

# Ethnic Comparison of Weight Loss in the Trial of Nonpharmacologic Interventions in the Elderly

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## Abstract

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**Objective:** To compare weight loss in blacks and whites in the Trial of Nonpharmacologic Interventions in the Elderly (TONE).

**Research Methods and Procedures:** TONE enrolled 421 overweight white and 164 overweight black adults, 60 to 79 years old, with blood pressure well-controlled on a single, antihypertensive drug. Drug therapy withdrawal was attempted 3 months after randomization to counseling for weight loss, sodium reduction, both weight loss and sodium reduction, or to usual care, with follow-up for 15 to 36 months after enrollment. Statistical procedures included repeated measures analysis of covariance and logistic and proportional hazards regression.

**Results:** In the weight-loss condition, net weight change (in kilograms) was  $-2.7$  in blacks and  $-5.9$  in whites ( $p < 0.001$ ; ethnic difference,  $p = 0.0002$ ) at 6 months and  $-2.0$  ( $p < 0.05$ ) in blacks and  $-4.9$  ( $p < 0.001$ ) in whites at the

end of follow-up (ethnic difference,  $p = 0.007$ ). In weight/sodium, net weight change was  $-2.1$  ( $p < 0.01$ ) in blacks and  $-2.8$  ( $p < 0.001$ ) in whites at 6 months, and  $-1.9$  in blacks and  $-1.7$  in whites at the end of follow-up ( $p < 0.05$ ; ethnic difference,  $p > 0.5$ ). Exploratory analyses suggested a more favorable pattern of weight change in blacks than in whites from 6 months onward. There was no ethnic difference in blood pressure outcomes.

**Discussion:** Whites lost more weight than blacks without, but not with, a concurrent focus on sodium reduction.

**Key words:** blood pressure, blacks, cultural factors, aged, behavior change

## Introduction

Several obesity-related chronic conditions disproportionately affect black Americans (1–3). However, behavioral weight-loss programs seem to have less success with black than with white participants (4–8). For example, after 6 months of follow-up in the Trials of Antihypertensive Interventions and Management, 23% of whites compared with 13% of blacks met the goal of a 10% weight loss (5). In the Hypertension Prevention Trial, the net weight loss (net of active intervention minus control) at 36 months was 2.7 kg less in black compared with white women and 1.4 kg less in black compared with white men (4). Net weight losses after 18 months were 2.2 and 2.0 kg less in black compared with white men and women, respectively, in phase I of the Trials of Hypertension Prevention (4). Other reports of smaller weight losses in blacks than in whites include a 1-year study of low-calorie or very-low-calorie diet therapy in individuals with type 2 diabetes (8) and clinical observations in individuals treated with very-low-calorie diets and behavioral therapy (6,7). These latter studies involved more stringent weight-loss regimens and reported larger weight losses and larger black–white differentials than in the previously mentioned hypertension trials: for example, 18.8 kg in

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whites vs. 13.3 kg in blacks in the study by Darga et al. (7); 14 kg in whites compared with 7 kg in blacks in the study by Wing and Anglin (8).

The Trial of Nonpharmacologic Interventions in the Elderly (TONE) provided an additional opportunity to compare weight loss in black and white participants enrolled in behavioral weight reduction programs. The TONE objective was to evaluate the efficacy of three nutrition interventions as alternatives to antihypertensive drug therapy for control of blood pressure among older adults (9): weight loss (WT), sodium reduction (Na), or combined weight loss and sodium reduction (WT/Na).

As reported previously (10), all three TONE dietary interventions were effective in maintaining blood pressure control without drug therapy for a significant proportion of those receiving the intervention. Over a 15- to 36-month period of follow-up, 37% to 46% of those randomized to either WT, Na, or WT/Na remained off drug therapy at the end of follow-up, compared with only 25% of those who received no dietary counseling (usual care [UC]). Predictors of success in maintaining blood pressure control without returning to drug therapy included assignment and adherence to interventions, pharmacological blood pressure control at baseline, and duration of hypertension (11).

Ethnic group (black vs. other) was not a significant predictor of the success of the TONE interventions in controlling hypertension without medication (11). However, a TONE pilot study suggested a greater lag time for commencement of weight loss among the black participants (12). In addition, preliminary analyses of the TONE weight reduction data suggested that black participants lost less weight than did white participants in only one of the weight reduction arms of the study (13). Therefore, we explored ethnic differences in both initial and overall weight reduction in each of the two weight interventions compared with those not assigned to these interventions. Several baseline characteristics and attendance at intervention contacts were examined as possible predictors of weight loss.

## Research Methods and Procedures

### Study Design

The principal aim of TONE was to assess whether interventions designed to reduce sodium intake and body weight, alone or in combination, could successfully substitute for pharmacological treatment of hypertension among persons 60 to 79 years old whose blood pressure was well-controlled by a single medication. Participants were recruited from the communities near four academic medical centers in Baltimore, Maryland; Memphis, Tennessee; New Brunswick, New Jersey; and Winston-Salem, North Carolina. The study design and intervention approaches have been described previously (9,10). Key intervention and measurement details are summarized here. Weight eligibility criteria were

body mass index (BMI)  $\geq 21$  kg/m<sup>2</sup> for men or women and  $\leq 33$  kg/m<sup>2</sup> for men or  $\leq 37$  kg/m<sup>2</sup> for women. These analyses include the 585 TONE participants with elevated BMI (defined as BMI  $\geq 27.8$  kg/m<sup>2</sup> for men and  $\geq 27.3$  kg/m<sup>2</sup> for women) who were eligible for randomization to a weight-reduction intervention.

The TONE intervention objectives were an average 4.5 kg (10 lb) of weight loss for WT and WT/Na and an average urinary sodium excretion of  $\leq 80$  mEq per 24 hours for Na. Participants assigned to the active interventions first met  $\sim 1$  month postrandomization and were scheduled to attend cycles of three group sessions and one individual counseling session in the following frequency: 12 group and 4 individual intervention sessions during the first 4 months; biweekly group and individual sessions during the next 4 months; and monthly group or individual sessions throughout the remainder of follow-up. UC participants met  $\sim 1$  month after randomization and quarterly thereafter for educational sessions unrelated to nutrition and cardiovascular disease (e.g., sleep problems, cancer, retirement issues, etc.). These sessions were expected to have little impact on participants' weight or sodium intake. Withdrawal of antihypertensive medications was attempted 90 days ( $\pm 14$  days) after the first intervention session. The study endpoint was either reinstatement on drug therapy to treat hypertension or the occurrence of a cardiovascular event (e.g., myocardial infarction or stroke).

Registered dietitians specially trained to deliver the TONE programs, in consultation with behavioral psychologists, delivered the interventions. Special considerations included the heterogeneity of older adults with respect to learner characteristics and health concerns, possible limitations on literacy, vision, and hearing in an older population (14,15), and cultural diversity within and across TONE study centers. For example, all printed materials were written for a sixth-grade reading level and all topics and illustrations were designed to be age-appropriate and to reflect different ethnic perspectives. Attention to individual needs was addressed in the scheduled one-to-one counseling sessions after sets of three-group sessions.

Each group session was  $\sim 60$  minutes long ( $\pm 15$  minutes for pre- or post-session activities such as weigh-ins or collection of food diaries). The counseling approach was behaviorally oriented and was adapted from effective approaches used in similar hypertension prevention or treatment trials (9). Participants were encouraged to share experiences, set goals, anticipate problems, and practice new behaviors in a supportive group or one-to-one counseling setting. Core strategies included keeping food diaries to self-monitor habitual eating behaviors and identify the main food sources of sodium (in Na), fat and calories (in WT), or both (in WT/Na), and identifying ways to reduce intakes of these factors through changes in food shopping, food preparation, selection of restaurant or take-out foods, and food

choices at social occasions. Participants in the weight interventions were also encouraged to find ways to increase their routine physical activity or to exercise regularly. The recommended type, frequency, and duration of exercise were individualized based on preferences and needs. Walking was the most recommended form of exercise. Group and, particularly, individual counseling sessions included feedback on and review of progress in meeting dietary change and weight change goals, as appropriate to the intervention condition.

The three active interventions were designed to have similar sequencing and delivery of content. The topic sequence in WT/Na matched that for WT except that most sessions also included attention to sodium reduction issues. The initial topic sequence was as follows: weight and/or sodium reduction and blood pressure control; physical activity and weight loss (weight interventions only) or advice on shopping and reading food labels for sodium content (sodium intervention); how to identify and reduce the calorie and/or sodium content of the morning, midday or main, and evening or light meals; food preparation; recipe modification; synthesis of previous sessions; choosing lower-calorie and lower-sodium foods in restaurants; social eating situations; and snacks.

#### **Baseline and Follow-Up Measurements**

All weight and blood pressure measurements used for these analyses were obtained at regularly scheduled baseline and follow-up visits that were separate from intervention contacts and conducted by nonintervention staff (9). Follow-up visits were every 3 months for 15 to 36 months. Demographic, lifestyle, and medical history data were collected with standardized questionnaires. Height and weight were measured using standardized protocols with participants standing, wearing light indoor clothing, with shoes and headgear removed. Height was measured to the nearest 0.5 in using a wall-mounted stadiometer with the person's head positioned in the Frankfort plane. Weight was measured to the nearest 0.5 lb on a double balance-beam scale. All blood pressure measurements were obtained by centrally trained and certified observers who were masked to intervention assignment. Systolic blood pressure was defined as the appearance of the first Korotkoff sound, and diastolic blood pressure as the point of disappearance of the fifth Korotkoff sound. At each visit, three blood pressure measurements were obtained after the participant rested 5 minutes quietly in the seated position. Random-zero sphygmomanometers were used to minimize observer bias.

Attendance at data collection visits was 90% to 95% of expected for black participants and 82% to 93% of expected for white participants; the highest percentages were generally earlier in follow-up. End-study follow-up assessments were completed for 95% of black participants and 90% of white participants. The median duration of follow-up was

27 months (a maximum of 36 months). Average follow-up times were slightly less for blacks than for whites (mean  $\pm$  SD = 25.6  $\pm$  5.3 and 27.6  $\pm$  4.3 months, respectively;  $p < 0.001$ ) due to a final wave of recruitment targeting black Americans.

#### **Statistical Analyses**

The baseline characteristics of participants were described by means ( $\pm$ SD) and percentages. Data for men and women were pooled after detailed preliminary analyses failed to show significant modification of weight-loss outcomes by gender and to maximize the statistical power for examining ethnic differences. The differences between ethnic groups after control for gender were assessed using analyses of covariance and logistic regression. Mean weight loss was examined separately for baseline to 6 months, 6 months to the end of follow-up, and baseline to the last on-study measurement. Some analyses were also performed for weight loss averaged over all follow-up visits. Serial measures of weights and weight changes from baseline were compared using Laird-Ware models fitted using maximum likelihood (16,17), which allowed for varying lengths of follow-up among participants. Within each ethnic group, the association of initial weight loss with weight loss from baseline to the last visit was examined with Pearson correlation coefficients for participants assigned to interventions. We also plotted mean weight change after 6 months separately for weight-intervention participants whose weight loss at that time was reasonably close to (within 80%) the 4.5-kg study weight-loss goal. Relationships of potential explanatory variables to weight loss and effects of weight loss (using individual weight loss averaged over all follow-up visits) on TONE endpoints were assessed using proportional hazards regression models in the total sample (18). Attendance at scheduled intervention sessions was converted to a  $z$  score to adjust for varying lengths of follow-up and expected visits among participants, as reported previously (19).

## **Results**

#### **Baseline Characteristics**

All 585 overweight participants were either black ( $N = 164$ ; 28%) or non-Hispanic white ( $N = 421$ ; 72%). Table 1 shows baseline characteristics by ethnicity and gender. Black participants comprised 17% of the men and 38% of the women. Overall, black participants were more likely to be smokers and less likely to drink alcohol (particularly women). Black participants were more likely to have been taking diuretics at baseline.

#### **Mean Weight Change**

The mean weight change within ethnicity and intervention assignment is shown in Table 2 and, graphically, in

**Table 1.** Baseline characteristics of the Trial of Nonpharmacologic Interventions in the Elderly (TONE) participants by ethnicity and gender

Baseline characteristics	Ethnicity and gender subgroup				Overall ethnic differences <i>p</i> value
	Black women ( <i>N</i> = 117)	Black men ( <i>N</i> = 47)	White women ( <i>N</i> = 189)	White men ( <i>N</i> = 232)	
Mean age ( $\pm$ SD)	65.5 $\pm$ 4.8	65.4 $\pm$ 4.4	65.8 $\pm$ 4.5	65.2 $\pm$ 4.3	0.61
Age group (%)					
60 to 69 years	79.5	78.7	79.9	82.3	0.59
70 to 79 years	20.5	21.3	20.1	17.7	
College graduate (%)	25.6	34.0	22.2	41.8	0.25
Current smoker (%)	8.5	12.8	3.7	2.2	<0.001
Alcohol intake (%)					
None	82.9	51.1	74.6	47.0	0.005
<1 drink/d	14.5	25.5	22.2	33.2	
$\geq$ 1 drink/d	2.6	23.4	3.2	19.8	
Mean body mass index ( $\pm$ SD)	32.0 $\pm$ 2.5	30.5 $\pm$ 1.4	31.7 $\pm$ 2.6	30.4 $\pm$ 1.6	0.19
Mean years of hypertension ( $\pm$ SD)	14.7 $\pm$ 10.4	13.2 $\pm$ 10.1	12.8 $\pm$ 9.9	12.7 $\pm$ 11.2	0.17
Mean blood pressure ( $\pm$ SD)					
Systolic	128.3 $\pm$ 12.4	127.6 $\pm$ 11.8	126.9 $\pm$ 11.9	128.2 $\pm$ 11.6	0.53
Diastolic	70.5 $\pm$ 8.1	72.3 $\pm$ 7.8	69.6 $\pm$ 9.1	73.1 $\pm$ 8.0	0.40
Number of antihypertensive medications at screening					
One	80.3	76.6	82.0	84.1	0.27
Two	19.7	23.4	18.0	15.9	
Previous cardiovascular disease (%)	33.3	23.4	24.9	21.6	0.06
Antihypertensive drug class (%)					
Ace-inhibitor	7.7	17.0	19.6	29.7	
$\beta$ -Blocker	5.1	6.4	11.1	10.8	<0.001
Ca channel blocker	23.1	31.9	23.8	33.2	
Diuretic	58.1	36.2	40.2	17.2	
Other	6.0	8.5	5.3	9.1	
Intervention assignment (%)					
Usual care	34.2	14.9	24.9	22.8	
Sodium restriction only	21.4	29.8	26.5	25.0	0.42
Weight loss only	26.5	25.5	25.9	22.4	
Combined sodium/weight	17.9	29.8	22.8	29.7	

Figure 1, A and B. In keeping with the study design, active intervention participants in WT only are compared with UC participants, and active intervention participants in WT/Na are compared with Na only participants. As shown, weight change from baseline was significant at both 6 months and the end of follow-up for blacks and whites in both WT and WT/Na and also when data for both interventions were pooled. However, the effect of ethnicity differed in WT and WT/Na. A significant ethnic difference in weight change was observed in WT at both 6 months ( $-2.7$  kg vs.  $-5.9$  kg

in blacks and whites, respectively;  $p = 0.0002$ ) and at the end of follow-up ( $-2.0$  kg in blacks compared with  $-4.9$  kg in whites;  $p = 0.007$ ). The net weight change between 6 months and the end of follow-up was 1.0 kg or less, with no ethnic difference ( $p = 0.90$ ). Black participants had similar weight loss in WT and WT/Na, whereas whites in WT/Na lost less weight than those in WT ( $p < 0.05$  for comparison across conditions at both 6 months and the end of the study). In contrast to the findings in WT, no ethnic difference in weight change was observed in WT/Na either initially

**Table 2.** Baseline sex-adjusted mean weight and change at 6 months, after 6 months, and at the end of follow-up, by ethnicity and weight-loss intervention

Ethnic group and randomization assignment	N	Baseline	Change at 6 months	Change after 6 months	Change at last on-study measurement
		Mean $\pm$ SE weight (kg)			
Black					
Weight only	39	89.1 $\pm$ 1.4	-2.9 $\pm$ 0.4	-0.3 $\pm$ 0.6	-3.2 $\pm$ 0.7
Usual care	47	86.5 $\pm$ 1.3	-0.2 $\pm$ 0.4	-1.0 $\pm$ 0.5	-1.2 $\pm$ 0.9
Net change			-2.7 $\pm$ 0.6*	0.7 $\pm$ 0.8	-2.0 $\pm$ 0.9‡
White					
Weight only	108	86.9 $\pm$ 0.9	-6.2 $\pm$ 0.4	0.9 $\pm$ 0.4	-5.2 $\pm$ 0.4
Usual care	100	87.3 $\pm$ 0.9	-0.2 $\pm$ 0.4	0.0 $\pm$ 0.4	-0.3 $\pm$ 0.5
Net change			-5.9 $\pm$ 0.5*	1.0 $\pm$ 0.3‡	-4.9 $\pm$ 0.6*
Ethnic difference			$p = 0.0002$	$p = 0.90$	$p = 0.007$
Black					
Weight/sodium	35	87.9 $\pm$ 1.5	-3.6 $\pm$ 0.6	0.2 $\pm$ 0.5	-3.4 $\pm$ 0.7
Sodium only	43	88.0 $\pm$ 1.4	-1.6 $\pm$ 0.6	0.1 $\pm$ 0.4	-1.5 $\pm$ 0.6
Net change			-2.1 $\pm$ 0.8†	-0.2 $\pm$ 0.5	-1.9 $\pm$ 1.0‡
White					
Weight/sodium	112	88.3 $\pm$ 0.9	-4.9 $\pm$ 0.4	1.8 $\pm$ 0.5	-3.1 $\pm$ 0.6
Sodium only	101	87.4 $\pm$ 0.9	-2.2 $\pm$ 0.4	0.8 $\pm$ 0.5	-1.4 $\pm$ 0.6
Net change			-2.8 $\pm$ 0.6*	1.1 $\pm$ 0.7*	-1.7 $\pm$ 0.9‡
Ethnic difference			$p = 0.51$	$p = 0.45$	$p = 0.90$
Black					
Both weight interventions	74	88.5 $\pm$ 1.0	-3.2 $\pm$ 0.4	0.0 $\pm$ 0.4	-3.3 $\pm$ 0.5
Both weight controls	90	87.3 $\pm$ 1.0	-0.9 $\pm$ 0.3	-0.5 $\pm$ 0.3	-1.4 $\pm$ 0.4
Net change			-2.3 $\pm$ 0.5*	0.5 $\pm$ 0.5	-1.9 $\pm$ 0.6†
White					
Both weight interventions	220	87.6 $\pm$ 0.7	-5.6 $\pm$ 0.3	1.4 $\pm$ 0.3	-4.2 $\pm$ 0.4
Both weight controls	201	87.4 $\pm$ 0.6	-1.2 $\pm$ 0.3	0.4 $\pm$ 0.3	-0.9 $\pm$ 0.4
Net change			-4.3 $\pm$ 0.4*	1.0 $\pm$ 0.4‡	-3.3 $\pm$ 0.5*
Ethnic difference			$p = 0.004$	$p = 0.51$	$p = 0.12$

\*  $p < 0.001$ , †  $p < 0.01$ , ‡  $p < 0.05$  for net change from baseline to 6 months, 6 months to end of study, or baseline to end of study.

(-2.1 kg vs. -2.8 kg at 6 months in blacks and whites, respectively;  $p = 0.51$ ) or at the end of the study (-1.9 kg vs. -1.7 kg in blacks and whites, respectively;  $p = 0.90$ ).

Averaged across follow-up and pooled for both weight interventions, the net weight loss was 2.3 kg in blacks vs. 3.9 kg in whites (data not shown; ethnic difference,  $p = 0.03$ ). A marginally significant interaction of gender by intervention assignment for WT/Na vs. Na ( $p = 0.06$ ) was noted, suggesting that the smaller weight loss in WT/Na in whites was more apparent in women. However, no differences in weight-loss trends were observed in either intervention that could be clearly attributed to gender.

#### ***Distribution of Individual Weight Change Averaged over Follow-Up***

The distribution of individual weight changes among blacks and whites assigned to weight interventions is shown in Figure 2 separately for WT and WT/Na. The frequencies rather than the percentages are shown because of the small numbers for black participants. The patterns of individual weight changes are consistent with the findings for group means. In WT, the ethnic difference in the distribution of individual weight change, indicative of larger weight losses in whites, was significant ( $p = 0.02$ ). The distributions of individual weight

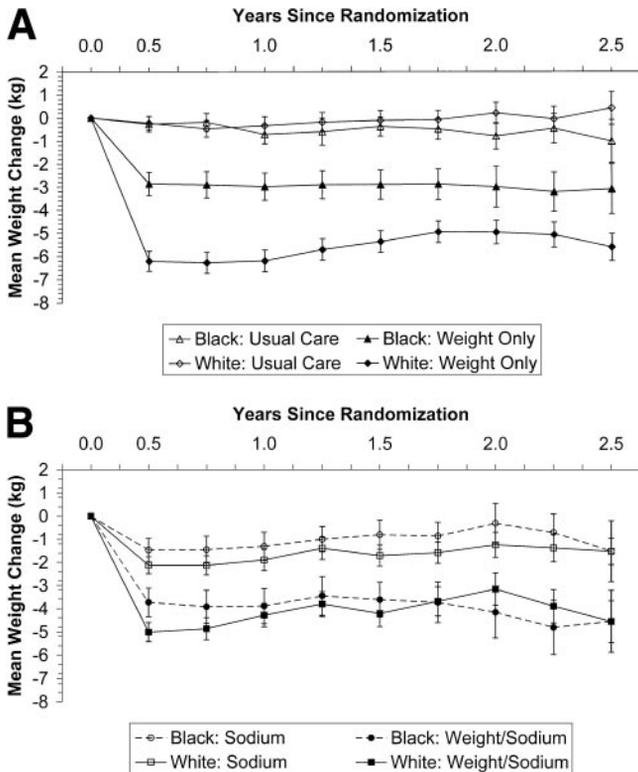


Figure 1: (A and B) Mean ( $\pm$ SE) changes in weight over time for overweight TONE participants grouped by ethnicity and intervention assignment.

change in WT/Na were not significantly different ( $p = 0.34$ ) for blacks and whites.

### Patterns of Weight Loss over Time

The data in Table 2 suggest that weight regain between 6 months and the end of the study was larger in whites than in blacks in both of the active interventions, although there was not a significant ethnic difference in net weight change during this time frame. We further explored the possibility of ethnic differences in the pattern of weight loss in response to these interventions over time with correlations and subgroup analyses. Weight change at 6 months was significantly correlated with weight loss between 6 months and the end of follow-up in the WT but not in the WT/Na group. The correlation in the WT group was inverse and of similar magnitude in black ( $-0.47$ ;  $p = 0.003$ ) and white ( $-0.35$ ;  $p = 0.0004$ ) participants, suggesting that under this condition, a larger initial weight loss was associated with larger regain, and the reverse (smaller loss with smaller regain). There was no correlation between initial and subsequent weight change in the WT/Na group ( $-0.03$ ;  $p = 0.85$  for black participants and  $0.05$ ;  $p = 0.60$  for white participants).

The relationship of initial and subsequent weight change was also examined in subgroup analyses in which data for

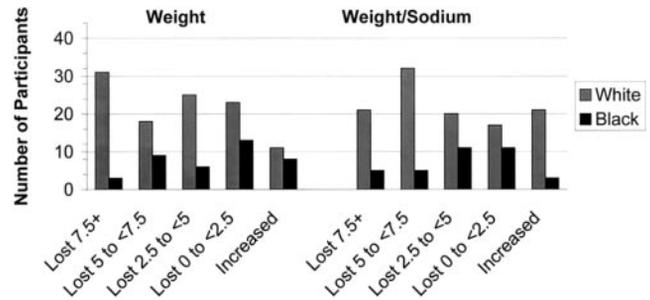


Figure 2: Distribution of individual weight changes (average follow-up weight – baseline weight) among blacks and whites assigned to weight interventions.

active intervention participants were analyzed separately according to whether they initially achieved ( $\sim 41\%$  of blacks and  $66\%$  of whites) or did not achieve ( $\sim 59\%$  of blacks and  $34\%$  of whites) the  $4.5$ -kg weight-loss goal, i.e., lost  $3.6$  kg or more at 6 months (Figure 3, A–D). Figure 3, A and B suggest that black participants who did not approximate the initial weight loss were able to lose or maintain weight during subsequent follow-up to a greater extent than whites. This ethnic difference was not statistically significant in the WT ( $p = 0.14$ ) or WT/Na ( $p = 0.08$ ) group when considered separately but was significant ( $p = 0.02$ ) in data pooled for the two interventions. Among participants who were initially more successful in losing weight (Figure 3, C and D), there was, on average, a slow erosion of the initial weight loss during the remaining follow-up, with no significant ethnic difference in WT ( $p = 0.85$ ), WT/Na ( $p = 0.36$ ), or pooled data ( $p = 0.60$ ).

### Predictors of Weight Change

Models were fitted to identify baseline variables that might explain ethnic differences in weight loss. These analyses were performed with weight averaged overall follow-up visits as the dependent variable, pooled for WT and WT/Na with a term for concurrent assignment to a sodium intervention. Other independent variables were gender, age, education, current smoking, alcohol use, BMI, years with hypertension, baseline blood pressure level, number of blood pressure medications at baseline, class of blood pressure medication, and history of cardiovascular disease. The size and statistical significance of the overall ethnic difference (i.e., less weight loss [mean  $\pm$  SE] in black than in white participants by  $1.6 \pm 0.7$  kg;  $p = 0.03$ ) were not substantially altered by adjustment for any of the explanatory variables ( $1.7 \pm 0.7$  kg;  $p = 0.02$  after adjustment for all covariates).

Session attendance was related to weight loss among those assigned to weight-loss interventions, with similar correlations in blacks and whites ( $r = 0.42$  and  $0.34$ , respectively;  $p < 0.001$ ). Attendance at weight-loss sessions

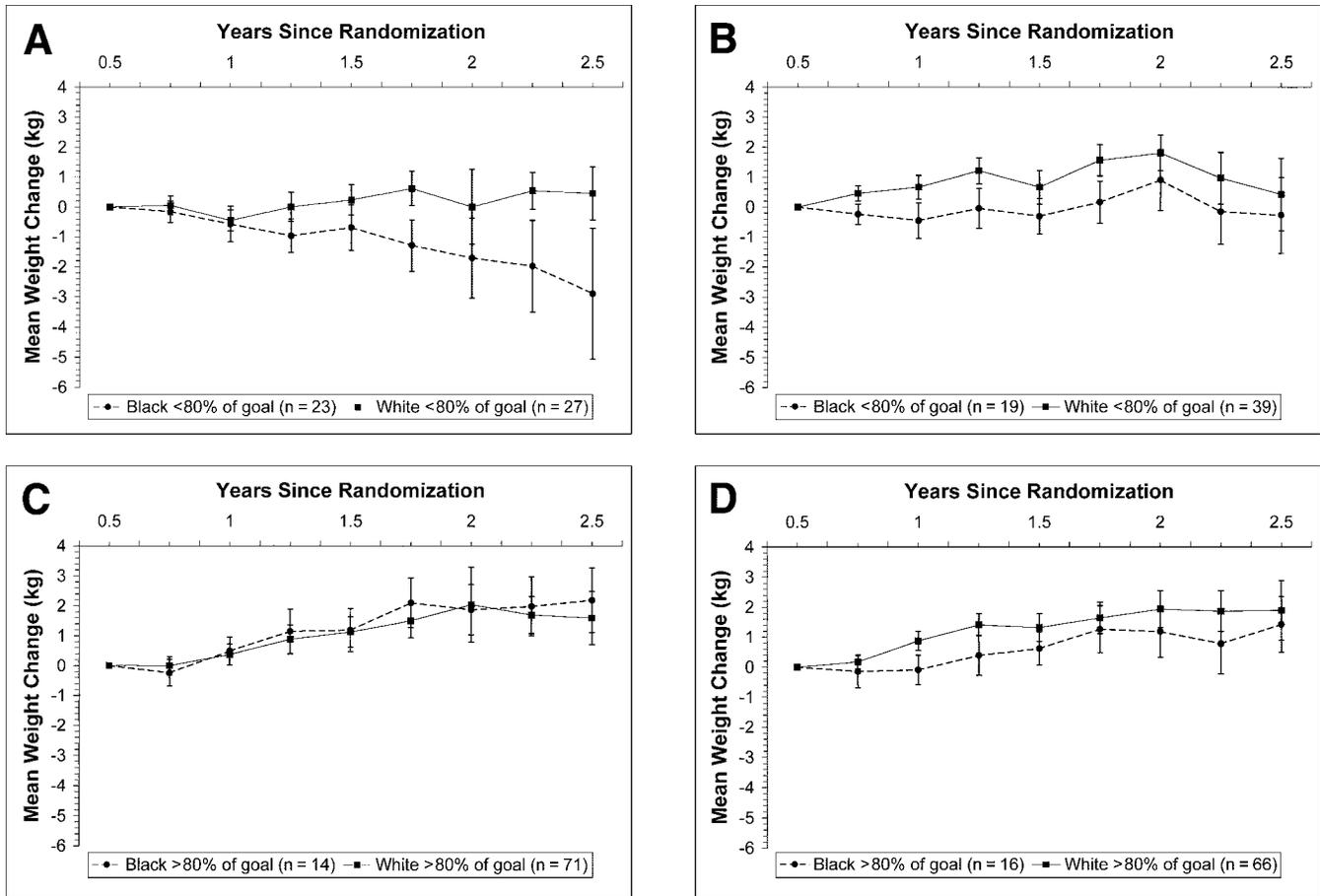


Figure 3: (A–D) Mean ( $\pm$ SE) change in weight after 6 months of intervention among active intervention participants in weight and weight/sodium whose initial weight loss was <80% or  $\geq$ 80% of the 4.5-kg goal.

was somewhat lower for blacks than for whites during the initial 4 months of intervention ( $p = 0.02$ ) but did not differ by ethnicity when averaged over the entire follow-up ( $p = 0.85$ ). However, including initial attendance in regression models did not statistically explain the ethnic differences in initial weight loss.

**Association of Weight Change and Blood Pressure Change**

As reported previously, both assignment to a weight-loss intervention and the amount of weight lost were independently associated with a significantly lower likelihood of a TONE endpoint: for example, required reinstatement of antihypertensive medication (11). Table 3 presents results of proportional hazards regression analyses to characterize the intensity of these relationships in blacks and whites. Clinic site, gender, and concomitant sodium intervention were included as covariates. Overall, assignment to a weight-loss intervention decreased the hazard of a TONE endpoint by a factor of 0.71 ( $p = 0.001$ ). The magnitude of this effect was very similar in blacks and whites (0.74 vs.

0.72;  $p = 0.92$ ) but did not reach statistical significance in the smaller cohort of blacks. After controlling for weight-loss intervention assignment, there was a graded relationship between achieved weight loss and the TONE endpoint overall. Participants who averaged weight losses of at least 80% of the goal across follow-up reduced their hazard of a TONE endpoint by a factor of 0.68 compared with those whose weight losses were <50% of the goal. Participants with intermediate successes in weight loss also had intermediate reductions in hazard. This relationship did not differ significantly between blacks and whites ( $p = 0.46$ ); however, the point estimates for blacks were less precise than those for whites and did not show the gradation.

**Discussion**

Both TONE weight interventions produced significant long-term weight losses in black and white participants over the 15 to 36 months of follow-up. The observed ethnic differences related to the amount of weight loss in WT vs. WT/Na and to the pattern of weight change. The overall

**Table 3.** Impact of achieved weight loss on the requirement for antihypertensive medications\*

	Blacks	Whites	Overall
Intervention assignment			
Weight loss or combined	0.74 (0.49, 1.11)	0.72 (0.57, 0.93)	0.71 (0.58, 0.88)
Sodium only or usual care	1.00	1.00	1.00
	$p = 0.14$	$p = 0.01$	$p = 0.001$
Ethnic differences		$p = 0.92$	
Achieved weight loss†			
≥80% goal	0.94 (0.56, 1.59)	0.63 (0.46, 0.87)	0.68 (0.52, 0.90)
50% to 79% goal	0.85 (0.50, 1.45)	0.83 (0.59, 1.18)	0.84 (0.63, 1.12)
<50% goal	1.00	1.00	1.00
	$p = 0.75$	$p = 0.006$	$p = 0.005$
Ethnic differences		$p = 0.46$	

\* Relative hazards (and 95% confidence intervals) for blacks and whites after controlling for clinic site, gender, and sodium intervention.

† After controlling for intervention assignment.

ethnic difference observed in WT, e.g., an ~3-kg weight-loss advantage for whites, is similar in magnitude to that observed in previous hypertension trials (4–8), with the possible exception of the Dietary Intervention to Stop Hypertension trial (DISH) (20,21). Like TONE, DISH evaluated the efficacy of a weight-loss program as a substitute for antihypertensive drug therapy (20). DISH participants lost an average of 4.5 kg that was well-maintained over 56 weeks of follow-up, with no difference in average overall weight loss between blacks and whites or among participants <60 vs. ≥60 years old (21). A weight-loss advantage for whites can be observed in the DISH data at 8 weeks, when only one-half as many black as white participants had achieved a 5% weight loss (11.5% vs. 22.6%). However, a similar or larger proportion of blacks than whites in DISH had achieved a 5% weight loss at 32 and 56 weeks of follow-up (21). This raises the possibility, also suggested by more recent data from phase II of the Trials of Hypertension Prevention (22), that better weight loss by whites than by blacks may be more characteristic in the short- vs. the long-term.

The dependence of the ethnic difference in weight loss on the type of intervention—reflecting both poorer response to WT/Na vs. WT in whites and equivalent response to WT and WT/Na in blacks—was unexpected. It is recognized that combined interventions are more complex than single-focus interventions and that one or more aspects of adherence may be compromised (23). However, the reason that this would apply to whites but not to blacks in TONE is unclear. Considering that TONE was not designed to study patterns and predictors of weight loss (for example, follow-up data did not include repeated assessments of physical activity or self-monitoring measures) and with the small

sample sizes for blacks, we did not attempt further formal analyses to explain the different results for blacks and whites by type of intervention. Visual examination of data on self-reported calorie and fat intake for black and white participants under the two conditions was not informative in this respect. One possible explanation would be ethnic differences in strategies for decreasing caloric intake. Strategies used by participants in the conditions with and without a concurrent focus on sodium reduction may have differed more for whites than for blacks. For example, use of low-fat dairy products is a more common strategy for lowering fat and calories in white than in black women (24,25). However, because such products may contain as much sodium as the regular versions, their use would be less applicable to a combined weight- and sodium-reduction program. Other examples might involve salad dressings or other types of foods for which usual intakes tend to differ for black and for white adults (26–28) and for which strategies effective in reducing calories as opposed to both calories and sodium would differ.

Consistent with other reports (29), our findings suggest that large initial weight losses are predictive of larger final weight losses. However, there may be some advantage to more detailed attention to weight loss after the first 6 months, particularly for black participants. Our exploratory analyses within the active intervention participants suggest that the smaller initial weight losses in black participants might be compensated for, in part, by weight loss occurring later in the follow-up period or by the fact that modest weight losses may be easier than larger weight losses to maintain. To summarize—at 6 months of follow-up in the WT group, the mean weight loss in blacks was less than in whites, and substantially fewer black than white participants

in TONE came within 80% of the study weight loss goal of 4.5 kg. Possibly due to later initiation of weight loss after program enrollment, as suggested by our pilot study (12), the peak weight loss may occur later than 6 months for black compared with white participants. As noted previously, results from phase II of the Trials of Hypertension Prevention (22), which had follow-up for all participants through 36 months, also suggested ethnic differences in patterns of long-term weight loss, reflecting a greater tendency to regain weight in whites: black–white differences in weight loss were larger at 6 months than at the end of the study (5.0 kg vs. 2.7 kg in whites and blacks, respectively, at 6 months attenuated to 0.5 kg, 2.0 kg vs. 1.5 kg in whites and blacks, respectively, at 36 months).

The TONE data reflect the responses to weight-loss interventions of a substantial number of black and white men and women for an extended period and with excellent follow-up rates. Together with results from other studies, these TONE findings raise the potentially important question of whether there are ethnic differences in the time-course of responses to weight-loss interventions that should be considered in program design. Even among those who are sufficiently motivated to enroll in a clinical trial, black participants may be less ready to change or may take longer to identify behavior change strategies that are feasible and appropriate to their personal contexts. This may be both reflected in and augmented by lower initial attendance (19), although attendance does not seem to explain the differential weight loss in TONE.

The possibility that, relative to whites, a greater proportion of blacks with unimpressive initial weight losses may be likely to improve during subsequent extended periods of intervention and follow-up is worth noting. Short-term studies, i.e., lasting only 2 to 6 months, in black populations have been discouraging as to the magnitude of weight losses that can be achieved (30). Our findings suggest that providing intensive intervention for a period longer than 6 months might be relatively more beneficial for blacks than for whites. Behavioral or psychosocial explanations for why black participants in weight-loss programs lose less weight or lose weight more slowly are numerous and supported by existing data (30). Readiness to lose weight is believed to be greater in whites than in blacks, on average, because of differences in body image and in perceptions about weight status and health (31–34). Background cultural and situational factors may limit the feasibility of adopting recommended eating and physical activity strategies to a greater extent for black than for white participants (30,35,36), and some data show a greater background predisposition to weight gain in blacks (7,37,38). This would weaken the effective dose of the intervention in blacks compared with whites, as would lower attendance or a lack of cultural relevance. Biological explanations for ethnic differences in

weight loss also have been proposed (39,40). The ethnic difference in TONE results by type of intervention tends to support behavioral explanations based on regimen adherence. There is no reason to expect that there would be biological differences by random intervention assignment.

The objective of TONE was to permit blood pressure control without the need for drug therapy. Within the weight-loss interventions, this goal was achieved similarly for black and white participants, despite slower and less overall weight loss in the black participants. Comparable benefits for blood pressure control among black participants assigned to weight loss interventions—despite differences in weight loss—have been observed previously (41). The explanation may lie in the nature of the dose–response of blood pressure change with weight change, for example, thresholds between which blood pressure does not respond to weight reduction or to factors other than weight loss that contribute to blood pressure control among black participants assigned to weight loss interventions (for example, other dietary or lifestyle changes). However, none of these studies, including TONE, was specifically designed to study ethnic differences in weight and blood pressure relationships and the ability to study these differences, in all cases, is limited by relatively low numbers of black participants.

In conclusion, the TONE weight-loss programs were successful in facilitating significant weight reduction and concomitant blood pressure control in both black and white older adults over 15 to 36 months of follow-up. Ethnic comparisons yielded results that were partly consistent with the expectation that weight losses would be less in black than in white participants but also yielded the additional, intriguing finding that this did not apply when weight reduction was combined with a focus on sodium reduction. The tentative impression of smaller weight loss in black participants that was better maintained or that occurred over a more protracted time-course is also of potential interest and implies differences in how weight loss is approached even in response to the same program. Although TONE was not designed to study ethnic differences in patterns of weight loss, these analyses suggest potentially fruitful areas for further inquiry. Systematic study of patterns of long-term weight loss among black men and women, of all ages and in varying contexts, may provide important insights about ways to improve weight management in general and particularly in black populations.

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