of participants who lost at least 5% of their initial weight, and change from baseline in body-mass index (BMI, the weight in kilograms divided by the square of the height in meters). The primary analysis was based on the intention-to-treat principle. All weights obtained before a protocol-defined censoring event (i.e., pregnancy, bariatric surgery, or amputation) were included in the analysis, which was conducted with the use of a saturated-means, repeated-measures, mixed-effects model for visit-specific weight, with indicators for missing data. Means were modeled as a function of the group assignment and study visit (at baseline and at 6, 12, and 24 months). The model included adjustment for clinic, sex, age, and race or ethnic group. An unstructured covariance structure was used to relate the repeated measures. In addition, robust standard errors were computed. This approach produces valid estimates if data are missing at random.

The same modeling approach was used for the dependent variables of percentage change in weight and change in BMI. In addition, percentages of participants in each of the three study groups who met various weight-loss thresholds were compared with the use of a binomial model. Analyses were conducted with the use of SAS software, version 9.2 (SAS Institute) or the statistical software system R, version 2.10.0. The Holm procedure was used to adjust for multiple comparisons.<sup>18</sup> The

trial was designed to have 80% power to detect a between-group difference in weight change of 2.75 kg for at least one of the two primary comparisons (the group receiving remote support only vs. the control group and the group receiving in-person support vs. the control group), each at a two-sided significance level of 0.025.

## RESULTS

### STUDY PARTICIPANTS

A total of 1370 persons registered at the recruitment Web site, and 415 underwent randomization (for details, see Fig. 1 in the Supplementary Appendix). Of the 415 participants, 63.6% were women and 41.0% were black; the mean age was 54.0 years (Table 2). At baseline, the mean BMI was 36.6. Most participants (83.6%) had attempted to lose weight during the 12 months preceding the study.

### WEIGHT LOSS

After randomization, weight was recorded for 366 participants (88.2%) at 6 months, for 355 (85.5%) at 12 months, and for 392 (94.5%) at 24 months. At 6 months, the mean ( $\pm$ SE) adjusted change in weight from baseline was  $-1.4\pm 0.4$  kg in the control group,  $-6.1\pm 0.5$  kg in the group receiving remote support only, and  $-5.8\pm 0.6$  kg in the group receiving in-person support. At 24 months, the mean change in weight from baseline was  $-0.8\pm 0.6$  kg in the control group,  $-4.6\pm 0.7$  kg in the group receiving remote support only, and  $-5.1\pm 0.8$  kg in the group receiving in-person support, corresponding to a weight change of  $-1.1\%$ ,  $-5.0\%$ , and  $-5.2\%$ , respectively (Fig. 1, and Tables 1 and 2 in the Supplementary Appendix). The net weight change at 24 months in the two intervention groups (the change in each intervention group minus the change in the control group) was  $-3.8$  kg (95% confidence interval [CI],  $-5.7$  to  $-1.9$ ;  $P<0.001$ ) in the group receiving remote support only and  $-4.3$  kg (95% CI,  $-6.3$  to  $-2.3$ ;  $P<0.001$ ) in the group receiving in-person support. There was no significant difference in weight change between the intervention groups at any time point. At 24 months, the mean difference in weight change between these two groups (the mean change in the group receiving in-person support minus the mean change in the group receiving remote support) was  $-0.5$  kg (95% CI,  $-2.5$  to  $1.5$ ;  $P=0.63$ ).

Table 3 shows the percentage of participants who met certain weight-change thresholds 6 and

24 months after randomization. At 24 months, the percentage of participants in the control group with a weight that was lower than their weight at baseline was 52.3% as compared with 74.4% in the group receiving in-person support and 77.1% in the group receiving remote support only. The percentage of participants whose weight at 24 months was at least 5% below their baseline weight was 18.8% in the control group, 41.4% in the group receiving in-person support, and 38.2% in the group receiving remote support only.

### PARTICIPATION RATES

Table 4 shows the actual and recommended rates of study participation in the intervention groups. In the group receiving remote support only, the median number of completed phone calls was 14 in the first 6 months and 16 for the remainder of the trial. In the group receiving in-person support, most contact with coaches during the first 6 months occurred in face-to-face group sessions. Participation in group sessions, although strongly encouraged, was initially low and declined further over the course of the study. The median number of group sessions attended was 6.5 in the first 6 months and 1 in the next 18 months, and the median number of individual sessions attended was 4 in the first 6 months and 1 in the last 18 months. In the group receiving in-person support only, the median number of phone calls was 4 in the first 6 months and 11 in the last 18 months. Both intervention groups used the Web site frequently. The number of reports reviewed by the PCPs was similar in the two groups. The percentage of participants who dropped out of the intervention (defined as having no contact with a coach and no use of study Web site for 2 months) was 5.0% at 6 months and 13.0% at 24 months for the group receiving remote support and 8.7% at 6 months and 15.9% at 24 months for the group receiving in-person support.

### ADVERSE EVENTS

There was one serious adverse event that may have been related to the study. One participant in the group receiving in-person support was assaulted while exercising and had musculoskeletal injuries. At data-collection visits, 48 hospitalizations were reported (15 in the control group, 15 in the group receiving remote support, and 18 in the group receiving in-person support). There were no deaths or serious hypoglycemic events.



Characteristic	Control (N=138)	Remote Support Only (N=139)	In-Person Support (N=138)	All Participants (N=415)
Age — yr	52.9±10.1	55.8±9.7	53.3±10.5	54.0±10.2
Weight — kg	104.4±18.6	102.1±13.9	105.01±20.7	103.4±17.9
BMI†	36.8±5.14	36.0±4.7	36.8±5.2	36.6±5.0
Waist circumference — cm	118.2±13.7	117.9±12.7	118.2±14.4	118.1±13.6
Race or ethnic group — no. (%)‡§				
Asian	2 (1.4)	2 (1.4)	0 (0.0)	4 (1.0)
Black	59 (42.8)	52 (37.4)	59 (42.8)	170 (41.0)
White	72 (52.2)	83 (59.7)	78 (56.5)	233 (56.1)
Other	5 (3.6)	2 (1.4)	1 (0.7)	8 (1.9)
Hispanic	3 (2.2)	3 (2.2)	3 (2.2)	9 (2.2)
Education — no. (%)				
High-school graduate or less	18 (13.0)	15 (10.8)	11 (8.0)	44 (10.6)
Some college	45 (32.6)	43 (30.9)	37 (26.8)	125 (30.1)
College graduate	75 (54.3)	81 (58.3)	90 (65.2)	246 (59.3)
Female sex — no. (%)	88 (63.8)	88 (63.3)	88 (63.8)	264 (63.6)
Household income — no. (%)				
<\$50,000	33 (23.9)	28 (20.1)	30 (21.7)	91 (21.9)
\$50,000–99,999	52 (37.7)	53 (38.1)	50 (36.2)	155 (37.3)
≥\$100,000	53 (38.4)	58 (41.7)	58 (42.0)	169 (40.7)
Employment status — no. (%)				
Employed	106 (76.8)	101 (72.7)	105 (76.1)	312 (75.2)
Retired	17 (12.3)	28 (20.1)	20 (14.5)	65 (15.7)
Other	15 (10.9)	10 (7.2)	13 (9.4)	38 (9.2)
Health insurance — no. (%)§				
Private or HMO	133 (96.4)	136 (97.8)	135 (97.8)	404 (97.3)
Medicare	11 (8.0)	20 (14.4)	13 (9.4)	44 (10.6)
Medicaid	0 (0.0)	0 (0.0)	2 (1.4)	2 (0.5)
Uninsured	3 (2.2)	1 (0.7)	0 (0.0)	4 (1.0)
Medical conditions — no. (%)				
Hypertension¶	106 (77.4)	112 (80.6)	98 (71.0)	316 (76.3)
Diabetes	32 (23.2)	31 (22.3)	33 (23.9)	96 (23.1)
Hypercholesterolemia	94 (68.1)	99 (71.2)	88 (63.8)	281 (67.7)
Daily Internet use — %	119 (86.2)	120 (86.3)	121 (87.7)	360 (86.7)
Weight loss attempted in last 12 mo — no. (%)	117 (84.8)	113 (81.3)	117 (84.8)	347 (83.6)

\* Plus-minus values are means ±SD. With the exception of age (P=0.03 by analysis of variance) there were no significant differences in baseline characteristics among the three study groups. HMO denotes health maintenance organization.

† The body-mass index (BMI) is the weight in kilograms divided by the square of the height in meters.

‡ Race or ethnic group was self-reported.

§ The categories listed under race or ethnic group and under health insurance are not mutually exclusive, and the percentages for these categories therefore do not sum to 100.

¶ Data on hypertension were not available for one participant in the control group.

## DISCUSSION

In this comparative effectiveness trial, in which obese medical patients with at least one cardiovascular risk factor were enrolled, two behavioral interventions — one involving no in-person contact with weight-loss coaches associated with the study or with other participants — achieved clinically relevant weight loss. The extent of weight loss was similar to that achieved in many efficacy studies.<sup>12-14</sup> In contrast with the findings in most weight-loss trials,<sup>19,20</sup> however, participants sustained weight loss to the end of the trial. A large percentage of participants lost 5% or more of their initial body weight, an amount of weight loss that has been associated with numerous health benefits, including improved control of diabetes and hypertension, a reduced risk of incident diabetes and hypertension, and lower levels of risk factors for cardiovascular disease.<sup>5-7,12,13</sup>

In contrast with most weight-loss trials, this was a trial of effectiveness rather than efficacy. At each point in its design and implementation, we tailored our approach to reflect the setting — namely, primary care practices. For example, we did not have a run-in period or conduct an adherence test before randomization, required only two

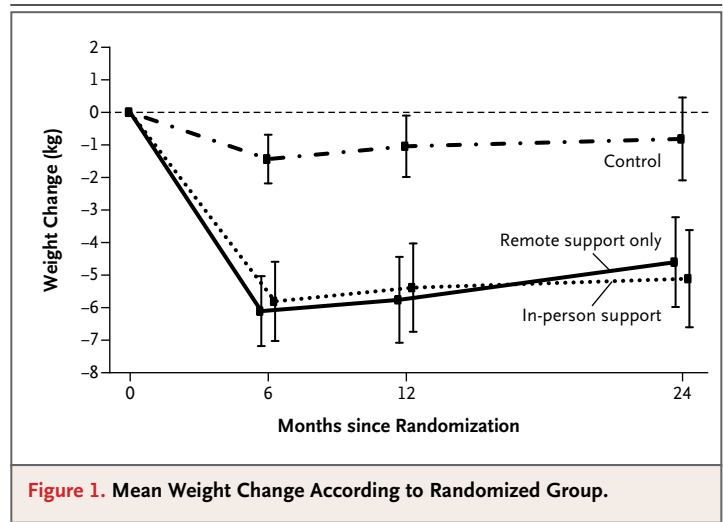


Figure 1. Mean Weight Change According to Randomized Group.

visits by potential participants to determine eligibility, and modified our interventions considerably, mostly by reducing the intensity of the intervention and increasing flexibility. For the participants in the group receiving in-person support, we encouraged but did not mandate participation in group sessions and gave these participants the option of maintaining individual contact by phone rather than in person. Unlike efficacy trials, in which one

Table 3. Proportion of Participants Who Met Various Weight-Loss Criteria at 6 and 24 Months of Follow-up.

Criterion	Control	Remote Support Only	In-Person Support	P Value		
				Remote Support Only vs. Control	In-Person Support vs. Control	In-Person Support vs. Remote Support Only
<i>no. of participants/total no. (%)</i>						
At or below baseline weight						
6 mo	75/113 (66.4)	110/129 (85.3)	105/124 (84.7)	<0.001	0.001	0.84
24 mo	67/128 (52.3)	101/131 (77.1)	99/133 (74.4)	<0.001	<0.001	0.81
At least 5% below baseline weight						
6 mo	16/113 (14.2)	68/129 (52.7)	57/124 (46.0)	<0.001	<0.001	0.23
24 mo	24/128 (18.8)	50/131 (38.2)	55/133 (41.4)	<0.001	<0.001	0.73
At least 10% below baseline weight						
6 mo	4/113 (3.5)	30/129 (23.3)	31/124 (25.0)	<0.001	<0.001	0.92
24 mo	11/128 (8.6)	24/131 (18.3)	26/133 (19.5)	0.02	0.01	0.69
BMI <30						
6 mo	12/113 (10.6)	36/129 (27.9)	27/124 (21.8)	<0.001	0.02	0.22
24 mo	10/128 (7.8)	36/131 (27.5)	25/133 (18.8)	<0.001	0.01	0.07

<b>Table 4. Numbers of Recommended and Actual Contacts According to Intervention Group.</b>								
Type of Contact	Beginning of Study to 6 Mo				7 Mo to End of Study*			
	Remote Support Only		In-Person Support		Remote Support Only		In-Person Support	
	Recommended†	Actual‡	Recommended†	Actual‡	Recommended†	Actual‡	Recommended†	Actual‡
<b>Coach</b>								
Total no. of contacts	15		21		18		36	
Median		14		14		16		16
Quartile 1		13		9		12		10
Quartile 3		15		17		18		20
Telephone calls (no.)	15		3		18		12	
Median		14		4		16		11
Quartile 1		13		2		12		6
Quartile 3		15		5		18		14
<b>In-person sessions (no.)</b>								
Individual			6				6	
Median				4				1
Quartile 1				2				0
Quartile 3				5				4
Group			12				18	
Median				6.5				1
Quartile 1				2				0
Quartile 3				9				4
<b>Study Web site</b>								
No. of wk with log-ins	26		26		72		72	
Median		23		20.5		35		32
Quartile 1		17		14		16		11
Quartile 3		25		25		59		58
No. of modules completed	12		12		18		18	
Median		12		12		16		8
Quartile 1		12		6		5		0
Quartile 3		12		12		17		16
<b>PCP</b>								
No. of reports reviewed with participant	NA		NA		NA		NA	
Median		1		1		1		1
Quartile 1		0		0		0		0
Quartile 3		1		1		2		2

\* The end of the study occurred 22 to 26 months after randomization. NA denotes not applicable.

† The recommended number of contacts was determined on the basis of a 24-month intervention period.

‡ The actual number of contacts was determined between 22 and 26 months after randomization.

eligibility criterion is confirmed availability for group sessions, we imposed no such requirement, a policy that no doubt contributed to low attendance at group sessions.

Few trials have attempted behavioral weight-loss strategies in the primary care setting, and none have implemented interventions similar to those tested in the POWER trial. Tsai and Wadden



conducted a systematic review of the literature on this topic.<sup>8</sup> Of the 10 trials identified, 4 trials tested the use of PCP counseling alone, 3 tested PCP counseling with pharmacotherapy, and 3 tested a collaborative approach in which the intervention was delivered by care providers other than PCPs. The results of these trials were inconsistent, and most of them had one or more limitations (e.g., small sample size, brief duration, low rate of follow-up, or a combination thereof).<sup>21-23</sup>

Our trial has limitations. Its duration, although longer than that of many weight-loss trials, was only 2 years. Still, to our knowledge, it is one of the longest trials of a remote (telephone- or Web-based) intervention.<sup>24,25</sup> Second, the study was a single-center trial, although it did involve six clinics. Third, the relative contribution of each component of the interventions (personalized counseling, reinforcement by PCPs, and Web-based support) is difficult to assess. Fourth, although we collected data on cardiovascular risk factors (in the Supplementary Appendix), we did not design the trial to reconfirm the well-established relationship between weight reduction and improvements in blood pressure, lipid profile, and glucose levels. Consequently, nonsignificant relationships should be interpreted cautiously. The trial also had several strengths, including a diverse population and high rates of adherence and follow-up.

Our results have implications for the delivery of behavioral interventions. First, in contrast with previous interventions involving only telephone- or Web-based interventions, the weight loss achieved in the group receiving remote support only was substantial and similar in magnitude to that

achieved in the group receiving in-person support in addition to remote support. The effectiveness of remote support is particularly noteworthy because of the flexibility it offers to both participants and coaches and because it is scalable.<sup>26</sup> Second, implementing programs similar to those used in the intervention groups in primary care could help stem the tide of obesity-related disease, but it would also require changes in health care delivery systems and reimbursement policies.<sup>27</sup> Although in our study a disease-management company delivered the intervention restricted to remote support only, other groups, including large physician practices and insurers, could implement such programs, which could also be part of patient-centered medical home initiatives. Finally, the paradigm of remote counseling, reinforcement of patient change by PCPs, and use of a Web site with portals for patients, counselors, and physicians could improve the management of other chronic conditions.

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## REFERENCES

1. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999-2008. *JAMA* 2010; 303:235-41.
2. Flegal KM, Graubard BI, Williamson DF, Gail MH. Excess deaths associated with underweight, overweight, and obesity. *JAMA* 2005;293:1861-7.
3. Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *Lancet* 2009;373:1083-96.
4. Finkelstein EA, Fiebelkorn IC, Wang G. National medical spending attributable to overweight and obesity: how much, and who's paying? *Health Aff (Millwood)* 2003; Suppl Web Exclusives:W3-219-W3-226.
5. 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;42:878-84.
6. The Look AHEAD Research Group. Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: four-year results of the Look AHEAD trial. *Arch Intern Med* 2010;170:1566-75.
7. 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;319:1173-9.
8. Tsai AG, Wadden TA. Treatment of obesity in primary care practice in the United States: a systematic review. *J Gen Intern Med* 2009;24:1073-9.
9. U.S. Preventive Services Task Force. Screening for obesity in adults: recommendations and rationale. *Ann Intern Med* 2003;139:930-2.
10. Jerome GJ, Yeh H, Dalcin A, et al. Treatment of obesity in primary care practice: the Practice Based Opportunities for Weight Reduction (POWER) Trial at Johns Hopkins. *Obesity Management. Obes Weight Manage* 2009;5:216-21.
11. Yeh HC, Clark JM, Emmons KE, et al. Independent but coordinated trials: insights from the Practice-based Opportunities for Weight Reduction Trials Collaborative Research Group. *Clin Trials* 2010; 7:322-32.
12. The Trials of Hypertension Prevention Collaborative Research Group. Effects of weight loss and sodium reduction inter-

- vention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure: the Trials of Hypertension Prevention, phase II. *Arch Intern Med* 1997;157:657-67.
13. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393-403.
14. 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;289:2083-93.
15. Diabetes Prevention Program (DPP) Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care* 2002;25:2165-71.
16. Funk KL, Elmer PJ, Stevens VJ, et al. PREMIER — a trial of lifestyle interventions for blood pressure control: intervention design and rationale. *Health Promot Pract* 2006;9:271-80.
17. Brantley P, Appel L, Hollis J, et al. Design considerations and rationale of a multi-center trial to sustain weight loss: the Weight Loss Maintenance Trial. *Clin Trials* 2008;5:546-56.
18. Holm S. A Simple Sequentially rejective multiple test procedure. *Scand J Stat* 1979;6:65-70.
19. Elmer PJ, Obarzanek E, Vollmer WM, et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. *Ann Intern Med* 2006;144:485-95.
20. 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;134:1-11.
21. Ashley JM, St Jeor ST, Schrage JP, et al. Weight control in the physician's office. *Arch Intern Med* 2001;161:1599-604.
22. Ely AC, Banitt A, Befort C, et al. Kansas primary care weighs in: a pilot randomized trial of a chronic care model program for obesity in 3 rural Kansas primary care practices. *J Rural Health* 2008;24:125-32.
23. Logue E, Sutton K, Jarjoura D, Smucker W, Baughman K, Capers C. Transtheoretical model—chronic disease care for obesity in primary care: a randomized trial. *Obes Res* 2005;13:917-27.
24. Tate DF, Jackvony EH, Wing RR. A randomized trial comparing human e-mail counseling, computer-automated tailored counseling, and no counseling in an Internet weight loss program. *Arch Intern Med* 2006;166:1620-5.
25. Digenio AG, Mancuso JP, Gerber RA, Dvorak RV. Comparison of methods for delivering a lifestyle modification program for obese patients: a randomized trial. *Ann Intern Med* 2009;150:255-62.
26. Krukowski RA, West DS, Harvey-Berino J. Recent advances in Internet-delivered, evidence-based weight control programs for adults. *J Diabetes Sci Technol* 2009;3:184-9.
27. Kushner RF. Tackling obesity: is primary care up to the challenge? *Arch Intern Med* 2010;170:121-3.

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