

Results of the *Diet, Exercise, and Weight Loss Intervention Trial (DEW-IT)*

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Abstract—National guidelines for the prevention and treatment of hypertension recommend sodium reduction, weight loss, the Dietary Approach to Stop Hypertension (DASH) diet, and regular aerobic exercise. However, no trial has assessed the efficacy of simultaneously implementing all of these recommendations. The objective of this study was to determine the effects on blood pressure and other cardiovascular disease risk factors of a comprehensive lifestyle intervention. We conducted a randomized controlled trial of 44 hypertensive, overweight adults on a single blood pressure medication. Participants were randomized to a lifestyle or control group. For 9 weeks, the lifestyle group was fed a hypocaloric version of the DASH diet that provided 100 mmol/d of sodium. This group also participated in a supervised, moderate-intensity exercise program 3 times per week. The control group received no intervention. Outcomes were ambulatory blood pressure, serum lipids, weight, and fitness. At the end of the intervention, mean weight loss in the lifestyle group, net of control, was 4.9 kilograms. In the lifestyle group mean net reductions in 24-hour ambulatory systolic and diastolic blood pressures were 9.5 mm Hg ($P<0.001$) and 5.3 mm Hg ($P<0.002$), respectively. Corresponding changes in daytime systolic and diastolic blood pressures were 12.1 mm Hg ($P<0.001$) and 6.6 mm Hg ($P<0.001$). The lifestyle group experienced mean reductions in total cholesterol (-25 mg/dL, $P<0.001$), low-density lipoprotein cholesterol (-18 mg/dL, $P=0.005$), high-density lipoprotein cholesterol (-5 mg/dL, $P<0.001$), net of control. In conclusion, among hypertensive overweight adults already on antihypertensive medication, a comprehensive lifestyle intervention can substantially lower blood pressure and improve blood pressure control. (*Hypertension*. 2002; 40:612-618.)

Key Words: hypertension, essential ■ clinical trials ■ nutrition ■ lifestyle

Elevated blood pressure is an extraordinarily common and important risk factor for cardiovascular disease and stroke. Because drug therapy for hypertension effectively reduces the risk for stroke and coronary disease,¹ efforts to control the epidemic of blood pressure-related cardiovascular disease have largely focused on pharmacological therapy of hypertension. Such evidence has provided the rationale for drug treatment on a massive scale. In the United States, it has been estimated that 23 million or 12.6% of adults take antihypertensive medication.² Still, despite the common use of antihypertensive medications, rates of hypertension control remain suboptimal.^{2,3}

The Sixth Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-VI)⁴ recommends several lifestyle modifications as adjuvant therapy in medication-treated hypertensives, yet there are considerable gaps in our knowledge about the effects of lifestyle therapies. For instance, most evidence is derived from behavioral modification trials where variable adherence limits the assessment of true biological effects.

More importantly, no trial has studied the efficacy of simultaneously implementing all current lifestyle recommendations. According to these recommendations, hypertensive patients should reduce their weight, eat a healthy diet (the DASH diet⁵), consume no more than 100 mmol/d of sodium, avoid excessive alcohol consumption, and exercise regularly. Lastly, surprisingly few studies have assessed the adjuvant effects of lifestyle modification in the setting of antihypertensive therapy.

The objective of this study is to examine the effects on blood pressure and other cardiovascular risk factors of a comprehensive lifestyle intervention in overweight persons with medication-treated hypertension.

Methods

The *Diet, Exercise, and Weight Loss Intervention Trial (DEW-IT)* was a single-center, parallel arm trial, in which participants were randomized to a comprehensive "lifestyle" intervention or a control group for 9 weeks. The comprehensive lifestyle intervention was designed to accomplish each of the JNC-VI lifestyle recommendations, namely, consumption of the DASH diet, a reduced sodium

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intake of 100 mmol/d, weight loss, and regular aerobic exercise. To attain these goals, participants in the lifestyle group were provided with all of their food for 9 weeks. They also exercised in a supervised setting. Participants in the control group received no active intervention until after the end of data collection. Outcomes were ascertained in a blinded fashion.

Participants

Participants were 45 adults, ages 22 to 70 years, with a screening systolic blood pressure (SBP) of 130 to 170 mm Hg and/or diastolic blood pressure (DBP) of 80 to 100 mm Hg while taking a stable dose (for at least 3 months) of a single antihypertensive medication or a fixed-dose combination pill. Screening blood pressure was the average of 6 random zero sphygmomanometer readings (2 readings from each of 3 visits). Other inclusion criteria were overweight or obesity, defined as a body mass index $>25 \text{ kg/m}^2$,⁶ a willingness to accept assignment to both groups, and a willingness to complete all intervention and data collection procedures.

Major exclusion criteria were active or prior cardiovascular disease, medication-treated diabetes, a random glucose of $>180 \text{ mg/dL}$, renal insufficiency, a fasting cholesterol $>260 \text{ mg/dL}$, pregnancy, lactation, unwillingness to stop all vitamin, mineral, or weight-loss supplements, unwillingness to stop antacids containing calcium or magnesium, and consumption of more than 14 alcoholic drinks per week.

Trial Conduct

An Institutional Review Board of the Johns Hopkins University reviewed and approved the trial protocol. All participants provided written informed consent. Primary recruitment strategies were mass mailings of brochures, enrollment of prior study participants, and advertisements in local newspapers. During the screening period before randomization and again during the ninth week of follow-up, a fasting specimen of blood and 24-hour urine specimen were collected, a fitness test was performed, and an ambulatory blood pressure monitor (ABPM) was applied. After randomization, weight and adherence to medication regimen were measured biweekly in all participants.

Randomization was stratified by race (African American and other), with an allocation ratio of 1:1 and a block size of 4. The order of randomization was constructed from a published list of random numbers; assignments were issued by the study coordinator who opened sealed opaque envelopes that contained the group assignment.

Lifestyle Intervention

The lifestyle intervention had 3 nutritional components (the DASH diet, reduced sodium, and weight loss). The DASH diet emphasizes fruits, vegetables, and low-fat dairy products; includes whole grains, poultry, fish, and nuts; and is reduced in red meat, sweets, sugar-containing beverages, total fat, saturated fat, and cholesterol. The DASH diet provides 18% kcal from protein, 55% kcal from carbohydrate, and 27% kcal from fat (6% kcal saturated, 13% kcal monounsaturated, and 8% kcal polyunsaturated fatty acids). The 2100 kcal level of the DASH diet provides 500 mg/d of magnesium, 1240 mg/d of calcium, 4700 mg/d of potassium, 31 g/d of fiber, and 150 mg/d of cholesterol.⁷ For this trial, the DASH diet provided a sodium level of 100 mmol/d, the recommended upper limit of sodium intake in JNC-VI. The nutrient composition of the DASH diet with 100 mmol/d of sodium was validated as part of the DASH-Sodium trial.⁸

The weight loss goal was 10 pounds (4.5 kg), which corresponds to 1.25 pounds (0.6 kg) per week during the first 8 weeks of feeding. To attain this goal, participants were fed the DASH diet with a calorie level that was $\approx 500 \text{ kcal/d}$ less than projected isocaloric needs. This level of calorie reduction was expected to result in an average weight loss of 1 pound (0.4 kg) per week if exercise patterns were unchanged. We estimated that the increased energy expenditure from the exercise program would lead to additional weight loss of at least 0.25 pounds (0.1 kg) per week. During the initial 8 weeks of

feeding, weight was measured each weekday, and calorie intake was adjusted to achieve weight loss goals. After 8 weeks, participants were placed on an isocaloric diet for the remaining week before final follow-up measurements were obtained.

Five energy levels (1350, 1600, 2100, 2600, 3100 kcal/d) of the DASH diet were used, depending on the energy requirements of each participant. A 7-day meal cycle was developed for each calorie level. For participants who required an intermediate energy level, we provided 100-kcal unit foods in the form of muffins with the DASH nutrient profile.

The study provided the lifestyle participants with all of their food during the 9 weeks of feeding. On weekdays, participants ate one meal per day at the clinic site and ate the rest of their meals and snacks at home or work. Weekend meals were distributed to participants on Fridays. Alcohol consumption was limited to a maximum of 2 drinks per day, and caffeinated beverages were limited to a maximum of 3 per day. Participants were instructed to eat only study foods and to consume all provided foods. The feeding protocol (menus, food production, food distribution, and quality control procedures) was virtually identical to those used in the DASH and DASH-Sodium trials.^{5,8}

The exercise goal of the lifestyle intervention was 30 to 45 minutes of supervised, moderate-intensity aerobic exercise on 3 days each week. Exercise sessions were scheduled before evening meals or on Saturday mornings. The options were brisk walking on a treadmill or nearby track or riding a cycle ergometer. Each session included a 5-minute warm-up period. Participants who had not previously been physically active started with 20 minutes of walking per session and increased the duration of exercise over several weeks until their goal was met.

Heart rate goals during exercise were based on achieving a minimum of 50% and maximum of 75% of maximum heart rate (MHR), as estimated from the equation, $\text{MHR} = 220 - \text{age}$. Participants wore heart rate monitors (Polar Vantage XL) during exercise to gauge their effort and monitor adherence with goals. Attendance, number of minutes spent in aerobic activity, and average heart rate during peak exercise were recorded.

Control Group

Each participant in the control group was paid \$40 for each biweekly data collection visit during follow-up and \$200 at the end of the study. Nutrition and lifestyle counseling were provided on completion of data collection.

Outcome Variables

Mean 24-hour ambulatory BP was the primary outcome. Trained certified technicians assessed each participant twice with a Space Labs 90207 monitor, once before randomization and again at the end of follow-up. Measurements were obtained after participants abstained from exercise for at least 24 hours. Blood pressure was recorded every 30 minutes. Daytime blood pressure was the average of blood pressures measured between 6:30 AM and 11:30 PM, and nighttime blood pressure was the average of measurements between 11:30 PM and 6:30 AM. Two participants worked night shifts or had irregular evening shifts. Data for these individuals were excluded from the daytime and nighttime analyses but were included in the 24-hour BP analyses. Blood pressure control was defined as having a 24-hour ambulatory SBP <135 and DBP $<85 \text{ mm Hg}$.

Manual blood pressures were measured at baseline and at 9 weeks by trained observers, using random-zero sphygmomanometers. Duplicate measurements of blood pressure were made in the seated position after 5 minutes of rest by standard protocol. Blood pressures from the 3 screening visits were averaged to determine baseline. Week 9 blood pressures were based on a single clinic visit.

Fasting blood specimens and 24-hour urine collections were obtained at baseline and at the end of follow-up. From the fasting blood specimen, total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), triglycerides, and glucose were measured. Low-density lipoprotein cholesterol (LDL-C) was estimated by the equation $(\text{LDL} = \text{TC} - \text{HDL} - \text{triglyceride}/5)$.⁹ From the 24-hour urine collections, urinary sodium (Na) and potassium (K) excretion

were used to estimate group compliance with dietary aspects of the intervention (ie, sodium excretion for salt intake and potassium excretion for fruit and vegetable intake).

A submaximal treadmill test was administered before randomization and again at the end of intervention period to estimate cardiorespiratory fitness. The treadmill protocol varied in speed and elevation across age and gender categories to produce multiple stages within a moderate intensity workload. The protocol had a warm-up stage, 2 progressive moderate-intensity workloads (with the highest designed to achieve approximately 75% of predicted MHR), and a cool-down stage. For each individual, the treadmill protocol was the same at baseline and end of follow-up. Change in heart rate at 5 minutes during the exercise protocol was considered to be indicative of a change in cardiorespiratory fitness. The Borg Ratings of Perceived Exertion (RPE) scale¹⁰ was administered during the last 30 seconds of each stage. The scale had a 14-point range, with 20 being a perceived maximum level of exertion and 6 being no exertion. Premature termination of the treadmill test occurred when a participant requested an end to the test or when the heart rate during the test exceeded 80% of estimated MHR.

Weight was measured biweekly by blinded personnel using a certified balance-beam scale.

Adherence

For the lifestyle participants, adherence with feeding was assessed by attendance at the dining facility, observation during meals, and completion of daily logs that queried participants about their consumption of study foods and nonstudy foods, if any. Likewise, adherence to the physical activity component of the lifestyle intervention was assessed by attendance and activity logs from the supervised exercise sessions. All participants were repeatedly advised to continue without change the blood pressure medications prescribed by their physicians. At biweekly visits, adherence with pill taking was assessed by a questionnaire that asked "during the last 14 days, how many days did you take your blood pressure lowering medication?"

Analytic Considerations

The target-sample size of 40 participants, equally allocated across 2 groups, was estimated to provide 80% power to detect a net between group differences of 7.7 and 5.1 mm Hg in 24-hour ambulatory systolic and diastolic BP at $\alpha=0.05$ (2-tailed), assuming a standard deviation (SD) on changes of 7.7 mm Hg and 5.6 mm Hg, respectively.

Initially we examined the distribution of all baseline, follow-up, and change measures. For continuous variables with a normal distribution, means and standard deviations are presented. For continuous variables with skewed distributions (triglycerides and RPE), medians with interquartile ranges are presented for baseline levels and medians, with 95% confidence intervals for change. Between-group differences were tested by robust regression analysis. In each regression model, the dependent variable was change from baseline. Covariates in each model were the baseline level of the

TABLE 1. Baseline Characteristics

Characteristic	Lifestyle (n=22)	Monitoring (n=23)	All (N=45)
Age, y	53 (11)	54 (8)	54 (9)
Women, %	57	68	62
Black, %	68	57	62
Weight, kg	92.0 (14.6)	97.0 (20.9)	94.6 (18.1)
Body mass index, kg/m ²	32.8 (5.4)	34.2 (6.2)	33.5 (5.8)
Using lipid medications, %	9	30	20
Drank alcohol, %	46	35	40
Current smokers, %	14	4	9
BP medication use, %*			
Diuretics	32	26	29
CCB	32	35	33
ARB/ACE	18	48	33
β -blockers	18	9	13
α -blockers	5	0	2
SBP-screening, mm Hg†	134.9 (8.9)	139.9 (9.9)	137.5 (9.7)
DBP-screening, mm Hg†	83.8 (5.5)	85.2 (4.8)	84.5 (5.1)
Ambulatory SBP, mm Hg‡			
24-hour	135.3 (11.1)	137.1 (12.1)	136.2 (11.6)
Awake	137.7 (10.6)	140.4 (12.3)	139.1 (11.5)
Asleep	122.5 (10.7)	127.1 (13.2)	124.9 (12.2)
Ambulatory DBP, mm Hg‡			
24-hour	83.6 (8.6)	83.6 (9.4)	83.6 (8.9)
Awake	86.1 (8.7)	86.1 (9.6)	86.1 (9.1)
Asleep	74.7 (10.8)	76.7 (10.8)	75.8 (10.7)

Values represent mean (SD) for continuous variables, (%) for categorical variables.

*Combination medicines assigned to specific classes: CCB, calcium channel blockers; ARB, angiotensin receptor blockers; ACE, angiotensin-converting inhibitors.

†Screening blood pressure averaged from screening visits 1–3.

‡Values for awake/asleep SBP and DBP exclude 2 participants with abnormal sleep schedules.

dependent variable as well as an indicator variable corresponding to group assignment. Differences in blood pressure control rates between groups was calculated based on change from baseline to the end of intervention by sign rank testing. Analyses were performed using STATA 6.0 software.

Results

Of the 237 individuals who were screened for the trial, 45 were randomized (Figure 1). Mean (SD) age was 54 (9) years, mean BMI (SD) was 33.5 (5.8) kg/m², and mean (SD) weight was 94.6 (18.1) kilograms; 62% were African American and 62% were women (Table 1). At entry, 29% of participants were taking a diuretic, either alone or in a combination pill; 33%, a calcium channel blocker; 33%, an angiotensin-converting enzyme inhibitor (ACE) or angiotensinogen receptor blocker (ARB), and 15%, another type of blood pressure-lowering medication.

All of the 23 participants assigned to the control group had complete follow-up. Of the 22 lifestyle-group participants, follow-up blood pressures were obtained in 20 (91%). One person assigned to the lifestyle group withdrew after random-

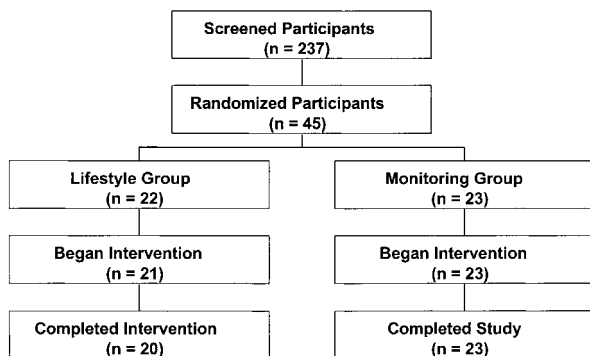


Figure 1. Participant flow during the trial.

TABLE 2. Urinary Electrolyte Excretion, Physical Characteristics, Fitness, and Lipids by Randomized Group*

Characteristic	Lifestyle Group			Control Group			Between-Group‡	
	Baseline	Follow-Up	Change†	Baseline	Follow-Up	Change†	Difference	P
Urinary electrolyte excretion								
24-hour urine Na, mmol/L	165 (60)	106 (53)	-61 (76)	170 (75)	155 (66)	-16 (70)	-44 (-88, 4)	0.07
24-hour urine K, mmol/L	58 (30)	72 (23)	13 (25)	63 (27)	58 (26)	-4 (27)	20 (5, 35)	0.009
Physical characteristics								
BMI	32.8 (5.4)	31.0 (5.3)	-1.9 (0.6)	34.5 (5.9)	34.3 (6.2)	-0.2 (0.8)	-1.7 (-2.2, -1.2)	0.000
Weight, kg	92.0 (14.6)	87.2 (14.6)	-5.5 (1.8)	97.0 (20.9)	96.4 (21.6)	-0.6 (2.2)	-4.9 (-6.3, -3.4)	0.000
Fitness								
Heart rate, 5-min	118.2 (17.1)	103.1 (12.4)	-14.8 (9.4)	118.9 (13.7)	111.4 (14.6)	-6.0 (11.7)	-8.6 (-15.1, -2.0)	0.011
Ratio perceived exertion (RPE)	11 (8, 11)	9 (7, 9)	-2 (-3, 0)	9 (9, 11)	11 (11, 13)	0 (-1, 1)	-2 (-3, 0)	0.035
Lipids								
Total cholesterol, mg/dL	198 (41)	181 (40)	-19 (24)	203 (26)	211 (35)	8 (30)	-25 (-37, -13)	0.000
HDL-C, mg/dL	55 (22)	47 (15)	-9 (12)	50 (13)	48 (10)	-3 (5)	-5 (-8, -2)	0.000
LDL-C, mg/dL	119 (38)	111 (36)	-5 (25)	126 (20)	139 (29)	12 (30)	-18 (-30, -6)	0.005
Triglyceride, mg/dL	83 (65, 141)	85 (80, 110)	-7 (-42, 12)	100 (88, 155)	116 (75, 154)	-6 (-19, 11)	7 (-24, 10)	0.43

*Baseline, follow-up, and change values reported as mean (SD) or median (95% CI) and difference reported as mean (95% CI) or median (95% CI).

†Change calculated as follow-up minus baseline.

‡Difference in change (change in lifestyle minus change in control) adjusted for baseline value.

ization but before feeding because of dissatisfaction with group assignment, and one lifestyle participant dropped out after 4 weeks of feeding because of time constraints.

Adherence

The 20 lifestyle participants who completed the intervention reported eating only study foods on 97% of the 63 total days of feeding. On the remaining 3% of feeding days, participants reported consumption of some nonstudy foods, but the majority of deviations were minor. In the lifestyle group (Table 2), mean (SD) urinary Na excretion decreased from 165 (60) mmol/d at baseline to 106 (53) mmol/d at the end of feeding, and urinary K excretion increased from 58 (30) mmol/d at baseline to 72 (30) mmol/d.

The lifestyle participants attended 86% of the prescribed exercise sessions. Seventeen of 20 who completed the trial had greater than 85% attendance at prescribed sessions, whereas only one person had less than 50% attendance. In addition to the required supervised sessions, many participants in the lifestyle group exercised other times; however, the number and duration of these sessions were not quantified.

Average pill compliance was 98.6% in the lifestyle group (range: 93% to 100%) and 97.5% in the control group (range: 71% to 100%). All participants in the lifestyle group and 96% in the control group reported better than 80% compliance with blood pressure-lowering pills.

Weight Change and Fitness

Participants in the lifestyle group lost an average of 5.5 (1.8) kilograms, compared with 0.6 (2.2) kilograms in the control group, resulting in a net reduction of 4.9 kilograms ($P<0.001$). Fourteen of 20 lifestyle participants and 2 of 23 control participants lost 10 or more pounds (4.5 kg). Heart rate at 5 minutes of the submaximal treadmill exercise test

was significantly reduced in the lifestyle group compared with the control group (-8.6 beats per minute, $P=0.011$), along with concomitant reductions in RPE (-1.8, net of control group, $P=0.035$).

Blood Pressure Change

The average (SD) number of BP measurements contributing to mean 24-hour daytime and nighttime ambulatory BP were 49.8 (6.8), 38.5 (6.2), and 11.7 (1.1), respectively. Hourly average systolic and diastolic blood pressures at baseline and at end of follow-up by randomized group are displayed in Figures 2 and 3. Changes in ambulatory BP within group and between groups are presented in Table 3. Mean change in 24-hour systolic and diastolic BP was -10.5/-5.9 mm Hg in the lifestyle group and -1.1/-0.6 mm Hg in the control group (net change of -9.5/-5.3 mm Hg, $P<0.0001$ and $P=0.002$, respectively). Corresponding changes in daytime systolic and diastolic BPs were -12.7/-7.0 mm Hg in the lifestyle group and -1.1/-0.4 mm Hg in the control group (net change of -12.1/-6.6 mm Hg, $P<0.001$ and $P<0.001$, respectively). Nighttime BP was also reduced in the lifestyle group (-7.1/-3.4 mm Hg) compared with the control group but was of borderline significance ($P=0.051$) for SBP and nonsignificant for DBP ($P=0.180$).

BP control rates, as determined by 24-hour ABPM (SBP <135 mm Hg and DBP <85 mm Hg), increased from 45% at baseline to 75% in the lifestyle group after the intervention ($P=0.025$), compared with 39% and 35%, respectively, in the control group ($P=0.668$), with a significant improvement in rates of BP control between groups ($P=0.012$).

Clinical measurement of BP by random zero sphygmomanometer at week 9 resulted in a net reduction in SBP from baseline of -7.4 mm Hg (-15.5, 0.7, $P=0.71$) and DBP -5.7 mm Hg (-11.7, 0.4, $P=0.61$).

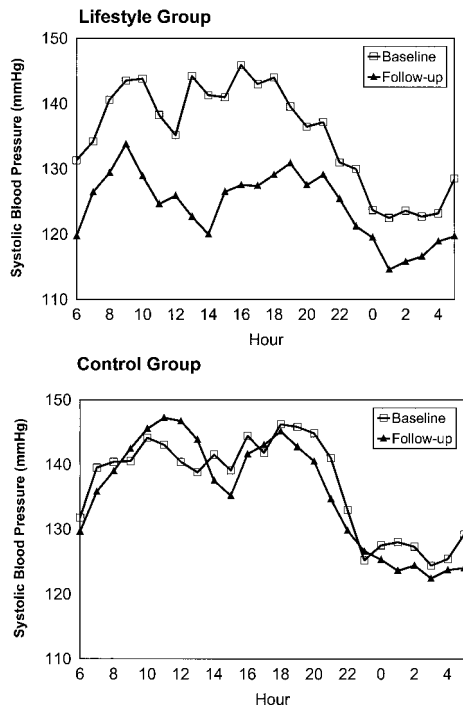


Figure 2. Mean 24-hour ambulatory systolic blood pressures at baseline and the end of study (follow-up) by hour in the lifestyle and control groups: □ baseline SBP; ▲ end of study SBP.

Lipids and Glucose

In the lifestyle group, change in total cholesterol, net of control, was -25 mg/dL (95% CI: -44 to -10 , $P=0.003$), change in LDL-C was -18 mg/dL (95% CI: -36 to 0 ,

$P=0.056$), and change in HDL-C was -4.5 mg/dL (95% CI: -11.6 to -0.8 , $P=0.026$) (Table 2). There was no significant net change in triglyceride levels (7 mg/dL [95% CI: -10 to 24 , $P=0.43$]), TC/HD ratio (-0.23 [95% CI: -0.75 to 0.28 , $P=0.36$]), or fasting glucose (-4 mg/dL [95% CI: -15 to 7 , $P=0.47$]).

Discussion

This trial demonstrated that a comprehensive lifestyle intervention can substantially lower BP and improve BP control in hypertensive overweight adults taking one antihypertensive agent. Specifically, the lifestyle intervention reduced mean 24-hour SBP by 9.5 mm Hg and DBP by 5.3 mm Hg. The largest reductions occurred during the awake hours (12.1/6.6 mm Hg). Blood pressure reductions of this magnitude are similar to those achieved with pharmacotherapy. Yet in contrast to drug therapy, comprehensive lifestyle changes also resulted in additional benefits beyond blood pressure reduction, that is, favorable effects on weight, fitness and serum total, and LDL cholesterol levels.

The BP reduction in DEW-IT was similar to that achieved in the subgroup of hypertensive participants (not on BP-lowering medications) in the DASH-sodium trial (-11.5 mm Hg).⁸ The magnitude of BP reduction achieved with combinations of nutritional and exercise interventions is difficult to predict, especially in persons on antihypertensive medications. Combinations of 2 or more lifestyle therapies tend to have subadditive effects.^{11,12} For instance, in the Trial of Hypertension Prevention, a 2×2 factorial trial of sodium reduction and weight loss, the effects of the combined therapies were less than that predicted based on the effects of each therapy alone.¹³ In addition, most trials of nonpharmacological therapy are conducted with individuals who are not taking antihypertensive medications. Subadditivity of effects from lifestyle therapy and medication is also plausible, that is, nonpharmacological therapy will reduce BP to a lesser extent in persons already on drug therapy than in persons not on drug therapy. Hence, in the setting of concomitant drug therapy, the magnitude of BP reduction observed in this trial is impressive.

In addition to lowering BP, the comprehensive lifestyle intervention likely improved overall cardiovascular disease risk status as a result of its favorable effects on total cholesterol, LDL-C, weight, and fitness. The lifestyle intervention also lowered HDL-C. Such reductions in HDL-C are commonplace in trials of low-fat, high-carbohydrate diets and could be anticipated based on similar findings in DASH and other trials.^{14,15} The clinical significance of diet-induced reductions in HDL-C is uncertain, especially in view of the large reductions in LDL-C and total cholesterol. Also noteworthy is the fact that triglycerides did not increase to the extent that would be expected with the higher carbohydrate content of the DASH diet. This suggests that either exercise, weight loss or the type of carbohydrates in the DASH diet (complex carbohydrates) mitigated the rise in triglycerides usually observed from diets high in carbohydrate.

By necessity, the duration of the intervention was short, just 9 weeks. Still, evidence from other trials with long-term follow-up suggests that BP reduction persists as long as participants adhere to therapy.^{16,17} For example, in the TONE

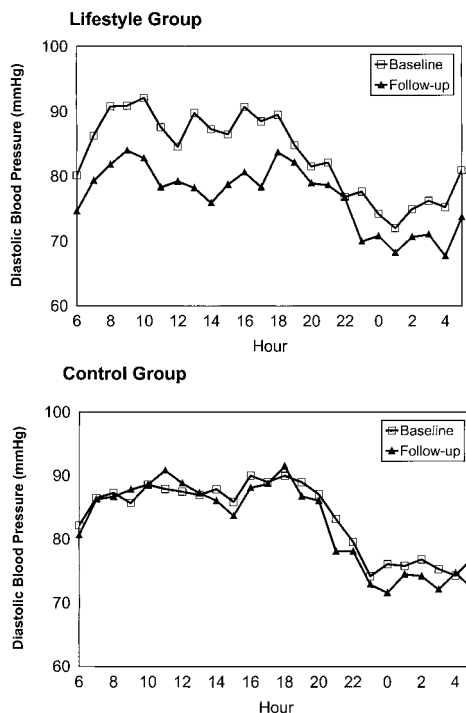


Figure 3. Mean 24-hour ambulatory diastolic blood pressures at baseline and the end of study (follow-up) by hour in the lifestyle and control groups: □ baseline DBP; ▲ end of study DBP.

TABLE 3. Ambulatory Blood Pressure Results*

	Lifestyle Group			Control Group			Between-Group	
	Baseline	Follow-Up	Change†	Baseline	Follow-Up	Change†	Difference‡	P
SBP, mm Hg								
24-hour	135.3 (11.1)	124.8 (14.5)	-10.5(8.3)	137.1 (12.1)	136.0 (12.5)	-1.1(7.7)	-9.5 (-14.5, -4.5)	0.000
Daytime	137.7 (10.6)	125.0 (11.5)	-12.7(8.1)	140.4 (12.3)	139.3 (12.6)	-1.1(7.5)	-12.1 (-17.0, -7.2)	0.000
Nighttime	122.5 (10.7)	113.4 (13.7)	-8.6(9.9)	127.1 (13.2)	124.4 (14.8)	-2.7(12.0)	-7.1 (14.2, 0.03)	0.051
DBP, mm Hg								
24-hour	83.6 (8.6)	77.7 (9.4)	-5.9(5.9)	83.6 (9.4)	83.0 (8.4)	-0.6(5.0)	-5.3 (-8.5, -2.1)	0.002
Daytime	86.1(8.7)	79.1 (9.0)	-7.0(5.9)	86.1 (9.6)	85.6 (8.7)	-0.4(4.7)	-6.6 (-9.8, -3.4)	0.000
Nighttime	74.7 (10.8)	69.0 (11.4)	-5.6(8.0)	76.7 (10.8)	73.9 (10.3)	-2.8(9.7)	-3.4 (-8.8, 1.7)	0.180

*Baseline, follow-up, and change values reported as mean (SD) and difference reported as mean (95% CI).

†Change calculated as follow-up minus baseline

‡Difference in change (change in lifestyle minus change in control) adjusted for baseline BP.

study,¹⁶ reduced sodium intake and weight loss resulted in a decreased long-term (29-month) need for antihypertensive medications in older hypertensives. Another limitation of our study was the small sample size that limited our power to do subgroup analyses on characteristics such as age, race, gender, and class of antihypertensive medication.

Among the strengths of the trial are its core design with the inclusion of a control group. Data collection was complete on 96% of randomized participants. Compliance with the lifestyle intervention was excellent as indicated by participant attendance, low drop-out rate, success in achieving projected weight loss goals, and expected changes in urinary excretion of sodium and potassium. The patient population was demographically heterogeneous. In addition, participants were on many classes of BP-lowering medications. Finally, the exercise intervention, DASH diet, and gradual weight-loss goals were well accepted by the participants and consistent with current national guidelines.

Perspectives

The results of this study highlight the efficacy of comprehensive lifestyle changes as adjuvant therapy in adults who are taking antihypertensive medication. First, lifestyle modification, if achieved, can improve hypertension control. This is especially important in view of survey data which indicate hypertension control rates of less than 27% nationwide.² Second, blood pressure reductions of the magnitude observed in this study are similar to blood pressure reductions from pharmacological therapy. Finally, such blood pressure reductions should further reduce the risk for coronary heart disease, kidney disease, and stroke. For hypertensive patients taking blood pressure-lowering medications, sustained BP reductions of the magnitude seen in DEW-IT could also facilitate medication step-down and, potentially, medication withdrawal.

The current challenge to clinicians is implementing lifestyle changes in the context of routine medical care. Results of DEW-IT, conducted under ideal conditions of compliance and monitoring and in highly motivated patients, demonstrate that lifestyle modification is extremely effective at lowering blood pressure and controlling hypertension. In view of these results, future research should focus on developing and

evaluating lifestyle interventions in the medical setting that overcome patient, physician, and organizational barriers.

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