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Effects of Comprehensive Lifestyle Modification on Diet, Weight, Physical Fitness, and Blood Pressure Control: 18-Month Results of a Randomized Trial

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Background: The main 6-month results from the PREMIER trial showed that comprehensive behavioral intervention programs improve lifestyle behaviors and lower blood pressure.

Objective: To compare the 18-month effects of 2 multicomponent behavioral interventions versus advice only on hypertension status, lifestyle changes, and blood pressure.

Design: Multicenter, 3-arm, randomized trial conducted from January 2000 through November 2002.

Setting: 4 clinical centers and a coordinating center.

Patients: 810 adult volunteers with prehypertension or stage 1 hypertension (systolic blood pressure, 120 to 159 mm Hg; diastolic blood pressure, 80 to 95 mm Hg).

Interventions: A multicomponent behavioral intervention that implemented long-established recommendations ("established"); a multicomponent behavioral intervention that implemented the established recommendations plus the Dietary Approaches to Stop Hypertension (DASH) diet ("established plus DASH"); and advice only.

Measurements: Lifestyle variables and blood pressure status. Follow-up for blood pressure measurement at 18 months was 94%.

Results: Compared with advice only, both behavioral interventions statistically significantly reduced weight, fat intake, and sodium intake. The established plus DASH intervention also statistically significantly increased fruit, vegetable, dairy, fiber, and mineral intakes. Relative to the advice only group, the odds ratios for hypertension at 18 months were 0.83 (95% CI, 0.67 to 1.04) for the established group and 0.77 (CI, 0.62 to 0.97) for the established plus DASH group. Although reductions in absolute blood pressure at 18 months were greater for participants in the established and the established plus DASH groups than for the advice only group, the differences were not statistically significant.

Limitations: The exclusion criteria and the volunteer nature of this cohort may limit generalizability. Although blood pressure is a well-accepted risk factor for cardiovascular disease, the authors were not able to assess intervention effects on clinical cardiovascular events in this limited time and with this sample size.

Conclusions: Over 18 months, persons with prehypertension and stage 1 hypertension can sustain multiple lifestyle modifications that improve control of blood pressure and could reduce the risk for chronic disease.

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The public health burden of chronic diseases related to suboptimal diet and physical inactivity is enormous. It has been estimated that these lifestyle factors contribute to approximately 20% of deaths in the United States (1). Incidence of atherosclerotic cardiovascular disease, overweight and obesity, elevated blood pressure and lipid levels, diabetes, osteoporosis, and cancer is increased by unhealthy lifestyles (2–8). Multiple lifestyle factors, such as physical inactivity; excessive intake of calories, sodium, saturated fat, and cholesterol; and inadequate intake of fruits, vegetables, and low-fat dairy products, are etiologically related to the development of these diseases (4, 5, 8–10).

To reduce the burden of chronic disease, increased physical activity and changes in diet are needed, yet few intervention studies have attempted to achieve many lifestyle changes simultaneously. The PREMIER randomized trial tested the effects of 2 multicomponent behavioral interventions on blood pressure (11). Both interventions promoted increased physical activity, weight loss, and reduced sodium intake, each of which is recommended by the 2005 Dietary Guidelines Scientific Advisory Committee (12). One intervention also added the Dietary Approaches to Stop Hypertension (DASH) diet (13). This diet, which is high in fruits, vegetables, and low-fat dairy products and low in saturated fat, total fat, and cholesterol, meets each of the major nutrient recommendations that were established by the Institute of Medicine (14–18).

We report the effects of the PREMIER interventions on lifestyle changes and blood pressure status at 18 months. The main results of PREMIER, namely change in blood pressure at 6 months, were reported previously (11).

See also:

Print
Editors' Notes 486
Summary for Patients I-27

Web-Only
CME quiz
Conversion of figure and tables into slides

Context

Can adults make sustained changes in unhealthy lifestyle behaviors?

Content

In this multicenter trial, 810 adult volunteers with pre hypertension or stage 1 hypertension were randomly assigned to a multicomponent behavioral intervention group, a group combining the behavioral intervention plus the Dietary Approaches to Stop Hypertension (DASH) diet, or an advice only group. At 18 months, participants in both behavioral intervention groups had less hypertension, more weight loss, and better reduction in sodium and fat intake than those receiving advice only. The participants in the DASH diet group also increased their intake of fruits, vegetables, and fiber.

Implications

Motivated adults can sustain several lifestyle changes over 18 months, which might reduce their risk for cardiovascular disease.

—The Editors

METHODS

The PREMIER study design and rationale (19) and intervention methods (11) have been described previously. The institutional review boards at each clinical center; an external protocol review committee appointed by the National Heart, Lung, and Blood Institute (NHLBI); and the NHLBI reviewed and approved the protocol (available at www.kpchr.org/public/premier/intervention/default.asp). The NHLBI also appointed a data and safety monitoring board to monitor the trial. Each participant provided written informed consent. The trial was conducted from January 2000 through November 2002.

Study Participants

Participants were generally healthy adults, age 25 years or older, who had prehypertension or stage 1 hypertension and met the Joint National Committee VI (JNC VI) criteria for a 6-month trial of nonpharmacologic therapy (2). Targeted recruitment methods were used to ensure adequate representation of clinically important subgroups, in particular, African-American persons. Specific methods varied from site to site but included direct mailings, radio and newspaper advertisements, and networking within the local African-American communities. Eligibility criteria included not taking antihypertensive medication and having a systolic blood pressure of 120 to 159 mm Hg and a diastolic blood pressure of 80 to 95 mm Hg, based on the average of 3 screening visits. Persons with prehypertension (systolic blood pressure of 120 to 139 mm Hg or diastolic blood pressure of 80 to 89 mm Hg) were included because of the excess risk for cardiovascular disease in those with blood pressure within this range (20). Major exclusion criteria were a body mass index less than 18.5 kg/mg^2 or greater than 45.0 kg/m^2, use of antihypertensive drugs or other drugs that affect blood pressure, JNC VI risk category C (target organ damage or diabetes), use of prescription weight loss medications, previous cardiovascular event, congestive heart failure, angina, cancer, and consumption of more than 21 alcoholic drinks per week.

Trial Conduct

Eligible participants were randomly assigned, with equal probability, to 1 of 3 groups: an advice only comparison group ("advice" only); an intervention group that targeted established, guideline-recommended lifestyle recommendations ("established") (2); or an intervention group targeting the established recommendations and adding the DASH dietary pattern ("established plus DASH") (13). Computer-generated treatment assignments were stratified by clinic and hypertension status and were assigned in blocks of varying sizes to provide balance over time. The actual assignments were administered by using a password-protected, Web-based application developed by the coordinating center and accessible only by authorized individuals. All clinic measurement staff were blinded to treatment assignment, and all intervention staff were blinded to clinic measurements. Hypertension was defined by using the JNC VI criteria for hypertension treatment: an average systolic blood pressure of 140 mm Hg, a diastolic blood pressure greater than 90 mm Hg, or use of antihypertensive medication. Normal blood pressure was defined as systolic blood pressure less than 120 mm Hg, diastolic blood pressure less than 80 mm Hg, and no use of antihypertensive medication (21) (**Figure**). Intervention was provided by master's degree–level counselors (dietitians and health educators trained in behavioral methods). The counselors were centrally trained before the start of the study, attended annual 3-day training sessions, and participated in monthly conference calls.

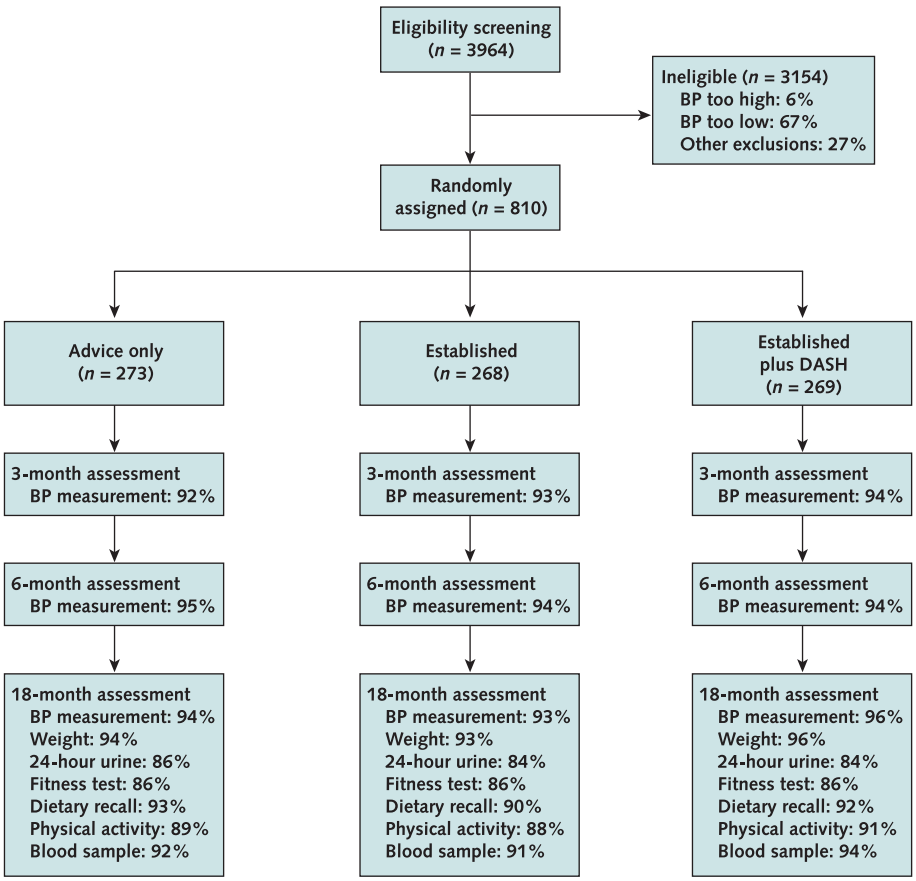
Advice Only Group

Participants in the advice group received advice to follow the National High Blood Pressure Education Program lifestyle recommendations for blood pressure control (2). Lifestyle recommendations included reducing weight (if overweight), following a reduced-sodium diet, engaging in regular moderate-intensity physical activity, and eating a heart-healthy diet, including the DASH diet. This advice was provided in two 30-minute individual sessions, 1 immediately after random assignment and 1 after the 6-month data collection visit. A PREMIER counselor reviewed the guidelines with the participant and provided printed educational materials and information about community resources. This intervention did not include advice to keep a food or exercise diary.

Behavioral Interventions in the Established and Established plus DASH Groups

Participant goals for the established and established plus DASH groups included weight loss of at least 6.8 kg (15 lb) for those with a body mass index of 25 kg/m^2 or

Figure. **Flow diagram of enrollment, measurements, and visit completion.**



BP = blood pressure; DASH = Dietary Approaches to Stop Hypertension.

greater, at least 180 minutes per week of moderate-intensity physical activity, no more than 100 mmol per day of dietary sodium, and alcohol consumption of no more than 30 mL (1 oz) per day (2 drinks) for men and 15 mL (0.5) oz per day (1 drink) for women. Participants assigned to the established plus DASH group (but not those in the established group) also received counseling on the DASH diet, with goals for increased consumption of fruits and vegetables (9 to 12 servings/d) and low-fat dairy products (2 to 3 servings/d) and reduced consumption of saturated fat (≤ 7% of energy) and total fat (≤ 25% of energy).

The intervention format, contact pattern, and behavior change strategies for the established and established plus DASH groups were identical. During the first 6 months, participants in both behavioral intervention groups attended 14 group sessions and 4 individual sessions; during months 7 to 18, they attended monthly group sessions supplemented with 3 individual counseling sessions.

Throughout the trial, participants in the established and established plus DASH groups (but not those in the advice group) kept food diaries, monitored dietary calorie and sodium intakes, and recorded minutes of physical activity. Self-monitoring was used to provide individualized feedback, reinforcement, problem solving, and support. Social support for initial behavior changes and maintenance of change was provided during the group sessions. More detailed descriptions of the behavorial intervention methods are available (22).

Measurements

Blood pressure was assessed twice at each measurement, and systolic and diastolic blood pressures were calculated by using the mean of all available measurements (4 sets before random assignment, 3 sets at 6 and 18 months, and 1 set at 3 and 12 months). For 4 participants who were started on antihypertensive drug therapy between the 12- and 18-month visits, we obtained an official set of blood pressure measurements before initiation of therapy and used these as our 18-month blood pressure values for analysis. A similar procedure was used to obtain the 6-month blood pressure value for the 1 participant who began taking antihypertensive drugs between the 3- and 6-month visits.

Two 24-hour dietary recalls, 1 obtained on a weekday and the other obtained on a weekend, were collected at baseline and at 6 and 18 months by telephone interview (23). Intakes of nutrients and food groups were calculated by using the Nutrition Data System for Research, version NDS-R 1998 (University of Minnesota, Minneapolis, Minnesota). Urinary excretion of sodium (reflecting salt intake) and potassium (reflecting fruit and vegetable intake) was obtained from 24-hour urinary collections at baseline and at 6 and 18 months.

Weight, cardiorespiratory fitness, and physical activity were also assessed at baseline and at 6 and 18 months. Weight was measured with participants wearing light indoor clothing and no shoes. Fitness was assessed by using a 2-stage, 10-minute submaximal treadmill exercise test (24) developed for PREMIER (19). A 7-day, interviewer-administered physical activity recall was used to assess energy expenditure from physical activity (25).

Blood Pressure Outcomes

Because national guidelines recommend that individuals with persistent systolic blood pressure greater than 140 mm Hg or diastolic blood pressure greater than 90 mm Hg be referred for treatment after a period of lifestyle modification (2), we anticipated that many participants would be referred for treatment at 6 months, thus requiring censoring of their blood pressure data in subsequent analyses. We also hypothesized that more participants in the advice group would be given medication compared with those in the behavorial intervention groups. Thus, although the primary outcome of PREMIER was systolic blood pressure at 6 months, we believed that hypertension status provided a more meaningful estimate of 18-month intervention effects than did blood pressure level. Other protocol-specified outcomes at 18 months were hypertension control (systolic blood pressure $<$ 140 mm Hg and diastolic blood pressure $<$ 90 mm Hg), change in systolic and diastolic blood pressures, and changes in lifestyle variables.

Blood pressure taken at any visit was censored if the participant reported using antihypertensive medication within the preceding month. Missing values for 6- and 18-month blood pressure were imputed by using the blood pressure from the immediately preceding (3- or 12-month, respectively) clinic visit, if available. Otherwise, they were imputed by using a single imputation hot-deck procedure (26) that used values from participants in the advice group who were similar at baseline with respect to variables that predicted future missing data. Overall, 3% of blood pressure measurements at 6 months were imputed using the immediately preceding blood pressure value, and 6% were imputed by using the hot-deck procedure. Comparable figures for blood pressure measurement at 18 months were 5% and 12%, respectively. Because 94% of participants attended each of the 6- and 18-month visits (**Figure**), the primary reason for missing blood pressure was censoring due to antihypertension medication (5% of participants at 6 months and 14% of participants at 18 months). Analyses for which hypertension was the main outcome were limited to the 94% of participants who attended the 18-month visit or those who had a valid termination blood pressure value as described previously.

Adverse Events

Blinded clinic staff asked about gastrointestinal, musculoskeletal, and cardiovascular symptoms at the 3-, 6-, 12-, and 18-month assessments; study clinicians reviewed responses and referred participants for additional care as needed. At these same time points, participants were also queried about possible serious adverse events, defined as self-reported doctor diagnosis of heart attack, stroke, transient ischemic attack, heart failure, coronary angioplasty or bypass surgery, angina pectoris, broken bone, torn ligament, and any other serious injury to the bone or muscle. Physician-confirmed angina following positive results on the Rose angina questionnaire also constituted a serious adverse event. Although they were not considered serious adverse events for this study, we also tracked the incidence of the following "other medical conditions": hyperlipidemia, gallbladder disease, diabetes, and cancer.

Statistical Analysis

Formal statistical analysis was restricted to the 18-month blood pressure data, although 6-month data (much of which has been previously published [11]) are presented to show the time trends. Blood pressure data were analyzed by using a general linear model in which change in blood pressure (mean 18-month blood pressure minus mean baseline blood pressure) was regressed on indicators of the 2 behavioral interventions, indicators for site and cohort, and baseline blood pressure. Models for the subgroup analyses (hypertensive and nonhypertensive participants) also included a term for hypertension status and an interaction term between the hypertension status term and the 2 treatment-group terms.

Similar analytic models were used to assess changes in weight, dietary intake, physical fitness, energy expenditure, and urinary excretions among treatment groups. Missing values were not imputed for these latter variables; participants were excluded from these analyses instead.

Hypertension status was based on blood pressure measured at 18 months or reported use of antihypertensive medication. Hypertension status at 18 months was assessed in the entire sample and separately for those who had hypertension at baseline (persistent hypertension) and those who did not (incident hypertension). Differences in the incidence, persistence, and prevalence of hypertension among treatment groups were assessed by using logistic regression, by adjusting for site and cohort effects and baseline hypertensive status. Subgroup analyses also included baseline hypertension status by treatment group interaction. A similar analytic approach was used to analyze normal blood pressure status.

Analyses were done by using SAS software, version 8

Table 1. **Baseline Characteristics by Randomly Assigned Group***

Variable	Advice Only Group (n = 273)	Established Group (n = 268)	Established plus DASH Group (n = 269)
Mean age (SD), *y*	49.5 (8.8)	50.2 (8.6)	50.2 (9.3)
Women, %	63.0	64.9	57.2
Race or ethnicity, %			
African American	36.6	37.3	29.4
Non-Hispanic white	61.2	60.8	67.3
All others	2.2	1.9	3.3
Mean BMI (SD), kg/m^2	32.9 (5.6)	33.0 (5.5)	33.3 (6.3)
BMI classification, %			
Not overweight (BMI < 25 kg/m^2)	5.5	4.9	6.0
Overweight (BMI 25–29.9 kg/m^2)	27.8	29.9	30.5
Obese (BMI ≥ 30 kg/m^2)	66.7	65.3	63.6

* BMI = body mass index; DASH = Dietary Approaches to Stop Hypertension.

(SAS Institute, Inc., Cary, North Carolina). In the Results section and in the tables, estimated effect sizes are presented with confidence intervals in parentheses following the estimate. Although nominal *P* values and 95% CIs are shown in the text, we used the Holm adjustment for multiple comparisons to declare statistical significance (27). Specifically, for any given outcome, we considered the pairwise contrasts of treatment values with advice only values to be statistically significantly different only if at least 1 of them achieved a *P* value of 0.025 or less. In that case, the other contrast with the advice group and the contrast between the established and the established plus DASH groups were tested by using a *P* value of 0.05 or less. Accordingly, the term *significant*, as used in this paper, refers to statistical significance per the Holm criteria.

The sample size for the trial was based on the primary outcome, namely, systolic blood pressure at 6 months. On the basis of a planned sample size of 800 (267 participants per group), the study had 90% power to detect pairwise between-group differences in systolic blood pressure of 1.6 to 1.8 mm Hg in the entire sample.

Role of the Funding Source

The study was conducted as a cooperative agreement with the NHLBI, which participated as a voting member on the steering committee and was actively involved in the design, conduct, and analysis of the study and in the decision to submit the manuscript for publication.

RESULTS

Baseline Characteristics and Follow-up Attendance

All participants (n = 810) were middle-aged, 62% were women, 34% were African American, 95% were overweight or obese, and 38% had hypertension. The mean systolic and diastolic blood pressures were 134.9 mm Hg (SD, 9.6) and 84.8 mm Hg (SD, 4.2), respectively. Among participants with hypertension at baseline, the mean systolic and diastolic blood pressures were 143.9 mm Hg (SD, 7.6) and 87.5 mm Hg (SD, 4.3), respectively. Corresponding blood pressure levels in those participants without hypertension were 129.5 mm Hg (SD, 5.8) and 83.2 mm Hg (SD, 3.1), respectively. Baseline characteristics were similar among the randomly assigned groups (**Table 1**).

During the 18 months, there were high rates of data collection at follow-up visits and attendance at intervention sessions. The percentage of participants who had a least 1 blood pressure measurement at baseline, at 6 months, and at 18 months was 100%, 94%, and 94%, respectively. Of the possible 33 intervention visits over 18 months, the mean number attended was 24 for the established group and 25 for the established plus DASH group. Ninety-nine percent of participants in the advice group attended their initial counseling session, and 63% attended their second session after the 6-month clinic visit.

Intervention Effects

Table 2 and **Table 3** show changes in the primary lifestyle variables during the 18-month intervention period for participants in each randomly assigned group, as well as mean between-group differences at 18 months. At 18 months, a mean weight loss from baseline was observed in each group. For both behavorial intervention groups, the mean weight loss was statistically significantly greater than that for the advice group (net mean difference of − 2.2 kg for the established group and − 2.7 kg for established plus DASH; $P < 0.001$ for each). At 18 months, approximately 25% of participants in the 2 behavorial intervention groups met the weight loss goal of 6.8 kg.

At 18 months, fitness, as measured by heart rate at stage 2 of the treadmill test, was improved for all study groups. Although the reduction in heart rate at stage 2 for participants in the established plus DASH group seems to differ significantly from advice group (−2.1 beats/min [95% CI, −4.0 to 0.1 beats/min]), the corresponding *P* value (0.035) did not reach the required 0.025 threshold (see Methods) to be declared statistically significant. Small increases in self-reported energy expenditure were reported from baseline to 18 months, with no statistically significant differences between the 2 behavioral intervention groups and the advice group.

Table 2. **Change in Weight, Fitness, Physical Activity, and Urine Sodium and Potassium Excretion from Baseline to 18 Months by Randomly Assigned Group***

Variable	Advice Only Group (A) (n = 241)	Established Group (B) (n = 235)	Established plus DASH Group (C) (n = 241)	Estimated Difference from Baseline to 18 Months	
				Pairwise Comparison	Estimate (95% CI)
Mean weight					
Participants with data, *n*	241	235	241		
Baseline (SD), *kg*	96.0 (17.2)	95.7 (17.6)	98.6 (19.1)	B vs. A	−2.2 (−3.3 to 1.1)
Change at 6 months (SD), *kg*	−1.1 (3.2)	−4.9 (5.5)	−5.8 (5.8)	C vs. A	−2.7 (−3.8 to 1.6)
Change at 18 months (SD), *kg*	−1.5 (5.0)	−3.8 (6.1)	−4.3 (7.4)	C vs. B	−0.5 (−1.6 to 0.6)
Mean fitness (heart rate at stage 2 of submaximal exercise test)					
Participants with data, *n*	233	225	225		
Baseline (SD), *beats/min*	129.8 (14.6)	130.5 (14.1)	130.0 (14.6)	B vs. A	−0.8 (−2.7 to 1.2)
Change at 6 months (SD), *beats/min*	−5.3 (9.7)	−8.0 (11.1)	−9.0 (10.7)	C vs. A	−2.1 (−4.0 to −0.1)
Change at 18 months (SD), *beats/min*	−7.4 (10.4)	−8.2 (11.2)	−9.5 (11.0)	C vs. B	−1.3 (−3.3 to 0.6)
Mean physical activity (daily energy expenditure)					
Participants with data, *n*	242	232	240		
Baseline (SD), *kcal/kg*	33.7 (2.5)	33.8 (2.6)	33.6 (2.4)	B vs. A	−0.2 (−0.7 to 0.3)
Change at 6 months (SD), *kcal/kg*	0.3 (2.9)	0.4 (2.9)	0.6 (2.4)	C vs. A	0.1 (−0.3 to 0.6)
Change at 18 months (SD), *kcal/kg*	0.6 (3.6)	0.3 (2.6)	0.8 (3.4)	C vs. B	0.3 (−0.1 to 0.8)
Mean urinary sodium excretion					
Participants with data, *n*	233	223	214		
Baseline (SD), *mmol/24 h*	173.2 (69.5)	165.4 (70.1)	177.3 (80.0)	B vs. A	−16.7 (−30.3 to −3.2)
Change at 6 months (SD), *mmol/24 h*	−20.6 (71.6)	−31.6 (74.7)	−32.6 (78.1)	C vs. A	−15.4 (−29.1 to −1.7)
Change at 18 months (SD), *mmol/24 h*	−5.6 (89.8)	−18.4 (83.3)	−24.5 (85.2)	C vs. B	1.3 (−12.6 to 15.2)
Mean urinary potassium excretion					
Participants with data, *n*	233	223	214		
Baseline (SD), *mmol/24 h*	66.9 (28.1)	66.6 (23.9)	68.1 (27.0)	B vs. A	2.7 (−2.2 to 7.6)
Change at 6 months (SD), *mmol/24 h*	−1.3 (28.7)	0.9 (22.3)	19.3 (32.1)	C vs. A	12.7 (7.8 to 17.7)
Change at 18 months (SD), *mmol/24 h*	−2.5 (26.9)	0.2 (30.1)	9.6 (30.4)	C vs. B	10.0 (5.0 to 15.0)

* "Participants with data" refers to those with baseline and 18-month data. DASH = Dietary Approaches to Stop Hypertension.

At 18 months, reductions in excretion of urinary sodium were statistically significant for both behavorial intervention groups compared with the advice group. The mean fruit and vegetable intake significantly increased in the established plus DASH group compared with the advice (2.6 servings/d) and the established (2.7 servings/d) groups. Urinary potassium excretion and self-reported intake of dairy products also increased significantly in the established plus DASH group compared with the other 2 groups. Total fat and saturated fat consumption was significantly reduced in both behavorial intervention groups compared with the advice group, and in the established plus DASH group relative to the established group. Dietary cholesterol intake also was significantly reduced for the established plus DASH group compared with the advice only and the established groups. Energy intake was significantly reduced for the established and established plus DASH groups compared with the advice group. Intakes of calcium, magnesium, fiber, and folate were all significantly higher in the established plus DASH group than in the advice and the established groups.

Blood Pressure Effects

Table 4 shows hypertension status and mean blood pressure levels during the course of the 18 months. At baseline, the prevalence of hypertension was 36% to 38%. By 18 months, it had decreased in all 3 treatment groups to 32% in the advice group, 24% in the established group, and 22% in the established plus DASH group. Relative to the advice group, the odds ratios for hypertension at 18 months were 0.83 (CI, 0.67 to 1.04) for the established and 0.77 (CI, 0.62 to 0.97) for the established plus DASH groups, with only the latter achieving statistical significance. Among participants who had hypertension at baseline, the prevalence of hypertension at 18 months had decreased to 63% in the advice group, to 40% in the established group, and to 38% in the established plus DASH group, with corresponding odds ratios for remaining hypertensive, versus the advice group, of 0.63 (CI, 0.46 to 0.85) for the established group and 0.60 (CI, 0.45 to 0.81) for the established plus DASH group. On the basis of study eligibility criteria, no participant had normal blood pressure at baseline; at 18 months, 18% of partici-

Table 3. **Change in Dietary Intake of Food Groups and Nutrients from Baseline to 18 Months by Randomly Assigned Group***

Variable	Advice Only Group (A) (n = 248)	Established Group (B) (n = 237)	Established plus DASH Group (C) (n = 243)	Estimated Difference from Baseline to 18 Months	
				Pairwise Comparison	Estimate (95% CI)
Mean fruit and vegetable intake (SD), *servings/d*					
Baseline	4.4 (2.3)	4.6 (2.3)	4.7 (2.5)	B vs. A	−0.1 (−0.5 to 0.4)
Change at 6 months	0.5 (2.8)	0.5 (2.6)	3.0 (3.6)	C vs. A	2.6 (2.2 to 3.1)
Change at 18 months	0.3 (2.7)	0.1 (2.7)	2.8 (3.4)	C vs. B	2.7 (2.2 to 3.2)
Mean dairy intake (SD), *servings/d*					
Baseline	1.6 (1.2)	1.6 (1.3)	1.7 (1.2)	B vs. A	−0.2 (−0.4 to 0.0)
Change at 6 months	0.1 (1.6)	−0.2 (1.5)	0.5 (1.6)	C vs. A	0.4 (0.2 to 0.6)
Change at 18 months	0.0 (1.3)	−0.2 (1.5)	0.4 (1.5)	C vs. B	0.6 (0.4 to 0.8)
Mean total fat intake (SD), *% of kcal*					
Baseline	32.7 (7.2)	33.5 (8.0)	33.2 (7.7)	B vs. A	−1.5 (−2.8 to −0.1)
Change at 6 months	−1.0 (7.9)	−3.9 (9.8)	−9.5 (9.5)	C vs. A	−6.0 (−7.4 to −4.7)
Change at 18 months	−1.0 (8.6)	−3.0 (9.7)	−7.4 (8.9)	C vs. B	−4.6 (−6.0 to −3.2)
Mean saturated fat intake (SD), *% of kcal*					
Baseline	10.9 (3.3)	10.9 (3.1)	10.9 (3.0)	B vs. A	−0.6 (−1.1 to 0.0)
Change at 6 months	−0.4 (3.9)	−1.5 (4.0)	−3.3 (3.9)	C vs. A	−2.3 (−2.8 to −1.8)
Change at 18 months	−0.6 (3.8)	−1.1 (3.7)	−2.9 (3.4)	C vs. B	−1.7 (−2.3 to −1.2)
Mean calorie intake (SD), *kcal*					
Baseline	1917 (622.7)	1928 (590.6)	1996 (652.1)	B vs. A	−130 (−217 to −44)
Change at 6 months	−169 (638.8)	−316 (535.5)	−261 (590.8)	C vs. A	−95 (−181 to −10)
Change at 18 months	−147 (596.7)	−281 (519.5)	−284 (637.0)	C vs. B	35 (−52 to 122)
Mean protein intake (SD), *% of kcal*					
Baseline	15.5 (3.8)	16.2 (4.6)	16.0 (3.8)	B vs. A	0.3 (−0.5 to 1.1)
Change at 6 months	1.2 (4.9)	1.0 (5.4)	2.0 (4.7)	C vs. A	1.0 (0.2 to 1.8)
Change at 18 months	1.4 (5.6)	1.3 (4.8)	2.1 (4.7)	C vs. B	0.7 (−0.1 to 1.5)
Mean carbohydrate intake (SD), *% of kcal*					
Baseline	52.1 (8.8)	50.4 (10.4)	50.9 (9.6)	B vs. A	1.0 (−0.7 to 2.7)
Change at 6 months	−0.1 (9.6)	3.4 (11.7)	8.9 (11.4)	C vs. A	5.8 (4.1 to 7.5)
Change at 18 months	−0.1 (10.7)	1.9 (11.8)	6.5 (10.2)	C vs. B	4.8 (3.2 to 6.5)
Mean cholesterol intake (SD), *mg/d*					
Baseline	264.0 (161.9)	279.5 (161.4)	278.6 (156.3)	B vs. A	−9.6 (−33.9 to 14.8)
Change at 6 months	−8.9 (212.0)	−64.0 (190.6)	−82.7 (178.1)	C vs. A	−39.7 (−63.8 to −15.6)
Change at 18 months	−22.3 (201.2)	−44.4 (180.3)	−73.7 (173.1)	C vs. B	−30.1 (−54.5 to −5.7)
Mean total dietary fiber intake (SD), *g/d*					
Baseline	17.1 (8.0)	17.0 (7.4)	17.3 (8.0)	B vs. A	−0.1 (−1.5 to 1.3)
Change at 6 months	−0.3 (7.4)	0.6 (6.9)	4.7 (8.5)	C vs. A	4.2 (2.9 to 5.6)
Change at 18 months	0.2 (8.3)	0.1 (7.3)	4.4 (9.4)	C vs. B	4.4 (3.0 to 5.8)
Mean calcium intake (SD), *mg/d*					
Baseline	728.3 (350.5)	722.0 (329.7)	752.9 (359.1)	B vs. A	−61.2 (−123.3 to 0.9)
Change at 6 months	−33.1 (418.1)	−44.9 (327.6)	177.2 (439.7)	C vs. A	148.6 (86.9 to 210.3)
Change at 18 months	16.0 (397.9)	−40.3 (349.7)	153.2 (409.5)	C vs. B	209.8 (147.4 to 272.2)
Mean magnesium intake (SD), *mg/d*					
Baseline	271.2 (111.5)	273.6 (94.7)	277.6 (107.1)	B vs. A	−6.5 (−23.2 to 10.2)
Change at 6 months	−11.6 (95.5)	−5.2 (88.4)	39.9 (101.2)	C vs. A	38.2 (21.6 to 54.8)
Change at 18 months	−1.0 (110.1)	−8.0 (93.4)	34.6 (109.1)	C vs. B	44.7 (27.9 to 61.5)
Mean folate intake, *μg/d*					
Baseline	346.8 (166.6)	343.5 (149.0)	345.5 (168.2)	B vs. A	−20.9 (−47.3 to 5.5)
Change at 6 months	7.1 (164.3)	10.1 (161.0)	72.3 (201.3)	C vs. A	64.9 (38.6 to 91.1)
Change at 18 months	19.6 (189.5)	1.3 (166.8)	86.0 (207.0)	C vs. B	85.8 (59.2 to 112.3)

* Sample size for participants with baseline and 18-month data. DASH = Dietary Approaches to Stop Hypertension.

pants in the advice group, 24% of those in the established group, and 24% of those in the established plus DASH group had normal blood pressure ($P > 0.050$ for each of the pairwise contrasts). At 18 months, the mean systolic and diastolic blood pressure had declined from baseline for participants in each treatment group. Although these re-

Table 4. **Outcomes: Prevalence of Normal Blood Pressure, Proportion Using Antihypertensive Medications, and Systolic and Diastolic Blood Pressure at Baseline, 6 Months, and 18 Months by Randomly Assigned Group***

Outcomes	All Participants					Participants Who Had Hypertension at Baseline				
	Advice Only Group (A)	Established Group (B)	Established plus DASH Group (C)	Pairwise Comparison	Odds Ratio or Difference from Baseline at 18 Months (95% CI)†	Advice Only Group (A)	Established Group (B)	Established plus DASH Group (C)	Pairwise Comparison	Odds Ratio or Difference from Baseline at 18 Months (95% CI)†
Prevalence of hypertension, %‡										
Baseline	38	36	38	B vs. A	0.83 (0.67 to 1.04)	100	100	100	B vs. A	0.63 (0.46 to 0.85)
6 months	26	17	12	C vs. A	0.77 (0.62 to 0.97)	52	34	23	C vs. A	0.60 (0.45 to 0.81)
18 months	32	24	22	C vs. B	0.93 (0.75 to 1.15)	63	40	38	C vs. B	0.96 (0.71 to 1.30)
Prevalence of normal blood pressure§										
Baseline	0	0	0	B vs. A	1.25 (0.91 to 1.72)	0	0	0	B vs. A	1.36 (0.76 to 2.43)
6 months	19	30	35	C vs. A	1.17 (0.84 to 1.63)	3	12	13	C vs. A	1.09 (0.59 to 2.01)
18 months	18	24	24	C vs. B	0.93 (0.69 to 1.26)	5	9	6	C vs. B	0.80 (0.46 to 1.39)
Use of antihypertensive medication										
Baseline	0	0	0	B vs. A	0.76 (0.56 to 1.01)	0	0	0	B vs. A	0.57 (0.41 to 0.81)
6 months	10	2	3	C vs. A	0.90 (0.69 to 1.17)	23	4	2	C vs. A	0.62 (0.45 to 0.85)
18 months	19	10	14	C vs. B	1.19 (0.90 to 1.58)	41	18	21	C vs. B	1.07 (0.74 to 1.55)
Mean systolic blood pressure (SD), *mm Hg*										
Baseline	134.2 (10.1)	135.5 (9.2)	134.9 (9.4)	B vs. A	−0.9 (−2.7 to 0.9)	143.5 (8.2)	144.2 (7.6)	144.1 (7.1)	B vs. A	−1.3 (−4.3 to 1.6)
Change at 6 months	−6.6 (9.2)	−10.5 (10.1)	−11.1 (9.9)	C vs. A	−1.9 (−3.7 to −0.1)	−7.8 (10.3)	−12.5 (11.5)	−14.2 (10.1)	C vs. A	−1.0 (−3.9 to 2.0)
Change at 18 months	−7.4 (10.8)	−8.6 (11.6)	−9.5 (10.8)	C vs. B	−1.0 (−2.8 to 0.8)	−9.9 (13.2)	−11.4 (13.5)	−11.0 (13.0)	C vs. B	0.4 (−2.6 to 3.3)
Mean diastolic blood pressure (SD), *mm Hg*										
Baseline	84.8 (4.3)	85.0 (4.1)	84.6 (4.0)	B vs. A	−0.6 (−1.9 to 0.6)	87.8 (4.5)	87.5 (4.5)	87.2 (4.0)	B vs. A	−1.0 (−3.0 to 1.1)
Change at 6 months	−3.8 (6.3)	−5.5 (6.7)	−6.4 (6.8)	C vs. A	−1.1 (−2.3 to 0.2)	−3.8 (7.1)	−5.8 (7.0)	−7.4 (7.1)	C vs. A	−1.0 (−3.0 to 1.0)
Change at 18 months	−5.2 (7.7)	−6.0 (7.3)	−6.2 (7.8)	C vs. B	−0.4 (−1.7 to 0.8)	−6.5 (9.6)	−7.3 (8.4)	−7.4 (8.8)	C vs. B	−0.1 (−2.1 to 1.9)

* DASH = Dietary Approaches to Stop Hypertension.
† For the prevalence of hypertension, prevalence of normal blood pressure, and use of antihypertensive medication, values are odds ratios; for systolic and diastolic blood pressure, values are differences.
‡ Hypertension was defined as an average systolic blood pressure of 140 mm Hg or greater, an average diastolic blood pressure of 90 mm Hg, or reported use of antihypertensive medication.
§ Normal blood pressure was defined as an average systolic blood pressure of less than 120 mm Hg, a diastolic blood pressure less than 80 mm Hg, and no reported use of antihypertensive medication.

ductions were greater for the established and the established plus DASH groups than for the advice group, (by 0.9 and 1.9 mm Hg systolic blood pressure, respectively), none of these contrasts was statistically significant.

Adverse Events

We did not find any significant pairwise differences between behavorial intervention groups in the cumulative rate of occurrence of serious adverse events or other medical conditions (see Methods) during the 18 months.

Discussion

The 18-month PREMIER results show that multiple lifestyle modifications can be achieved and maintained by persons with prehypertension and stage 1 hypertension. Participants in both behavioral intervention groups lost weight and reduced dietary sodium and fat intakes during the 18 months. In the established plus DASH group, participants made additional dietary changes, significantly increasing their intakes of fruits, vegetables, and dairy products and further reducing their intake of saturated and total fats. As a consequence, their hypertension status improved.

Although adherence to these lifestyle changes lessened between the 6- and 18-month measurement visits (**Tables 2** and **3**), many significant differences between the behavorial intervention groups still persisted after 18 months. Approximately three fourths of the 5% to 6% weight loss from baseline to 6 months was maintained, which resulted in a mean weight reduction of approximately 4% from baseline to 18 months. These modest reductions should be viewed in the context of public health goals that emphasize prevention of additional weight gain, rather than weight loss, because of the well-documented difficulties of sustain-

ing weight loss (28, 29). Similarly, modest reductions in dietary sodium intake were achieved from relatively high baseline levels of 172 mmol/d. Approximately 60% to 75% of sodium reductions at 6 months were maintained at 18 months.

The participants in the established plus DASH group maintained a fruit and vegetable intake of 7.5 servings per day through 18 months, a 60% increase compared with baseline and with the established and advice groups, well above the traditional national recommendation of 5 servings per day (30, 31). Compared with the participants in the advice and established groups, those in the established plus DASH group also substantially increased their intakes of other important nutrients, such as fiber, folate, and minerals (for example, calcium, potassium, and magnesium), that may reduce the risk for chronic disease (8, 32–37).

Results of the PREMIER trial mitigate concerns that individuals cannot simultaneously make behavior changes in several lifestyle domains (38, 39). The success of the interventions in this regard may be at least partly attributable to the use of modern behavioral approaches, such as self-monitoring, feedback and reinforcement, and problem solving that also promote social and environmental support and personal motivation.

Hypertension status was the principal blood pressure–related outcome at 18 months. In the established and established plus DASH groups, the prevalence of hypertension at 18 months was 40% and 38%, respectively, corresponding to control rates of 60% and 62%, respectively. These control rates compare favorably with community data in which drug therapy controls blood pressure in approximately 50% of patients with hypertension (40). In both PREMIER behavorial intervention groups, the best rates of hypertension control (lowest prevalences of hypertension) and the greatest reductions in blood pressure were observed at 6 months; favorable trends in hypertension status and blood pressure persisted after 6 months, but were attenuated. This attenuation probably reflects a diminution of adherence to lifestyle goals, objectively observed by some recidivism from 6 months to 18 months in weight loss (approximately 25%), urinary sodium (approximately 25% to 40%), and urinary potassium (approximately 50%), rather than a diminution of the effects on blood pressure of lifestyle change over the long term (41).

At 18 months, we observed only small and nonsignificant differences in blood pressure and hypertension status between the behavorial and intervention groups. One probable reason is that the observed dietary contrasts between these 2 groups were far less than those achieved between the intervention and control groups in the original DASH study (42). Participants in the established plus DASH group achieved only approximately 60% to 75% of the original DASH goal of 9 to 12 servings of fruit and vegetables per day and approximately 85% of the DASH goal of 2 to 3 servings of dairy per day. For example, the participants in the established group consumed a diet that was intermediate between the original DASH and control diets. In addition, several studies have observed that the cumulative effect on blood pressure when several intervention components are implemented simultaneously is less than what would be predicted based on their separate effects implemented alone (39, 43, 44). For example, weight loss is known to be highly effective in reducing blood pressure (45), and the added effect of the DASH diet may be lessened under conditions of weight loss; similar results were seen when the DASH diet was consumed in the context of a low-sodium diet (1500 mg/d) (45). Nevertheless, recommendations for blood pressure control should include all lifestyle changes that are known to improve blood pressure status when implemented alone, because some degree of additivity is probable (44, 45).

Unanticipated findings were the extent of lifestyle changes in the participants in the Advice group, who made some lifestyle changes at both 6 and 18 months. These lifestyle changes may have led to blood pressure reductions that attenuated pairwise contrasts in blood pressure and other measures between this group and the behavioral interventions groups. Of note, the participants in the advice group lost approximately 1.5 kg (a 1.6% reduction in body weight) at 18 months, whereas in several earlier blood pressure and lifestyle trials, control groups that received usual care gained weight (38, 41, 46, 47).

The participants in the advice only group received information just after being randomly assigned and again at 6 months; they also attended 12 data collection visits during the 18-month study that included blood draws and measurement of blood pressure, weight, diet, and fitness. These contacts may have enhanced awareness of blood pressure, hypertension status, and adherence to lifestyle recommendations. Highly motivated volunteers are typically recruited in randomized, controlled trials, and thus trial participants tend to be less representative of the general public. As a result, generalizability of trial results to the broader population is reduced. However, random assignment leads to high internal validity, particularly when follow-up rates are high and strong quality control procedures are in place. Consequently, observed differences among treatment groups probably reflect the effects of the intervention rather than other, potentially unmeasured, confounding factors.

Overall, findings from PREMIER show that individuals with prehypertension and stage 1 hypertension can make and sustain, during a period of 18 months, multiple lifestyle modifications can control blood pressure and reduce the risk for chronic disease. In light of recent national data showing an alarming increase in the prevalence of hypertension (48), there is a critical public health need for improved behavioral intervention programs, including those appropriate for delivery in the clinical setting, that enable individuals with or at risk for hypertension to adopt long-term healthier lifestyles. In addition, the enormously high prevalence of chronic disease and adverse lifestyles (3,

4, 7, 8, 21, 48–50) argues for concomitant public health strategies and policies that affect entire populations.

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