

## Results of PREMIER A Clinical Trial of Comprehensive Lifestyle Modification: BP, Weight, Diet, Insulin Sensitivity

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for the  
PREMIER Research Group



## PREMIER Collaborative Research Group

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- ◆ Sponsor
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PREMIER Research Group. Apple et al. JAMA 2003; 289: 2083-2089



## Background

- ◆ Weight loss, sodium reduction and increased physical activity are 'established' recommendations that lower BP [JNC V and VI]
- ◆ The DASH diet (rich in fruit, vegetables and low-fat dairy products and reduced in saturated and total fat) also lowers BP [JNC VI]
- ◆ No trial has simultaneously implemented these lifestyle recommendations



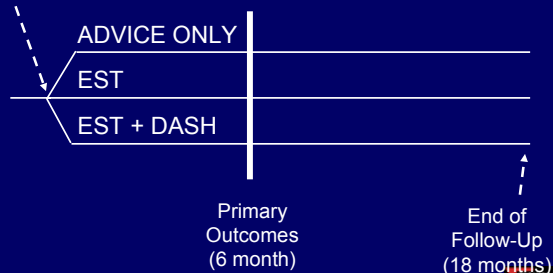
## Objective

- ◆ to determine the effects on BP of two multicomponent behavioral interventions
  - ESTABLISH -EST
  - ESTABLISHED PLUS DASH -EST + DASH
 compared to an ADVICE ONLY comparison group
- ◆ to determine the additional effects of the DASH diet beyond 'established' recommendations



## Design

Randomization



## Behavioral Intervention Goals

- ◆ Goals of both EST and EST + DASH groups
  - Weight loss, >15 lb (6.8 kg)
  - Increased physical activity, at least 180 min/wk
  - Reduced sodium intake, < 100 mmol/day
- ◆ Additional goals for 'EST + DASH' group
  - Increased fruits/vegetables, 9-12 servings/d
  - Increased low-fat dairy products, 2-3 servings/d
  - Reduced saturated fat, < 7% kcal
  - Reduced total fat, < 25% kcal
- ◆ 18 counseling sessions over 6 months



## Eligibility Criteria

- ◆ Age  $\geq 25$  years
- ◆ SBP 120-159 mmHg and DBP 80-95 mmHg  
--Pre-hypertension and Stage 1 hypertension
- ◆ Not taking antihypertensive medication
- ◆ No clinical cardiovascular disease
- ◆ Body mass index 18.5 - 45 kg/m<sup>2</sup>
- ◆ < 21 alcoholic drinks/week



## OUTCOMES

- ◆ Primary outcome: Change in systolic BP (6 month minus baseline)
- ◆ Secondary outcomes: Change in diastolic BP, hypertension status
- ◆ Other measurements
  - Weight
  - Fitness (heart rate at end of stage 2 of exercise test)
  - 24 Hour Urine Collections (sodium excretion)
  - 24 Hour Dietary Recalls (fruit/vegetable, dairy, fat)



## Baseline Characteristics

N	810
Women	62%
African-American	34%
Age	50 yrs
Blood Pressure	135/85
% Hypertensive	38%
% Overweight	95%

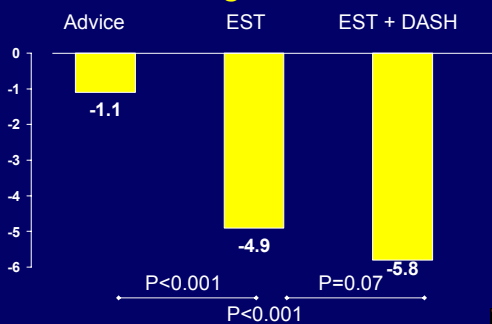


## Follow-up and Intervention Attendance

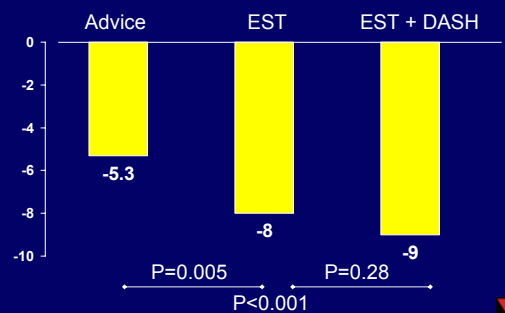
- ◆ 94% had  $\geq$  one BP measured at 6 months
- ◆ Attendance
  - EST : 70% attended  $\geq 15$  of 18 group and individual sessions
  - 'EST + DASH : 78% attended  $\geq 15$  of 18 group and individual sessions



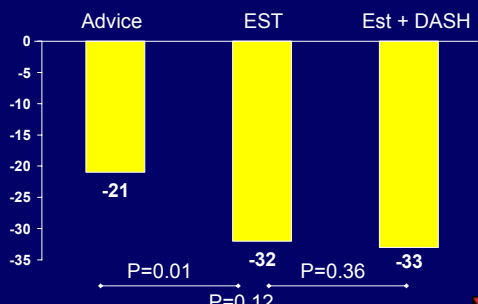
## Mean Weight Loss (Kg), Baseline=98 kg



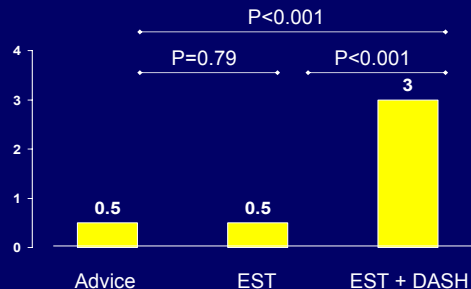
## Fitness: Reduction in Heart Rate at Stage 2 of Exercise Test, Baseline=130 beats/min



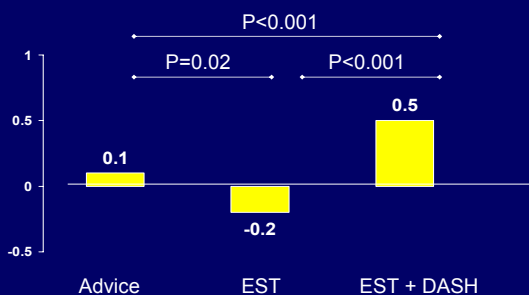
### Mean Reduction in Urinary Sodium Excretion, Baseline=178 mmol/d



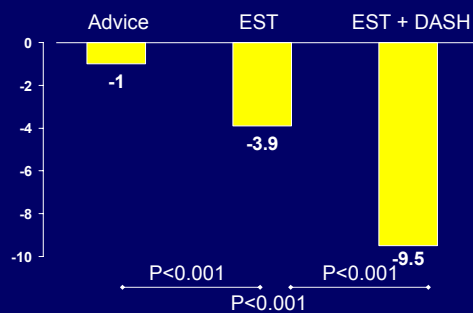
### Increase in Fruits +Vegetables Baseline=4.5 servings/day



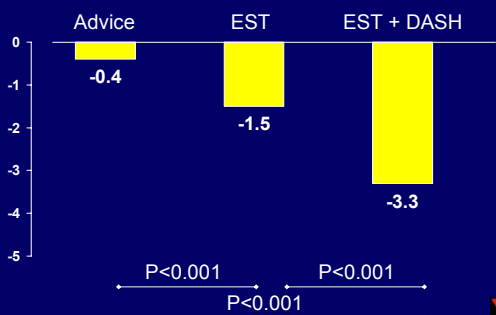
### Change in Dairy Products, Baseline=1.7 servings/day



### Reduction in Total Fat, Baseline=33% kcal



### Reduction in Saturated Fat, Baseline=11% kcal



### Intervention Effects

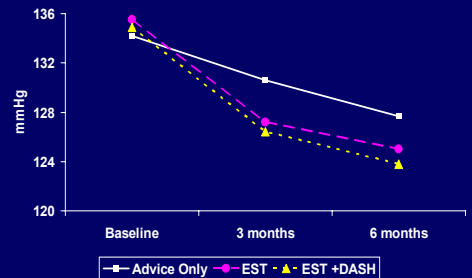
		Mean Change from Baseline		
		Advice	EST	EST + DASH
Weight	97 Kg	-1.1	-4.9*	-5.8*
Fitness	130 beats/min	-5.3	-8.0*	-9.0*
Sodium	170 mmol/24hr	-21	-32*	-33

\* p<0.05 compared to ADVICE, † P<0.05 EST vs EST + DASH

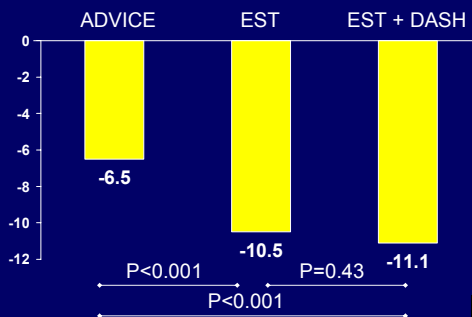
## Intervention Effects

		Mean Change from Baseline		
	Baseline	ADVICE	EST	EST + DASH
Fruit / Veg	4.6 servings/d	0.5	0.5	3.0*†
Dairy	1.7 servings/d	0.1	-0.2	0.5*†
Sat Fat	11 %kcal	-0.4	-1.5*	-3.3*†
Total Fat	33 %kcal	-1.0	-3.9*	-9.5 *†

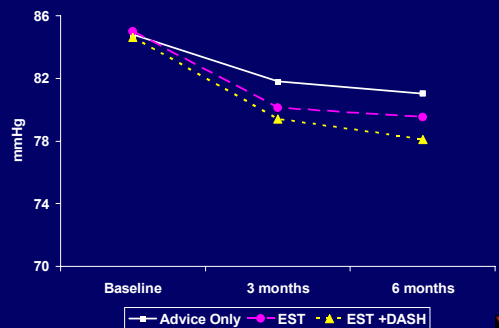
## Systolic Blood Pressure



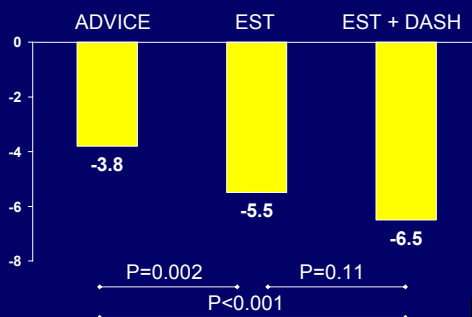
## Mean Reduction in Systolic BP, Baseline=135 mmHg



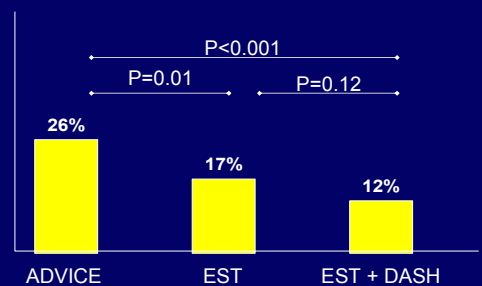
## Diastolic Blood Pressure



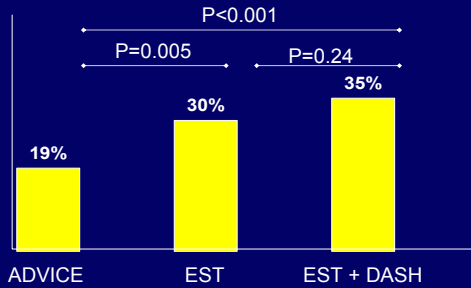
## Mean Reduction in Diastolic BP, Baseline=85 mmHg



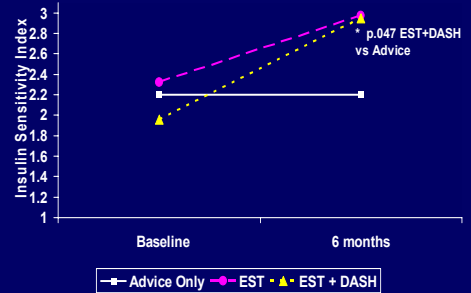
## % Hypertensive at 6 months, Baseline = 37%



### % with Optimal BP at 6 months (SBP < 120 + DBP < 80 mmHg)



### Insulin Sensitivity



## SUMMARY

- ◆ Relative to the Advice Only group, the EST and the EST + DASH interventions:
  - ↓ weight
  - ↓ sodium
  - ↑ physical fitness
  - ↓ saturated and total fat intake
  - ↓ systolic and diastolic BP
  - ↓ the prevalence of hypertension
  - ↑ the prevalence of optimal BP

## SUMMARY

- ◆ Relative to the EST intervention, the EST + DASH intervention:
  - increased fruit / vegetable intake
  - increased dairy intake
  - further reduced saturated and total fat intake
- ◆ Despite beneficial trends, none of the differences in BP and hypertension status between EST and EST + DASH were statistically significant

## LIMITATION

- ◆ The Advice Only comparison group appears to have made some lifestyle changes (e.g. reduced weight, sodium)
- ◆ These modest lifestyle changes could have attenuated pair-wise differences in BP between Advice Only and each of the behavioral interventions

## CONCLUSION

- ◆ Individuals with above Optimal BP including Stage 1 hypertension can make multiple lifestyle changes that lower BP and that should reduce their CVD risk