Obesity Treatment for Socioeconomically Disadvantaged Patients in Primary Care Practice

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Abstract

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Background—Few evidence-based weight loss treatment options exist for medically vulnerable patients in the primary care setting.

Methods—We conducted a 2-arm, 24-month randomized effectiveness trial in 3 Boston community health centers (from February 1, 2008, through May 2, 2011). Participants were 365 obese patients receiving hypertension treatment (71.2% black, 13.1% Hispanic, 68.5% female, and 32.9% with less than a high school educational level). We randomized participants to usual care or a behavioral intervention that promoted weight loss and hypertension self-management using eHealth components. The intervention included tailored behavior change goals, self-monitoring, and skills training, available via a website or interactive voice response; 18 telephone counseling calls; primary care provider endorsement; 12 optional group support sessions; and links with community resources.

Results—At 24 months, weight change in the intervention group compared with that in the usual care group was −1.03 kg (95% CI, −2.03 to −0.03 kg). Twenty-four-month change in body mass index (calculated as weight in kilograms divided by height in meters squared) in the intervention group compared with that in the usual care group was −0.38 (95% CI, −0.75 to −0.004). Intervention participants had larger mean weight losses during the 24 months compared with that in the usual care group (area under the receiver operating characteristic curve, −1.07 kg; 95% CI, −1.94 to −0.22). Mean systolic blood pressure was not significantly lower in the intervention arm compared with the usual care arm.

Conclusion—The intervention produced modest weight losses, improved blood pressure control, and slowed systolic blood pressure increases in this high-risk, socioeconomically disadvantaged patient population.

Obesity is not sufficiently addressed in the US primary care system.[1-4] Primary care providers infrequently diagnose obesity and offer weight loss counseling to only one-fifth of obese patients.[4] Evidence-based weight management strategies have not proven sustainable in real-world clinical practice, and few published primary care–based obesity treatment trials[5] have yielded clinically significant long-term outcomes.

The socioeconomically disadvantaged patients (disproportionately members of a racial/ethnic minority group) who seek care at community health centers are particularly affected by the limited availability of obesity treatments. These high-risk patients have disproportionately elevated rates of obesity[6,7] and obesity-associated health conditions[8-11] (particularly hypertension and cardiovascular disease)[12] due, in part, to their high levels of adulthood weight gain[13-15] and prolonged exposure to obesogenic environments.[16,17] High-risk patient populations have been severely underrepresented in obesity trials, and evidence-based weight loss strategies are less effective in these groups,[18-21] including in the few published obesity trials[5] conducted in primary care settings. Furthermore, although behavioral and clinical hypertension management strategies have been widely tested[22,23] and disseminated,[24] hypertension control rates remain suboptimal,[25] particularly for socioeconomically disadvantaged patients with high cardiovascular disease risk.

We conducted a pragmatic randomized controlled trial[26-28] to evaluate the effectiveness of a behavioral intervention that emphasized weight loss and hypertension medication adherence among primary care patients in the community health center setting.

Methods

Be Fit, Be Well was a 2-arm, 24-month patient-randomized effectiveness trial conducted among 365 obese adult primary care patients with hypertension, as described previously.[29] Supported under a cooperative agreement from the National Heart, Lung, and Blood Institute, the trial was part of the Practice-based Opportunities for Weight Reduction

(POWER) trials.[30] Participants were recruited from 3 community health centers in Boston from February 1, 2008, through April 30, 2009. All study protocols were fully approved by the Harvard School of Public Health Institutional Review Board and the POWER Data Safety Monitoring Board.

Study Setting

We sought urban community health centers that served a predominately racial/ethnic minority patient population, used an electronic medical record or automated scheduling system, and had interest in research participation. Study investigators approached 7 community health centers (Figure 1). All sites indicated interest; 4 were excluded because they did not have an electronic medical record or automated scheduling system.

Participants

Inclusion criteria included body mass index (calculated as weight in kilograms divided by height in meters squared) from 30 to 50, weight less than 180 kg, use of 1 or more antihypertensive medication, age at least 21 years, and 1 or more medical visits in the 12 months before study entry. In addition, we required English or Spanish fluency, written informed consent, and willingness to change diet, physical activity, and weight. Exclusion criteria included history of a vascular event 6 months or less before study entry or of a medical condition that might affect measurement or trajectory of weight loss, previous or planned bariatric surgery, use of weight loss medications or medications known to increase weight, recent pregnancy or breast-feeding or plans to become pregnant within 2 years, and/ or plans to relocate within the 2-year study period. We sought primary care provider–approval before enrolling those with diabetes mellitus, a cardiovascular event 6 months or more before study entry, or known stable cardiovascular or peripheral vascular disease.

Participant Recruitment and Allocation

Research staff conducted medical chart reviews at each health center to identify potentially eligible participants (n=2631; Figure 1). Primary care providers excluded those deemed unsuitable for participation. Study staff contacted 507 of the potentially eligible participants by telephone and screened them for eligibility. Only 4.9% of potentially eligible patients were uninterested in participation. Eligible individuals were invited to attend a baseline study visit at their health center, at which they provided informed consent and completed a computer-based questionnaire battery. Research staff collected anthropometric and blood pressure measures. Participants (n=365; 72.0% of those contacted by telephone) were randomized to treatment arm using computer-generated allocations, blocked by clinic and sex. The trial design precluded blinding either patients or interventionists to treatment assignment.

Treatment Arms

We provided the National Heart, Lung, and Blood Institute's "Aim for a Healthy Weight" self-help booklet[31] to the usual care participants at baseline. The research team made no other attempts to influence care delivered to usual care participants.

Intervention

The intervention used theory-based[32] and evidence-based[33,34] principles to promote weight loss and hypertension self-management for 24 months. The intervention is described in greater detail elsewhere.[29] Briefly, we used a behavioral weight loss approach designed for use in resource-constrained settings.[29] The intervention approach was designed for delivery in populations with limited literacy and numeracy and impaired access to health-promoting resources. Patients are prescribed 3 tailored goals to modify routine obesogenic lifestyle

behaviors.[29,33] Behavior change goals were modeled on evidence-based recommendations[31,34] that were tailored to the patient population and phrased so that they could be easily self-monitored. New goals were selected at subsequent 13-week intervals. For the duration of the study, participants maintained a hypertension medication adherence goal (to take their medication as prescribed daily).

Participants chose to self-monitor their progress using either the study website or an interactive voice response system, available in English and Spanish. Both tracking systems provided real-time tailored feedback. Participants could switch their intervention platform at any time.

Trained community health educators delivered counseling calls monthly during the first 12 months of intervention and bimonthly during the second year (18 total scheduled calls). The community health educators were trained by study investigators in principles of motivational interviewing[35,36] and conducted 15- to 20-minute calls (in English or Spanish) that covered self-monitoring data, problem solving, and behavioral skills training. The community health educators also led 12 optional monthly group sessions that were held at a community location. The community health educators were trained and certified at baseline, were recertified annually, and received weekly supervision throughout the study.

Primary care providers delivered at least 1 brief, standardized message about the importance of intervention participation. We also provided a personalized behavior change "prescription" that included the primary care provider's electronic signature.[37]

Finally, we provided tailored behavioral skills training materials, adapted from previous studies.[34] We also provided tailored information on community resources (eg, public parks, walking groups, and farmers' markets) and distributed a walking kit that included a pedometer and maps (with step counts) of destinations in the local community.

Measurements

Change in body weight (in kilograms) was the primary outcome. Change in systolic blood pressure (SBP; in millimeters mercury) was a secondary endpoint. Trained research staff administered a computer-based questionnaire battery and collected anthropometric and blood pressure measurements at baseline and 6, 12, 18, and 24 months after baseline. We offered a $50 reimbursement at the first 3 follow-up visits and $75 at 24 months.

Trained staff collected weight measurements using a digital scale (Seca 770; Seca), with participants dressed in lightweight indoor clothing. Weight was measured twice to the nearest 0.1 kg; the mean of the 2 measures was used in analysis. Height to the nearest 0.1 cm was measured once at baseline using a calibrated, wall-mounted stadiometer (Seca 240; Seca). Blood pressure was assessed using an automated device (Omron 907; Omron). Three measurements were taken at 30-second intervals after 5 minutes of rest; the mean of the 3 measurements was used in analysis. We used the Hill-Bone Compliance to Hypertension Therapy Scale[38] to assess hypertension self-management behaviors, including medication adherence, sodium intake, and appointment keeping.

Follow-Up and Alerts

As noted in Figure 1, we collected 24-month follow-up data on 314 participants (86.0%), and 350 (95.9%) completed at least 1 follow-up assessment. During the study, 71 participants (19.5%) were hospitalized (35 from the usual care group and 36 from the intervention group). Blood pressure alerts followed American Heart Association guidelines and were equally distributed (12 from the usual care group and 12 from the intervention

group). Depression alerts followed the Patient Health Questionnaire[39] (scores 20) (8 from the usual care group and 11 from the intervention group).

Statistical Analysis

The primary intent-to-treat analysis was based on the mean difference in weight between treatment arms at 24 months, after adjusting for sex and health center. We estimated mixed-effects regression models with Proc Mixed (SAS Institute, Inc) (see eMethods for full analytic models; http://www.archinternmed.com) using a random intercept and an unstructured covariance matrix. All 365 participants are included in the primary outcomes analysis, including 15 participants (4.1%) who had only a baseline assessment. Participants with missing visits are treated as missing at random. In addition, 1 participant (0.3%) was censored for reported bariatric surgery. We also compared the difference in weight during the 24-month study period between arms, estimated by the area under the receiver operating characteristic curve (AUC), calculated as follows:

AUC = mean (all available weights at 6, 12, 18, and 24 months) – baseline weight.

This measure was available for 350 participants (95.9%). The mixed-effects and AUC analyses were also performed for percent weight change, body mass index, and blood pressure. We used mixed-effects models with additional adjustment for baseline blood pressure to examine change in hypertension medication adherence.

Because the treatment effect for blood pressure appeared to increase over time, we also fit mixed models examining the different rates of SBP and diastolic blood pressure (DBP) change between intervention and usual care arms. Finally, we compared blood pressure control (SBP < 140 and DBP <90 mm Hg) between intervention and usual care groups using generalized estimating equation models with Proc Genmod (SAS Institute, Inc) using a logistic link, a binomial distribution, and an unstructured covariance matrix.

The trial was designed to provide 80% power to detect a mean weight change in 24 months of 2.75 kg in the intervention arm, assuming no weight change in usual care.

Results

Participants were mostly women (68.5%), of racial/ethnic minority populations (96.8% [71.2% black]), and with a mean age of 54.5 years (Table 1). Most (86.3%) had an educational level lower than a college degree, annual household income less than $25 000 (54.5%), and public health insurance coverage (54.2%).

Three hundred fourteen participants completed the 24-month follow-up (86.0%). Women were more likely than men to complete the 24-month assessment (88.8% vs 80.0%; P=.02); there were no other observed differences in 24-month visit completion by race, income, educational level, age, sex, work status, health center, smoking status, or primary language.

Intervention Engagement

At 24 months, intervention participants completed 70.6% of telephone counseling calls; this included 80.4% completion of calls 1 to 6, then 65.0% completion of calls 7 to 12, and then 66.7% completion of calls 13 to 18. Across both self-monitoring platforms, 40.0% of intervention participants tracked their behavior change goals weekly for at least 50% of trial weeks; 25.0% tracked weekly for at least 75% of trial weeks.

Change in Weight

Intervention participants had greater 24-month weight losses compared with those receiving usual care (difference, −1.03 kg; 95% CI, −2.03 to −0.03 kg; Table 2). In addition, the intervention promoted larger mean weight losses in 24 months relative to usual care (AUC difference, −1.07 kg; 95% CI, −1.94 to −0.22 kg). The proportion of those who lost at least 5% of their initial body weight during the 24 months was 19.5% for usual care and 20.0% for intervention participants. Similar patterns were observed for percent weight loss and change in body mass index (Table 2). Sex and health center did not significantly modify the weight change outcomes, nor did the mode of self-monitoring chosen by participants within the intervention arm.

Change in Blood Pressure

Intervention participants had a lower mean change in SBP and DBP than usual care participants at each follow-up visit (Figure 2). During 24 months (Table 3), mean SBP was lower in the intervention group compared with the usual care group but not significantly different (AUC difference, −2.50 mm Hg; 95% CI, −5.40 to 0.40 mm Hg). The slope of increasing SBP per year was significantly higher in usual care (1.23 mm Hg/y) compared with the intervention arm (0.07 mm Hg/y) (P=.02). Blood pressure changes became most apparent at 12 months of intervention. In AUC analyses including data from months 12 through 24, intervention participants had larger mean changes in SBP than usual care participants (AUC difference, −3.8 mm Hg; 95% CI, −6.9 to −0.7 mm Hg) but not in DBP (−0.1 mm Hg; −2.9 to 1.1 mm Hg). We observed no significant differences between groups for DBP.

We next assessed blood pressure control (Table 3). The proportion of participants with controlled blood pressure decreased steadily in the usual care arm and was stable in the intervention arm (Figure 2D). At 24 months, intervention participants had greater odds of blood pressure control than usual care participants (odds ratio, 1.52; 95% CI, 1.01-2.30), and the difference in trend was significant (P=.05).

Change in Hypertension Self-Management Behaviors

To contextualize the blood pressure findings, we examined change in hypertension self-management behaviors (Table 4). Intervention participants had significantly greater improvement in overall hypertension self-management at months 6, 12, and 18. Specifically, intervention participants showed significantly greater change in medication adherence at months 6 and 12. Similarly, the intervention produced positive change in self-reported sodium intake at all follow-up assessments, relative to usual care. We observed no change in hypertension treatment appointment keeping.

Adverse Events

During the study, 1 cardiovascular event and 2 cases of gallbladder disease were reported in the usual care group. Among intervention participants, 1 serious musculoskeletal injury was reported. We could not conclusively determine whether these events were related to study participation.

Comment

The Be Fit, Be Well lifestyle intervention slowed weight and blood pressure increases in this high-risk patient population. Although 6-month weight losses were modest, they were sustained for 24 months and were associated with clinically significant alterations in blood pressure trajectories. We did not observe the expected pattern of large initial (6-month) weight losses followed by weight regain. Rather, 6-month weight changes were modest but

sustained through 24 months of follow-up. Weight gain prevention (although unintended in our trial) nonetheless may have clinical and public health significance.[40] This is particularly the case for black populations (especially black females) who experience, relative to whites, weaker associations of adiposity with cardiovascular risk factors,[41-43] as well as cardiovascular disease[44-46] and all-cause mortality.[47,48] For such groups, promoting weight stability (particularly at body mass index 40) may have clinical utility. Be Fit, Be Well shows that weight gain prevention can be achieved at intensity levels that might be sustainable in resource-deprived practice settings.

The net SBP changes produced by Be Fit, Be Well compare favorably with those of behavioral hypertension control trials.[49] Given the magnitude of weight loss, we suspect that the observed blood pressure outcomes were driven primarily by improved hypertension self-management. We found that the intervention—which included training to help participants improve self-management and provider communication—promoted positive change, particularly in medication adherence and sodium intake. Blood pressure control is a major clinical challenge in this population,[50-52] as demonstrated by the trend toward worsening blood pressure levels among usual care participants.

Despite their vastly increased risk, socioeconomically disadvantaged and racial/ethnic minority populations have been underrepresented in clinical trials. Existing evidence-based treatment approaches are less effective in these groups. Across a wide variety of studies, blacks demonstrate poorer weight loss outcomes relative to whites,[18-20] even in well-powered, highly controlled trials.[49,53] Absolute weight losses among high-risk populations are usually small. With few exceptions,[54] most purely behavioral weight loss trials (ie, without use of meal replacements or pharmacotherapy) do not produce 12-month outcomes greater than 3.5 kg in these groups, independent of setting (clinical vs nonclinical).[18]

Several considerations affect interpretations drawn from our findings. In consultation with the participating health centers, we implemented several design options to decrease participant burden. We did not collect blood samples and we gathered limited medication data. The intervention only minimally involved providers because the participating health centers did not believe that they could sustain greater levels of provider involvement. Our sodium intake findings should be treated as preliminary given the limitations of the measure. To enhance the study's dissemination potential, we designed broadly accessible technologies and did not select participants on the basis of technology access or experience. Patient engagement with the intervention technologies was less than desired but was not inconsistent with other trials.[55,56] Sustaining participant engagement remains a major challenge for new-media behavioral intervention strategies.[56]

Finally, our participants were considerably more socioeconomically disadvantaged than in comparable trials.[5,18] Findings from trials demonstrating larger weight loss outcomes for racial/ethnic minorities[53,54] are not necessarily comparable with Be Fit, Be Well, given the much lower socioeconomic standing of our trial participants. Socioeconomic factors strongly pattern exposure to obesogenic environmental factors, adoption of obesogenic risk behaviors,[9,57] and the limited availability of weight management resources.[4] Socioeconomic challenges were exacerbated during the trial, given the national economic crisis. During this time, food stamp use in the target communities rose as high as 43%.[58] Rates of home foreclosure in these neighborhoods were among the highest in the city.[58] Because of the extreme macroeconomic changes, we surveyed 144 participants at the 24-month follow-up (eTable); 50.0% expressed having some difficulty paying bills, 41.0% reported that food sometimes ran out, 27.3% had their telephone disconnected for 2 months or longer, 11.9% had utilities deactivated, and at least 5 participants (3.5%) were homeless at some point

during the trial. These challenges are ubiquitous for the medically underserved areas in which community health centers are located.

As a pragmatic[26-28] effectiveness trial, our findings are arguably more generalizable to real-world health center settings than are those of highly controlled efficacy trials with larger treatment effects. Although the field has made strides in obesity treatment, we should not assume that evidence-based approaches work in populations in which they were not tested. More work is necessary to best address the needs of socioeconomically disadvantaged patients who bear the greatest risk and disease burden of obesity.

Acknowledgments

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Patient enrollment
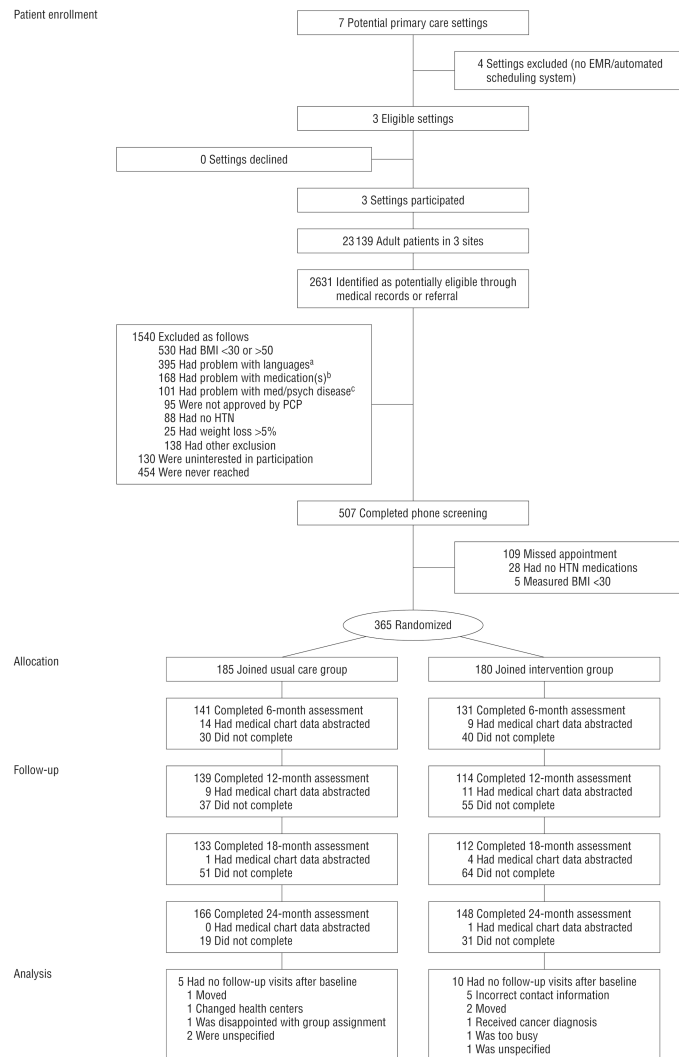
Figure 1.
CONSORT flow diagram. BMI indicates body mass index (calculated as weight in kilograms divided by height in meters squared); EMR, electronic medical record; HTN, hypertension; PCP, primary care provider. [a]Non-English or non-Spanish speakers. [b]Chronic use of medications likely to cause weight gain or prevent weight loss. [c]Participants excluded due to a serious medical condition or psychiatric condition.
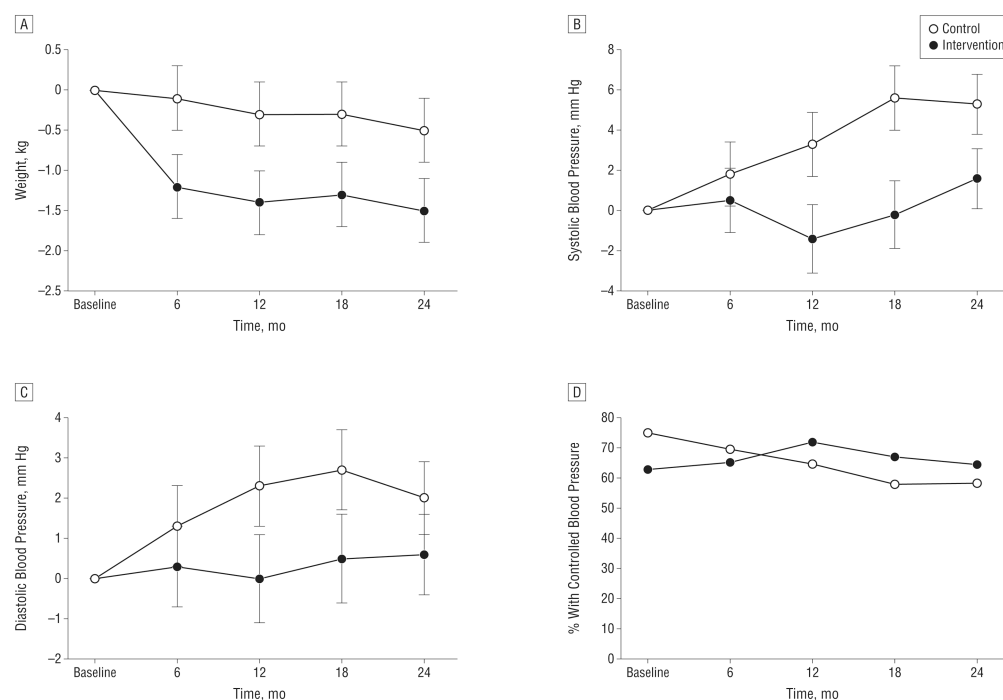
Figure 2.
Effects of Be Fit, Be Well lifestyle intervention on (A) weight, (B) systolic and (C) diastolic blood pressure, and (D) blood pressure control. Error bars indicate 95% CIs.

Table 1

Baseline Characteristics of Participants

Characteristic	Usual Care (n = 185)	Intervention (n = 180)	OR (95% CI) or Mean (SD) Difference	*P* Value
Sex, No. (%)				
Male	63 (34.1)	52 (28.9)	1 [Reference]	
Female	122 (65.9)	128 (71.1)	1.27 (0.82-1.98)	.29
Race/ethnicity, No. (%)				
Non-Hispanic white	4 (2.2)	9 (5.0)	1 [Reference]	
Non-Hispanic black	131 (70.8)	129 (71.7)	0.44 (0.10-1.62)	
Hispanic	23 (12.4)	25 (13.9)	0.49 (0.10-2.05)	
American Indian	3 (1.6)	3 (1.7)	0.47 (0.04-5.09)	
Asian	1 (0.5)	1 (0.6)	0.47 (0.01-43.53)	.46
Hawaiian/Pacific Islander	1 (0.5)	1 (0.6)	0.47 (0.01-43.53)	
>1 Race	19 (10.3)	12 (6.7)	0.29 (0.05-1.33)	
Unknown	3 (1.6)	0	0.15 (0.00-1.64)	
Educational level, No. (%)				
<12th Grade	73 (39.5)	47 (26.1)	1 [Reference]	
High school/GED	50 (27.0)	59 (32.8)	2.33 (1.19-4.57)	
Some college/associate's degree	42 (22.7)	44 (24.4)	1.63 (0.93-2.85)	.04
Bachelor's degree	20 (10.8)	30 (16.7)	1.83 (1.08-3.10)	
Income, $, No. (%)				
<10000	54 (29.2)	41 (22.8)	1 [Reference]	
10000 to <25000	51 (27.6)	53 (29.4)	1.37 (0.78-2.39)	
25000 to <50000	57 (30.8)	53 (29.4)	1.23 (0.71-2.13)	.30
50000	23 (12.4)	33 (18.3)	1.89 (0.97-3.69)	
Employment, No. (%)				
Employed	98 (53.0)	94 (52.2)	1 [Reference]	
Unemployed	23 (12.4)	27 (15.0)	1.22 (0.66-2.28)	
Retired	21 (11.4)	22 (12.2)	1.09 (0.56-2.12)	.85
Disabled	43 (23.2)	37 (20.6)	0.90 (0.53-1.51)	
Health insurance, No. (%)				
Medicaid	58 (31.4)	65 (36.1)	1 [Reference]	
Medicare	41 (22.2)	34 (18.9)	0.74 (0.41-1.32)	
Private insurance	68 (36.8)	69 (38.3)	0.91 (0.56-1.47)	.54
Other	18 (9.7)	12 (6.7)	0.60 (0.26-1.34)	
Age, mean (SD) difference, y	54.67 (11.03)	54.58 (10.77)	0.08 (10.90)	.94
Weight, mean (SD) difference, kg	100.60 (18.67)	99.70 (16.29)	0.91 (17.53)	.62
BMI, mean (SD) difference	36.99 (5.24)	37.03 (4.96)	−0.04 (5.11)	.94
SBP, mean (SD) difference, mm Hg	128.50 (19.73)	130.20 (18.89)	−1.67 (19.32)	.41
DBP, mean (SD) difference, mm Hg	77.45 (13.77)	79.34 (12.73)	−1.89 (13.27)	.17
Taking diabetes medication, No. (%)				

Characteristic	Usual Care (n = 185)	Intervention (n = 180)	OR (95% CI) or Mean (SD) Difference	P Value
No	121 (65.4)	136 (75.6)	1 [Reference]	.03
Yes	64 (34.6)	44 (24.4)	0.61 (0.38-0.96)	
Taking cholesterol medication, No. (%)				
No	119 (64.3)	114 (63.3)	1 [Reference]	.84
Yes	66 (35.7)	66 (36.7)	1.04 (0.68-1.60)	

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); DBP, diastolic blood pressure; GED, general equivalency diploma; OR, odds ratio; SBP, systolic blood pressure.

Table 2

Baseline Levels and Changes From Baseline by Treatment Group[a]

| Variable | Mean (SD) at Baseline | Change From Baseline | | | | AUC[b] |
		Month 6	Month 12	Month 18	Month 24	
Weight change, mean (SE)						
Usual care	100.61 (18.67)	−0.13 (0.35)	−0.32 (0.36)	−0.33 (0.38)	−0.5 (0.35)	−0.33 (0.30)
Intervention	99.70 (16.29)	−1.25 (0.37)	−1.37 (0.38)	−1.28 (0.40)	−1.53 (0.37)	−1.41 (0.30)
Difference between arms, mean (95% CI)		−1.11 (−2.12 to −0.10)	−1.05 (−2.09 to −0.01)	−0.95 (−2.03 to 0.14)	−1.03 (−2.03 to −0.03)	−1.07 (−1.94 to −0.22)
Weight change, mean % (SE)						
Usual care	100.61 (18.67)	−0.24 (0.36)	−0.42 (0.37)	−0.51 (0.38)	−0.67 (0.36)	−0.47 (0.31)
Intervention	99.70 (16.29)	−1.32 (0.38)	−1.54 (0.39)	−1.4 (0.41)	−1.68 (0.38)	−1.54 (0.32)
Difference between arms, mean (95% CI)		−1.08 (−2.09 to −0.06)	−1.12 (−2.16 to −0.08)	−0.89 (−1.97 to 0.20)	−1.02 (−2.02 to −0.005)	−1.08 (−1.95 to −0.20)
BMI change, mean (SE)						
Usual care	36.99 (5.24)	−0.05 (0.13)	−0.12 (0.13)	−0.15 (0.14)	−0.20 (0.13)	−0.13 (0.11)
Intervention	37.04 (4.96)	−0.48 (0.14)	−0.54 (0.14)	−0.50 (0.15)	−0.58 (0.14)	−0.54 (0.12)
Difference between arms, mean (95% CI)		−0.43 (−0.80 to −0.05)	−0.42 (−0.80 to −0.03)	−0.35 (−0.75 to 0.06)	−0.38 (−0.75 to −0.004)	−0.41 (−0.73 to −0.09)

Abbreviations: AUC, area under the receiver operating characteristic curve; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

[a]There were 185 participants in the usual care group and 180 in the intervention group.

[b]Calculated as AUC = mean (all available weights at 6, 12, 18, and 24 months) − baseline weight, adjusted for baseline weight, sex, and clinic.

Table 3

Baseline Levels and Blood Pressure Changes by Treatment Group[a]

Variable	Mean (SD) at Baseline	Change From Baseline					AUC[b]	Slope per Year
		Month 6	Month 12	Month 18	Month 24			
SBP change, mean (SE)								
Usual care	128.55 (19.73)	1.78 (1.55)	3.35 (1.56)	5.61 (1.58)	5.30 (1.47)		4.34 (1.02)	1.23 (1.80)
Intervention	130.22 (18.89)	0.49 (1.60)	−1.38 (1.68)	−0.22 (1.69)	1.56 (1.54)		1.84 (1.06)	0.07 (1.61)
Difference between arms, mean (95% CI)		−1.30 (−5.67 to 3.08)	−4.73 (−9.23 to −0.22)	−5.83 (−10.38 to −1.28)	−3.73 (−7.91 to 0.45)		−2.50 (−5.40 to 0.40)	−1.16 (−2.12 to −0.20)
P value							.02	
DBP change, mean (SE)								
Usual care	77.45 (13.77)	1.28 (1.00)	2.30 (1.00)	2.73 (1.02)	2.00 (0.94)		1.99 (0.66)	1.33 (1.20)
Intervention	79.34 (12.73)	0.30 (1.03)	0.04 (1.08)	0.49 (1.09)	0.56 (0.99)		1.35 (0.69)	0.92 (1.09)
Difference between arms, mean (95% CI)		−0.98 (−3.80 to 1.83)	−2.26 (−5.15 to 0.64)	−2.24 (−5.16 to 0.69)	−1.44 (−4.13 to 1.24)		−0.63 (−2.52 to 1.26)	−0.41 (−1.03 to 0.21)
P value							.40	
BP control, % of participants								
Usual care	74.59	69.50	64.75	57.89	58.43			0.34 (0.10)[c]
Intervention	62.78	64.89	71.93	66.96	64.63			0.14 (0.12)
OR (95% CI)[d]	0.57 (0.37 to 0.90)	1.02 (0.58 to 1.79)	1.39 (0.98 to 1.98)	1.28 (0.90 to 1.82)	1.52 (1.01 to 2.30)			Difference: −0.21 (−0.41 to 0.00)
P value								.05

Abbreviations: AUC, area under the receiver operating characteristic curve; BP, blood pressure; DBP, diastolic blood pressure; OR, odds ratio; SBP, systolic blood pressure.

[a] There were 185 participants in the usual care group and 180 in the intervention group.

[b] Calculated as AUC = mean (all available BPs at 6, 12, 18, and 24 months) − baseline BP, adjusting for baseline BP, sex, and clinic.

[c] Slope in log odds of % BP control per year adjusting for sex and clinic.

[d] Adjusted for baseline BP control, sex, and clinic.

Table 4

Baseline Levels and Change in Hypertension-Related Self-Management Behaviors

Variable	Mean (SD) at Baseline	Change From Baseline				
		Month 6	Month 12	Month 18	Month 24	
Hill-Bone score change, mean (SE)						
Usual care	19.97 (4.16)	−0.49 (0.26)	−0.42 (0.27)	−0.78 (0.27)	−1.02 (0.25)	
Intervention	20.75 (4.65)	−1.74 (0.27)	−2.00 (0.29)	−1.72 (0.29)	−1.64 (0.27)	
Difference between arms, mean (95% CI)		−1.25 (−1.99 to −0.5)	−1.59 (−2.36 to −0.82)	−0.94 (−1.72 to −0.16)	−0.62 (−1.34 to 0.10)	
Medication adherence subscale change, mean (SE)						
Usual care	10.11 (2.78)	−0.37 (0.19)	−0.31 (0.19)	−0.76 (0.19)	−0.55 (0.18)	
Intervention	10.59 (3.29)	−1.06 (0.20)	−1.16 (0.21)	−1.06 (0.21)	−0.91 (0.19)	
Difference between arms, mean (95% CI)		−0.69 (−1.22 to −0.15)	−0.85 (−1.40 to −0.30)	−0.31 (−0.86 to 0.25)	−0.36 (−0.88 to 0.15)	
P value		0.01	.002	.28	.17	
Sodium intake subscale change, mean (SE)						
Usual care	5.23 (1.50)	−0.15 (0.08)	−0.13 (0.08)	−0.18 (0.09)	−0.27 (0.08)	
Intervention	5.52 (1.58)	−0.60 (0.09)	−0.64 (0.09)	−0.57 (0.09)	−0.61 (0.09)	
Difference between arms, mean (95% CI)		−0.45 (−0.68 to −0.21)	−0.51 (−0.76 to −0.27)	−0.39 (−0.63 to −0.14)	−0.33 (−0.56 to −0.11)	
P value		<.001	<.001	.002	.004	
Appointment-keeping subscale change, mean (SE)						
Usual care	4.63 (1.48)	0.02 (0.12)	0.02 (0.12)	0.14 (0.12)	−0.2 (0.11)	
Intervention	4.64 (1.44)	−0.13 (0.12)	−0.24 (0.13)	−0.13 (0.13)	−0.15 (0.12)	
Difference between arms, mean (95% CI)		−0.15 (−0.49 to 0.18)	−0.26 (−0.61 to 0.09)	−0.27 (−0.63 to 0.08)	0.05 (−0.27 to 0.38)	
P value		.37	.14	.13	.74	