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The Women's Health Initiative Dietary Modification Trial: Overview and Baseline Characteristics of Participants

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INTRODUCTION

The Dietary Modification (DM) component of the Women's Health Initiative (WHI) is a randomized controlled evaluation of a low-fat diet that is high in fruits, vegetables, and grains. This low-fat dietary pattern is hypothesized to reduce the risk of breast and colorectal cancer and secondarily, coronary heart disease, in postmenopausal women. To test these hypotheses, 48,836 postmenopausal women were randomly assigned to either the low-fat eating pattern (40%) or self-selected dietary behavior (60%). The nutrition goals for women in the intervention arm are to reduce energy from fat to 20% and energy from saturated fat to 7%, and to increase fruit and vegetable intake to at least five servings per day and grains to at least six servings per day. Participants will be followed for an average of 8.5 years.

The DM was motivated by animal studies (1, 2), international ecologic studies of diet and disease (3, 4), migrant studies (5–7), and epidemiologic studies (8) indicating that the diet, particularly lower levels of fat intake, has the potential to reduce risk of breast cancer, colon cancer, and heart disease. Within-country analytic epidemiologic studies of fat and breast and colorectal cancers have yielded inconsistent or null results (9–11). However there are substantial obstacles to finding clear and interpretable relationships in these studies (12):

- Current or recent fat intakes may differ from intakes during the years pertinent to the development of chronic diseases, likely attenuating associations.
- Fat intakes in Western populations may not be highly variable, in spite of the variety of foods available.
- It is difficult to estimate the relationship between fat intake and disease because diet is a complex mixture of foods, nutrients, and other bioactive compounds.
- Dietary patterns often relate to other disease risk factors, offering the potential for confounding (or over-control) in these studies.
- Considerable random, systematic, and person-specific errors exist in all available dietary assessment methods and the key measurement properties of these instruments are not well understood.

The purpose of this report is to describe the baseline characteristics of participants in the DM trial, with emphasis on sociodemographics, health behavior, medical history, dietary intake, and other factors that could relate to the clinical outcomes.

METHODS

Screening and Eligibility for the Dietary Modification Trial

The WHI included postmenopausal women aged 50 to 79 years. Women with previous or existing breast cancer or invasive cancer of any type within the past 10 years were excluded. General WHI trial eligibility criteria are provided in Hays' article in this issue. The DM component also

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excluded women who were: 1) on a low-fat diet (<32% energy from fat); 2) had dietary needs incompatible with the intervention program (e.g. celiac sprue); 3) ate 10 or more meals per week outside the home; 4) could not complete a 4-day food record; 5) had type I diabetes mellitus, been diagnosed with colon cancer, or had any gastrointestinal conditions that contraindicated a high-fiber diet; or 6) had a bilateral prophylactic mastectomy.

During the baseline clinic visits, approximately half of the women screened were excluded from the DM because they consumed a diet with less than 32% energy from fat, as estimated by the food frequency questionnaire (FFQ). The purpose of this screening was to enroll a group having a relatively high fat intake and thereby increase the difference in average percent energy from fat between women randomized to the dietary intervention vs. control groups, which increases study power for each clinical outcome. Because of this screening, the distribution of percent energy from fat from the FFQ at baseline is truncated (Figure 1A). This truncation imposes an upward bias on the usual estimates of mean intake of energy and fat and all nutrients correlated with energy or fat. To avoid this problem of regression to the mean, we present FFQ data from control participants at Year 1 of the trial. As shown in Figure 1B, in this group percent energy from fat is approximately normally distributed. In addition, data from a random sample of food records analyzed from baseline and Year 1 indicate no substantial secular changes in dietary patterns in control participants over the first year of the trial. For example, energy from fat from food records in this group was 33.0% at baseline and 33.1% at Year 1. Therefore, the Year 1 control group data should provide a reasonably unbiased representation of the dietary intake of all dietary modification participants at baseline.

The WHI Dietary Modification Intervention Program

Each participant received an individualized fat gram goal that was approximately 20% of her estimated daily energy intake during the intervention. The philosophy of the intervention is that of a self-directed, self-controlled eating plan that views dietary changes as a series of activities that ultimately become part of everyday life. Participants self-monitor fat, fruit/vegetable, and grain intake, which helps them make appropriate food choices while receiving feedback on their performance in relation to the WHI nutrition goals. The DM intervention is delivered in a group setting by trained nutritionists and each session includes information and activities that reflect both nutritional and behavioral principles. Participants also receive individual contacts and can participate in peer-led sessions to provide additional support and enhance adherence. Details of the intervention are published (13).

Dietary Assessment in the WHI Dietary Modification Trial

The primary dietary assessment instrument in the DM is the food frequency questionnaire. All participants completed an FFQ at baseline and Year 1. Thereafter, each woman completes an FFQ every 3 years for purposes of trial monitoring. The WHI FFQ was based on instruments previously used in the Women's Health Trial (14, 15) and the Women's Health Trial Feasibility Study in Minority Populations (16). WHI scientists modified the questionnaire to include additional questions on fat-related food preparation methods and reduced-fat foods to increase its sensitivity to changes in fat intake (17). The instrument also includes items reflecting regional and ethnic eating patterns throughout the United States. Information about the measurement characteristics of the WHI FFQ has been published (17).

In addition to the comprehensive FFQ assessment, randomly selected subsamples of participants complete food records and/or 24-hour dietary recalls each year to provide other types of dietary assessment data for monitoring DM adherence. Vitamin and mineral supplement use is assessed using a simplified inventory procedure. WHI participants bring their supplements to the clinic and trained non-nutritionists conduct the inventory at a computer station and directly enter data about multiple-vitamin(s) and single supplement(s), including dose, frequency, and duration of use. Details of this simplified supplement inventory procedure have been published (18).

Other Measures

At baseline, all DM participants completed extensive questionnaires about demographics, socioeconomic status, medical history, health-related behavior, psychosocial factors, and a 4-day food record. Details on the assessment of these items are given in the appendix to Anderson's article. During the screening clinic visits participants had physical and blood pressure measurements taken, breast examinations, electrocardiograms, and provided blood samples. Participants were asked to bring all medications to the clinic for entry into a medication inventory. Food records and blood samples were analyzed on a randomly selected subsample of these participants with over-sampling for minorities.

RESULTS

Similar to the presentation of results for the other components, the baseline description of participants in the Dietary Modification trial is stratified by age. Because there was a study-wide emphasis on inclusion of minorities, all demographic, medical history, dietary intake and blood analytes are given by race/ethnicity group in the Appendix to

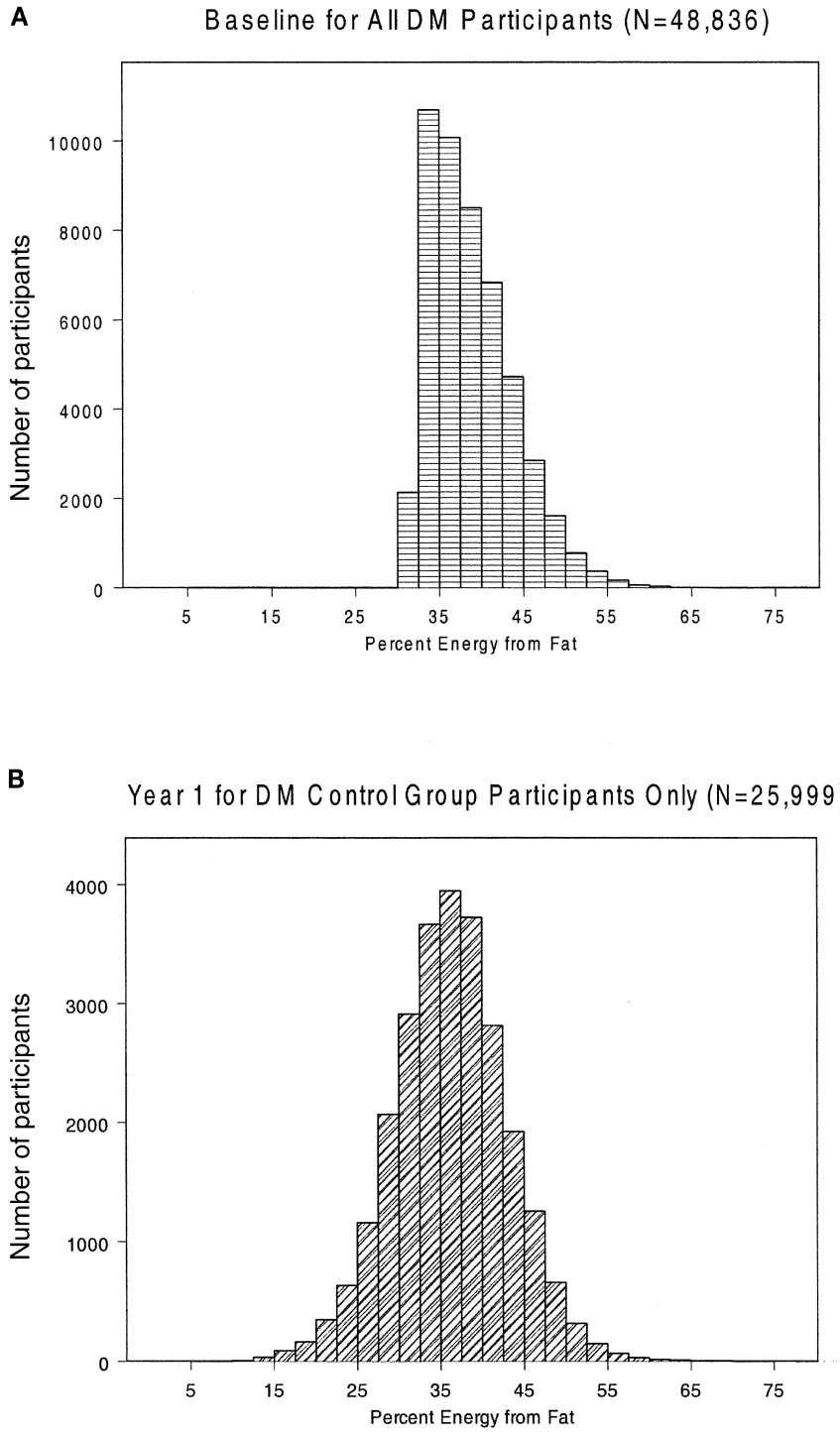

FIGURE 1. Distribution of percent energy from fat in WHI diet modification participants, as estimated by a food frequency questionnaire.

Hays' article. Differences by age and race/ethnicity are generally statistically significant because of the large sample sizes. Therefore, we simply present means, distributions, and differences, with emphasis on those factors that could be related to the clinical outcomes.

Participant Characteristics by Age (Table 1)

The age distributions (and design assumptions) are as follows: 37% (30%) of women were aged 50 to 59 years, 47% (45%) aged 60 to 69 years, and 17% (25%) aged 70 to 79 years, indicating lower than designed enrollment

TABLE 1. Baseline demographic and general health characteristics of WHI Dietary Modification participants by age

	Age at screening (y)											
	50–59 (N = 18,003)			60–69 (N = 22,713)			70–79 (N = 8120)			Total (N = 48,836)		
Characteristic	N	%	Mean ± SD	N	%	Mean ± SD	N	%	Mean ± SD	N	%	Mean ± SD
Race/Ethnicity												
American Indian	89	0.5		91	0.4		23	0.3		203	0.4	
Asian/Pacific Islander	496	2.8		461	2.0		150	1.8		1107	2.3	
Black	2386	13.3		2267	10.0		613	7.5		5266	10.8	
Hispanic	972	5.4		739	3.3		143	1.8		1854	3.8	
White	13,806	76.7		18,877	83.1		7077	87.2		39,760	81.4	
Unknown	254	1.4		278	1.2		114	1.4		646	1.3	
Education												
0–8 years	188	1.1		279	1.2		109	1.3		576	1.2	
Some high school	440	2.5		813	3.6		386	4.8		1639	3.4	
High school diploma/GED	2463	13.8		4461	19.8		1594	19.7		8518	17.6	
School after high school	7083	39.6		8849	39.2		3376	41.8		19,308	39.8	
College degree or higher	7708	43.1		8168	36.2		2612	32.3		18,488	38.1	
Body mass index (BMI), kg/m^2												
Underweight (<18.5)	54	0.3		75	0.3		25	0.3		154	0.3	
Normal (18.5–24.9)	4826	27.0		5479	24.2		2198	27.2		12,503	25.7	
Overweight (25.0–29.9)	6032	33.7		8210	36.3		3145	38.9		17,387	35.8	
Obesity I (30.0–34.9)	4046	22.6		5308	23.5		1844	22.8		11,198	23.0	
Obesity II (35.0–39.9)	1961	11.0		2435	10.8		652	8.1		5048	10.4	
Obesity III (≥40)	988	5.5		1108	4.9		226	2.8		2322	4.8	
Height, (cm)	17,945		163.2 ± 6.5	22,647		162.0 ± 6.4	8093		160.0 ± 6.4	48,685		162.1 ± 6.5
Weight, (kg)	17,981		78.1 ± 17.4	22,696		77.1 ± 16.4	8118		72.9 ± 14.6	48,795		76.7 ± 16.6
Waist, (cm)	17,953		88.4 ± 14.3	22,657		89.7 ± 13.7	8101		88.7 ± 12.7	48,711		89.0 ± 13.8
Smoking												
Never smoked	8902	49.9		11498	51.2		4548	56.9		24,948	51.7	
Past smoker	7346	41.2		9610	42.8		3145	39.4		20,101	41.6	
Current smoker	1600	9.0		1356	6.0		294	3.7		3250	6.7	
Alcohol intake												
Never drinker	1494	8.4		2311	10.2		958	11.9		4763	9.8	
Past drinker	3106	17.4		4195	18.6		1599	19.9		8900	18.4	
Current drinker	13,279	74.3		16,065	71.2		5481	68.2		34,825	71.8	
Alcohol servings/wk for drinkers	16,367		2.3 ± 4.1	20,255		2.3 ± 4.1	7073		2.2 ± 4.0	43,695		2.3 ± 4.1
Physical activity												
No activity	3432	22.0		3919	18.9		1270	17.1		8621	19.7	
Some activity	6489	41.6		9221	44.4		3454	46.6		19,164	43.8	
2–<4 episodes/wk of moderate + activity	2668	17.1		3558	17.1		1297	17.5		7523	17.2	
4+ episodes/wk of moderate + activity	3015	19.3		4052	19.5		1387	18.7		8454	19.3	
Any supplement use												
No	7250	40.3		7546	33.2		2470	30.4		17,266	35.4	
Yes	10,753	59.7		15,167	66.8		5650	69.6		31,570	64.6	
Multivitamin use (with or without minerals)												
No	12,249	68.0		14,331	63.1		4917	60.6		31,497	64.5	
Yes	5754	32.0		8381	36.9		3203	39.4		17,338	35.5	

TABLE 2. Baseline medical history status of WHI Dietary Modification participants by age

	Age at screening (y)							
	50–59 (N = 18,003)		60–69 (N = 22,713)		70–79 (N = 8120)		Total (N = 48,836)	
Medical History	N	%	N	%	N	%	N	%
Age at first birth (y)[a]								
Never had term pregnancy	616	4.1	428	2.3	184	2.9	1228	3.0
<20	3152	21.0	3134	16.6	606	9.4	6892	17.1
20–29	10,034	66.9	13,924	73.7	4840	75.4	28,798	71.5
30+	1191	7.9	1401	7.4	788	12.3	3380	8.4
Age at menopause (y)								
<40	1674	10.0	2203	10.4	665	8.9	4542	10.0
40–49	7371	43.9	7788	36.8	2849	38.0	18,008	39.6
50+	7753	46.2	11,183	52.8	3978	53.1	22,914	50.4
Hysterectomy[b]								
No	10,627	59.0	12,606	55.5	4401	54.2	27,634	56.6
Yes	7376	41.0	10,107	44.5	3719	45.8	21,202	43.4
History of PHT use[c]								
Never	6225	34.6	9561	42.2	4023	49.6	19,809	40.6
Past	2059	11.5	3166	14.0	1540	19.0	6765	13.9
Current	9695	53.9	9949	43.9	2546	31.4	22,190	45.5
Total PHT duration among ever users (y)								
<5	6071	51.5	4118	31.3	1431	34.9	11,620	40.0
5–<10	3321	28.2	2703	20.6	528	12.9	6552	22.6
10–<15	1477	12.5	2721	20.7	487	11.9	4685	16.1
15+	909	7.7	3610	27.4	1651	40.3	6170	21.3
History of E-alone use[c]								
Never	11,613	64.6	13,950	61.5	4756	58.7	30,319	62.2
Past	1407	7.8	2701	11.9	1498	18.5	5606	11.5
Current	4967	27.6	6033	26.6	1853	22.9	12,853	26.3
Total E-alone duration among ever users (y)								
<5 (y)	3033	47.5	2879	32.9	1187	35.3	7099	38.3
5–<10 (y)	1687	26.4	1481	16.9	441	13.1	3609	19.5
10–<15 (y)	921	14.4	1555	17.7	396	11.8	2872	15.5
15+	749	11.7	2848	32.5	1340	39.8	4937	26.7
History of E + P use[c]								
Never	11,456	63.7	16,807	74.0	6969	85.9	35,232	72.2
Past	1689	9.4	1879	8.3	438	5.4	4006	8.2
Current	4844	26.9	4013	17.7	710	8.7	9567	19.6
Total E + P duration among ever users (y)								
<5 (y)	4208	64.3	2492	42.2	538	46.7	7238	53.2
5–<10 (y)	1779	27.2	1694	28.7	206	17.9	3679	27.0
10–<15 (y)	462	7.1	1207	20.4	177	15.4	1846	13.6
15+	97	1.5	513	8.7	230	20.0	840	6.2
Benign breast disease								
No	12,466	80.6	16,131	78.3	5775	78.5	34,372	79.1
Yes, 1 biopsy	2194	14.2	3218	15.6	1093	14.9	6505	15.0
Yes, 2+ biopsies	814	5.3	1255	6.1	492	6.7	2561	5.9
Family history of breast cancer								
No	14,257	82.8	17,627	82.0	6079	80.3	37,963	82.0
Yes	2955	17.2	3882	18.0	1488	19.7	8325	18.0
Systolic blood pressure (mm Hg)								
≤120	8716	48.4	7565	33.3	1817	22.4	18,098	37.1
>120–140	6985	38.8	9984	44.0	3561	43.9	20,530	42.0
>140	2301	12.8	5163	22.7	2742	33.8	10,206	20.9
Diastolic blood pressure (mm Hg)								
<90	16,442	91.3	21,097	92.9	7654	94.4	45,193	92.6
≥90	1561	8.7	1611	7.1	458	5.6	3630	7.4

(continued)

TABLE 2. *Continued*

	Age at screening (y)							
	50–59 (N = 18,003)		60–69 (N = 22,713)		70–79 (N = 8120)		Total (N = 48,836)	
Medical History	N	%	N	%	N	%	N	%
History of hypertension								
Never hypertensive	11,220	72.5	12,776	62.1	3985	54.5	27,981	64.5
Untreated hypertensive	1178	7.6	1723	8.4	602	8.2	3503	8.1
Treated hypertensive	3081	19.9	6071	29.5	2731	37.3	11,883	27.4
Treated diabetes (pills or shots)								
No	17,402	96.7	21,569	95.0	7658	94.3	46,629	95.5
Yes	599	3.3	1142	5.0	461	5.7	2202	4.5
Treated hypercholesterolemia (pills)								
No	14,158	92.4	17,675	86.3	6160	83.8	37,993	88.0
Yes	1172	7.6	2812	13.7	1188	16.2	5172	12.0
History of cardiovascular disease[d]								
No	16,689	93.6	19,973	89.0	6641	83.2	43,303	89.7
Yes	1143	6.4	2469	11.0	1338	16.8	4950	10.3
History of polyp removal								
No	14,530	94.7	18,462	90.7	6302	87.2	39,294	91.6
Yes	806	5.3	1889	9.3	926	12.8	3621	8.4
Family history of myocardial infarction								
No	9024	52.5	9787	45.5	3351	44.4	22,162	47.9
Yes	8155	47.5	11,709	54.5	4202	55.6	24,066	52.1
Family history of colorectal cancer								
No	14,358	86.1	17,248	83.0	5821	80.0	37,427	83.7
Yes	2309	13.9	3525	17.0	1451	20.0	7285	16.3
Parent broke bone after age 40								
No	10,002	60.1	12,405	59.3	4670	62.9	27,077	60.2
Yes	6635	39.9	8524	40.7	2749	37.1	17,908	39.8

PHT, postmenopausal hormone therapy; E-alone, estrogen alone; E+P, estrogen + progestin.
[a]Applies only to participants who have ever been pregnant.
[b]Hysterectomy at randomization.
[c]Based on estrogen and progesterone pills and patches only (creams and shots excluded). Episodes less than 3 months are excluded.
[d]Includes MI, stroke, CHF, angina, carotid endarterectomy/angioplasty, DVT, PE, peripheral arterial disease, and CABG/PTCA.

of older women. Inclusion of a diverse population was successful with over 18% of participants belonging to a minority group. Overall, this appears to be a sample of healthy and health-conscious women, with high educational attainment (about 40% had college degrees), low rates of smoking (93% non-smokers), and high vitamin supplement use (65%). However, almost 40% of participants were obese with slightly lower rates in women aged 70 to 79 years.

In comparison to Whites, Blacks were more likely to be smokers, less likely to drink alcohol or engage in physical activity, and had higher body mass indices (BMI): 36% of Whites were obese compared with 58% of Blacks (appendix to Hays' article). Compared with Whites, Hispanics were generally younger, had lower educational attainment, and were somewhat more likely to be obese. Asian/Pacific Islanders had highest levels of education and were least likely to drink, smoke, or be obese. American Indians were similar to Whites in smoking, exercise, and alcohol consumption; but had lower education levels and higher obesity levels (51% were obese compared with 36% of Whites). Whites and Asian/Pacific Islanders were more likely to use dietary supplements than other race/ethnicity groups.

Medical History Variables (Table 2)

Prevalence of potential risk factors for breast cancer, colorectal cancer, and cardiovascular events by age are given in Table 2. In relation to breast cancer risk, only a few variables showed differences by age. A greater percentage of older women were over the age of 30 before having their first birth and had never used hormone replacement therapy. As would be expected, a greater percentage of older women reported treatment for hypertension, diabetes, and high blood cholesterol levels as well as history of cardiovascular disease and polyp removal.

Compared with White participants, Blacks were more likely to have been less than 20 years of age at first birth (15% vs. 35%, respectively), less likely to be taking hormone replacement therapy (48% vs. 27%), and more likely to be treated for hypertension (25% vs. 46%) or diabetes (3% vs. 12%) (appendix to Hays' article). Compared with

TABLE 3. Dietary intake of WHI Dietary Modification control participants by age, from a Food Frequency Questionnaire[a]

	Age at screening (y)							
	50–59 (N = 9360)		60–69 (N = 12,235)		70–79 (N = 4404)		Total (N = 25,999)	
Nutrient[b]	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD
Energy (kcal)		1528 ± 566		1501 ± 541		1476 ± 534		1506 ± 549
Total fat (g)		60 ± 27		60 ± 26		58 ± 25		60 ± 26
% Energy from fat		35 ± 7		36 ± 7		36 ± 6		36 ± 7
% Energy from carbohydrates		46 ± 8		46 ± 8		47 ± 8		46 ± 8
% Energy from protein		17 ± 3		17 ± 3		16 ± 3		17 ± 3
Total PFA (g)		12 ± 6		12 ± 5		12 ± 5		12 ± 5
Total MFA (g)		22 ± 10		22 ± 9		22 ± 9		22 ± 10
Total SFA (g)		21 ± 10		20 ± 9		20 ± 9		20 ± 9
Total trans fatty acid (g)		3.6 ± 1.5		3.6 ± 1.5		3.6 ± 1.6		3.6 ± 1.5
Animal protein (g)		44 ± 20		44 ± 19		42 ± 19		44 ± 20
Vegetable protein (g)		17 ± 7		17 ± 7		17 ± 7		17 ± 7
Dietary fiber (g)		14 ± 6		15 ± 6		15 ± 6		14 ± 6
Cholesterol (mg/1000 kcal)		135 ± 47		135 ± 48		134 ± 49		135 ± 48
Total vitamin A (mcg Re)		7158 ± 3785		7807 ± 3994		8362 ± 4213		7655 ± 3977
Total alpha-toc eq (mg)		7.8 ± 3.1		7.9 ± 3.1		7.9 ± 3.1		7.9 ± 3.1
Vitamin C (mg)		85 ± 47		91 ± 49		97 ± 50		90 ± 49
Roboflavin (mg)		1.5 ± 0.4		1.6 ± 0.4		1.6 ± 0.4		1.6 ± 0.4
Niacin (mg)		16 ± 6		16 ± 5		16 ± 6		16 ± 6
Vitamin B6 (mg)		1.5 ± 0.4		1.5 ± 0.4		1.6 ± 0.4		1.5 ± 0.4
Folacin (mcg)		210 ± 87		221 ± 88		226 ± 89		218 ± 88
Vitamin B12 (mcg)		4.9 ± 2.2		4.9 ± 2.2		4.8 ± 2.2		4.9 ± 2.2
Calcium (mg)		642 ± 339		641 ± 331		651 ± 338		643 ± 335
Magnesium (mg)		233 ± 88		236 ± 87		235 ± 87		235 ± 87
Iron (mg)		12 ± 5		12 ± 5		12 ± 5		12 ± 5
Zinc (mg)		9.7 ± 3.8		9.6 ± 3.8		9.4 ± 3.7		9.6 ± 3.8
Total carotenoids (mcg)		11,990 ± 6300		12,100 ± 6158		12,122 ± 6190		12,064 ± 6215
Beta-carotene (mcg)		2832 ± 1763		3127 ± 1882		3380 ± 1990		3057 ± 1866
Lycopene (mcg)		6444 ± 4193		6138 ± 3958		5795 ± 3806		6186 ± 4020
Lutein + zeaxanthin (mcg)		1317 ± 692		1360 ± 724		1394 ± 750		1350 ± 717
	(N = 9605)		(N = 12,544)		(N = 4514)		(N = 26,663)	
Fruits and vegetables (servings/day)		3.1 ± 1.2		3.4 ± 1.3		3.6 ± 1.4		3.3 ± 1.3
0 to <3	47.9		40.3		35.3		42.2	
3 to <5	34.9		38.4		38.9		37.3	
5+	17.2		21.2		25.8		20.5	
Grains (servings/day)		4.5 ± 1.9		4.2 ± 1.7		3.9 ± 1.6		4.3 ± 1.8

[a]Year 1 control participant data are presented to represent baseline intake. Baseline dietary data are biased because of eligibility screening (i.e., women with fat intakes less than 32% energy from fat were ineligible for the Diet Modification trial).
[b]Means and standard deviations were computed on the log scale and back-transformed values are reported.

Whites, Hispanic women were more likely to have been less than 20 years of age at first birth (15% vs. 24%, respectively), less likely to be taking hormone replacement therapy (48% vs. 39%), and more likely to be treated for diabetes (3% vs. 6%). Asian/Pacific Islanders tended to be similar to Whites on these variables. However, compared with Whites, they were more likely to be treated for hypertension (25% vs. 31%, respectively), diabetes (3% vs. 6%), or taking cholesterol lowering drugs (12% vs. 18%). Compared with Whites, American Indians were more likely to have been less than 20 years of age at first birth (15% vs. 31%, respectively), less likely to be taking hormone replacement therapy (48% vs. 38%, respectively), more likely to be treated for diabetes (3% vs. 6%) and hypertension (25% vs. 32%) and more likely to have a family history of heart disease (10% vs. 15%, respectively).

Dietary Intake Estimates (from Food Only) by Age (Table 3) and Race Ethnicity (Table 4)

Although Table 3 gives data on an extensive list of nutrients, the narrative here is focused on nutrients related to the dietary intervention aims of the trial. Mean energy intake estimates were about 1500 kcals per day, energy from fat was 36%, and dietary fiber intake was 14 grams per day. There was little variability by age. Participants consumed

TABLE 4. Dietary intake of WHI Dietary Modification control participants by race/ethnicity, from a Food Frequency Questionnaire[a]

	Race/Ethnicity											
	American Indian (N = 94)		Asian/Pacific Islander (N = 611)		Black (N = 2447)		Hispanic (N = 870)		White (N = 21,643)		Total[b] (N = 25,999)		
Nutrient[c]	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	N	%	Mean ± SD
Energy (kcal)		1430 ± 546		1450 ± 550		1411 ± 582		1456 ± 604		1523 ± 540	21,943		1506 ± 549
Total Fat (g)		59 ± 27		58 ± 27		57 ± 28		57 ± 29		60 ± 26	21,943		60 ± 26
% Energy from fat		37 ± 8		36 ± 7		36 ± 7		35 ± 7		36 ± 7	21,943		36 ± 7
% Energy from carbohydrates		45 ± 9		48 ± 8		47 ± 9		47 ± 9		46 ± 8	21,943		46 ± 8
% Energy from protein		16 ± 3		16 ± 3		16 ± 3		16 ± 3		17 ± 3	21,943		17 ± 3
Total PFA (g)		12 ± 5		13 ± 6		12 ± 6		12 ± 6		12 ± 5	21,943		12 ± 6
Total MFA (g)		22 ± 10		22 ± 10		22 ± 10		22 ± 11		22 ± 9	21,943		22 ± 10
Total SFA (g)		20 ± 10		18 ± 9		19 ± 9		19 ± 10		21 ± 9	21,943		20 ± 9
Total trans fatty acid (g)		3.4 ± 1.3		3.1 ± 1.3		3.9 ± 1.8		3.0 ± 1.4		3.6 ± 1.5	21,943		3.6 ± 1.5
Animal protein (g)		40 ± 18		38 ± 20		38 ± 20		41 ± 21		45 ± 19	21,943		44 ± 20
Vegetable protein (g)		17 ± 8		19 ± 8		16 ± 7		17 ± 8		18 ± 7	21,943		17 ± 7
Dietary fiber (g)		14 ± 6		13 ± 5		13 ± 5		14 ± 6		15 ± 6	21,943		15 ± 6
Cholesterol (mg/1000 kcal)		146 ± 59		139 ± 49		142 ± 57		143 ± 54		133 ± 47	21,943		135 ± 48
Total Vitamin A (mcg Re)		6706 ± 3710		7745 ± 4307		7245 ± 4288		6016 ± 3490		7787 ± 3918	21,943		7655 ± 3977
Total Alpha-Toc Eq (mg)		7.3 ± 2.6		8.0 ± 3.1		7.4 ± 3.1		7.2 ± 3.1		8.0 ± 3.1	21,943		7.9 ± 3.1
Vitamin C (mg)		82 ± 47		83 ± 48		84 ± 51		80 ± 48		91 ± 48	21,943		90 ± 49
Riboflavin (mg)		1.4 ± 0.3		1.3 ± 0.3		1.3 ± 0.4		1.4 ± 0.4		1.6 ± 0.4	21,943		1.6 ± 0.4
Niacin (mg)		15 ± 6		16 ± 6		15 ± 6		15 ± 6		17 ± 6	21,943		16 ± 6
Vitamin B6 (mg)		1.4 ± 0.3		1.4 ± 0.3		1.3 ± 0.3		1.4 ± 0.4		1.6 ± 0.4	21,943		1.5 ± 0.4
Folacin (mcg)		203 ± 82		197 ± 83		192 ± 87		187 ± 83		223 ± 87	21,943		218 ± 88
Vitamin B12 (mcg)		4.6 ± 2		4.8 ± 241		5.3 ± 2.9		4.4 ± 2.2		4.9 ± 2.1	21,943		4.9 ± 2.2
Calcium (mg)		556 ± 285		467 ± 241		478 ± 257		609 ± 337		674 ± 338	21,943		643 ± 335
Magnesium (mg)		223 ± 85		214 ± 80		198 ± 84		213 ± 87		241 ± 86	21,943		235 ± 87
Iron (mg)		11 ± 4		11 ± 4		11 ± 5		11 ± 5		12 ± 5	21,943		12 ± 5
Zinc (mg)		8.6 ± 3.3		8.8 ± 3.7		8.1 ± 3.5		8.7 ± 3.8		9.9 ± 3.7	21,943		9.6 ± 3.8
Total carotenoids (mcg)		11,625 ± 6275		11,314 ± 6035		10,087 ± 5949		10,320 ± 6145		12,423 ± 6164	21,943		12,064 ± 6215
Beta-carotene (mcg)		2662 ± 1810		3434 ± 2114		2944 ± 2000		2351 ± 1594		3097 ± 1844	21,943		3057 ± 1866
Lycopene (mcg)		6332 ± 3938		4747 ± 3296		4322 ± 3349		5551 ± 4326		6524 ± 3988	21,943		6186 ± 4020
Lutein + Zeaxanthin (mcg)		1306 ± 794		1501 ± 876		1494 ± 916		1172 ± 669		1339 ± 689	21,943		1350 ± 717
		(N = 97)		(N = 628)		(N = 2615)		(N = 918)		(N = 22,059)			(N = 26,663)
Fruits and vegetables (servings/day)		2.8 ± 1.1		3.0 ± 1.2		2.9 ± 1.2		2.6 ± 1.1		3.4 ± 1.3	26,657		3.3 ± 1.3
0 to <3	52.6		50.5		54.1		61.2		39.6		11,254	42.2	
3 to <5	34.0		33.4		30.5		25.2		38.8		9931	37.3	
5+	13.4		16.1		15.4		13.6		21.6		5472	20.5	
Grains (servings/day)		3.9 ± 1.7		4.4 ± 1.7		3.8 ± 1.8		4.9 ± 2.4		4.3 ± 1.7	26,656		4.3 ± 1.8

[a]Year 1 control participant data are presented to represent baseline intake. Beseline dietary data are biased because of eligibility screening (i.e., women with fat intakes less than 32% energy from fat were ineligible for the Diet Modification trial).
[b]Total includes Unknown race/ethnicity.
[c]Means and standard deviations were computed on the log scale and back-transformed values are reported.

approximately three servings of fruits and vegetables per day and only 20% met the recommendation to consume five or more servings per day. Older women were more likely to meet this recommendation, with 26% of women aged 70 to 79 years consuming five a day compared with only 17% among women aged 50 to 59 years. Average grain servings per day was four. Average daily dietary calcium intake was only 640 mg.

Among White participants, average daily energy intake was about 1500 kcals (Table 4). Minority women reported somewhat lower levels (1410–1450 kcals). Mean energy from fat was 36% with little variation by race/ethnicity. Twenty-two percent of Whites met the recommendation to consume five or more fruits and vegetables per day compared with only fourteen to sixteen percent among the minority groups. Hispanics reported consuming the most servings of grains. There were marked differences in calcium intakes: Whites consumed almost 700 mg per day compared with only 500 to 600 mg among the minority groups.

Blood Analytes by Race/Ethnicity (Appendix to Hays' article)

Total serum cholesterol was about 220 mg/dl and varied only slightly by race/ethnicity. Lp(a) was 2-fold higher in Blacks compared with other race/ethnicity groups. Triglycerides were notably lower in Blacks (143 mg/dl) compared with other groups (about 150 mg/dl). Compared with Whites, glucose was higher in Blacks and American Indians and serum insulin levels were somewhat higher for Blacks, Hispanics, and American Indians. There was no consistent pattern of variability in concentrations of carotenoids by race/ethnicity.

DISCUSSION

Comparisons of Key Variables to National Data

Since DM participants were not recruited as a representative sample from the US population, it is instructive to compare this sample to US women aged 50 to 79 years. Compared with women from the NHANES III, DM participants are more obese. Specifically, in the three age decades, 73%, 76%, and 73% of DM participants have BMI greater than 25 as compared with 64%, 64%, and 58% of NHANES III women (19). In contrast, DM participants have lower rates of hypertension: 28%, 38%, and 45% compared with 27%, 47%, and 57% in the NCHS study sample (20). DM participants are also much less likely to be current smokers than older US women. For example, 22% of women aged 55 to 64 years in the US currently smoke as measured by the Behavioral Risk Factor Surveillance Survey (21) compared with 9% of women aged 50 to 59 years and 6% of women aged 60 to 69 years in the DM.

Mean energy intakes for DM women were lower than those estimated from 24-hour recalls in NHANES III (22). For example, NHANES III values for women aged 60 to 69 years were 1578 kcals compared with 1506 kcals in WHI. This may be due, in part, to the different dietary assessment methods. In general, FFQs appear to underestimate energy intake compared with 24-hour recalls or diet records (23) more among women (24–27) and among Blacks compared with Whites (28). The latter bias may partially explain differences in energy intake by ethnicity in WHI.

A substudy comparing the WHI FFQ to food records and recalls also suggested that there was underreporting of energy intake from the FFQ (17). This study of 113 DM participants found that the FFQ under-estimated energy intake by 100 to 130 kcals and provided an unbiased estimate of absolute fat intake in grams, such that the percentage energy from fat estimated from the FFQ was biased upward from the recall estimate by approximately three percentage points. Precision of the FFQ was good as evidenced by a correlation coefficient of 0.6 for percentage energy from fat estimated by the FFQ compared with the criterion measure (8 days of food records and recalls). Nonetheless, it is clear from studies of doubly-labeled water that energy intake is underestimated in all self-report methods of assessing dietary intake (23, 29, 30) and some research suggests that fat may be differentially underreported (31). In addition, many person-specific biases have been identified, including underreporting associated with obesity (32, 33), social desirability (34), and dietary interventions themselves (35). Therefore, although the collection of dietary data is useful for monitoring trial performance and may provide valuable information for addressing secondary hypotheses about diet and disease risk, the randomized nature of the DM trial is its chief strength.

Comparison of the WHI Dietary Modification Trial Component to Other Dietary Intervention Trials

There are several large ongoing, or recently completed, dietary interventions for prevention of cancer or cardiovascular disease (36–41). WHI is unique among them in that it combines all the following design elements: the intervention is a dietary pattern and thus intervenes on multiple nutrients simultaneously; the duration of the intervention is longer than most (average 8.5 years) and should be adequate to observe hypothesized health outcomes; there are multiple endpoints (both cancer and cardiovascular) that focus on disease occurrence rather than risk factors or intermediate outcomes; and finally, it is a primary rather than secondary prevention trial. These features are particularly noteworthy given the recent null results of two dietary intervention trials (one of a low-fat high-fiber diet and one of fiber supplements) on the recurrence of colorectal adenomas (36,

37), where it was noted that the results of these short-terms trials do not provide definitive answers to questions regarding diet and colorectal cancer risk (42).

Given the considerable limitations of observational epidemiologic studies and short term clinical trials, the randomized controlled Dietary Modification trial will provide a new and much needed line of evidence for resolving the important public health question of whether older women, by changing to a low-fat dietary pattern, can lower their risk of breast cancer, colon cancer, and heart disease.

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