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ORIGINAL ARTICLE

Effect of lifestyle modifications on blood pressure by race, sex, hypertension status, and age

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Recommendations for control of high blood pressure (BP) emphasize lifestyle modification, including weight loss, reduced sodium intake, increased physical activity, and limited alcohol consumption. The Dietary Approaches to Stop Hypertension (DASH) dietary pattern also lowers BP. The PREMIER randomized trial tested multicomponent lifestyle interventions on BP in demographic and clinical subgroups. Participants with above-optimal BP through stage 1 hypertension were randomized to an Advice Only group or one of two behavioural interventions that implement established recommendations (Est) or established recommendations plus DASH diet (Est plus DASH). The primary outcome was change in systolic BP at 6 months. The study population was 810 individuals with an average age of 50 years, 62% women, 34% African American (AA), 95% overweight/obese, and 38% hypertensive. Participants in all the three groups made lifestyle changes. Mean net reductions in systolic (S) BP in the Est intervention were 1.2 mmHg in AA women, 6.0 in AA men, 4.5 in non-AA women, and 4.2 in non-AA men. The mean effects of the Est Plus DASH intervention were 2.1, 4.6, 4.2, and 5.7 mmHg in the four race–sex subgroups, respectively. BP changes were consistently greater in hypertensives than in nonhypertensives, although interaction tests were nonsignificant. The Est intervention caused statistically significant BP reductions in individuals over and under age 50. The Est Plus DASH intervention lowered BP in both age groups, and significantly more so in older individuals. In conclusion, diverse groups of people can adopt multiple lifestyle changes that can lead to improved BP control and reduced CVD risk.
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Introduction

Current national recommendations for the prevention and treatment of high blood pressure (BP) emphasize lifestyle modification.[1,2] Long-established lifestyle modifications that effectively lower BP include weight loss, reduced sodium intake, increased physical activity, and limited alcohol consumption.[2] In addition, the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, which is rich in fruits, vegetables, and low-fat dairy products and is reduced in total and saturated fat, also lowers BP.[2–4]

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These lifestyle modifications are recommended for nonhypertensive individuals with above-optimal BP ('pre-hypertensives'[5]), and as initial therapy in stage 1 hypertension.[2] For individuals taking antihypertensive medication, lifestyle modification is recommended as adjunctive therapy. The PREMIER trial evaluated the effects on blood pressure of two multicomponent behavioural lifestyle interventions compared to an advice only intervention. In our report of the main results of the PREMIER trial,[6] we demonstrated that multiple lifestyle changes can be achieved simultaneously and can lead to significant BP lowering through frequent behavioural counselling compared to brief, infrequent advice.

Previous data suggest that individual lifestyle recommendations have differential effects in some population subgroups. For example, reducing sodium intake has a greater effect on BP in hyperten-

sives, African Americans, and older individuals than in nonhypertensives, non-African Americans, and younger individuals.[7–9] Likewise, these groups appear to experience greater BP reduction from the DASH dietary pattern.[9–11] Conclusions about intervention effects in subgroups are often based on studies that highly controlled conditions (eg, by providing all foods) and/or test only one intervention at a time. In order to understand the potential public health impact of multiple lifestyle interventions, it is necessary to test these interventions in free-living individuals with a broad range of demographic and clinical characteristics. We now report the effect of two multicomponent lifestyle interventions on BP in various subgroups of PREMIER participants.

Materials and methods

The design and rationale for PREMIER[12] have been published. The main results have also been published.[6] Participating institutions included the NHLBI Project Office (Bethesda, MD, USA), the Coordinating Center (Kaiser Permanente Center for Health Research in Portland, OR, USA) and four clinical centres (Duke University Medical Center, Durham, NC, USA; Johns Hopkins University, Baltimore, MD, USA; Pennington Biomedical Research Center, Baton Rouge, LA, USA; and Kaiser Permanente Center for Health Research, Portland, OR, USA). The protocol was reviewed by an external protocol review committee and the NHLBI, was approved by the Institutional review board at each centre. Each participant provided written informed consent.

Study participants

The target population consisted of generally healthy adults with above-optimal BP including individuals with stage 1 hypertension, who met the national guidelines criteria for at least a 6-month trial of nonpharmacologic therapy.[2] These criteria correspond to pre- and stage 1 hypertension by JNC-VII criteria, which were established after the study was completed.[5] Persons were eligible if they were not taking antihypertensive medication and had a systolic (S)BP of 120–159 mmHg and diastolic (D)BP of 80–95 mmHg, based on the mean BP across three screening visits. (A fourth noneligibility BP was assessed just prior to randomization.) Other inclusion criteria were age 25 or older and body mass index (BMI) 18.5–45.0 kg/m^2. Major exclusion criteria were the regular use of drugs that affect BP, JNC-VI risk category C (target organ damage and/or diabetes),[2] use of weight-loss medications, prior cardiovascular event, heart failure, angina, cancer diagnosis or treatment in the past 2 years, consumption of >21 alcoholic drinks/week, pregnancy, planned pregnancy, or lactation. Targeted recruitment methods were used to ensure adequate representation of clinically important subgroups such as African Americans.

Intervention

After eligibility was established, study participants were randomly assigned to one of three intervention groups: a behavioural intervention ('Established') that implemented traditional lifestyle recommendations;[2] a similar behavioural intervention ('Established Plus DASH') that implemented the same traditional recommendations plus the DASH diet;[3,13] or an 'Advice Only' comparison group. The intervention lasted a total of 18 months; this report includes the first 6 months after randomization, designated during study design as the period of primary outcome analysis.

Participant goals for both the Established and Established Plus DASH interventions were weight loss of at least 15 lb (6.8 kg) at 6 months for those with a BMI $\geqslant 25$ kg/m^2, at least 180 min/week of moderate-intensity physical activity, no more than 100 mmol/day of dietary sodium, and no more than 1 oz/day of alcohol (two drinks) for men and $\frac{1}{2}$ oz/day (one drink) for women. In addition, individuals in the Established Plus DASH intervention were counselled to consume the DASH dietary pattern, with the following goals: 9–12 servings of fruits and vegetables, 2–3 servings of low-fat dairy products per day, and intake of total fat and saturated fat of no more than 25 and 7% of total calories, respectively.[13] To achieve weight loss, both interventions emphasized increased physical activity and reduced total energy intake; in addition to these strategies, the Established Plus DASH intervention also emphasized substitution of fruits and vegetables for high-fat, high-calorie foods.

In contrast, the Advice Only comparison group received a single 30-min individual advice session at the time of randomization. At that session, participants received verbal instructions and written materials that provided information on established recommendations and the DASH dietary pattern. No counselling or further intervention contact was provided until after completion of the 6-month data collection visits.

Individuals assigned to either Established or Established Plus DASH were scheduled to attend 18 face-to-face intervention contacts (14 group meetings and four individual counselling sessions). Intervention sessions were conducted by trained and certified interventionists. These interventions were based on social cognitive theory,[14] self-applied behaviour modification techniques such as 'behavioural self-management',[15] and the transtheoretical 'stages of change' model.[16] Important components included self-monitoring, goal-setting, motivational counselling, and social support.

Measurements

All measurements were obtained at baseline and 6 months after randomization by staff who were masked to randomization assignment. BP measurements were obtained by trained, certified individuals using a random-zero sphygmomanometer. The BP measurement protocol was similar to that used in several prior BP studies.[3,9,17] After the participant sat quietly for 5 min, the observer measured BP in the right arm with an appropriately sized cuff. At each visit, two BP measurements separated by at least 30 s were obtained. SBP was the appearance of the first Korotkoff sound, and DBP was the disappearance of Korotkoff sounds. At each assessment point, BP was the mean of all available measurements (eight BPs across four visits prior to randomization and six BPs across three visits at the 6-month follow-up).

Weight was measured using a calibrated scale, and height was measured using a wall-mounted stadiometer. Fitness was defined as the heart rate at a fixed work load (Stage 2) of a submaximal treadmill stress test.[18] Other data included the Rose Angina questionnaire;[19] a medication questionnaire; a symptoms/side effects questionnaire; 24-h urine collections for excretion of sodium, potassium, phosphorus, and urea nitrogen as indicators of dietary intake of salt, fruits and vegetables, dairy foods, and protein; measurement of waist circumference; fasting blood for measurement of glucose and lipids; and a 7-day physical activity recall.[20]

Intake of nutrients and food groups was assessed from unannounced 24-h dietary recalls conducted by telephone interviewers.[21] Two recalls (one obtained on a week day and the other on a weekend day) were obtained at baseline and at 6 months by the Diet Assessment Center of Pennsylvania State University. Nutrient and food group intakes were then calculated using the Nutrition Data System Version NDS-R 1998 (University of Minnesota).

Analysis strategy

Protocol-specified subgroups of interest were self-reported race (African American *vs* non-African American), sex, hypertension status (present if SBP was $\geqslant$140 or DBP was $\geqslant$90 mmHg at baseline; individuals on antihypertensive medication were excluded), and age (50 and older *vs* less than 50 years old). Assuming a study population that is 30% hypertensive and 40% African American, the study was designed to have 90% power to detect SBP differences of approximately 3.4 mmHg in hypertensives and 2.7 mmHg in African Americans, comparing either the Established or the Established Plus DASH interventions to Advice Only.

We used general linear models to describe the influence of treatment on change in BP while controlling for potential confounding factors. Specifically, we regressed change in BP on indicators of the two active intervention arms, baseline BP, and indicators of site and cohort (participants were recruited and randomized in distinct cohorts over time). For any given subgroup variable (eg, race or sex), we also included a main effect for the subgroup as well as interactions of this indicator variable with each of the two treatment group indicators. The effects of the confounding factors were assumed to be constant across subgroups. For analyses that looked jointly at race and sex, we also included three-way interactions between race, sex, and the treatment group indicators. All analyses were conducted using the GLM procedure in SAS version 8.2 (SAS, Cary, NC, USA).

Although nominal *P*-values are reported in the text, per Protocol comparisons of either the Established or the Established Plus DASH interventions *vs* Advice Only within a given subgroup are deemed significant if at least one *P*-value is $\leqslant$0.025, in which case the other contrast is assessed for significance at the 0.05 level, as is the comparison of the two active interventions against each other. No multiple comparison adjustment is applied to tests of subgroup differences in treatment effects.

Results

The study population included 810 randomized individuals with an average age of 50 years, of whom 62% were women, 34% were African American (AA), 95% were overweight or obese, and 38% were hypertensive. Among the AA participants, 74% were women compared to 55% of non-AAs. Overall, 26% of the study population were AA women, 9% AA men, 36% non-AA women, and 29% non-AA men.

Table 1 provides the baseline characteristics of the study population by subgroup. Owing to the probability that clinical and behavioural variables vary by both sex and race, combined with the imbalanced enrollment of men by race, each race–sex category is presented separately, both in Table 1 and throughout the Results section. Attendance at intervention sessions and data collection visits was similar in all subgroups. Overall, participants attended an average of 15 out of 18 possible intervention sessions (Table 2), and in each group 94–95% had a follow-up BP measurement at 6 months.

Lifestyle changes

Table 3 and Figure 1 show the degree to which individuals in the four race–sex subgroups made lifestyle changes. All three interventions were associated with lifestyle change. AA women lost an average of 3.2 kg (7 pounds) over 6 months with either the Established intervention or Established Plus DASH. Furthermore, 13% of overweight/obese AA women in the Established group and 15% in the Established Plus DASH group achieved their weight

Table 1 Baseline characteristics by subgroup

	African American		*Non-African American*		*HTN status*		*Age*	
	Women	*Men*	*Women*	*Men*	*HTN*	*Non-HTN*	*Age⩾50*	*Age<50*
N	207	72	293	238	304	506	409	401
% African American	—	—	—		34.9	34.2	29.3	39.7
% Female	—	—	—	—	63.5	60.7	60.4	63.1
Age (mean years, s.d.)	48.6 (9.2)	48.2 (9.9)	50.7 (8.0)	50.8 (9.2)	52 (8.9)	48.7 (8.7)	56.9 (5.8)	42.9 (5.1)
Weight category (%)—women								
Normal (BMI 18.5–24.9 kg/m^2)	1	—	9	—	6	6	8	3
Overweight (BMI 25–29.9 kg/m^2)	25	—	26	—	31	22	32	19
Stage 1 obesity (BMI 30–34.9 kg/m^2)	30	—	28	—	26	30	30	28
Stage 2 obestity (BMI ⩾35 kg/m^2)	43	—	38	—	37	42	30	50
Weight category (%)—men								
Normal (BMI 18.5–24.9 kg/m^2)	—	6	—	5	5	5	7	3
Overweight (BMI 25–29.9 kg/m^2)	—	25	—	39	29	39	40	30
Stage 1 obesity (BMI 30–34.9 kg/m^2)	—	31	—	31	39	27	35	26
Stage 2 obestity (BMI ⩾35 kg/m^2)	—	39	—	25	27	29	17	41
BP (mean mmHg, s.d.)								
SBP	135.7 (9.4)	133.3 (9.0)	135.8 (10.0)	133.6 (9.2)	143.9 (7.6)	129.5 (5.8)	137.2 (9.7)	132.6 (8.8)
DBP	84.5 (4.3)	85.6 (4.1)	83.9 (3.9)	85.9 (4.1)	87.5 (4.3)	83.2 (3.1)	84.6 (4.0)	85.0 (4.3)
% with HTN	40.6	30.6	37.2	37.4			45.7	29.2
Total chol (mean, s.d.)	204.4 (37.6)	209.8 (37.1)	216.6 (38.5)	212.3 (38.1)	211.3 (37.4)	211.8 (38.8)	217.2 (36.4)	206.1 (39.2)
LDL-C (mean, s.d.)	133.3 (35.4)	141.0 (30.4)	133.3 (33.0)	137.4 (34.6)	135.2 (33.6)	135.1 (34.1)	138.5 (33.6)	131.9 (34.0)
HDL-C (mean, s.d.)	52.6 (13.0)	44.7 (10.4)	53.0 (13.1)	39.8 (8.4)	49.3 (13.8)	47.8 (12.6)	50.3 (14.2)	46.5 (11.5)
Triglyc (mean, s.d.)	94.3 (62.8)	119.0 (76.1)	151.1 (96.0)	183.7 (113.3)	137.0 (88.6)	146.6 (104.3)	145.5 (91.9)	140.4 (104.9)
Lipid meds (%)	1	5.6	2.4	5	2.3	3.6	4.7	1.5
Physical activity (% sedentary)[a]	86	76.4	88	73.1	83.1	81.4	82.1	82
Alcohol intake (% with any alcohol intake)	26.1	41.7	49.5	66	48	47.4	49.1	46.1
Education (%)								
Grade school	0	0	0	0	0	0	0	0
Some HS	1	1	1	0	1	1	2	1
Complete HS	10	10	9	4	8	8	9	6
Some college	42	32	37	24	37	32	30	38
Complete college	26	29	23	26	22	26	22	28
Postgrad work	21	28	30	46	31	33	37	27
Income (%)								
No answer	4	4	3	3	3	4	5	2
<$29 999	23	11	6	4	10	11	9	12
$30–59 999	35	33	37	21	33	31	29	34
$60k or higher	37	51	54	71	54	55	56	53

[a]Sedentary defined at Physical Activity Recall (PAR) score ⩽35 kcal/kg/day.

loss goal of at least 6.8 kg (Figure 1a). AA men lost an average of 5.1 kg with the Established intervention, and 3.2 kg with Established Plus DASH, with 38 and 29% of overweight/obese AA men in these groups achieving the weight loss goal, respectively. Non-AA women and men lost 5.7 and 5.4 kg, respectively, with the Established intervention and 6.7 and 6.6 kg, respectively, with the Established Plus DASH intervention, with at least one-third of them achieving the weight loss goal. Even race–sex subgroups in the Advice Only group lost weight, though not to the same extent as those in the two active intervention groups.

The interventions were associated with a decrease in heart rate at a fixed work load, indicating increased fitness, which occurred in all race–sex subgroups and all treatment groups. Fitness improved more in the Established and Established Plus DASH groups than in the Advice Only group, with a reduction ranging from 6 to 8.6 beats per minute (bpm) in the Established intervention, and from 7.4 to 9.7 bpm in Established Plus DASH intervention.

Table 2 Attendance at intervention sessions, by subgroup

	Average number of intervention sessions attended		*Percent of participants attending at least 15 sessions*		*Percent of participants attending 6-month intervention session*
Treatment group	*EST*	*EST + DASH*	*EST*	*EST+DASH*	*ADVICE ONLY*
Subgroup					
AA women	13.4	14.5	56	71	51
AA men	15.9	13.5	81	46	62
Non-AA women	15.1	15.6	77	82	68
Non-AA men	14.4	16.1	70	87	71
HTN	14.3	15.5	70	78	63
Non-HTN	14.7	15.3	70	78	63
Age $\geqslant$ 50	15.1	16.1	77	84	74
Age $<$ 50	13.8	14.5	62	71	54

Changes in the intake of food group and nutrients associated with the DASH dietary pattern were comparable for all race–sex subgroups in the Established Plus DASH intervention. Fruit and vegetable (F/V) intake increased in this intervention group only, reflecting the focus on the DASH dietary pattern, with increases of 2.1–3.5 servings/day. Increases in F/V intake were reflected in increased urinary potassium excretion (data not shown). Again reflecting the emphasis on the DASH dietary pattern, participants from each race–sex subgroup in the Established Plus DASH intervention increased dairy intake by 0.4–0.9 servings/day. All race–sex subgroups reduced saturated fat intake, with greater reductions generally seen for the Established Plus DASH than in the Established intervention in most race–sex groups. Figure 1b–d shows the extent to which race–sex subgroups achieved their DASH dietary pattern goals.

Although both behavioural intervention groups were counselled to reduce sodium intake, sodium intake did not change, relative to the Advice Only group, in AA and non-AA women. AA men in the Established intervention and non-AA men in both the Established and Established Plus DASH interventions did reduce sodium intake. However, in all groups the reduction in sodium intake was not sufficient to achieve the PREMIER (and JNC-VI[2]) goal of no more than 100 mmol/day. This goal was reached in less than 50% of individuals in each race–sex group, regardless of the treatment group. In all race–sex subgroups, the greatest percent achieving the sodium intake goal occurred in the Established intervention (Figure 1e).

Neither hypertension status nor age was a significant determinant of lifestyle change. As noted in Table 3, changes in weight, fitness, dietary pattern, and sodium intake were similar in hypertensive and nonhypertensive individuals. Similarly, the PREMIER data suggest that both older and younger individuals made multiple, simultaneous lifestyle changes.

BP changes

As noted in Table 4 and Figures 2–4, the lifestyle changes noted above were generally reflected in changes in BP. Table 4 demonstrates that the reduction in SBP attributable to the Established intervention (ie, net of the SBP change in the Advice Only group) was 1.2 mmHg in AA women, 6.0 in AA men, 4.5 in non-AA women, and 4.2 in non-AA men. The net effects of the Established Plus DASH intervention were 2.1, 4.6, 4.2, and 5.7 mmHg in the four race–sex subgroups, respectively. The net effect of the Established and Established Plus DASH interventions in AA women was both smaller in magnitude than other subgroups and was not statistically significant. The net effect of Established Plus DASH in AA men was slightly larger than in AA women. Consistent with these differences, we found a significant three-way interaction between sex, race, and the indicator for the Established treatment group. However, we did not see a significant three-way interaction with the Established Plus DASH group, and the overall 2-degree-of-freedom interaction for sex by race by treatment was not significant. As in the overall study population,[6] we found no significant difference in SBP effect when comparing the Established to the Established Plus DASH intervention. Similar changes within and between subgroups were seen in DBP, but of smaller magnitude.

Data from previous studies suggest that the BP effects of single lifestyle interventions and the DASH dietary pattern are more pronounced in individuals with hypertension than in those with pre-hypertension or high-normal blood pressure.[10,11,22] Similarly, we found that BP changes were consistently greater in hypertensives than in nonhypertensives, with a statistically significant interaction in the Established Plus DASH group (Table 4 and Figure 3).

Previous data might also suggest that lifestyle intervention is more effective in older than younger

Table 3 Liftestyle changes in subgroups by treatment group, mean (s.d.)

	Af Am women			*Af Am men*			*Non-Af Am women*			*Non-Af Am men*			*HTN*			*Non-HTN*			*⩾50 years*			*<50 years*		
	Advice	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*	*Advice*	*Est*	*Est+ DASH*
N[a]																								
Weight (kg)																								
Baseline	92.0	95.5	93.7	104.7	104.0	113.7	91.1	90.3	94.4	102.7	102.3	103.1	94.7	94.7	98.1	96.4	96.9	99.2	92.6	92.5	93.5	98.5	100.2	105.2
	(16.3)	(16.6)	(17.1)	(18.3)	(18.7)	(20.6)	(15.6)	(15.6)	(19.9)	(16.1)	(18.9)	(17.2)	(16.0)	(17.8)	(18.4)	(17.6)	(17.8)	(19.8)	(16.2)	(15.7)	(16.0)	(17.3)	(19.1)	(20.9)
Change	−0.8	−3.2	−3.2	−1.6	−5.1	−3.2	−1.9	−5.7	−6.7	−0.5	−5.4	−6.6	−1.3	−4.9	−5.9	−1.0	−4.8	−5.5	−1.3	−4.6	−5.8	−0.9	−5.2	−5.5
	(2.8)	(4.7)	(3.7)	(3.4)	(6.5)	(10.3)	(3.8)	(5.6)	(5.7)	(2.6)	(5.4)	(6.5)	(3.4)	(5.3)	(5.9)	(3.1)	(5.6)	(6.5)	(2.9)	(4.6)	(6.7)	(3.4)	(6.3)	(5.6)
Fitness (HR at stage 2 or last available HR at stage 1)																								
Baseline	136.4	136.8	135.8	129.3	128.9	135.6	129.2	129.9	131.8	125.7	125.4	124.2	130.5	128.4	128.5	130.2	131.7	131.0	125.3	126.7	125.5	134.8	135.1	136.0
	(13.1)	(12.0)	(14.9)	(18.4)	(12.9)	(14.5)	(12.7)	(14.5)	(12.9)	(15.4)	(14.5)	(14.3)	(13.6)	(12.7)	(14.1)	(15.3)	(15.0)	(14.9)	(14.1)	(13.0)	(13.2)	(13.8)	(14.4)	(14.3)
Change	−4.9	−6.0	−7.8	−5.5	−7.0	−7.4	−5.0	−8.6	−9.7	−5.6	−8.4	−8.3	−6.1	−6.8	−7.4	−4.6	−8.2	−9.4	−5.8	−7.8	−8.8	−4.7	−7.6	−8.5
	(10.0)	(11.5)	(10.9)	(12.2)	(10.5)	(9.3)	(10.7)	(11.0)	(11.5)	(7.1)	(10.3)	(9.7)	(9.4)	(10.3)	(10.3)	(9.8)	(11.2)	(10.7)	(9.7)	(10.8)	(10.3)	(9.6)	(11.1)	(11.0)
Fruits and Vegetables (servings/day)																								
Baseline	4.1	4.1	4.2	4.1	4.3	4.9	4.4	4.4	4.7	4.7	5.3	5.2	4.1	4.7	4.8	4.6	4.5	4.9	5.0	4.6	5.0	3.9	4.5	4.5
	(2.4)	(2.6)	(1.7)	(2.6)	(2.4)	(2.4)	(2.0)	(2.3)	(2.7)	(2.4)	(2.2)	(2.6)	(2.1)	(2.3)	(2.4)	(2.4)	(2.4)	(2.5)	(2.3)	(2.0)	(2.6)	(2.2)	(2.8)	(2.3)
Change	0.2	0.8	2.1	1.5	0.7	3.5	0.6	0.7	3.0	0.5	−0.1	3.5	0.5	0.6	3.2	0.5	0.5	2.9	0.3	0.5	3.1	0.7	0.6	2.9
	(2.6)	(2.5)	(2.9)	(3.3)	(2.0)	(3.3)	(2.8)	(2.6)	(3.2)	(2.7)	(2.8)	(4.3)	(2.6)	(2.5)	(3.8)	(2.8)	(2.7)	(3.5)	(2.6)	(2.5)	(3.8)	(2.9)	(2.7)	(3.3)
Dairy (servings/day)																								
Baseline	1.0	1.1	1.3	1.0	1.7	1.2	1.9	1.9	2.0	2.1	1.9	2.0	1.5	1.8	1.9	1.7	1.6	1.7	1.6	1.6	1.8	1.7	1.7	1.8
	(0.8)	(0.8)	(1.0)	(0.9)	(1.9)	(0.8)	(1.2)	(1.4)	(1.3)	(1.3)	(1.4)	(1.4)	(1.2)	(1.3)	(1.6)	(1.2)	(1.4)	(1.1)	(1.1)	(1.3)	(1.5)	(1.3)	(1.5)	(1.0)
Change	0.3	−0.2	0.4	1.5	−0.8	0.9	−0.2	−0.2	0.5	0	0.1	0.6	0.1	−0.3	0.4	0.1	−0.1	0.6	0.1	−0.1	0.6	0.1	−0.2	0.5
	(1.4)	(1.0)	(1.4)	(2.1)	(2.0)	(1.4)	(1.4)	(1.3)	(1.6)	(1.8)	(1.7)	(1.7)	(1.8)	(1.2)	(1.7)	(1.5)	(1.6)	(1.5)	(1.5)	(1.6)	(1.7)	(1.7)	(1.3)	(1.5)
Urinary Sodium (mmol/24h)																								
Baseline	160.6	157.5	155.3	182.6	202.9	197.2	162.9	154.4	156.8	195.2	184.4	208.2	176.3	166.9	175.8	171.5	168.3	179.5	168.2	164.9	173.5	178.6	171.8	184.4
	(57.6)	(57.9)	(67.6)	(8305)	(96.4)	(65.1)	(64.5)	(68.9)	(67.1)	(69.0)	(62.7)	(87.2)	(65.8)	(70.6)	(72.1)	(67.4)	(69.8)	(82.6)	(68.2)	(65.7)	(78.1)	(65.1)	(75.7)	(79.9)
Change	−21.5	−13.1	−8.5	−37.9	−63.2	−35.3	−20.3	−27.4	−24.9	−15.9	−43.7	−53.2	−21.3	−40.6	−35.5	−20.1	−26.5	−31.0	−17.7	−34.1	−41.2	−23.5	−28.0	−21.3
	(61.6)	(78.8)	(68.7)	(81.6)	(56.0)	(86.2)	(65.5)	(73.5)	(74.2)	(84.7)	(74.6)	(81.6)	(72.1)	(62.6)	(70.7)	(71.6)	(80.4)	(82.1)	(72.9)	(73.1)	(77.8)	(70.5)	(77.1)	(77.5)
Saturated fat (% of kcal)																								
Baseline	10.5	10.3	11.2	10.0	10.7	11.5	11.5	11.2	11.3	11.1	10.9	10.4	11.3	10.8	11.1	10.8	10.9	10.9	10.6	10.8	10.5	11.3	10.9	11.6
	(3.1)	(2.9)	(2.8)	(2.8)	(3.0)	(3.0)	(3.6)	(3.2)	(3.2)	(3.1)	(3.6)	(3.2)	(3.3)	(3.4)	(3.2)	(3.3)	(3.2)	(3.1)	(3.5)	(3.3)	(3.1)	(3.1)	(3.2)	(3.1)
Change	−0.2	−1.5	−3.6	0.5	−2.4	−2.4	−1.1	−1.3	−3.8	−0.1	−1.2	−2.9	−1.1	−1.8	−3.3	−0.1	−1.2	−3.3	−0.6	−1.4	−3.4	−0.3	−1.6	−3.2
	(3.9)	(3.4)	(3.4)	(3.5)	(3.9)	(2.6)	(4.3)	(4.1)	(3.9)	(3.4)	(4.5)	(4.2)	(3.3)	(4.2)	(4.4)	(4.1)	(3.9)	(3.5)	(3.6)	(4.3)	(3.7)	(4.1)	(3.7)	(4.1)

[a]*N* vary for each lifestyle measure due to variations in completeness of data collection.[6]

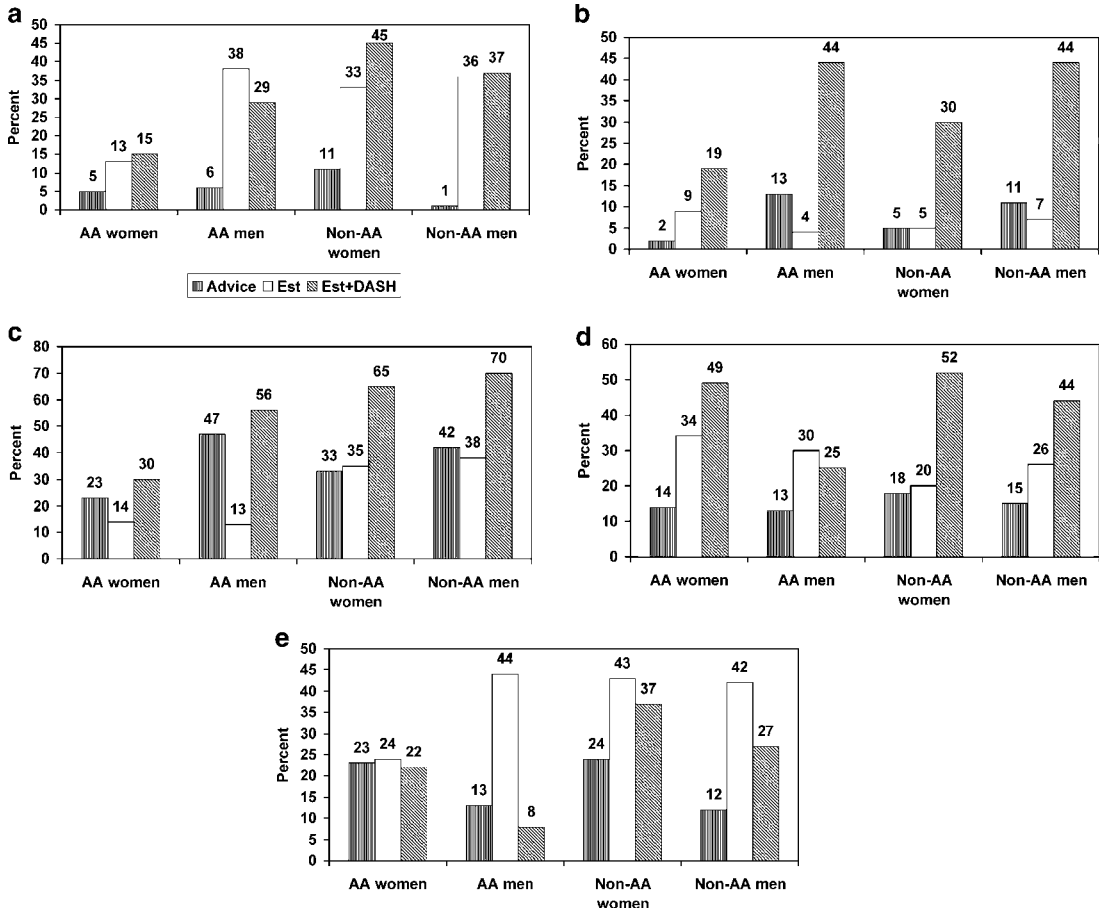


Figure 1 (a–e) Percent of PREMIER participants in race–sex subgroups achieving intervention goals: (a) weight loss of $\geqslant$6.8 kg (15 lb); (b) fruit and vegetable intake of $\geqslant$9 servings/day; (c) dairy intake of $\geqslant$2 servings/day; (d) saturated fat intake $\leqslant$7% of total kcal; (e) sodium intake of $\leqslant$100 mmol/day.

individuals.[10,11,23,24] In the PREMIER trial, the Established intervention led to similar and statistically significant BP reductions in individuals under and those 50 years of age and older (Table 4 and Figure 4). The Established Plus DASH intervention also significantly lowered BP, relative to the Advice Only intervention, in both age groups. However, for individuals 50 years or older, the Established Plus DASH intervention lowered both systolic and diastolic BP significantly more than the Established intervention (-2.9 mmHg, $P=0.008$ and -1.7, $P=0.022$, respectively). This difference between the Established Plus DASH and the Established intervention was not seen in those younger than 50 years, despite levels of lifestyle change that were similar to those in the older age group.

Discussion

These subgroup results from the PREMIER trial demonstrate that a broad range of individuals can make multiple lifestyle changes and that, consistent with the evidence from efficacy studies, these lifestyle changes lead to clinically significant reductions in blood pressure.

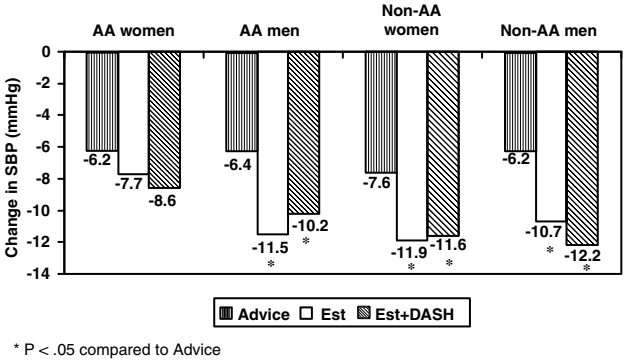
Both AAs and non-AAs made major lifestyle changes in PREMIER that were greater than what has been seen in other similar studies. Both men and women also made substantial lifestyle changes. Even among African American women, who experienced the least amount of weight loss and other lifestyle changes, the changes that were observed were greater than has been reported in other studies,[22,25] and were of a magnitude that has been associated with significant BP change.[26,27] The degree to which individuals in different race–sex subgroups were able to achieve lifestyle change may have been a reflection of our efforts to make these interventions culturally appropriate;[12] greater success may be achieved by making them even more so.[28] Our data suggest that promoting even more successful lifestyle change in AA women is an important challenge for the future.

As expected from efficacy studies, greater BP reduction was observed in subgroups that achieved the greatest lifestyle change. The systolic BP change associated with the Established intervention (net of

Table 4 BP change (mmHg) in sugroups

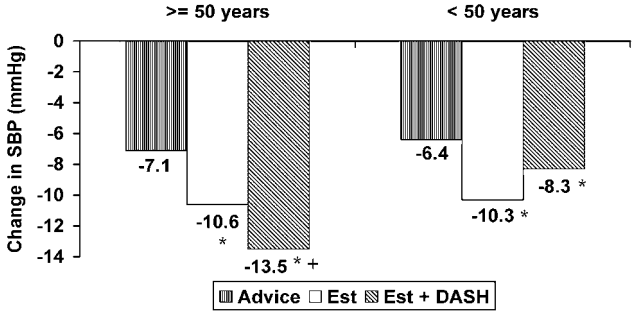
	Change in Established minus Change in Advice Only			*Change in Established+DASH minus Change in Advice Only*			*Change in Established+DASH minus Change in Established*		
	Mean	*95% CI*	P-*value*	*Mean*	*95% CI*	P-*value*	*Mean*	*95% CI*	P-*value*
Systolic BP									
All	−3.7	(−5.3, −2.1)	<0.0001	−4.3	(−5.9, −2.8)	<0.0001	−0.6	(−2.2, 0.9)	0.4246
African Am Women	−1.2	(−4.1, 1.6)	0.4028	−2.1	(−5.2, 1.0)	0.1851	−0.9	(−4.1, 2.4)	0.5962
African Am Men	−6.0	(−10.3, −1.6)	0.0076	−4.6	(−9.2, −0.1)	0.0450	1.3	(−3.8, 6.4)	0.6145
Non-African Am Women	−4.5	(−7.0, −2.0)	0.0005	−4.2	(−6.7, −1.6)	0.0013	0.3	(−2.3, 2.9)	0.8089
Non-African Am Men	−4.2	(−7.1, −1.3)	0.0048	−5.7	(−8.4, −3.1)	<0.0001	−1.5	(−4.5, 1.4)	0.3028
Hypertensives	−4.6	(−7.2, −2.1)	0.0004	−6.3*	(−8.9, −3.8)	<0.0001	−1.7	(−4.3, 0.9)	0.1965
Non-Hypertensives	−3.1	(−5.1, −1.1)	0.0025	−3.1	(−5.1, −1.1)	0.0022	0.0	(−2.0, 2.0)	0.9741
Age⩾50	−3.5	(−5.7, −1.3)	0.0020	−6.4*	(−8.6, −4.2)	<0.0001	−2.9*	(−5.0, −0.8)	0.0081
Age<50	−3.9	(−6.1, −1.7)	0.0005	−1.9	(−4.1, 0.3)	0.0897	2.0	(−0.3, 4.3)	0.0848
Diastolic BP									
All	−1.7	(−2.8, −0.6)	0.0019	−2.6	(−3.7, −1.5)	<0.0001	−0.9	(−2.0, 0.2)	0.1116
African Am Women	0.5	(−1.4, 2.5)	0.5958	−0.9	(−3.0, 1.3)	0.4187	−1.4	(−3.6, 0.8)	0.2172
African Am Men	−4.1	(−7.1, −1.0)	0.0085	−4.3	(−7.4, −1.1)	0.0075	−0.2	(−3.8, 3.3)	0.9011
Non-African Am Women	−2.2	(−3.9, −0.4)	0.0152	−2.4	(−4.1, −0.6)	0.0084	−0.2	(−2.0, 1.6)	0.8291
Non-African Am Men	−2.6	(−4.6, −0.5)	0.0129	−3.4	(−5.3, −1.6)	0.0003	−0.9	(−2.9, 1.1)	0.3890
Hypertensives	−2.0	(−3.8, −0.3)	0.0253	−3.6	(−5.4, −1.9)	<0.0001	−1.6	(−3.4, 0.2)	0.0765
Non-Hypertensives	−1.6	(−2.9, −0.2)	0.0268	−2.0	(−3.4, −0.6)	0.0045	−0.4	(−1.8, 0.9)	0.5330
Age⩾50	−0.8	(−2.4, 0.7)	0.2908	−2.6	(−4.1, −1.0)	0.0011	−1.7	(−3.2, −0.3)	0.0218
Age<50	−2.5	(−4.0, −0.9)	0.0015	−2.4	(−3.9, −0.8)	0.0025	0.1	(−1.5, 1.7)	0.8987

*$P<0.05$ for subgroup × treatment interaction.



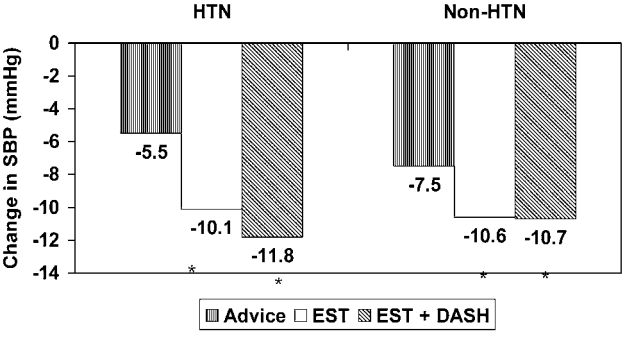
* P < .05 compared to Advice

Figure 2 Mean reduction in SBP by treatment group and race–sex subgroup.



* P < .05 compared to Advice; + P < .05 compared to Est

Figure 4 Mean reduction in SBP by treatment group and age subgroup.



* P < .05 compared to Advice

Figure 3 Mean reduction in SBP by treatment group and hypertension subgroup.

change with the Advice Only intervention) was statistically significant in AA men, non-AA women and non-AA men (4.2–6.0 mmHg), and was of a magnitude that is clinically significant. For all groups, maximum blood pressure benefit requires maximizing the effectiveness of lifestyle change interventions.

An important public health challenge is to motivate nonhypertensive individuals with a 'pre-risk factor' (such as pre-hypertension[5]) to make healthful lifestyle changes. For individuals with established hypertension, who may be especially motivated to institute behaviour modification, the PREMIER interventions (net of Advice Only) lowered SBP by 4.6 mmHg (Established) and 6.3 mmHg

(Established Plus DASH). These changes are sufficient to reach treatment goals nonpharmacologically in many individuals with Stage 1 hypertension. However, the PREMIER data demonstrate that individuals with prehypertension can be just as successful as those with Stage 1 hypertension in making these lifestyle changes. Among prehypertensives, the PREMIER interventions lowered SBP (net of Advice Only) to an extent (3.1 mmHg) that could be expected to prevent hypertension and reduce the CVD risk associated with above-optimal BP.

Age was not a deterrent to the PREMIER lifestyle changes. Despite a general assumption that older individuals are 'set in their ways', age did not affect the ability to make lifestyle change in this study and in others.[23] These lifestyle changes were reflected in BP reductions of a magnitude sufficient to reduce CVD risk. As the absolute risk of CVD is higher in older individuals, public health strategies for implementing multicomponent lifestyle intervention should include this segment of the population. In addition, the greater BP reduction with the Established Plus DASH intervention, compared to the Established intervention, along with the other health benefits of the DASH dietary pattern (eg, bone preservation[29]), suggest that the Established Plus DASH intervention should especially be the focus of implementation efforts in individuals over age 50 years. Indeed, such an argument can be made in all subgroups. In addition, there should be other health benefits of the Established Plus DASH intervention in all populations (eg, reduced CVD from reduced total and saturated fat; reduced osteoporosis from increased calcium intake; and perhaps reduced cancer risk from increased intake of fruits and vegetables).[30,31]

We saw surprisingly large lifestyle changes, particularly weight loss, in the Advice Only group (see Figure 1). Control groups in other similar trials tended to gain weight over time, with a consequent increase in BP.[25] The fact that the PREMIER Advice Only intervention led to weight loss, other lifestyle changes, and a reduction in BP may reflect the high level of motivation among study volunteers. Recruitment for PREMIER presumably attracted volunteers who were ready to make significant lifestyle change, and the extensive screening process led to the enrollment of a highly motivated group of individuals. The multiple BP and other measurements made during the study may also have had some intervention effect, as may the limited advice that the 'control' group received. The reasons for the success achieved by the Advice Only group merits further investigation as we continue to pursue both the most effective and the most efficient methods for preventing CVD. In the meantime, future research should include effectiveness trials of the PREMIER interventions in community settings. In conclusion, we have shown that diverse groups of people can adopt multiple lifestyle changes that can lead to improved BP control and reduced CVD risk.

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