



**Women's Health Initiative
2005 Annual Progress Report**

**Data as of: September 12, 2005
Events through Study Closeout**

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Executive Summary

The Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) completed follow-up on all study participants on March 31, 2005. The final database for the study was created on September 12, 2005. This report documents the status of each study component in this database with regard to intermediate outcomes, vital status and clinical outcome event rates. Event rates are provided by study component, age, and race/ethnicity but not by CT randomized assignment as final results have not yet been published. For the Dietary Modification (DM) trial information on baseline and follow-up dietary intake is also provided. Statistical methods have been described in previous reports.

Lists of published and proposed papers and approved ancillary studies are also provided.

WHI Clinical Centers and their Principal Investigators at study termination are listed in *Table 1.1*. The Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center, Seattle WA was led throughout the study by Ross Prentice, PhD.

Table 2.1
Hormone Replacement Therapy Component Age – and Race/Ethnicity – Specific Recruitment

Data as of September 12, 2005; Events through Study Closeout

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	27,347			
50-54	3,420	125%	13%	10%
55-59	5,413	99%	20%	20%
60-69	12,360	100%	45%	45%
70-79	6,154	90%	23%	25%
Without Uterus	10,739			
50-54	1,396	113%	13%	10%
55-59	1,917	78%	18%	20%
60-69	4,851	88%	45%	45%
70-79	2,575	84%	24%	25%
With Uterus	16,608			
50-54	2,024	135%	12%	10%
55-59	3,496	116%	21%	20%
60-69	7,509	111%	45%	45%
70-79	3,579	95%	22%	25%
Race/Ethnicity				
Overall	27,347			
American Indian	130		<1%	
Asian	527		2%	
Black	2,738		10%	
Hispanic	1,537		6%	
White	22,030		81%	
Unknown	385		1%	
Without Uterus	10,739			
American Indian	75		1%	
Asian	164		2%	
Black	1,616		15%	
Hispanic	651		6%	
White	8,084		75%	
Unknown	149		1%	
With Uterus	16,608			
American Indian	55		<1%	
Asian	363		2%	
Black	1,122		7%	
Hispanic	886		5%	
White	13,946		84%	
Unknown	236		1%	

Table 2.2
Blood Specimen Analysis: HRT Participants

Data as of September 12, 2005; Events through Study Closeout

Micronutrients	Without Uterus			With Uterus		
	N	Mean ¹	S.D. ¹	N	Mean ¹	S.D. ¹
Alpha-Carotene (µg/ml)						
Baseline	1163	0.07	0.07	1468	0.09	0.08
AV-1	1022	0.07	0.06	1365	0.08	0.08
AV-3	884	0.06	0.06	1206	0.07	0.08
AV-6	809	0.06	0.05	1122	0.07	0.07
AV-1 – Baseline	1000	-0.01	0.06	1332	-0.01	0.06
AV-3 – Baseline	868	-0.01	0.06	1177	-0.01	0.07
AV-6 – Baseline	792	-0.02	0.07	1093	-0.02	0.07
Beta-Carotene (µg/ml)						
Baseline	1162	0.29	0.27	1468	0.34	0.33
AV-1	1021	0.26	0.25	1366	0.31	0.30
AV-3	884	0.25	0.25	1206	0.32	0.38
AV-6	809	0.26	0.28	1122	0.33	0.43
AV-1 – Baseline	999	-0.03	0.22	1333	-0.04	0.21
AV-3 – Baseline	867	-0.04	0.25	1177	-0.03	0.31
AV-6 – Baseline	792	-0.03	0.27	1093	-0.02	0.34
Alpha-tocopherol (µg/ml)						
Baseline	1163	16.09	7.04	1468	16.31	7.70
AV-1	1022	17.70	8.91	1366	16.82	7.42
AV-3	884	17.83	8.30	1206	18.26	8.17
AV-6	810	18.65	8.83	1122	18.41	7.83
AV-1 – Baseline	1000	1.63	6.25	1333	0.51	5.73
AV-3 – Baseline	868	1.76	6.80	1177	2.00	7.28
AV-6 – Baseline	793	2.65	7.77	1093	2.32	7.87
Gamma-tocopherol (µg/ml)						
Baseline	1163	2.48	1.65	1468	2.24	1.40
AV-1	1022	2.22	1.84	1366	1.84	1.24
AV-3	884	2.00	1.49	1206	1.66	1.24
AV-6	810	1.86	1.37	1122	1.69	1.26
AV-1 – Baseline	1000	-0.30	1.13	1333	-0.37	0.93
AV-3 – Baseline	868	-0.54	1.19	1177	-0.57	1.17
AV-6 – Baseline	793	-0.66	1.40	1093	-0.57	1.27
Beta-Cryptoxanthine (µg/ml)						
Baseline	1163	0.08	0.08	1468	0.09	0.10
AV-1	1022	0.08	0.07	1365	0.09	0.09
AV-3	884	0.08	0.07	1206	0.10	0.09
AV-6	809	0.09	0.12	1122	0.11	0.11
AV-1 – Baseline	1000	-0.00	0.06	1332	-0.01	0.07
AV-3 – Baseline	868	-0.00	0.07	1177	0.00	0.09
AV-6 – Baseline	792	0.01	0.12	1093	0.01	0.11

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¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.2 (continued)
Blood Specimen Analysis: HRT Participants

Data as of September 12, 2005; Events through Study Closeout

	Without Uterus			With Uterus		
	N	Mean ¹	S.D. ¹	N	Mean ¹	S.D. ¹
Lycopene (µg/ml)						
Baseline	1163	0.40	0.20	1468	0.41	0.20
AV-1	1022	0.39	0.19	1366	0.40	0.19
AV-3	884	0.35	0.18	1206	0.38	0.21
AV-6	809	0.35	0.18	1122	0.37	0.19
AV-1 – Baseline	1000	-0.01	0.17	1333	-0.01	0.17
AV-3 – Baseline	868	-0.05	0.20	1177	-0.03	0.21
AV-6 – Baseline	792	-0.05	0.22	1093	-0.04	0.21
Lutein and Zeaxanthin (µg/ml)						
Baseline	1163	0.20	0.10	1468	0.21	0.09
AV-1	1022	0.20	0.10	1366	0.21	0.10
AV-3	884	0.19	0.10	1206	0.20	0.09
AV-6	809	0.17	0.10	1122	0.19	0.09
AV-1 – Baseline	1000	0.00	0.07	1333	0.00	0.07
AV-3 – Baseline	868	-0.01	0.07	1177	-0.02	0.08
AV-6 – Baseline	792	-0.02	0.09	1093	-0.02	0.09
Retinol (µg/ml)						
Baseline	1163	0.60	0.15	1468	0.60	0.15
AV-1	1022	0.63	0.16	1366	0.61	0.15
AV-3	884	0.62	0.16	1206	0.61	0.16
AV-6	810	0.65	0.17	1122	0.63	0.17
AV-1 – Baseline	1000	0.03	0.11	1333	0.01	0.10
AV-3 – Baseline	868	0.02	0.13	1177	0.00	0.13
AV-6 – Baseline	793	0.05	0.15	1093	0.03	0.14
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	1121	128.49	28.82	1415	123.49	28.32
AV-1	973	139.42	35.19	1319	129.63	31.01
AV-3	848	135.80	33.71	1148	128.21	31.65
AV-6	809	128.99	33.99	1102	119.56	30.68
AV-1 – Baseline	927	10.40	25.42	1248	5.94	22.52
AV-3 – Baseline	807	8.02	30.71	1084	4.92	28.04
AV-6 – Baseline	762	1.08	33.83	1036	-4.13	30.34
Factor VII C (%)²						
Baseline	1101	129.99	28.24	1396	125.15	27.13
AV-1	961	136.32	31.68	1308	124.89	27.96
AV-3	844	135.30	34.41	1141	127.15	32.21
AV-6	806	141.78	39.24	1101	132.47	33.62
AV-1 – Baseline	899	6.23	23.93	1220	-0.58	21.84
AV-3 – Baseline	787	7.42	29.14	1062	2.12	27.50
AV-6 – Baseline	744	13.23	32.97	1020	6.56	29.33
Fibrinogen (mg/dl)						
Baseline	1118	312.18	63.50	1413	306.41	59.37
AV-1	971	301.34	61.46	1316	299.11	59.45
AV-3	848	294.21	59.18	1146	290.92	57.51
AV-6	807	298.82	64.25	1106	295.55	56.99
AV-1 – Baseline	923	-11.50	52.68	1243	-7.95	53.17
AV-3 – Baseline	804	-17.88	61.65	1080	-15.41	56.61
AV-6 – Baseline	758	-12.07	63.20	1037	-9.87	58.66

(continues)

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

² Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.2 (continued)
Blood Specimen Analysis: HRT Participants

Data as of September 12, 2005; Events through Study Closeout

	Without Uterus			With Uterus		
	N	Mean ¹	S.D. ¹	N	Mean ¹	S.D. ¹
Hormones / Other						
Glucose (mg/dl)						
Baseline	1160	105.16	35.35	1466	100.47	26.73
AV-1	1020	102.91	31.69	1362	98.72	24.60
AV-3	903	101.96	31.58	1222	98.65	26.39
AV-6	815	104.37	27.14	1129	101.50	25.62
AV-1 – Baseline	995	-2.76	21.30	1326	-1.94	17.24
AV-3 – Baseline	885	-3.60	26.12	1192	-2.50	20.45
AV-6 – Baseline	795	0.33	25.31	1098	1.53	22.38
Insulin (µU/ml)						
Baseline	1139	12.88	10.62	1421	11.42	6.86
AV-1	1004	12.16	8.14	1317	11.38	7.18
AV-3	853	13.60	11.32	1155	12.40	7.29
AV-6	815	11.84	37.28	1128	10.57	14.12
AV-1 – Baseline	964	-0.74	5.98	1264	-0.09	5.56
AV-3 – Baseline	822	0.58	9.12	1092	1.06	6.61
AV-6 – Baseline	783	-1.27	33.26	1066	-0.64	12.53
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	1163	162.97	99.73	1469	146.01	74.89
AV-1	1020	176.31	132.80	1365	149.30	75.05
AV-3	902	169.67	82.73	1220	152.49	81.18
AV-6	816	167.44	83.14	1124	144.79	65.57
AV-1 – Baseline	997	13.67	73.57	1332	3.11	55.64
AV-3 – Baseline	883	7.35	81.70	1191	6.51	64.92
AV-6 – Baseline	797	3.74	101.47	1095	-1.01	62.07
Total Cholesterol (mg/dl)						
Baseline	1163	229.63	41.21	1469	224.84	36.85
AV-1	1020	223.25	40.59	1365	215.84	35.22
AV-3	902	218.71	36.84	1220	215.04	35.21
AV-6	816	209.87	37.54	1124	211.54	35.49
AV-1 – Baseline	997	-6.04	29.85	1332	-8.79	28.18
AV-3 – Baseline	883	-10.82	34.49	1191	-8.65	31.79
AV-6 – Baseline	797	-18.34	41.62	1095	-13.06	37.85
LDL-C (mg/dl)						
Baseline	1139	142.06	36.82	1444	138.73	32.93
AV-1	998	128.48	35.85	1340	127.13	32.49
AV-3	881	126.90	34.80	1196	127.03	33.00
AV-6	802	119.14	33.95	1114	124.71	32.45
AV-1 – Baseline	966	-13.26	27.27	1298	-11.34	25.66
AV-3 – Baseline	853	-15.50	32.02	1153	-10.60	29.43
AV-6 – Baseline	769	-21.96	38.40	1070	-13.47	34.93
HDL-C (mg/dl)						
Baseline	1157	55.59	14.52	1464	56.92	14.38
AV-1	1018	59.92	16.83	1365	59.12	14.89
AV-3	895	58.65	16.57	1217	58.20	15.20
AV-6	815	57.94	15.51	1123	57.92	14.58
AV-1 – Baseline	993	4.11	9.36	1327	2.28	8.15
AV-3 – Baseline	873	2.97	10.28	1184	-1.32	9.46
AV-6 – Baseline	791	2.52	10.81	1091	0.76	9.65

(continues)

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.2 (continued)
Blood Specimen Analysis: HRT Participants

Data as of September 12, 2005; Events through Study Closeout

	Without Uterus			With Uterus		
	N	Mean ¹	S.D. ¹	N	Mean ¹	S.D. ¹
HDL-2 (mg/dl)						
Baseline	1133	16.92	7.52	1423	17.72	7.57
AV-1	995	19.35	8.80	1332	19.05	8.12
AV-3	882	16.51	6.82	1197	16.29	6.38
AV-6	808	17.62	7.94	1115	17.82	7.72
AV-1 – Baseline	952	2.05	5.05	1263	1.19	4.67
AV-3 – Baseline	845	-0.60	5.55	1133	-1.54	5.37
AV-6 – Baseline	768	0.73	6.35	1051	-0.17	6.29
HDL-3 (mg/dl)						
Baseline	1134	38.75	8.41	1423	39.14	8.11
AV-1	997	40.86	9.49	1333	40.10	8.18
AV-3	882	42.05	10.63	1197	41.80	9.45
AV-6	808	40.39	9.56	1115	40.12	8.79
AV-1 – Baseline	954	2.10	5.77	1264	1.02	5.20
AV-3 – Baseline	846	3.57	7.31	1133	2.74	6.64
AV-6 – Baseline	769	1.75	7.34	1051	0.86	6.78
Lp(a) (mg/dl)						
Baseline	1141	26.81	26.19	1449	27.34	27.77
AV-1	1005	25.40	27.00	1351	25.26	27.27
AV-3	872	22.09	21.88	1182	22.71	23.33
AV-6	814	30.30	26.94	1121	31.47	28.69
AV-1 – Baseline	970	-1.12	10.84	1303	-2.00	10.88
AV-3 – Baseline	841	-4.42	15.18	1140	-4.31	15.12
AV-6 – Baseline	780	4.03	16.98	1077	4.47	15.67

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.3
Bone Mineral Density¹ Analysis: HRT Participants

Data as of September 12, 2005; Events through Study Closeout

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline	938	1.01	0.11	1025	0.99	0.10
AV1	843	1.01	0.11	928	1.00	0.10
AV3	775	1.03	0.12	857	1.02	0.10
AV6	689	1.04	0.12	746	1.02	0.11
AV9	343	1.06	0.13	357	1.05	0.13
AV1 % Change from baseline BMD ²	841	0.44	2.81	925	0.26	2.35
AV3 % Change from baseline BMD ²	773	2.17	4.41	852	1.99	3.81
AV6 % Change from baseline BMD ²	682	2.58	5.78	733	2.56	5.40
AV9 % Change from baseline BMD ²	219	3.57	7.89	244	3.46	7.26
Spine Scan						
Baseline	903	0.97	0.16	985	0.95	0.16
AV1	815	0.99	0.16	887	0.97	0.16
AV3	755	1.00	0.17	827	0.99	0.17
AV6	656	1.01	0.17	719	0.99	0.17
AV9	333	1.00	0.17	338	0.98	0.17
AV1 % Change from baseline BMD ²	811	1.98	4.56	885	2.18	4.33
AV3 % Change from baseline BMD ²	751	3.51	6.16	824	4.10	6.05
AV6 % Change from baseline BMD ²	648	4.38	7.58	707	4.83	7.58
AV9 % Change from baseline BMD ²	212	5.39	9.41	230	5.57	8.54
Hip Scan						
Baseline	934	0.86	0.14	1024	0.84	0.13
AV1	841	0.86	0.14	928	0.84	0.13
AV3	775	0.88	0.14	860	0.86	0.13
AV6	688	0.86	0.14	757	0.84	0.13
AV9	344	0.86	0.15	357	0.84	0.13
AV1 % Change from baseline BMD ²	838	0.75	3.21	925	0.67	3.12
AV3 % Change from baseline BMD ²	769	2.04	4.62	854	1.98	4.55
AV6 % Change from baseline BMD ²	678	-0.07	5.73	737	0.33	5.60
AV9 % Change from baseline BMD ²	219	-1.50	6.69	244	-1.48	6.45

¹ Measured in (g/cm³).

² AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 2.4
Lost-to-Follow-up and Vital Status: HRT Participants by Hysterectomy Status

Data as of September 12, 2005; Events through Study Closeout

Vital Status/Participation	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Deceased	727	6.8	918	5.5	1645	6.0
Alive: Current Participation ¹	9302	86.6	14897	89.7	24199	88.5
Alive: Recent Participation ²	89	0.8	78	0.5	167	0.6
Alive: Past/Unknown Participation ³	4	<0.1	4	<0.1	8	<0.1
Stopped Follow-Up ⁴	475	4.4	538	3.2	1013	3.7
Lost to Follow-Up ⁵	142	1.3	173	1.0	315	1.2

¹ Participants who have filled in a Form 33 within the last 9 months.

² Participants who last filled in a Form 33 between 9 and 18 months ago.

³ Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

⁴ Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.

⁵ Participants not in any of the above categories.

Table 2.5
Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of September 12, 2005; Events through Study Closeout

Outcomes	Age				
	Total	50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	94.5	100.2	97.2	93.6	90.7
Cardiovascular					
CHD ¹	1047 (0.49%)	52 (0.18%)	111 (0.25%)	481 (0.50%)	403 (0.87%)
CHD death ²	300 (0.14%)	13 (0.05%)	22 (0.05%)	121 (0.13%)	144 (0.31%)
Total MI ³	840 (0.39%)	41 (0.14%)	96 (0.22%)	388 (0.40%)	315 (0.68%)
Clinical MI	806 (0.37%)	40 (0.14%)	94 (0.21%)	371 (0.38%)	301 (0.65%)
Evolving Q-wave MI ⁴	35 (0.02%)	1 (<0.01%)	2 (<0.01%)	18 (0.02%)	14 (0.03%)
Possible evolving Q-wave MI ⁴	173 (0.08%)	18 (0.06%)	22 (0.05%)	71 (0.07%)	62 (0.13%)
Angina	1085 (0.50%)	52 (0.18%)	139 (0.32%)	525 (0.54%)	369 (0.79%)
CABG/PTCA	1256 (0.58%)	58 (0.20%)	165 (0.38%)	621 (0.64%)	412 (0.89%)
Carotid artery disease	221 (0.10%)	5 (0.02%)	23 (0.05%)	117 (0.12%)	76 (0.16%)
Congestive heart failure	804 (0.37%)	41 (0.14%)	75 (0.17%)	332 (0.34%)	356 (0.77%)
Stroke	730 (0.34%)	27 (0.09%)	69 (0.16%)	322 (0.33%)	312 (0.67%)
Non-disabling stroke	407 (0.19%)	21 (0.07%)	48 (0.11%)	172 (0.18%)	166 (0.36%)
Fatal/disabling stroke	266 (0.12%)	3 (0.01%)	15 (0.03%)	121 (0.13%)	127 (0.27%)
Unknown status from stroke	57 (0.03%)	3 (0.01%)	6 (0.01%)	29 (0.03%)	19 (0.04%)
PVD	206 (0.10%)	8 (0.03%)	19 (0.04%)	109 (0.11%)	70 (0.15%)
DVT	407 (0.19%)	23 (0.08%)	54 (0.12%)	187 (0.19%)	143 (0.31%)
Pulmonary embolism	286 (0.13%)	19 (0.07%)	44 (0.10%)	137 (0.14%)	86 (0.18%)
CHD ¹ /Possible evolving Q-wave MI	1208 (0.56%)	70 (0.25%)	133 (0.30%)	548 (0.57%)	457 (0.98%)
Coronary disease ⁵	2711 (1.26%)	146 (0.51%)	320 (0.73%)	1261 (1.31%)	984 (2.12%)
DVT/PE	558 (0.26%)	31 (0.11%)	74 (0.17%)	271 (0.28%)	182 (0.39%)
Total cardiovascular disease	3967 (1.84%)	206 (0.72%)	468 (1.07%)	1852 (1.92%)	1441 (3.10%)
Cancer					
Breast cancer	941 (0.44%)	90 (0.32%)	171 (0.39%)	446 (0.46%)	234 (0.50%)
Invasive breast cancer	758 (0.35%)	66 (0.23%)	141 (0.32%)	351 (0.36%)	200 (0.43%)
Non-invasive breast cancer	187 (0.09%)	24 (0.08%)	31 (0.07%)	98 (0.10%)	34 (0.07%)
Ovarian cancer	79 (0.04%)	3 (0.01%)	16 (0.04%)	41 (0.04%)	19 (0.04%)
Endometrial cancer ⁶	96 (0.04%)	5 (0.02%)	23 (0.05%)	51 (0.05%)	17 (0.04%)
Colorectal cancer	325 (0.15%)	18 (0.06%)	34 (0.08%)	164 (0.17%)	109 (0.23%)
Other cancer ⁷	1270 (0.59%)	96 (0.34%)	176 (0.40%)	597 (0.62%)	401 (0.86%)
Total cancer	2597 (1.21%)	206 (0.72%)	410 (0.93%)	1239 (1.28%)	742 (1.59%)
Fractures					
Hip fracture	381 (0.18%)	3 (0.01%)	22 (0.05%)	117 (0.12%)	239 (0.51%)
Vertebral fracture	364 (0.17%)	12 (0.04%)	38 (0.09%)	142 (0.15%)	172 (0.37%)
Other fracture ⁷	3268 (1.52%)	362 (1.27%)	515 (1.17%)	1530 (1.59%)	861 (1.85%)
Total fracture	3789 (1.76%)	374 (1.31%)	562 (1.28%)	1711 (1.77%)	1142 (2.45%)
Deaths					
Cardiovascular deaths	535 (0.25%)	22 (0.08%)	39 (0.09%)	207 (0.21%)	267 (0.57%)
Cancer deaths	713 (0.33%)	34 (0.12%)	86 (0.20%)	339 (0.35%)	254 (0.55%)
Other known cause	328 (0.15%)	15 (0.05%)	44 (0.10%)	125 (0.13%)	144 (0.31%)
Unknown cause	65 (0.03%)	4 (0.01%)	5 (0.01%)	29 (0.03%)	27 (0.06%)
Not yet adjudicated	4 (<0.01%)	0 (0.00%)	0 (0.00%)	2 (<0.01%)	2 (<0.01%)
Total death	1645 (0.76%)	75 (0.26%)	174 (0.40%)	702 (0.73%)	694 (1.49%)

¹ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.² "CHD death" includes definite and possible CHD death.³ "Total MI" includes clinical MI and evolving Q-wave MI.⁴ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.⁵ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.⁶ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.⁷ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.5 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Replacement Therapy

Data as of September 12, 2005; Events through Study Closeout

Outcomes	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	91.6	90.1	93.8	91.9	95.0	90.9
Cardiovascular						
CHD ¹	5 (0.50%)	13 (0.33%)	105 (0.49%)	31 (0.26%)	873 (0.50%)	20 (0.69%)
CHD death ²	2 (0.20%)	5 (0.13%)	50 (0.23%)	6 (0.05%)	234 (0.13%)	3 (0.10%)
Total MI ³	4 (0.40%)	11 (0.28%)	69 (0.32%)	26 (0.22%)	712 (0.41%)	18 (0.62%)
Clinical MI	4 (0.40%)	10 (0.25%)	68 (0.32%)	24 (0.20%)	683 (0.39%)	17 (0.58%)
Evolving Q-wave MI ⁴	0 (0.00%)	1 (0.03%)	1 (<0.01%)	2 (0.02%)	30 (0.02%)	1 (0.03%)
Possible evolving Q-wave MI ⁴	0 (0.00%)	2 (0.05%)	19 (0.09%)	8 (0.07%)	142 (0.08%)	2 (0.07%)
Angina	7 (0.71%)	14 (0.35%)	126 (0.59%)	44 (0.37%)	882 (0.51%)	12 (0.41%)
CABG/PTCA	7 (0.71%)	12 (0.30%)	113 (0.53%)	47 (0.40%)	1060 (0.61%)	17 (0.58%)
Carotid artery disease	1 (0.10%)	1 (0.03%)	8 (0.04%)	2 (0.02%)	207 (0.12%)	2 (0.07%)
Congestive heart failure	3 (0.30%)	9 (0.23%)	99 (0.46%)	29 (0.25%)	653 (0.37%)	11 (0.38%)
Stroke	5 (0.50%)	14 (0.35%)	99 (0.46%)	22 (0.19%)	578 (0.33%)	12 (0.41%)
Non-disabling stroke	3 (0.30%)	8 (0.20%)	48 (0.22%)	13 (0.11%)	329 (0.19%)	6 (0.21%)
Fatal/disabling stroke	2 (0.20%)	6 (0.15%)	40 (0.19%)	6 (0.05%)	208 (0.12%)	4 (0.14%)
Unknown status from stroke	0 (0.00%)	0 (0.00%)	11 (0.05%)	3 (0.03%)	41 (0.02%)	2 (0.07%)
PVD	2 (0.20%)	1 (0.03%)	21 (0.10%)	2 (0.02%)	180 (0.10%)	0 (0.00%)
DVT	1 (0.10%)	2 (0.05%)	42 (0.20%)	7 (0.06%)	353 (0.20%)	2 (0.07%)
Pulmonary embolism	3 (0.30%)	1 (0.03%)	34 (0.16%)	4 (0.03%)	242 (0.14%)	2 (0.07%)
CHD ¹ /Possible evolving Q-wave MI	5 (0.50%)	15 (0.38%)	123 (0.57%)	39 (0.33%)	1004 (0.58%)	22 (0.75%)
Coronary disease ⁵	12 (1.21%)	31 (0.78%)	304 (1.42%)	101 (0.86%)	2225 (1.28%)	38 (1.30%)
DVT/PE	4 (0.40%)	2 (0.05%)	60 (0.28%)	9 (0.08%)	480 (0.28%)	3 (0.10%)
Total cardiovascular disease	19 (1.91%)	45 (1.14%)	442 (2.07%)	130 (1.10%)	3284 (1.88%)	47 (1.61%)
Cancer						
Breast cancer	3 (0.30%)	20 (0.51%)	84 (0.39%)	30 (0.25%)	796 (0.46%)	8 (0.27%)
Invasive breast cancer	3 (0.30%)	15 (0.38%)	68 (0.32%)	23 (0.20%)	643 (0.37%)	6 (0.21%)
Non-invasive breast cancer	0 (0.00%)	5 (0.13%)	16 (0.07%)	7 (0.06%)	157 (0.09%)	2 (0.07%)
Ovarian cancer	0 (0.00%)	1 (0.03%)	6 (0.03%)	0 (0.00%)	70 (0.04%)	2 (0.07%)
Endometrial cancer ⁶	1 (0.10%)	0 (0.00%)	5 (0.02%)	5 (0.04%)	84 (0.05%)	1 (0.03%)
Colorectal cancer	1 (0.10%)	8 (0.20%)	28 (0.13%)	13 (0.11%)	269 (0.15%)	6 (0.21%)
Other cancer ⁷	7 (0.71%)	24 (0.61%)	96 (0.45%)	40 (0.34%)	1089 (0.62%)	14 (0.48%)
Total cancer	12 (1.21%)	53 (1.34%)	210 (0.98%)	83 (0.71%)	2211 (1.27%)	28 (0.96%)
Fractures						
Hip fracture	1 (0.10%)	4 (0.10%)	10 (0.05%)	7 (0.06%)	357 (0.20%)	2 (0.07%)
Vertebral fracture	2 (0.20%)	5 (0.13%)	5 (0.02%)	6 (0.05%)	341 (0.20%)	5 (0.17%)
Other fracture ⁷	13 (1.31%)	41 (1.04%)	174 (0.81%)	108 (0.92%)	2890 (1.66%)	42 (1.44%)
Total fracture	15 (1.51%)	47 (1.19%)	187 (0.87%)	115 (0.98%)	3380 (1.94%)	45 (1.54%)
Deaths						
Cardiovascular deaths	3 (0.30%)	10 (0.25%)	88 (0.41%)	10 (0.08%)	419 (0.24%)	5 (0.17%)
Cancer deaths	5 (0.50%)	14 (0.35%)	64 (0.30%)	22 (0.19%)	599 (0.34%)	9 (0.31%)
Other known cause	4 (0.40%)	2 (0.05%)	31 (0.14%)	3 (0.03%)	282 (0.16%)	6 (0.21%)
Unknown cause	0 (0.00%)	1 (0.03%)	15 (0.07%)	2 (0.02%)	46 (0.03%)	1 (0.03%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.01%)	3 (<0.01%)	0 (0.00%)
Total Death	12 (1.21%)	27 (0.68%)	198 (0.93%)	38 (0.32%)	1349 (0.77%)	21 (0.72%)

¹ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

² "CHD death" includes definite and possible CHD death.

³ "Total MI" includes clinical MI and evolving Q-wave MI.

⁴ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁵ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁶ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

⁷ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.6
Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of September 12, 2005; Events through Study Closeout

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	94.0		94.8	
Cardiovascular				
CHD ¹	492	(0.58%)	555	(0.42%)
CHD death ²	159	(0.19%)	141	(0.11%)
Total MI ³	386	(0.46%)	454	(0.35%)
Clinical MI	371	(0.44%)	435	(0.33%)
Evolving Q-wave MI ⁴	15	(0.02%)	20	(0.02%)
Possible evolving Q-wave MI ⁴	64	(0.08%)	109	(0.08%)
Angina	570	(0.68%)	515	(0.39%)
CABG/PTCA	593	(0.70%)	663	(0.51%)
Carotid artery disease	117	(0.14%)	104	(0.08%)
Congestive heart failure	421	(0.50%)	383	(0.29%)
Stroke	321	(0.38%)	409	(0.31%)
Non-disabling stroke	169	(0.20%)	238	(0.18%)
Fatal/disabling stroke	120	(0.14%)	146	(0.11%)
Unknown status from stroke	32	(0.04%)	25	(0.02%)
PVD	95	(0.11%)	111	(0.08%)
DVT	159	(0.19%)	248	(0.19%)
Pulmonary embolism	107	(0.13%)	179	(0.14%)
CHD ¹ /Possible evolving Q-wave MI	552	(0.66%)	656	(0.50%)
Coronary disease ⁵	1321	(1.57%)	1390	(1.06%)
DVT/PE	222	(0.26%)	336	(0.26%)
Total cardiovascular disease	1856	(2.21%)	2111	(1.61%)
Cancer				
Breast cancer	316	(0.38%)	625	(0.48%)
Invasive breast cancer	260	(0.31%)	498	(0.38%)
Non-invasive breast cancer	57	(0.07%)	130	(0.10%)
Ovarian cancer	20	(0.02%)	59	(0.04%)
Endometrial cancer ⁶	0	N/A	96	(0.07%)
Colorectal cancer	136	(0.16%)	189	(0.14%)
Other cancer ⁷	501	(0.60%)	769	(0.59%)
Total cancer	944	(1.12%)	1653	(1.26%)
Fractures				
Hip fracture	142	(0.17%)	239	(0.18%)
Vertebral fracture	137	(0.16%)	227	(0.17%)
Other fracture ⁷	1266	(1.50%)	2002	(1.53%)
Total fracture	1462	(1.74%)	2327	(1.77%)
Deaths				
Cardiovascular deaths	258	(0.31%)	277	(0.21%)
Cancer deaths	302	(0.36%)	411	(0.31%)
Other known cause	137	(0.16%)	191	(0.15%)
Unknown cause	28	(0.03%)	37	(0.03%)
Not yet adjudicated	2	(<0.01%)	2	(<0.01%)
Total death	727	(0.86%)	918	(0.70%)

¹ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

² "CHD death" includes definite and possible CHD death.

³ "Total MI" includes clinical MI and evolving Q-wave MI.

⁴ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁵ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁶ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

⁷ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.7
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity
for HRT Participants who did not report a prevalent condition at baseline

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	94.5	100.2	97.3	93.6	90.7
Hospitalizations					
Ever	14124 (6.56%)	1267 (4.44%)	2254 (5.14%)	6584 (6.83%)	4019 (8.64%)
Two or more	8033 (3.73%)	597 (2.09%)	1140 (2.60%)	3739 (3.88%)	2557 (5.49%)
Other					
Diabetes (treated)	2305 (1.13%)	319 (1.16%)	444 (1.07%)	1074 (1.18%)	468 (1.07%)
Gallbladder disease ¹	2117 (1.18%)	282 (1.15%)	443 (1.18%)	988 (1.24%)	404 (1.07%)
Hysterectomy	719 (0.55%)	62 (0.37%)	135 (0.48%)	365 (0.62%)	157 (0.58%)
Glaucoma	3201 (1.55%)	286 (1.02%)	548 (1.28%)	1519 (1.64%)	848 (1.97%)
Osteoporosis	6111 (2.99%)	475 (1.69%)	962 (2.26%)	2954 (3.23%)	1720 (4.10%)
Osteoarthritis ²	4946 (3.69%)	630 (2.90%)	997 (3.25%)	2257 (3.90%)	1062 (4.48%)
Rheumatoid arthritis	1696 (0.82%)	211 (0.77%)	341 (0.81%)	763 (0.83%)	381 (0.87%)
Intestinal polyps	4047 (2.02%)	417 (1.51%)	733 (1.75%)	2050 (2.29%)	847 (2.06%)
Lupus	305 (0.14%)	35 (0.12%)	65 (0.15%)	138 (0.14%)	67 (0.14%)
Kidney stones ²	769 (0.42%)	94 (0.40%)	143 (0.39%)	346 (0.42%)	186 (0.46%)
Cataracts ²	8646 (5.34%)	505 (2.12%)	1344 (3.66%)	4577 (6.19%)	2220 (8.09%)
Pills for hypertension	7513 (4.91%)	839 (3.64%)	1467 (4.33%)	3445 (5.15%)	1762 (6.03%)

Outcomes	Race/Ethnicity					
	Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	91.6	90.1	93.8	91.9	95.0	90.9
Hospitalizations						
Ever	70 (7.05%)	202 (5.10%)	1439 (6.72%)	623 (5.29%)	11605 (6.66%)	185 (6.34%)
Two or more	46 (4.64%)	96 (2.42%)	845 (3.95%)	304 (2.58%)	6642 (3.81%)	100 (3.43%)
Other						
Diabetes (treated)	13 (1.51%)	52 (1.44%)	366 (1.95%)	209 (1.93%)	1632 (0.98%)	33 (1.22%)
Gallbladder disease ¹	13 (1.72%)	32 (0.89%)	187 (0.97%)	129 (1.47%)	1730 (1.20%)	26 (1.08%)
Hysterectomy	2 (0.48%)	6 (0.22%)	45 (0.51%)	36 (0.53%)	623 (0.56%)	7 (0.39%)
Glaucoma	16 (1.73%)	60 (1.57%)	408 (2.07%)	190 (1.67%)	2480 (1.48%)	47 (1.73%)
Osteoporosis	32 (3.41%)	141 (3.71%)	348 (1.69%)	338 (3.08%)	5159 (3.12%)	93 (3.36%)
Osteoarthritis ²	30 (0.14%)	104 (0.34%)	506 (0.87%)	346 (1.46%)	3883 (1.42%)	77 (4.08%)
Rheumatoid arthritis	15 (1.71%)	30 (0.79%)	272 (1.39%)	219 (1.96%)	1125 (0.67%)	35 (1.27%)
Intestinal polyps	21 (2.30%)	65 (1.80%)	421 (2.11%)	197 (1.75%)	3301 (2.04%)	42 (1.56%)
Lupus	2 (0.20%)	4 (0.10%)	34 (0.16%)	24 (0.21%)	240 (0.14%)	1 (0.03%)
Kidney stones ²	9 (0.04%)	25 (0.07%)	82 (0.10%)	62 (0.15%)	583 (0.15%)	8 (0.32%)
Cataracts ²	44 (0.18%)	143 (0.39%)	790 (1.07%)	450 (1.64%)	7106 (2.11%)	113 (5.15%)
Pills for hypertension	47 (6.74%)	140 (5.05%)	686 (6.47%)	471 (5.34%)	6083 (4.75%)	86 (4.53%)

¹ "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

² These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 3.1
Dietary Modification Component Age - and Race/Ethnicity - Specific Recruitment

Data as of September 12, 2005; Events through Study Closeout

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	48,835			
50-54	6,961	149%	14%	10%
55-59	11,037	118%	23%	20%
60-69	22,715	108%	47%	45%
70-79	8,122	70%	17%	25%
Race/Ethnicity	48,835			
American Indian	202		<1%	
Asian	1,105		2%	
Black	5,262		11%	
Hispanic	1,845		4%	
White	39,762		81%	
Unknown	659		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of September 12, 2005; Events through Study Closeout

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean ¹	SE	p-value ²
% Energy from Fat									
FFQ Baseline	19541	38.8	5.0	29294	38.8	5.0	0.0	0.0	0.83
FFQ Year 1 ³	18099	25.2	7.5	26776	36.1	6.9	10.9	0.1	<.01
FFQ Year 2 ⁴	5929	26.3	7.6	8670	36.3	7.0	9.9	0.1	<.01
FFQ Year 3 ⁵	3241	27.7	7.9	4890	37.3	7.1	9.6	0.2	<.01
FFQ Year 4 ⁶	5056	28.6	8.1	7878	37.6	7.1	9.0	0.1	<.01
FFQ Year 5 ⁷	5815	29.1	8.2	9001	37.8	7.3	8.7	0.1	<.01
FFQ Year 6 ⁸	7142	29.8	8.3	10836	38.0	7.2	8.2	0.1	<.01
FFQ Year 7 ⁹	4621	30.5	8.6	7215	38.3	7.4	7.8	0.1	<.01
FFQ Year 8 ¹⁰	2702	30.9	8.7	4432	38.6	7.5	7.7	0.2	<.01
FFQ Year 9 ¹¹	1569	31.5	8.5	2338	38.8	7.8	7.3	0.3	<.01
FFQ Year 10 ¹²	416	32.0	8.6	625	38.6	7.4	6.6	0.5	<.01
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	805	21.7	7.3	1171	32.9	6.8	11.3	0.3	<.01
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	<.01
24 Hr Recall, Year 2	214	23.8	9.7	244	32.5	8.0	8.7	0.8	<.01
24 Hr Recall, Year 3	209	25.1	9.2	249	33.3	8.6	8.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	24.8	8.5	1183	33.0	7.6	8.3	0.4	<.01
24 Hr Recall, Year 4	222	25.8	9.2	251	33.4	8.5	7.6	0.8	<.01
24 Hr Recall, Year 5	196	26.4	9.4	248	34.1	8.7	7.6	0.9	<.01
24 Hr Recall, Year 6	194	27.9	9.9	221	35.1	8.1	7.2	0.9	<.01
24 Hr Recall, Year 6 Cohort	766	26.6	9.1	1167	33.9	7.8	7.3	0.4	<.01
24 Hr Recall, Year 7	133	27.5	9.5	143	34.6	8.4	7.1	1.1	<.01
24 Hr Recall, Year 8	68	29.7	9.0	91	36.2	9.4	6.5	1.5	<.01
24 Hr Recall, Year 9	24	27.3	8.8	34	37.1	8.4	9.7	2.3	<.01
24 Hr Recall, Year 9 Cohort	154	28.5	8.6	264	35.2	8.4	6.7	0.9	<.01

¹ Absolute difference.

² P-values based on testing in the natural log scale except for % Energy from fat.

³ 4954 (27%) Intervention women had <=20% energy from fat at year 1.

⁴ 1270 (21%) Intervention women had <=20% energy from fat at year 2.

⁵ 566 (17%) Intervention women had <=20% energy from fat at year 3.

⁶ 769 (15%) Intervention women had <=20% energy from fat at year 4.

⁷ 785 (13%) Intervention women had <=20% energy from fat at year 5.

⁸ 769 (11%) Intervention women had <=20% energy from fat at year 6.

⁹ 479 (10%) Intervention women had <=20% energy from fat at year 7.

¹⁰ 267 (10%) Intervention women had <=20% energy from fat at year 8.

¹¹ 110 (7%) Intervention women had <=20% energy from fat at year 9.

¹² 21 (5%) Intervention women had <=20% energy from fat at year 10.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of September 12, 2005; Events through Study Closeout

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean ¹	SE	p-value ²
Total Energy (kcal)									
FFQ Baseline	19541	1789.1	713.3	29294	1789.4	706.6	0.3	6.6	0.93
FFQ Year 1	18099	1473.9	534.5	26776	1584.3	641.6	110.4	5.8	<.01
FFQ Year 2	5929	1479.4	534.7	8670	1575.7	625.5	96.3	9.9	<.01
FFQ Year 3	3241	1476.1	538.0	4890	1571.5	644.3	95.4	13.7	<.01
FFQ Year 4	5056	1443.0	536.5	7878	1561.9	635.0	118.9	10.8	<.01
FFQ Year 5	5815	1450.9	539.7	9001	1552.5	638.6	101.6	10.1	<.01
FFQ Year 6	7142	1410.5	552.5	10836	1533.1	634.4	122.6	9.2	<.01
FFQ Year 7	4621	1394.1	534.2	7215	1529.4	638.4	135.3	11.3	<.01
FFQ Year 8	2702	1383.8	540.1	4432	1530.5	638.5	146.8	14.7	<.01
FFQ Year 9	1569	1394.1	591.0	2338	1488.2	607.6	94.1	19.6	<.01
FFQ Year 10	416	1402.1	566.9	625	1483.2	600.6	81.2	37.2	0.02
4DFR Baseline	892	1707.2	454.3	1351	1712.9	459.4	5.7	19.7	0.79
4DFR Year 1	805	1422.8	355.7	1171	1627.0	446.9	204.2	18.9	<.01
24 Hr Recall, Post-baseline	226	1519.8	418.2	262	1652.8	516.5	133.0	43.0	<.01
24 Hr Recall, Year 1	221	1482.1	417.8	268	1635.8	477.0	153.6	41.0	<.01
24 Hr Recall, Year 2	214	1436.4	430.0	244	1603.8	523.4	167.4	45.1	<.01
24 Hr Recall, Year 3	209	1443.3	427.8	249	1589.2	504.2	145.9	44.2	<.01
24 Hr Recall, Year 3 Cohort	787	1431.8	391.6	1183	1589.9	489.3	158.1	20.8	<.01
24 Hr Recall, Year 4	222	1431.8	395.7	251	1537.2	461.8	105.4	39.8	0.02
24 Hr Recall, Year 5	196	1382.8	467.6	248	1563.1	508.8	180.3	46.9	<.01
24 Hr Recall, Year 6	194	1364.6	435.7	221	1651.7	550.6	287.1	49.2	<.01
24 Hr Recall, Year 6 Cohort	766	1388.8	391.0	1167	1544.2	482.1	155.4	20.8	<.01
24 Hr Recall, Year 7	133	1359.4	395.8	143	1518.5	487.5	159.1	53.7	0.01
24 Hr Recall, Year 8	68	1366.8	388.5	91	1541.9	500.1	175.2	73.1	0.02
24 Hr Recall, Year 9	24	1289.2	375.0	34	1445.2	386.7	155.9	101.8	0.13
24 Hr Recall, Year 9 Cohort	154	1406.7	384.6	264	1516.8	452.9	110.2	43.5	0.02
Total Fat (g)									
FFQ Baseline	19541	77.9	35.3	29294	77.8	34.7	0.0	0.3	0.87
FFQ Year 1	18099	41.5	21.8	26776	64.5	31.7	23.0	0.3	<.01
FFQ Year 2	5929	43.4	22.3	8670	64.5	31.3	21.0	0.5	<.01
FFQ Year 3	3241	45.8	23.7	4890	66.0	32.5	20.2	0.7	<.01
FFQ Year 4	5056	46.2	23.9	7878	66.2	32.2	20.0	0.5	<.01
FFQ Year 5	5815	47.4	24.5	9001	66.2	32.8	18.8	0.5	<.01
FFQ Year 6	7142	47.0	24.7	10836	65.6	32.5	18.6	0.5	<.01
FFQ Year 7	4621	47.7	25.2	7215	66.1	33.1	18.4	0.6	<.01
FFQ Year 8	2702	47.9	25.2	4432	66.5	33.0	18.7	0.7	<.01
FFQ Year 9	1569	49.2	27.6	2338	64.9	31.7	15.7	1.0	<.01
FFQ Year 10	416	50.1	27.4	625	64.3	30.5	14.2	1.9	<.01
4DFR Baseline	892	63.0	23.6	1351	63.8	24.6	0.8	1.0	0.71
4DFR Year 1	805	34.1	14.5	1171	60.4	23.5	26.3	0.9	<.01
24 Hr Recall, Post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	<.01
24 Hr Recall, Year 1	221	36.9	17.1	268	60.6	25.1	23.7	2.0	<.01
24 Hr Recall, Year 2	214	38.8	22.6	244	59.3	27.2	20.5	2.4	<.01
24 Hr Recall, Year 3	209	40.9	21.2	249	60.3	27.9	19.4	2.4	<.01
24 Hr Recall, Year 3 Cohort	787	39.8	18.7	1183	59.9	25.6	20.0	1.1	<.01
24 Hr Recall, Year 4	222	41.4	20.1	251	58.7	25.8	17.2	2.1	<.01
24 Hr Recall, Year 5	196	41.3	23.5	248	60.5	27.4	19.2	2.5	<.01
24 Hr Recall, Year 6	194	42.6	21.7	221	66.0	29.8	23.4	2.6	<.01
24 Hr Recall, Year 6 Cohort	766	41.5	20.0	1167	59.7	26.1	18.1	1.1	<.01
24 Hr Recall, Year 7	133	42.7	22.5	143	59.0	24.3	16.3	2.8	<.01
24 Hr Recall, Year 8	68	45.4	19.0	91	63.6	31.2	18.2	4.3	<.01
24 Hr Recall, Year 9	24	40.3	20.3	34	60.9	25.5	20.6	6.3	<.01
24 Hr Recall, Year 9 Cohort	154	45.1	18.6	264	60.9	26.3	15.9	2.4	<.01

¹ Absolute difference.² P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of September 12, 2005; Events through Study Closeout

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean ¹	SE	p-value ²
Saturated Fat (g)									
FFQ Baseline	19541	27.4	13.4	29294	27.3	13.2	0.1	0.1	0.85
FFQ Year 1	18099	14.2	8.1	26776	22.5	11.9	8.4	0.1	<.01
FFQ Year 2	5929	14.8	8.2	8670	22.5	11.7	7.7	0.2	<.01
FFQ Year 3	3241	15.5	8.9	4890	22.9	12.2	7.4	0.2	<.01
FFQ Year 4	5056	15.7	8.9	7878	23.1	12.2	7.4	0.2	<.01
FFQ Year 5	5815	16.2	9.1	9001	23.2	12.4	7.0	0.2	<.01
FFQ Year 6	7142	15.9	9.1	10836	22.9	12.3	6.9	0.2	<.01
FFQ Year 7	4621	16.4	9.4	7215	23.1	12.6	6.7	0.2	<.01
FFQ Year 8	2702	16.3	9.3	4432	23.3	12.7	7.0	0.3	<.01
FFQ Year 9	1569	16.9	10.2	2338	22.7	11.9	5.9	0.4	<.01
FFQ Year 10	416	17.3	10.3	625	22.9	11.9	5.6	0.7	<.01
4DFR Baseline	892	20.6	8.9	1351	20.9	9.3	0.3	0.4	0.72
4DFR Year 1	805	10.6	5.2	1171	19.5	8.3	9.0	0.3	<.01
24 Hr Recall, Post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	<.01
24 Hr Recall, Year 1	221	11.7	6.2	268	20.1	10.1	8.4	0.8	<.01
24 Hr Recall, Year 2	214	12.3	8.2	244	19.5	9.9	7.2	0.9	<.01
24 Hr Recall, Year 3	209	13.4	7.7	249	20.3	10.8	6.9	0.9	<.01
24 Hr Recall, Year 3 Cohort	787	12.4	6.8	1183	19.7	9.3	7.3	0.4	<.01
24 Hr Recall, Year 4	222	13.4	7.6	251	19.7	10.2	6.3	0.8	<.01
24 Hr Recall, Year 5	196	13.2	8.1	248	20.4	10.2	7.2	0.9	<.01
24 Hr Recall, Year 6	194	13.5	7.8	221	21.6	11.4	8.1	1.0	<.01
24 Hr Recall, Year 6 Cohort	766	13.1	7.1	1167	19.5	9.7	6.4	0.4	<.01
24 Hr Recall, Year 7	133	13.0	7.4	143	19.3	8.9	6.3	1.0	<.01
24 Hr Recall, Year 8	68	14.6	6.9	91	20.6	11.0	6.0	1.5	<.01
24 Hr Recall, Year 9	24	13.3	7.9	34	19.7	7.9	6.4	2.1	<.01
24 Hr Recall, Year 9 Cohort	154	14.5	6.8	264	20.6	10.2	6.1	0.9	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	19541	15.3	7.6	29294	15.3	7.6	0.0	0.1	0.79
FFQ Year 1	18099	7.9	4.4	26776	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	5929	8.3	4.5	8670	12.4	6.5	4.1	0.1	<.01
FFQ Year 3	3241	8.8	4.7	4890	12.8	6.8	4.0	0.1	<.01
FFQ Year 4	5056	9.0	4.9	7878	12.8	6.7	3.8	0.1	<.01
FFQ Year 5	5815	9.2	5.0	9001	12.8	6.9	3.7	0.1	<.01
FFQ Year 6	7142	9.2	5.1	10836	12.7	6.7	3.5	0.1	<.01
FFQ Year 7	4621	9.2	5.1	7215	12.8	6.7	3.6	0.1	<.01
FFQ Year 8	2702	9.2	5.1	4432	12.8	6.6	3.5	0.1	<.01
FFQ Year 9	1569	9.5	5.6	2338	12.5	6.7	3.1	0.2	<.01
FFQ Year 10	416	9.6	5.7	625	12.1	6.1	2.6	0.4	<.01
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.3	0.3	0.40
4DFR Year 1	805	7.4	3.4	1171	12.7	6.2	5.3	0.2	<.01
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.6	0.5	<.01
24 Hr Recall, Year 2	214	8.3	5.7	244	12.5	7.6	4.2	0.6	<.01
24 Hr Recall, Year 3	209	8.5	5.5	249	12.2	6.6	3.8	0.6	<.01
24 Hr Recall, Year 3 Cohort	787	8.7	4.6	1183	12.2	6.9	3.6	0.3	<.01
24 Hr Recall, Year 4	222	8.7	4.9	251	11.9	6.9	3.1	0.6	<.01
24 Hr Recall, Year 5	196	8.8	6.0	248	12.0	7.5	3.3	0.7	<.01
24 Hr Recall, Year 6	194	9.1	5.8	221	13.8	7.3	4.7	0.7	<.01
24 Hr Recall, Year 6 Cohort	766	8.8	4.6	1167	12.3	6.2	3.5	0.3	<.01
24 Hr Recall, Year 7	133	9.6	6.6	143	12.2	6.4	2.6	0.8	<.01
24 Hr Recall, Year 8	68	9.4	4.7	91	13.6	7.8	4.2	1.1	<.01
24 Hr Recall, Year 9	24	8.4	4.4	34	11.7	7.6	3.3	1.7	0.04
24 Hr Recall, Year 9 Cohort	154	9.6	4.4	264	12.2	5.7	2.7	0.5	<.01

¹ Absolute difference.

² P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of September 12, 2005; Events through Study Closeout

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean ¹	SE	p-value ²
Fruits and Vegetables (servings)									
FFQ Baseline	19470	3.6	1.8	29216	3.6	1.8	0.0	0.0	0.67
FFQ Year 1	18018	5.1	2.3	26694	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	5905	5.1	2.4	8637	3.9	2.0	1.2	0.0	<.01
FFQ Year 3	3235	5.2	2.5	4876	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	5046	5.1	2.4	7864	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	5792	5.1	2.4	8975	3.8	2.1	1.2	0.0	<.01
FFQ Year 6	7118	4.9	2.5	10811	3.8	2.0	1.2	0.0	<.01
FFQ Year 7	4601	4.8	2.4	7199	3.8	2.0	1.0	0.0	<.01
FFQ Year 8	2688	4.8	2.4	4415	3.8	2.0	1.0	0.1	<.01
FFQ Year 9	1553	4.8	2.4	2321	3.7	2.0	1.1	0.1	<.01
FFQ Year 10	411	4.7	2.4	623	3.6	1.9	1.1	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19468	4.7	2.5	29214	4.8	2.5	0.0	0.0	0.41
FFQ Year 1	18014	5.1	2.7	26684	4.2	2.3	0.8	0.0	<.01
FFQ Year 2	5904	4.9	2.5	8631	4.1	2.2	0.7	0.0	<.01
FFQ Year 3	3234	4.6	2.5	4871	4.0	2.2	0.7	0.1	<.01
FFQ Year 4	5042	4.4	2.4	7852	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	5788	4.3	2.3	8963	3.8	2.1	0.5	0.0	<.01
FFQ Year 6	7115	4.1	2.3	10795	3.7	2.1	0.4	0.0	<.01
FFQ Year 7	4597	3.9	2.2	7189	3.6	2.0	0.3	0.0	<.01
FFQ Year 8	2686	3.8	2.2	4403	3.6	2.1	0.2	0.1	<.01
FFQ Year 9	1551	3.7	2.2	2316	3.4	1.9	0.3	0.1	<.01
FFQ Year 10	411	3.6	2.2	623	3.4	2.0	0.2	0.1	0.53

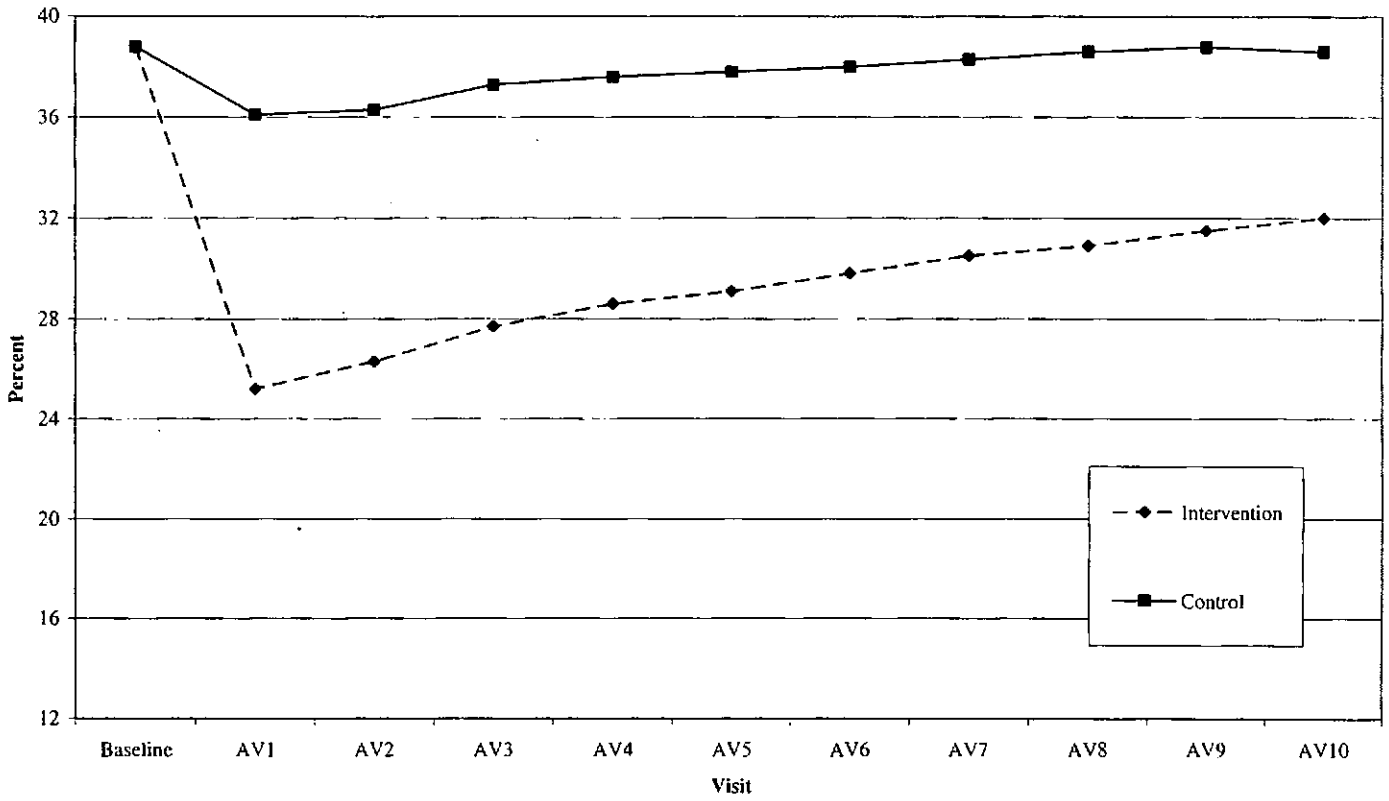
¹ Absolute difference.

² P-values based on testing in the natural log scale except for % Energy from fat.

Figure 3.1
Nutrient Intake

Data as of September 12, 2005; Events through Study Closeout

% Energy from Fat

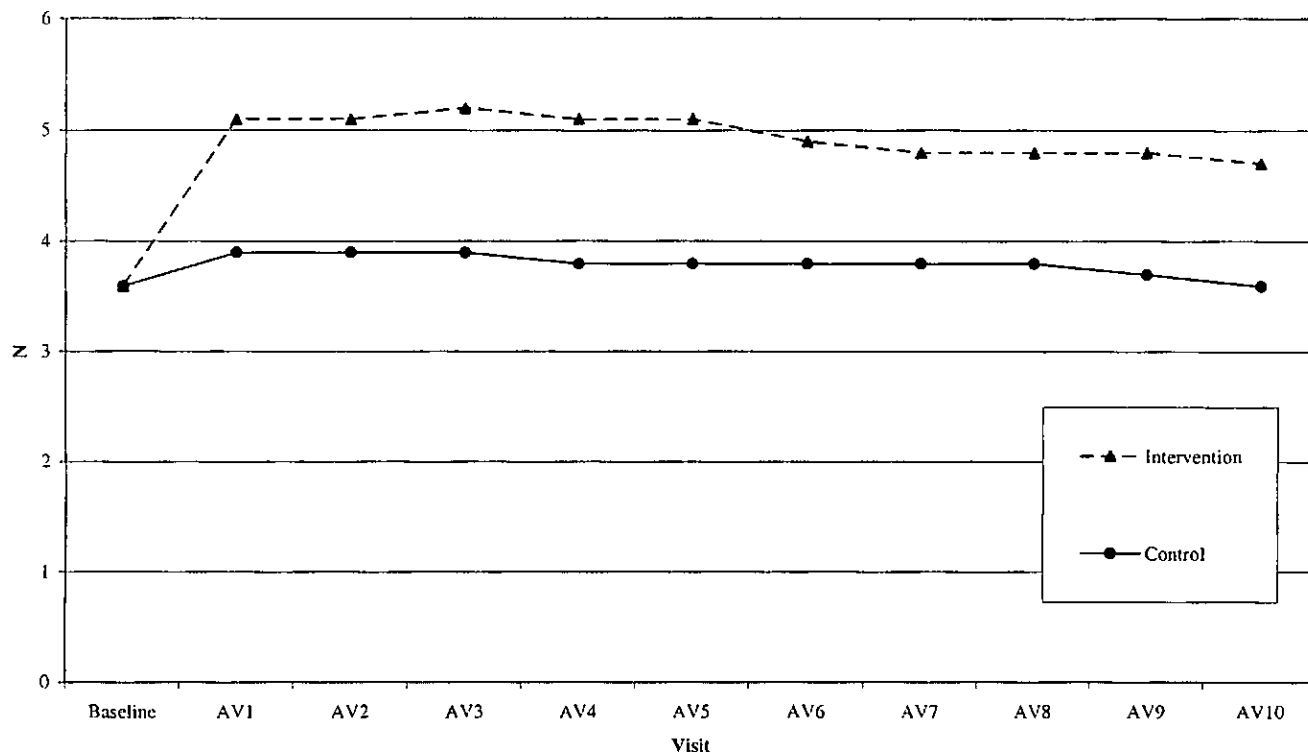


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Figure 3.1 (continued)
Nutrient Intake

Data as of September 12, 2005; Events through Study Closeout

Fruit & Vegetable Servings per Day



Grain Servings per Day

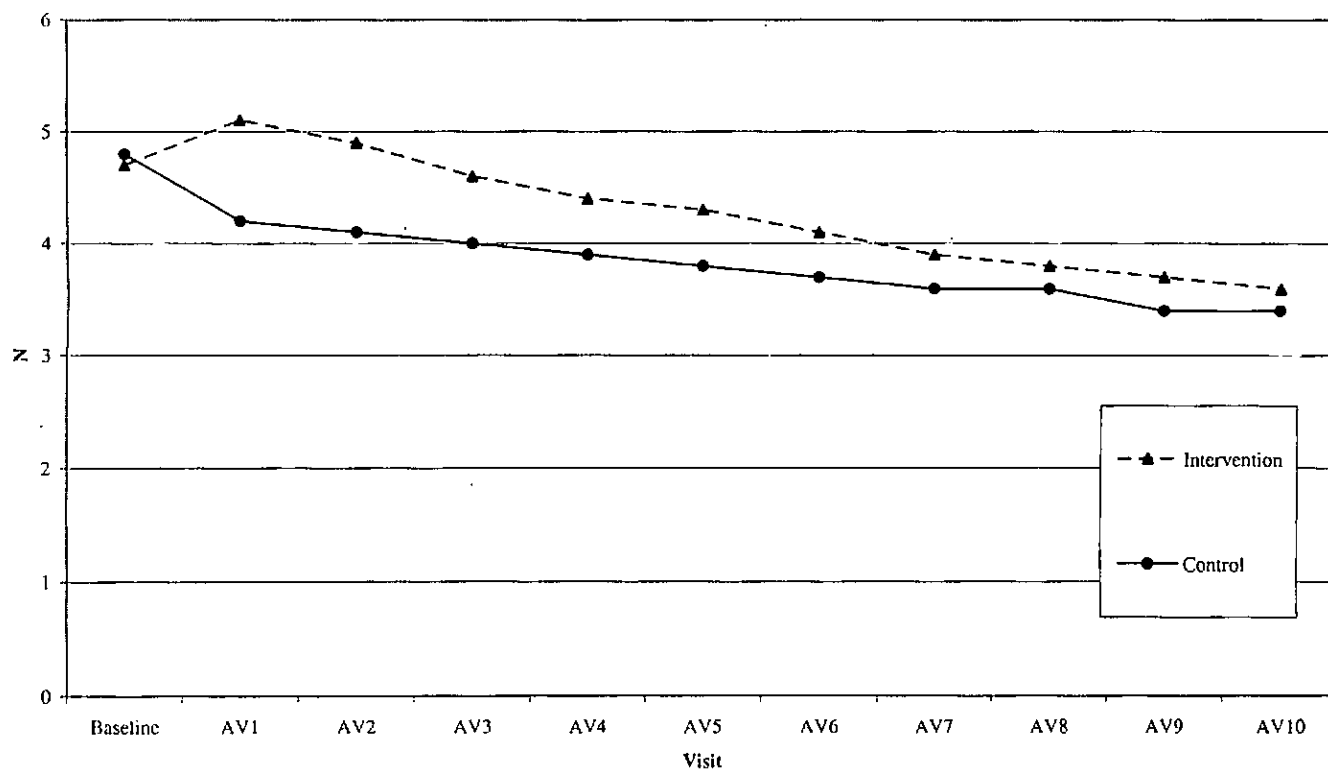
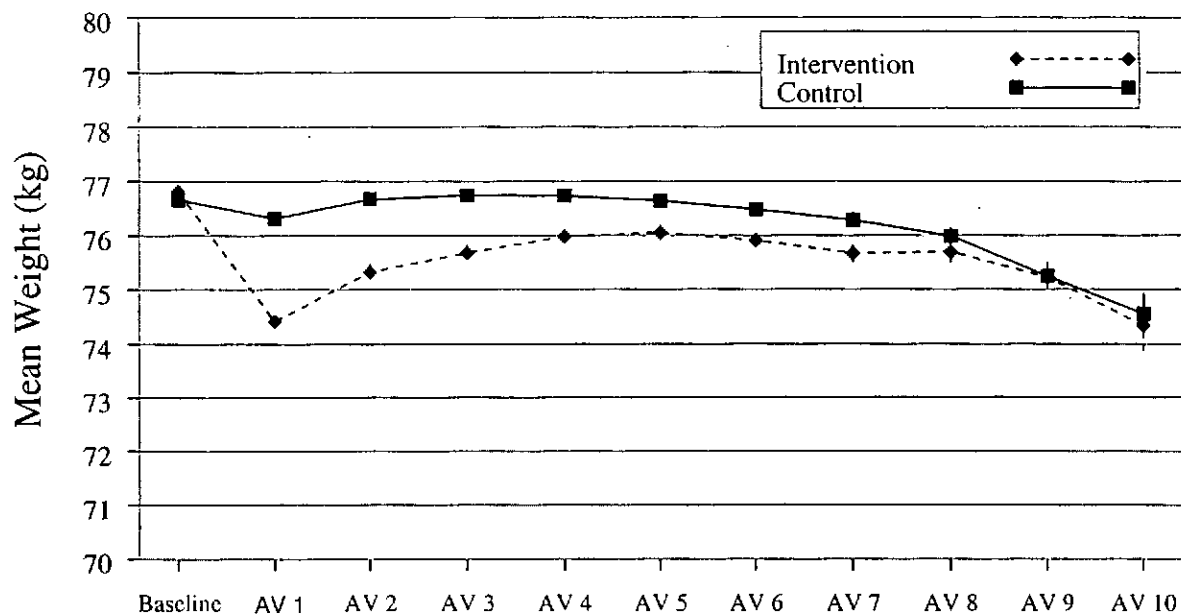


Figure 3.2
Mean Body Weight for DM Participants
Stratified by Treatment Arm

Data as of September 12, 2005; Events through Study Closeout

Mean Weight for DM Participants



Mean Differences in Weight for DM Participants

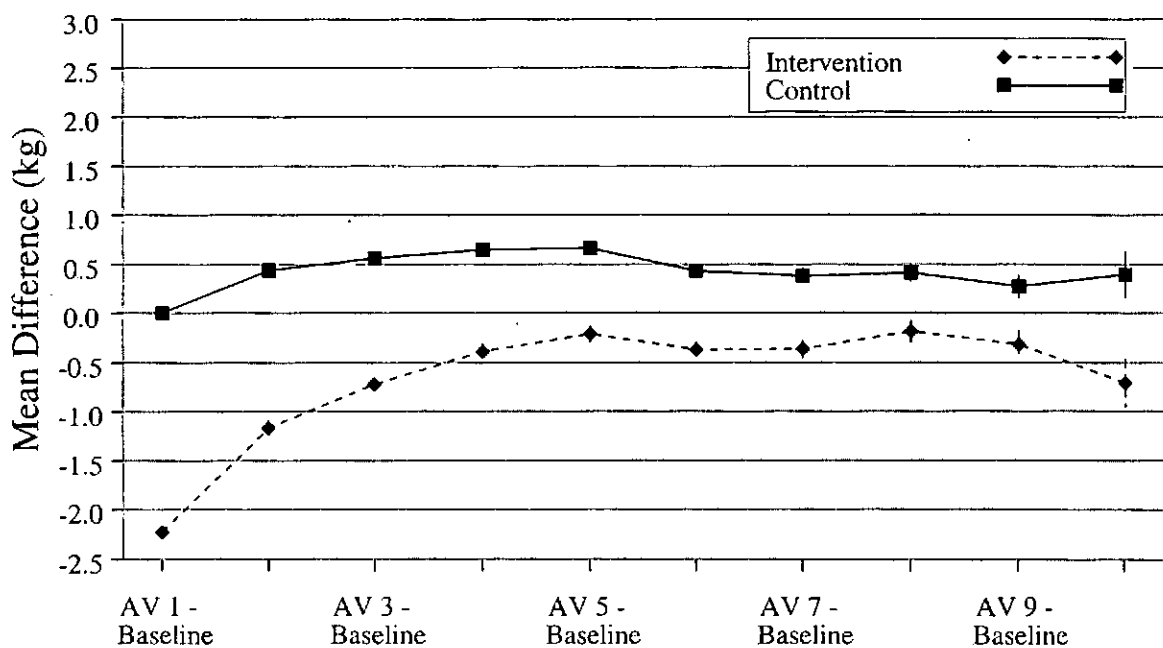


Table 3.3
Blood Specimen Analysis: DM Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean ¹	S.D. ¹
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	2731	0.08	0.08
AV-1	2500	0.08	0.07
AV-3	2204	0.07	0.07
AV-6	2072	0.07	0.07
AV-1 – Baseline	2425	0.00	0.06
AV-3 – Baseline	2133	-0.01	0.07
AV-6 – Baseline	2005	-0.01	0.07
Beta-Carotene (µg/ml)			
Baseline	2731	0.30	0.28
AV-1	2500	0.30	0.29
AV-3	2204	0.29	0.29
AV-6	2072	0.31	0.33
AV-1 – Baseline	2425	0.00	0.22
AV-3 – Baseline	2133	-0.00	0.26
AV-6 – Baseline	2005	0.01	0.31
Alpha-tocopherol (µg/ml)			
Baseline	2731	16.28	7.30
AV-1	2500	16.95	7.52
AV-3	2204	18.19	7.71
AV-6	2073	18.75	7.98
AV-1 – Baseline	2425	0.76	5.49
AV-3 – Baseline	2133	1.91	6.76
AV-6 – Baseline	2006	2.54	7.73
Gamma-tocopherol (µg/ml)			
Baseline	2731	2.21	1.42
AV-1	2499	1.85	1.31
AV-3	2204	1.68	1.32
AV-6	2073	1.64	1.27
AV-1 – Baseline	2424	-0.36	0.92
AV-3 – Baseline	2133	-0.54	1.13
AV-6 – Baseline	2006	-0.59	1.22
Beta-Cryptoxanthine (µg/ml)			
Baseline	2731	0.09	0.07
AV-1	2499	0.09	0.07
AV-3	2204	0.10	0.08
AV-6	2072	0.11	0.10
AV-1 – Baseline	2424	0.00	0.06
AV-3 – Baseline	2133	0.01	0.07
AV-6 – Baseline	2005	0.02	0.09
Lycopene (µg/ml)			
Baseline	2731	0.41	0.19
AV-1	2500	0.41	0.19
AV-3	2204	0.38	0.20
AV-6	2072	0.37	0.20
AV-1 – Baseline	2425	-0.01	0.16
AV-3 – Baseline	2133	-0.03	0.20
AV-6 – Baseline	2005	-0.04	0.21

(continues)

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.3 (continued)
Blood Specimen Analysis: DM Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean ¹	S.D. ¹
Lutein and Zeaxanthin (µg/ml)			
Baseline	2731	0.21	0.10
AV-1	2500	0.22	0.10
AV-3	2204	0.20	0.10
AV-6	2072	0.19	0.10
AV-1 – Baseline	2425	0.00	0.07
AV-3 – Baseline	2133	-0.02	0.08
AV-6 – Baseline	2005	-0.03	0.09
Retinol (µg/ml)			
Baseline	2731	0.61	0.15
AV-1	2500	0.62	0.15
AV-3	2204	0.61	0.15
AV-6	2073	0.64	0.16
AV-1 – Baseline	2425	0.00	0.10
AV-3 – Baseline	2133	-0.00	0.13
AV-6 – Baseline	2006	0.03	0.14
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2640	130.69	32.41
AV-1	2398	130.70	32.64
AV-3	2108	131.99	33.20
AV-6	2047	124.47	31.53
AV-1 – Baseline	2275	-0.23	22.36
AV-3 – Baseline	1982	0.53	28.14
AV-6 – Baseline	1920	-6.58	29.33
Factor VII C (%)²			
Baseline	2595	129.82	30.74
AV-1	2367	127.30	30.37
AV-3	2099	130.98	33.84
AV-6	2035	135.70	36.18
AV-1 – Baseline	2211	-2.82	22.49
AV-3 – Baseline	1936	0.77	28.23
AV-6 – Baseline	1873	5.16	29.90
Fibrinogen (mg/dl)			
Baseline	2630	299.80	60.77
AV-1	2391	297.59	60.63
AV-3	2109	289.34	59.25
AV-6	2046	289.11	60.30
AV-1 – Baseline	2264	-2.55	49.77
AV-3 – Baseline	1975	-10.52	52.49
AV-6 – Baseline	1911	-9.46	58.94
Hormones/Other			
Glucose (mg/dl)			
Baseline	2729	100.17	26.76
AV-1	2492	98.81	26.23
AV-3	2230	99.26	26.63
AV-6	2081	100.69	25.67
AV-1 – Baseline	2417	-1.33	18.98
AV-3 – Baseline	2157	-1.07	20.95
AV-6 – Baseline	2013	1.43	23.38

(continues)

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

² Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.3 (continued)
Blood Specimen Analysis: DM Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean ¹	S.D. ¹
Insulin (μU/ml)			
Baseline	2661	11.69	8.77
AV-1	2430	11.30	10.33
AV-3	2127	12.76	10.04
AV-6	2079	10.39	26.01
AV-1 – Baseline	2319	-0.31	8.54
AV-3 – Baseline	2009	1.03	8.44
AV-6 – Baseline	1966	-1.19	23.18
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	2730	157.45	86.55
AV-1	2498	159.30	86.45
AV-3	2230	160.27	89.36
AV-6	2082	154.57	82.00
AV-1 – Baseline	2423	2.51	54.98
AV-3 – Baseline	2157	1.94	74.02
AV-6 – Baseline	2015	-2.97	73.07
Total Cholesterol (mg/dl)			
Baseline	2730	224.13	38.13
AV-1	2498	217.41	37.33
AV-3	2230	215.58	35.64
AV-6	2082	212.54	36.81
AV-1 – Baseline	2423	-6.62	26.67
AV-3 – Baseline	2157	-8.17	31.96
AV-6 – Baseline	2015	-11.85	36.83
LDL-C (mg/dl)			
Baseline	2680	133.82	35.18
AV-1	2453	126.48	34.05
AV-3	2192	125.51	33.66
AV-6	2054	123.84	33.89
AV-1 – Baseline	2359	-6.91	23.78
AV-3 – Baseline	2092	-7.52	29.26
AV-6 – Baseline	1956	-9.81	34.74

(continues)

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.3 (continued)
Blood Specimen Analysis: DM Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean ¹	S.D. ¹
HDL-C (mg/dl)			
Baseline	2722	59.05	15.68
AV-1	2496	59.28	15.30
AV-3	2226	58.74	15.63
AV-6	2079	58.39	14.84
AV-1 – Baseline	2415	-0.08	8.79
AV-3 – Baseline	2147	-0.42	9.89
AV-6 – Baseline	2005	-1.12	10.53
HDL-2 (mg/dl)			
Baseline	2662	18.29	8.17
AV-1	2455	18.84	8.36
AV-3	2198	16.44	6.63
AV-6	2065	17.90	7.62
AV-1 – Baseline	2329	0.31	4.97
AV-3 – Baseline	2079	-1.92	5.62
AV-6 – Baseline	1949	-0.64	6.19
HDL-3 (mg/dl)			
Baseline	2664	40.86	9.05
AV-1	2456	40.47	8.58
AV-3	2198	42.18	9.77
AV-6	2065	40.53	9.05
AV-1 – Baseline	2332	-0.51	5.55
AV-3 – Baseline	2081	1.41	6.93
AV-6 – Baseline	1950	-0.46	7.39
Lp(a) (mg/dl)			
Baseline	2693	25.96	26.14
AV-1	2465	25.12	25.93
AV-3	2166	23.23	23.36
AV-6	2066	31.69	29.03
AV-1 – Baseline	2366	-0.65	10.20
AV-3 – Baseline	2075	-2.34	13.78
AV-6 – Baseline	1971	5.89	16.34

¹ Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.4
Bone Mineral Density¹ Analysis: DM Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean	S.D.
Whole Body Scan			
Baseline	3621	1.03	0.11
AV1	3278	1.03	0.11
AV3	3101	1.04	0.11
AV6	2788	1.05	0.12
AV9	1782	1.07	0.13
AV1 % Change from baseline BMD ²	3249	0.18	2.50
AV3 % Change from baseline BMD ²	3073	1.30	3.62
AV6 % Change from baseline BMD ²	2743	2.10	5.33
AV9 % Change from baseline BMD ²	1356	2.54	6.69
Spine Scan			
Baseline	3497	0.99	0.17
AV1	3165	1.00	0.17
AV3	3005	1.01	0.17
AV6	2683	1.02	0.18
AV9	1715	1.02	0.17
AV1 % Change from baseline BMD ²	3144	0.88	3.82
AV3 % Change from baseline BMD ²	2980	2.21	5.18
AV6 % Change from baseline BMD ²	2646	3.34	6.86
AV9 % Change from baseline BMD ²	1304	3.55	8.18
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3276	0.87	0.14
AV3	3099	0.88	0.14
AV6	2814	0.88	0.14
AV9	1775	0.86	0.13
AV1 % Change from baseline BMD ²	3255	0.04	2.74
AV3 % Change from baseline BMD ²	3071	0.96	4.02
AV6 % Change from baseline BMD ²	2765	-0.12	5.06
AV9 % Change from baseline BMD ²	1347	-1.56	6.17

¹ Measured in (g/cm²).

² AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 3.5
Lost-to-Follow-up and Vital Status: DM Participants

Data as of September 12, 2005; Events through Study Closeout

Vital Status/Participation	DM Participants (N = 48,835)	
	N	%
Deceased	2404	4.9
Alive: Current Participation ¹	44116	90.3
Alive: Recent Participation ²	235	0.5
Alive: Past/Unknown Participation ³	5	<0.1
Stopped Follow-Up ⁴	1553	3.2
Lost to Follow-Up ⁵	522	1.1

¹ Participants who have filled in a Form 33 within the last 9 months.

² Participants who last filled in a Form 33 between 9 and 18 months ago.

³ Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

⁴ Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.

⁵ Participants not in any of the above categories.

Table 3.6
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	97.0	104.0	99.9	95.0	92.8
Cancer					
Breast cancer	2150 (0.54%)	257 (0.43%)	488 (0.53%)	1017 (0.57%)	388 (0.62%)
Invasive breast cancer	1727 (0.44%)	187 (0.31%)	399 (0.43%)	824 (0.46%)	317 (0.50%)
Non-invasive breast cancer	440 (0.11%)	73 (0.12%)	92 (0.10%)	199 (0.11%)	76 (0.12%)
Ovarian cancer	182 (0.05%)	21 (0.03%)	37 (0.04%)	83 (0.05%)	41 (0.07%)
Endometrial cancer ¹	305 (0.08%)	34 (0.06%)	73 (0.08%)	145 (0.08%)	53 (0.08%)
Colorectal cancer	506 (0.13%)	31 (0.05%)	84 (0.09%)	249 (0.14%)	142 (0.23%)
Other cancer ²	2068 (0.52%)	176 (0.29%)	356 (0.39%)	1048 (0.58%)	488 (0.78%)
Total cancer	4986 (1.26%)	500 (0.83%)	992 (1.08%)	2428 (1.35%)	1066 (1.70%)
Cardiovascular					
CHD ³	1429 (0.36%)	77 (0.13%)	173 (0.19%)	671 (0.37%)	508 (0.81%)
CHD death ⁴	392 (0.10%)	19 (0.03%)	29 (0.03%)	182 (0.10%)	162 (0.26%)
Total MI ⁵	1163 (0.29%)	60 (0.10%)	152 (0.17%)	545 (0.30%)	406 (0.65%)
Clinical MI	1108 (0.28%)	54 (0.09%)	145 (0.16%)	519 (0.29%)	390 (0.62%)
Evolving Q-wave MI ⁶	58 (0.01%)	7 (0.01%)	7 (0.01%)	28 (0.02%)	16 (0.03%)
Possible evolving Q-wave MI ⁶	260 (0.07%)	27 (0.04%)	37 (0.04%)	124 (0.07%)	72 (0.11%)
Angina	1629 (0.41%)	95 (0.16%)	231 (0.25%)	859 (0.48%)	444 (0.71%)
CABG/PTCA	1830 (0.46%)	90 (0.15%)	253 (0.28%)	952 (0.53%)	535 (0.85%)
Carotid artery disease	292 (0.07%)	11 (0.02%)	34 (0.04%)	154 (0.09%)	93 (0.15%)
Congestive heart failure	1167 (0.30%)	52 (0.09%)	120 (0.13%)	526 (0.29%)	469 (0.75%)
Stroke	1071 (0.27%)	46 (0.08%)	116 (0.13%)	499 (0.28%)	410 (0.65%)
PVD	261 (0.07%)	13 (0.02%)	34 (0.04%)	125 (0.07%)	89 (0.14%)
CHD ³ /Possible evolving Q-wave MI	1673 (0.42%)	103 (0.17%)	209 (0.23%)	784 (0.44%)	577 (0.92%)
Coronary disease ⁷	3969 (1.00%)	227 (0.38%)	525 (0.57%)	1969 (1.09%)	1248 (1.99%)
Total cardiovascular disease	5161 (1.31%)	279 (0.46%)	673 (0.73%)	2556 (1.42%)	1653 (2.63%)
Fractures					
Hip fracture	500 (0.13%)	12 (0.02%)	32 (0.03%)	195 (0.11%)	261 (0.42%)
Vertebral fracture	552 (0.14%)	22 (0.04%)	56 (0.06%)	252 (0.14%)	222 (0.35%)
Other fracture ²	5340 (1.35%)	651 (1.08%)	1076 (1.17%)	2512 (1.40%)	1101 (1.75%)
Total fracture	6095 (1.54%)	682 (1.13%)	1152 (1.25%)	2831 (1.57%)	1430 (2.28%)
Deaths					
Cardiovascular deaths	715 (0.18%)	32 (0.05%)	51 (0.06%)	306 (0.17%)	326 (0.52%)
Cancer deaths	1126 (0.29%)	68 (0.11%)	158 (0.17%)	557 (0.31%)	343 (0.55%)
Other known cause	484 (0.12%)	28 (0.05%)	53 (0.06%)	198 (0.11%)	205 (0.33%)
Unknown cause	73 (0.02%)	2 (<0.01%)	6 (0.01%)	39 (0.02%)	26 (0.04%)
Not yet adjudicated	6 (<0.01%)	2 (<0.01%)	0 (0.00%)	2 (<0.01%)	2 (<0.01%)
Total death	2404 (0.61%)	132 (0.22%)	268 (0.29%)	1102 (0.61%)	902 (1.44%)

¹ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

² Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

³ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

⁴ "CHD death" includes definite and possible CHD death.

⁵ "Total MI" includes clinical MI and evolving Q-wave MI.

⁶ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁷ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.6 (continued)
 Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of September 12, 2005; Events through Study Closeout

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	95.4	93.8	95.5	92.0	97.7	92.8
Cancer						
Breast cancer	5 (0.31%)	48 (0.56%)	169 (0.40%)	55 (0.39%)	1848 (0.57%)	25 (0.49%)
Invasive breast cancer	4 (0.25%)	36 (0.42%)	128 (0.31%)	43 (0.30%)	1496 (0.46%)	20 (0.39%)
Non-invasive breast cancer	1 (0.06%)	12 (0.14%)	42 (0.10%)	12 (0.08%)	368 (0.11%)	5 (0.10%)
Ovarian cancer	1 (0.06%)	5 (0.06%)	11 (0.03%)	7 (0.05%)	155 (0.05%)	3 (0.06%)
Endometrial cancer ¹	0 (0.00%)	3 (0.03%)	20 (0.05%)	8 (0.06%)	269 (0.08%)	5 (0.10%)
Colorectal cancer	4 (0.25%)	7 (0.08%)	55 (0.13%)	16 (0.11%)	417 (0.13%)	7 (0.14%)
Other cancer ²	6 (0.37%)	32 (0.37%)	159 (0.38%)	43 (0.30%)	1801 (0.56%)	27 (0.53%)
Total cancer	15 (0.93%)	90 (1.04%)	395 (0.94%)	122 (0.86%)	4303 (1.33%)	61 (1.20%)
Cardiovascular						
CHD ³	4 (0.25%)	14 (0.16%)	157 (0.38%)	26 (0.18%)	1209 (0.37%)	19 (0.37%)
CHD death ⁴	0 (0.00%)	3 (0.03%)	59 (0.14%)	8 (0.06%)	312 (0.10%)	10 (0.20%)
Total MI ⁵	4 (0.25%)	13 (0.15%)	117 (0.28%)	21 (0.15%)	993 (0.31%)	15 (0.29%)
Clinical MI	4 (0.25%)	13 (0.15%)	112 (0.27%)	20 (0.14%)	945 (0.29%)	14 (0.27%)
Evolving Q-wave MI ⁶	0 (0.00%)	1 (0.01%)	5 (0.01%)	1 (0.01%)	50 (0.02%)	1 (0.02%)
Possible evolving Q-wave MI ⁶	3 (0.19%)	7 (0.08%)	29 (0.07%)	7 (0.05%)	212 (0.07%)	2 (0.04%)
Angina	7 (0.44%)	18 (0.21%)	213 (0.51%)	50 (0.35%)	1319 (0.41%)	22 (0.43%)
CABG/PTCA	6 (0.37%)	14 (0.16%)	176 (0.42%)	37 (0.26%)	1579 (0.49%)	18 (0.35%)
Carotid artery disease	2 (0.12%)	1 (0.01%)	21 (0.05%)	3 (0.02%)	261 (0.08%)	4 (0.08%)
Congestive heart failure	2 (0.12%)	10 (0.12%)	178 (0.43%)	31 (0.22%)	930 (0.29%)	16 (0.31%)
Stroke	4 (0.25%)	19 (0.22%)	153 (0.37%)	26 (0.18%)	854 (0.26%)	15 (0.29%)
PVD	3 (0.19%)	2 (0.02%)	48 (0.11%)	2 (0.01%)	202 (0.06%)	4 (0.08%)
CHD ³ /Possible evolving Q-wave MI	7 (0.44%)	20 (0.23%)	185 (0.44%)	32 (0.23%)	1408 (0.44%)	21 (0.41%)
Coronary disease ⁷	15 (0.93%)	43 (0.50%)	508 (1.21%)	98 (0.69%)	3256 (1.01%)	49 (0.96%)
Total cardiovascular disease	22 (1.37%)	64 (0.74%)	655 (1.56%)	125 (0.88%)	4229 (1.31%)	66 (1.30%)
Fractures						
Hip fracture	2 (0.12%)	3 (0.03%)	15 (0.04%)	9 (0.06%)	466 (0.14%)	5 (0.10%)
Vertebral fracture	1 (0.06%)	11 (0.13%)	8 (0.02%)	10 (0.07%)	510 (0.16%)	12 (0.24%)
Other fracture ²	17 (1.06%)	79 (0.91%)	313 (0.75%)	133 (0.94%)	4728 (1.46%)	70 (1.37%)
Total fracture	18 (1.12%)	92 (1.07%)	332 (0.79%)	146 (1.03%)	5424 (1.68%)	83 (1.63%)
Deaths						
Cardiovascular deaths	2 (0.12%)	10 (0.12%)	106 (0.25%)	13 (0.09%)	573 (0.18%)	11 (0.22%)
Cancer deaths	6 (0.37%)	16 (0.19%)	99 (0.24%)	31 (0.22%)	955 (0.30%)	19 (0.37%)
Other known cause	8 (0.50%)	7 (0.08%)	58 (0.14%)	11 (0.08%)	394 (0.12%)	6 (0.12%)
Unknown cause	0 (0.00%)	1 (0.01%)	18 (0.04%)	1 (0.01%)	52 (0.02%)	1 (0.02%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.01%)	5 (<0.01%)	0 (0.00%)
Total death	16 (1.00%)	34 (0.39%)	281 (0.67%)	57 (0.40%)	1979 (0.61%)	37 (0.73%)

¹ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

² Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

³ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

⁴ "CHD death" includes definite and possible CHD death.

⁵ "Total MI" includes clinical MI and evolving Q-wave MI.

⁶ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁷ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.7
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity
for DM Participants who did not report a prevalent condition at baseline

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	97.1	104.0	99.9	95.0	92.9
Hospitalizations					
Ever	24816 (6.28%)	2658 (4.41%)	4767 (5.19%)	12034 (6.69%)	5357 (8.52%)
Two or more	13557 (3.43%)	1167 (1.93%)	2305 (2.51%)	6720 (3.74%)	3365 (5.35%)
Other					
DVT ¹	528 (0.14%)	31 (0.05%)	80 (0.09%)	254 (0.15%)	163 (0.27%)
Pulmonary embolism	354 (0.09%)	23 (0.04%)	56 (0.06%)	184 (0.10%)	91 (0.15%)
Diabetes (treated)	3770 (1.00%)	528 (0.90%)	852 (0.96%)	1751 (1.02%)	639 (1.07%)
Gallbladder disease ²	3830 (1.16%)	573 (1.07%)	902 (1.15%)	1802 (1.22%)	553 (1.09%)
Hysterectomy	1549 (0.69%)	228 (0.67%)	358 (0.64%)	738 (0.74%)	225 (0.66%)
Glaucoma	5315 (1.40%)	567 (0.95%)	1098 (1.22%)	2587 (1.50%)	1063 (1.83%)
Osteoporosis	10217 (2.74%)	1128 (1.91%)	1968 (2.21%)	5020 (2.98%)	2101 (3.74%)
Osteoarthritis ³	9623 (3.94%)	1457 (3.23%)	2278 (3.63%)	4401 (4.20%)	1487 (4.73%)
Rheumatoid arthritis	2848 (0.75%)	399 (0.68%)	631 (0.71%)	1319 (0.77%)	499 (0.84%)
Intestinal polyps	7838 (2.14%)	1009 (1.73%)	1738 (1.99%)	3899 (2.36%)	1192 (2.13%)
Lupus	503 (0.13%)	82 (0.14%)	116 (0.13%)	237 (0.13%)	68 (0.11%)
Kidney stones ³	1319 (0.40%)	175 (0.36%)	281 (0.37%)	654 (0.43%)	209 (0.39%)
Cataracts ³	15479 (5.14%)	1157 (2.33%)	2858 (3.77%)	8460 (6.11%)	3004 (8.01%)
Pills for hypertension	12611 (4.58%)	1680 (3.47%)	2823 (4.07%)	5963 (4.94%)	2145 (5.75%)

Outcomes	Race/Ethnicity					
	Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	95.4	93.8	95.5	92.0	97.7	92.8
Hospitalizations						
Ever	101 (6.29%)	395 (4.57%)	2634 (6.29%)	769 (5.43%)	20607 (6.37%)	310 (6.08%)
Two or more	60 (3.74%)	172 (1.99%)	1513 (3.61%)	380 (2.69%)	11258 (3.48%)	174 (3.41%)
Other						
DVT ¹	1 (0.07%)	0 (0.00%)	48 (0.12%)	9 (0.07%)	463 (0.15%)	7 (0.14%)
Pulmonary embolism	2 (0.13%)	1 (0.01%)	35 (0.08%)	5 (0.04%)	307 (0.10%)	4 (0.08%)
Diabetes (treated)	18 (1.20%)	105 (1.29%)	692 (1.86%)	210 (1.58%)	2690 (0.86%)	55 (1.14%)
Gallbladder disease ²	14 (1.22%)	60 (0.77%)	304 (0.81%)	152 (1.42%)	3250 (1.21%)	50 (1.14%)
Hysterectomy	5 (0.66%)	30 (0.55%)	101 (0.54%)	47 (0.62%)	1355 (0.72%)	11 (0.38%)
Glaucoma	30 (1.95%)	108 (1.30%)	762 (1.95%)	201 (1.47%)	4150 (1.33%)	64 (1.33%)
Osteoporosis	43 (2.81%)	272 (3.33%)	678 (1.68%)	409 (3.11%)	8675 (2.85%)	140 (2.96%)
Osteoarthritis ³	42 (0.09%)	219 (0.35%)	997 (0.95%)	413 (1.31%)	7808 (2.85%)	144 (4.59%)
Rheumatoid arthritis	23 (1.59%)	49 (0.59%)	505 (1.29%)	222 (1.65%)	1998 (0.64%)	51 (1.06%)
Intestinal polyps	40 (2.69%)	165 (2.08%)	866 (2.22%)	252 (1.87%)	6403 (2.13%)	112 (2.39%)
Lupus	4 (0.25%)	8 (0.09%)	72 (0.17%)	20 (0.14%)	392 (0.12%)	7 (0.14%)
Kidney stones ³	9 (0.02%)	27 (0.04%)	137 (0.09%)	58 (0.11%)	1071 (0.28%)	17 (0.40%)
Cataracts ³	61 (0.12%)	306 (0.40%)	1509 (1.09%)	537 (1.43%)	12862 (3.81%)	204 (5.21%)
Pills for hypertension	46 (4.47%)	266 (4.59%)	1325 (6.33%)	519 (4.95%)	10297 (4.40%)	158 (4.61%)

¹ Inpatient DVT only.

² "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

³ These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 4.1
Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment

Data as of September 12, 2005; Events through Study Closeout

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	36,282			
50-54	5,153	118%	14%	10%
55-59	8,269	95%	23%	20%
60-69	16,519	84%	46%	45%
70-79	6,341	58%	17%	25%
Race/Ethnicity	36,282			
American Indian	149		<1%	
Asian	721		2%	
Black	3,315		9%	
Hispanic	1,502		4%	
White	30,155		83%	
Unknown	440		1%	

Table 4.2
Bone Mineral Density¹ Analysis: CaD Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean	S.D.
Whole Body Scan			
AV1	2440	1.02	0.11
AV3	2284	1.03	0.11
AV6	2040	1.05	0.12
AV9	1183	1.07	0.13
AV3 % Change from AV1 BMD ²	2211	1.46	3.39
AV6 % Change from AV1 BMD ²	1956	2.25	5.32
AV9 % Change from AV1 BMD ²	858	3.24	6.99
Spine Scan			
AV1	2343	1.00	0.16
AV3	2215	1.01	0.17
AV6	1964	1.02	0.17
AV9	1140	1.02	0.17
AV3 % Change from AV1 BMD ²	2146	1.52	4.20
AV6 % Change from AV1 BMD ²	1882	2.61	5.96
AV9 % Change from AV1 BMD ²	821	2.88	7.00
Hip Scan			
AV1	2431	0.87	0.14
AV3	2285	0.87	0.14
AV6	2057	0.87	0.14
AV9	1179	0.86	0.13
AV3 % Change from AV1 BMD ²	2211	1.17	3.42
AV6 % Change from AV1 BMD ²	1964	-0.08	4.83
AV9 % Change from AV1 BMD ²	852	-1.15	5.71

¹ Measured in (g/cm³).

² AVX % Change from AV1 BMD is defined as $((AVX-AV1)/AV1) \times 100$.

Table 4.3
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of September 12, 2005; Events through Study Closeout

Vital Status/Participation	CaD Participants (N = 36,282)	
	N	%
Deceased	1551	4.3
Alive: Current Participation ¹	32652	90.0
Alive: Recent Participation ²	1099	3.0
Alive: Past/Unknown Participation ³	27	0.1
Stopped Follow-Up ⁴	684	1.9
Lost to Follow-Up ⁵	269	0.7

¹ Participants who have filled in a Form 33 within the last 9 months.

² Participants who last filled in a Form 33 between 9 and 18 months ago.

³ Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

⁴ Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.

⁵ Participants not in any of the above categories.

Table 4.4
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number of participants	36282	5153	8269	16519	6341
Mean follow-up (months)	84.4	90.6	87.0	82.7	80.6
Fractures					
Hip fracture	374 (0.15%)	6 (0.02%)	35 (0.06%)	125 (0.11%)	208 (0.49%)
Vertebral fracture	378 (0.15%)	13 (0.03%)	40 (0.07%)	164 (0.14%)	161 (0.38%)
Other fracture ¹	3712 (1.45%)	456 (1.17%)	748 (1.25%)	1711 (1.50%)	797 (1.87%)
Total fracture	4260 (1.67%)	472 (1.21%)	812 (1.35%)	1914 (1.68%)	1062 (2.49%)
Cancer					
Colorectal cancer	339 (0.13%)	22 (0.06%)	48 (0.08%)	166 (0.15%)	103 (0.24%)
Breast cancer	1369 (0.54%)	165 (0.42%)	320 (0.53%)	640 (0.56%)	244 (0.57%)
Invasive breast cancer	1087 (0.43%)	119 (0.31%)	259 (0.43%)	511 (0.45%)	198 (0.47%)
Non-invasive breast cancer	292 (0.11%)	46 (0.12%)	62 (0.10%)	133 (0.12%)	51 (0.12%)
Ovarian cancer	125 (0.05%)	14 (0.04%)	35 (0.06%)	52 (0.05%)	24 (0.06%)
Endometrial cancer ²	184 (0.07%)	21 (0.05%)	45 (0.07%)	84 (0.07%)	34 (0.08%)
Other cancer ¹	1399 (0.55%)	118 (0.30%)	234 (0.39%)	697 (0.61%)	350 (0.82%)
Total cancer	3289 (1.29%)	332 (0.85%)	662 (1.10%)	1572 (1.38%)	723 (1.70%)
Cardiovascular					
CHD ³	982 (0.38%)	52 (0.13%)	123 (0.21%)	462 (0.41%)	345 (0.81%)
CHD death ⁴	258 (0.10%)	12 (0.03%)	22 (0.04%)	106 (0.09%)	118 (0.28%)
Total MI ⁵	804 (0.31%)	42 (0.11%)	105 (0.18%)	393 (0.35%)	264 (0.62%)
Clinical MI	753 (0.29%)	38 (0.10%)	100 (0.17%)	369 (0.32%)	246 (0.58%)
Evolving Q-wave MI ⁶	53 (0.02%)	4 (0.01%)	5 (0.01%)	26 (0.02%)	18 (0.04%)
Possible evolving Q-wave MI ⁶	210 (0.08%)	25 (0.06%)	29 (0.05%)	93 (0.08%)	63 (0.15%)
Angina	1114 (0.44%)	60 (0.15%)	162 (0.27%)	579 (0.51%)	313 (0.74%)
CABG/PTCA	1281 (0.50%)	67 (0.17%)	180 (0.30%)	662 (0.58%)	372 (0.87%)
Carotid artery disease	219 (0.09%)	10 (0.03%)	21 (0.04%)	122 (0.11%)	66 (0.16%)
Congestive heart failure	801 (0.31%)	33 (0.08%)	83 (0.14%)	375 (0.33%)	310 (0.73%)
Stroke	744 (0.29%)	34 (0.09%)	80 (0.13%)	331 (0.29%)	299 (0.70%)
PVD	196 (0.08%)	7 (0.02%)	24 (0.04%)	96 (0.08%)	69 (0.16%)
CHD ³ /Possible evolving Q-wave MI	1180 (0.46%)	77 (0.20%)	151 (0.25%)	546 (0.48%)	406 (0.95%)
Coronary disease ⁷	2770 (1.09%)	159 (0.41%)	378 (0.63%)	1349 (1.19%)	884 (2.08%)
Total cardiovascular disease	3637 (1.42%)	200 (0.51%)	481 (0.80%)	1768 (1.55%)	1188 (2.79%)
Deaths					
Cardiovascular deaths	470 (0.18%)	21 (0.05%)	36 (0.06%)	193 (0.17%)	220 (0.52%)
Cancer deaths	726 (0.28%)	50 (0.13%)	103 (0.17%)	360 (0.32%)	213 (0.50%)
Other known cause	300 (0.12%)	15 (0.04%)	39 (0.07%)	129 (0.11%)	117 (0.27%)
Unknown cause	52 (0.02%)	4 (0.01%)	7 (0.01%)	24 (0.02%)	17 (0.04%)
Not yet adjudicated	3 (<0.01%)	1 (<0.01%)	0 (0.00%)	1 (<0.01%)	1 (<0.01%)
Total death	1551 (0.61%)	91 (0.23%)	185 (0.31%)	707 (0.62%)	568 (1.33%)

¹ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

² Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

³ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

⁴ "CHD death" includes definite and possible CHD death.

⁵ "Total MI" includes clinical MI and evolving Q-wave MI.

⁶ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁷ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.4 (continued)
 Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of September 12, 2005; Events through Study Closeout

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number of participants	149	721	3315	1502	30155	440
Mean follow-up (months)	84.2	80.6	83.2	82.5	84.8	80.9
Fractures						
Hip fracture	2 (0.19%)	5 (0.10%)	7 (0.03%)	3 (0.03%)	356 (0.17%)	1 (0.03%)
Vertebral fracture	1 (0.10%)	6 (0.12%)	4 (0.02%)	8 (0.08%)	349 (0.16%)	10 (0.34%)
Other fracture ¹	16 (1.53%)	42 (0.87%)	186 (0.81%)	89 (0.86%)	3334 (1.56%)	45 (1.52%)
Total fracture	18 (1.72%)	51 (1.05%)	195 (0.85%)	100 (0.97%)	3843 (1.80%)	53 (1.79%)
Cancer						
Colorectal cancer	3 (0.29%)	5 (0.10%)	31 (0.13%)	9 (0.09%)	288 (0.14%)	3 (0.10%)
Breast cancer	4 (0.38%)	26 (0.54%)	96 (0.42%)	37 (0.36%)	1193 (0.56%)	13 (0.44%)
Invasive breast cancer	3 (0.29%)	17 (0.35%)	74 (0.32%)	29 (0.28%)	952 (0.45%)	12 (0.40%)
Non-invasive breast cancer	1 (0.10%)	9 (0.19%)	23 (0.10%)	8 (0.08%)	250 (0.12%)	1 (0.03%)
Ovarian cancer	0 (0.00%)	4 (0.08%)	7 (0.03%)	5 (0.05%)	107 (0.05%)	2 (0.07%)
Endometrial cancer ²	1 (0.10%)	2 (0.04%)	8 (0.03%)	4 (0.04%)	166 (0.08%)	3 (0.10%)
Other cancer ¹	5 (0.48%)	24 (0.50%)	91 (0.40%)	30 (0.29%)	1236 (0.58%)	13 (0.44%)
Total cancer	12 (1.15%)	58 (1.20%)	224 (0.97%)	79 (0.77%)	2883 (1.35%)	33 (1.11%)
Cardiovascular						
CHD ³	5 (0.48%)	7 (0.14%)	93 (0.40%)	23 (0.22%)	838 (0.39%)	16 (0.54%)
CHD death ⁴	1 (0.10%)	2 (0.04%)	39 (0.17%)	6 (0.06%)	203 (0.10%)	7 (0.24%)
Total MI ⁵	5 (0.48%)	6 (0.12%)	64 (0.28%)	19 (0.18%)	697 (0.33%)	13 (0.44%)
Clinical MI	5 (0.48%)	6 (0.12%)	61 (0.27%)	18 (0.17%)	651 (0.31%)	12 (0.40%)
Evolving Q-wave MI ⁶	0 (0.00%)	0 (0.00%)	3 (0.01%)	1 (0.01%)	48 (0.02%)	1 (0.03%)
Possible evolving Q-wave MI ⁶	1 (0.10%)	5 (0.10%)	24 (0.10%)	8 (0.08%)	172 (0.08%)	0 (0.00%)
Angina	3 (0.29%)	11 (0.23%)	119 (0.52%)	42 (0.41%)	925 (0.43%)	14 (0.47%)
CABG/PTCA	4 (0.38%)	10 (0.21%)	114 (0.50%)	38 (0.37%)	1099 (0.52%)	16 (0.54%)
Carotid artery disease	1 (0.10%)	1 (0.02%)	10 (0.04%)	3 (0.03%)	202 (0.09%)	2 (0.07%)
Congestive heart failure	2 (0.19%)	7 (0.14%)	102 (0.44%)	29 (0.28%)	652 (0.31%)	9 (0.30%)
Stroke	5 (0.48%)	18 (0.37%)	85 (0.37%)	19 (0.18%)	605 (0.28%)	12 (0.40%)
PVD	2 (0.19%)	2 (0.04%)	25 (0.11%)	1 (0.01%)	165 (0.08%)	1 (0.03%)
CHD ³ /Possible evolving Q-wave MI	6 (0.57%)	12 (0.25%)	115 (0.50%)	30 (0.29%)	1001 (0.47%)	16 (0.54%)
Coronary disease ⁷	9 (0.86%)	25 (0.52%)	305 (1.33%)	85 (0.82%)	2313 (1.09%)	33 (1.11%)
Total cardiovascular disease	14 (1.34%)	42 (0.87%)	395 (1.72%)	106 (1.03%)	3035 (1.42%)	45 (1.52%)
Deaths						
Cardiovascular deaths	1 (0.10%)	10 (0.21%)	69 (0.30%)	12 (0.12%)	370 (0.17%)	8 (0.27%)
Cancer deaths	2 (0.19%)	15 (0.31%)	55 (0.24%)	17 (0.16%)	625 (0.29%)	12 (0.40%)
Other known cause	6 (0.57%)	4 (0.08%)	30 (0.13%)	5 (0.05%)	251 (0.12%)	4 (0.13%)
Unknown cause	0 (0.00%)	1 (0.02%)	14 (0.06%)	0 (0.00%)	37 (0.02%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (<0.01%)	0 (0.00%)
Total death	9 (0.86%)	30 (0.62%)	168 (0.73%)	34 (0.33%)	1286 (0.60%)	24 (0.81%)

¹ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

² Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

³ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

⁴ "CHD death" includes definite and possible CHD death.

⁵ "Total MI" includes clinical MI and evolving Q-wave MI.

⁶ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁷ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity
for CaD Participants who did not report a prevalent condition at baseline

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	84.4	90.6	87.0	82.7	80.6
Hospitalizations					
Ever	16973 (6.65%)	1762 (4.53%)	3240 (5.40%)	8100 (7.12%)	3871 (9.09%)
Two or more	8831 (3.46%)	732 (1.88%)	1524 (2.54%)	4281 (3.76%)	2294 (5.39%)
Other					
DVT ¹	379 (0.15%)	21 (0.05%)	68 (0.12%)	172 (0.16%)	118 (0.29%)
Pulmonary embolism	239 (0.09%)	17 (0.04%)	46 (0.08%)	126 (0.11%)	50 (0.12%)
Diabetes (treated)	2736 (1.12%)	407 (1.08%)	596 (1.03%)	1274 (1.17%)	459 (1.14%)
Gallbladder disease ²	2483 (1.15%)	366 (1.06%)	602 (1.17%)	1156 (1.22%)	359 (1.03%)
Hysterectomy	965 (0.65%)	133 (0.59%)	231 (0.63%)	451 (0.68%)	150 (0.63%)
Glaucoma	3719 (1.51%)	399 (1.04%)	766 (1.31%)	1769 (1.62%)	785 (1.98%)
Osteoporosis	7121 (2.93%)	731 (1.91%)	1357 (2.33%)	3447 (3.19%)	1586 (4.10%)
Osteoarthritis ³	6627 (4.15%)	1007 (3.46%)	1560 (3.78%)	2989 (4.42%)	1071 (4.91%)
Rheumatoid arthritis	1868 (0.76%)	266 (0.71%)	434 (0.75%)	829 (0.76%)	339 (0.84%)
Intestinal polyps	5290 (2.22%)	674 (1.79%)	1161 (2.03%)	2579 (2.45%)	876 (2.31%)
Lupus	351 (0.14%)	56 (0.14%)	82 (0.14%)	149 (0.13%)	64 (0.15%)
Kidney stones ³	816 (0.37%)	110 (0.34%)	178 (0.35%)	383 (0.38%)	145 (0.39%)
Cataracts ³	11104 (5.69%)	817 (2.55%)	2091 (4.21%)	5928 (6.75%)	2268 (8.86%)
Pills for hypertension	9472 (5.19%)	1260 (3.97%)	2134 (4.62%)	4362 (5.58%)	1716 (6.56%)

Outcomes	Race/Ethnicity					
	American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	149	721	3315	1502	30155	440
Mean follow-up (months)	84.2	80.6	83.2	82.5	84.8	80.9
Hospitalizations						
Ever	70 (6.70%)	250 (5.17%)	1570 (6.83%)	562 (5.44%)	14323 (6.72%)	198 (6.68%)
Two or more	45 (4.30%)	103 (2.13%)	866 (3.77%)	268 (2.60%)	7442 (3.49%)	107 (3.61%)
Other						
DVT ¹	3 (0.30%)	1 (0.02%)	34 (0.15%)	7 (0.07%)	331 (0.16%)	3 (0.10%)
Pulmonary embolism	3 (0.29%)	0 (0.00%)	22 (0.10%)	3 (0.03%)	208 (0.10%)	3 (0.10%)
Diabetes (treated)	12 (1.24%)	73 (1.61%)	410 (2.00%)	189 (1.95%)	2010 (0.97%)	42 (1.51%)
Gallbladder disease ²	10 (1.26%)	39 (0.89%)	169 (0.81%)	121 (1.52%)	2116 (1.18%)	28 (1.12%)
Hysterectomy	2 (0.45%)	16 (0.51%)	49 (0.50%)	35 (0.61%)	856 (0.67%)	7 (0.42%)
Glaucoma	20 (2.01%)	58 (1.25%)	471 (2.19%)	177 (1.77%)	2960 (1.44%)	33 (1.17%)
Osteoporosis	30 (3.01%)	156 (3.34%)	406 (1.83%)	299 (3.09%)	6148 (3.03%)	82 (2.96%)
Osteoarthritis ³	36 (5.42%)	128 (3.63%)	602 (4.30%)	328 (4.63%)	5441 (4.10%)	92 (4.72%)
Rheumatoid arthritis	17 (1.83%)	29 (0.63%)	304 (1.43%)	150 (1.52%)	1341 (0.65%)	27 (0.97%)
Intestinal polyps	31 (3.22%)	88 (1.97%)	521 (2.42%)	171 (1.73%)	4418 (2.22%)	61 (2.24%)
Lupus	4 (0.39%)	3 (0.06%)	41 (0.18%)	16 (0.16%)	285 (0.13%)	2 (0.07%)
Kidney stones ³	7 (0.79%)	18 (0.42%)	73 (0.37%)	46 (0.52%)	664 (0.36%)	8 (0.31%)
Cataracts ³	51 (6.24%)	178 (4.77%)	909 (5.12%)	440 (5.27%)	9391 (5.79%)	135 (5.83%)
Pills for hypertension	36 (5.48%)	175 (5.25%)	882 (7.39%)	444 (5.58%)	7836 (5.00%)	99 (5.27%)

¹ Inpatient DVT only.

² "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

³ These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of September 12, 2005; Events through Study Closeout

	Total Enrolled	Distribution
Age	93,676	
50-54	12,381	13%
55-59	17,329	18%
60-69	41,200	44%
70-79	22,766	24%
Race/Ethnicity	93,676	
American Indian	421	<1%
Asian	2,671	3%
Black	7,635	8%
Hispanic	3,609	4%
White	78,016	83%
Unknown	1,324	1%

Table 5.2
Bone Mineral Density¹ Analysis: OS Participants

Data as of September 12, 2005; Events through Study Closeout

	N	Mean	S.D.
Whole Body Scan			
Baseline	6415	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5103	1.01	0.11
Baseline (for ppts. with an AV6 scan)	4476	1.01	0.11
Baseline (for ppts. with an AV9 scan)	1992	1.02	0.10
AV3	5158	1.02	0.11
AV6	4522	1.04	0.12
AV9	2007	1.05	0.13
AV3 % Change from baseline BMD ²	5096	0.95	3.70
AV6 % Change from baseline BMD ²	4212	1.97	5.61
AV9 % Change from baseline BMD ²	1679	1.96	6.85
Spine Scan			
Baseline	6236	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4994	0.98	0.17
Baseline (for ppts. with an AV6 scan)	4307	0.98	0.17
Baseline (for ppts. with an AV9 scan)	1943	0.98	0.16
AV3	5033	0.99	0.17
AV6	4342	1.00	0.18
AV9	1949	1.02	0.18
AV3 % Change from baseline BMD ²	4986	1.73	5.14
AV6 % Change from baseline BMD ²	4044	3.21	6.93
AV9 % Change from baseline BMD ²	1636	4.65	8.50
Hip Scan			
Baseline	6419	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5146	0.84	0.14
Baseline (for ppts. with an AV6 scan)	4512	0.85	0.14
Baseline (for ppts. with an AV9 scan)	2007	0.84	0.13
AV3	5186	0.85	0.14
AV6	4548	0.84	0.13
AV9	2012	0.83	0.13
AV3 % Change from baseline BMD ²	5114	0.41	4.18
AV6 % Change from baseline BMD ²	4215	-0.30	5.29
AV9 % Change from baseline BMD ²	1674	-1.77	6.04

¹ Measured in (g/cm²).

² AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x 100.

Table 5.3
Lost-to-Follow-up and Vital Status: OS Participants

Data as of September 12, 2005; Events through Study Closeout

Vital Status/Participation	OS Participants (N = 93,676)	
	N	%
Deceased	6260	6.7
Alive: Current Participation ¹	78092	83.4
Alive: Recent Participation ²	4818	5.1
Alive: Past/Unknown Participation ³	51	0.1
Stopped Follow-Up ⁴	2347	2.5
Lost to Follow-Up ⁵	2105	2.2

¹ Participants who have filled in a Form 33 within the last 15 months.

² Participants who last filled in a Form 33 between 15 and 24 months ago.

³ Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.

⁴ Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.

⁵ Participants not in any of the above categories.

Table 5.4
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	90.9	95.7	93.9	90.2	87.4
Cardiovascular					
CHD ¹	2471 (0.35%)	88 (0.09%)	190 (0.14%)	990 (0.32%)	1203 (0.73%)
CHD death ²	824 (0.12%)	21 (0.02%)	40 (0.03%)	268 (0.09%)	495 (0.30%)
Clinical MI	1898 (0.27%)	73 (0.07%)	162 (0.12%)	799 (0.26%)	864 (0.52%)
Angina	2837 (0.40%)	124 (0.13%)	318 (0.23%)	1320 (0.43%)	1075 (0.65%)
CABG/PTCA	3136 (0.44%)	119 (0.12%)	317 (0.23%)	1506 (0.49%)	1194 (0.72%)
Carotid artery disease	574 (0.08%)	27 (0.03%)	48 (0.04%)	243 (0.08%)	256 (0.15%)
Congestive heart failure	2305 (0.32%)	81 (0.08%)	174 (0.13%)	886 (0.29%)	1164 (0.70%)
Stroke	2011 (0.28%)	50 (0.05%)	161 (0.12%)	781 (0.25%)	1019 (0.61%)
PVD	526 (0.07%)	17 (0.02%)	44 (0.03%)	223 (0.07%)	242 (0.15%)
Coronary disease ³	6766 (0.95%)	274 (0.28%)	639 (0.47%)	2917 (0.94%)	2936 (1.77%)
Total cardiovascular disease	9232 (1.30%)	353 (0.36%)	845 (0.62%)	3899 (1.26%)	4135 (2.49%)
Cancer					
Breast cancer	4106 (0.58%)	450 (0.46%)	709 (0.52%)	1891 (0.61%)	1056 (0.64%)
Invasive breast cancer	3426 (0.48%)	367 (0.37%)	581 (0.43%)	1569 (0.51%)	909 (0.55%)
Non-invasive breast cancer	701 (0.10%)	89 (0.09%)	130 (0.10%)	330 (0.11%)	152 (0.09%)
Ovarian cancer	362 (0.05%)	36 (0.04%)	60 (0.04%)	166 (0.05%)	100 (0.06%)
Endometrial cancer ⁴	551 (0.08%)	45 (0.05%)	85 (0.06%)	254 (0.08%)	167 (0.10%)
Colorectal cancer	908 (0.13%)	50 (0.05%)	98 (0.07%)	404 (0.13%)	356 (0.21%)
Other cancer ⁵	4061 (0.57%)	278 (0.28%)	532 (0.39%)	1862 (0.60%)	1389 (0.84%)
Total cancer	9516 (1.34%)	829 (0.84%)	1423 (1.05%)	4359 (1.41%)	2905 (1.75%)
Fractures					
Hip fracture	1132 (0.16%)	30 (0.03%)	72 (0.05%)	359 (0.12%)	671 (0.40%)
Vertebral fracture ⁶	123 (0.24%)	6 (0.08%)	10 (0.10%)	45 (0.20%)	62 (0.50%)
Other fracture ^{5,6}	697 (1.33%)	83 (1.08%)	115 (1.18%)	293 (1.30%)	206 (1.68%)
Total fracture⁷	1878 N/A	117 N/A	191 N/A	674 N/A	896 N/A
Deaths					
Cardiovascular deaths	1802 (0.25%)	44 (0.04%)	103 (0.08%)	581 (0.19%)	1074 (0.65%)
Cancer deaths	2654 (0.37%)	143 (0.14%)	312 (0.23%)	1159 (0.37%)	1040 (0.63%)
Other known cause	1384 (0.19%)	61 (0.06%)	117 (0.09%)	498 (0.16%)	708 (0.43%)
Unknown cause	293 (0.04%)	16 (0.02%)	21 (0.02%)	108 (0.03%)	148 (0.09%)
Not yet adjudicated	127 (0.02%)	7 (0.01%)	15 (0.01%)	52 (0.02%)	53 (0.03%)
Total death	6260 (0.88%)	271 (0.27%)	568 (0.42%)	2398 (0.77%)	3023 (1.82%)

¹ "CHD" includes clinical MI and CHD death.

² "CHD death" includes definite and possible CHD death.

³ "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁴ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

⁵ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

⁶ For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.

⁷ Hip fractures are adjudicated at all clinics, while other fractures for OS participants are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.4 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of September 12, 2005; Events through Study Closeout

Outcomes	Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	421	2671	7635	3609	78016	1324
Mean follow-up (months)	85.8	88.7	86.7	83.6	91.8	88.4
Cardiovascular						
CHD ¹	16 (0.53%)	40 (0.20%)	234 (0.42%)	41 (0.16%)	2103 (0.35%)	37 (0.38%)
CHD death ²	9 (0.30%)	16 (0.08%)	116 (0.21%)	12 (0.05%)	656 (0.11%)	15 (0.15%)
Clinical MI	9 (0.30%)	29 (0.15%)	144 (0.26%)	34 (0.14%)	1655 (0.28%)	27 (0.28%)
Angina	18 (0.60%)	40 (0.20%)	250 (0.45%)	80 (0.32%)	2415 (0.40%)	34 (0.35%)
CABG/PTCA	16 (0.53%)	42 (0.21%)	203 (0.37%)	80 (0.32%)	2749 (0.46%)	46 (0.47%)
Carotid artery disease	3 (0.10%)	6 (0.03%)	25 (0.05%)	11 (0.04%)	518 (0.09%)	11 (0.11%)
Congestive heart failure	16 (0.53%)	22 (0.11%)	235 (0.43%)	42 (0.17%)	1956 (0.33%)	34 (0.35%)
Stroke	12 (0.40%)	49 (0.25%)	201 (0.36%)	42 (0.17%)	1675 (0.28%)	32 (0.33%)
PVD	3 (0.10%)	4 (0.02%)	55 (0.10%)	6 (0.02%)	446 (0.07%)	12 (0.12%)
Coronary disease ³	43 (1.43%)	95 (0.48%)	623 (1.13%)	158 (0.63%)	5757 (0.96%)	90 (0.92%)
Total cardiovascular disease	52 (1.73%)	153 (0.77%)	862 (1.56%)	210 (0.84%)	7819 (1.31%)	136 (1.40%)
Cancer						
Breast cancer	12 (0.40%)	90 (0.46%)	275 (0.50%)	99 (0.39%)	3591 (0.60%)	39 (0.40%)
Invasive breast cancer	11 (0.37%)	75 (0.38%)	221 (0.40%)	83 (0.33%)	3003 (0.50%)	33 (0.34%)
Non-invasive breast cancer	1 (0.03%)	16 (0.08%)	56 (0.10%)	17 (0.07%)	604 (0.10%)	7 (0.07%)
Ovarian cancer	1 (0.03%)	5 (0.03%)	17 (0.03%)	11 (0.04%)	326 (0.05%)	2 (0.02%)
Endometrial cancer ⁴	0 (0.00%)	9 (0.05%)	18 (0.03%)	8 (0.03%)	506 (0.08%)	10 (0.10%)
Colorectal cancer	3 (0.10%)	15 (0.08%)	101 (0.18%)	21 (0.08%)	756 (0.13%)	12 (0.12%)
Other cancer ⁵	14 (0.47%)	75 (0.38%)	268 (0.49%)	80 (0.32%)	3568 (0.60%)	56 (0.57%)
Total cancer	30 (1.00%)	184 (0.93%)	646 (1.17%)	213 (0.85%)	8333 (1.40%)	110 (1.13%)
Fractures						
Hip fracture	5 (0.17%)	11 (0.06%)	27 (0.05%)	11 (0.04%)	1062 (0.18%)	16 (0.16%)
Vertebral fracture ⁶	1 (0.14%)	0 (0.00%)	3 (0.04%)	6 (0.17%)	113 (0.28%)	0 (0.00%)
Other fracture ^{5, 6}	9 (1.27%)	3 (1.46%)	46 (0.68%)	39 (1.08%)	594 (1.46%)	6 (1.74%)
Total fracture⁷	14 N/A	14 N/A	73 N/A	53 N/A	1703 N/A	21 N/A
Deaths						
Cardiovascular deaths	14 (0.47%)	41 (0.21%)	222 (0.40%)	35 (0.14%)	1460 (0.24%)	30 (0.31%)
Cancer deaths	11 (0.37%)	53 (0.27%)	227 (0.41%)	65 (0.26%)	2265 (0.38%)	33 (0.34%)
Other known cause	22 (0.73%)	29 (0.15%)	128 (0.23%)	58 (0.23%)	1132 (0.19%)	15 (0.15%)
Unknown cause	1 (0.03%)	5 (0.03%)	48 (0.09%)	11 (0.04%)	224 (0.04%)	4 (0.04%)
Not yet adjudicated	1 (0.03%)	2 (0.01%)	12 (0.02%)	6 (0.02%)	105 (0.02%)	1 (0.01%)
Total death	49 (1.63%)	130 (0.66%)	637 (1.15%)	175 (0.70%)	5186 (0.87%)	83 (0.85%)

¹ "CHD" includes clinical MI and CHD death.

² "CHD death" includes definite and possible CHD death.

³ "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁴ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

⁵ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

⁶ For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.

⁷ Hip fractures are adjudicated at all clinics, while other fractures for OS participants are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity
for OS Participants who did not report a prevalent condition at baseline

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age				
		50-54	55-59	60-69	70-79	
Number randomized	93676	12381	17329	41200	22766	
Mean follow-up (months)	90.9	95.7	93.9	90.2	87.4	
Hospitalizations						
Ever	44449 (6.26%)	4136 (4.19%)	6538 (4.82%)	20012 (6.46%)	13763 (8.29%)	
Two or more	22911 (3.23%)	1715 (1.74%)	2878 (2.12%)	10250 (3.31%)	8068 (4.86%)	
Other						
DVT ¹	762 (0.11%)	53 (0.05%)	93 (0.07%)	342 (0.12%)	274 (0.17%)	
Pulmonary embolism	480 (0.07%)	42 (0.04%)	65 (0.05%)	214 (0.07%)	159 (0.10%)	
Diabetes (treated)	5079 (0.74%)	640 (0.67%)	929 (0.71%)	2301 (0.78%)	1209 (0.76%)	
Gallbladder disease ²	5690 (0.95%)	835 (0.96%)	1153 (0.98%)	2549 (0.99%)	1153 (0.85%)	
Hysterectomy	3340 (0.47%)	464 (0.47%)	623 (0.46%)	1536 (0.50%)	717 (0.43%)	
Glaucoma	8516 (1.26%)	852 (0.88%)	1379 (1.04%)	3910 (1.32%)	2375 (1.56%)	
Osteoporosis	20767 (3.20%)	2110 (2.21%)	3384 (2.62%)	9540 (3.38%)	5733 (4.00%)	
Osteoarthritis ³	15619 (3.78%)	2037 (2.86%)	2886 (3.25%)	7003 (4.05%)	3693 (4.62%)	
Rheumatoid arthritis	4607 (0.68%)	638 (0.67%)	885 (0.68%)	1898 (0.65%)	1186 (0.76%)	
Intestinal polyps	13183 (2.05%)	1557 (1.65%)	2557 (2.01%)	6158 (2.21%)	2911 (2.03%)	
Lupus	1001 (0.14%)	143 (0.15%)	200 (0.15%)	440 (0.14%)	218 (0.13%)	
Kidney stones ³	2327 (0.39%)	292 (0.36%)	436 (0.39%)	996 (0.38%)	603 (0.43%)	
Cataracts ³	27206 (5.31%)	1735 (2.12%)	4109 (3.70%)	14089 (6.16%)	7273 (8.05%)	
Pills for hypertension	21589 (4.26%)	2504 (3.06%)	3825 (3.62%)	9551 (4.44%)	5709 (5.49%)	

Outcomes	Race/Ethnicity					
	American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	421	2671	7635	3609	78016	1324
Mean follow-up (months)	85.8	88.7	86.7	83.6	91.8	88.4
Hospitalizations						
Ever	220 (7.31%)	809 (4.09%)	3489 (6.32%)	1298 (5.16%)	38042 (6.37%)	591 (6.06%)
Two or more	124 (4.12%)	330 (1.67%)	1810 (3.28%)	556 (2.21%)	19788 (3.31%)	303 (3.11%)
Other						
DVT ¹	4 (0.14%)	4 (0.02%)	71 (0.13%)	10 (0.04%)	663 (0.12%)	10 (0.11%)
Pulmonary embolism	1 (0.03%)	4 (0.02%)	38 (0.07%)	4 (0.02%)	429 (0.07%)	4 (0.04%)
Diabetes (treated)	47 (1.83%)	179 (0.95%)	777 (1.59%)	324 (1.39%)	3667 (0.63%)	85 (0.91%)
Gallbladder disease ²	31 (1.31%)	81 (0.45%)	377 (0.77%)	232 (1.18%)	4892 (0.97%)	77 (0.94%)
Hysterectomy	15 (0.50%)	65 (0.33%)	209 (0.38%)	149 (0.59%)	2847 (0.48%)	55 (0.56%)
Glaucoma	45 (1.63%)	253 (1.34%)	997 (1.97%)	312 (1.31%)	6787 (1.19%)	122 (1.31%)
Osteoporosis	92 (3.34%)	630 (3.49%)	1078 (2.05%)	739 (3.19%)	17902 (3.29%)	326 (3.65%)
Osteoarthritis ³	60 (3.54%)	490 (3.53%)	1266 (3.96%)	724 (4.38%)	12842 (3.74%)	237 (4.00%)
Rheumatoid arthritis	38 (1.37%)	98 (0.52%)	664 (1.32%)	385 (1.65%)	3333 (0.59%)	89 (0.98%)
Intestinal polyps	46 (1.67%)	330 (1.87%)	1059 (2.09%)	409 (1.74%)	11169 (2.07%)	170 (1.93%)
Lupus	8 (0.27%)	18 (0.09%)	104 (0.19%)	50 (0.20%)	806 (0.14%)	15 (0.15%)
Kidney stones ³	18 (0.72%)	41 (0.24%)	266 (0.56%)	125 (0.58%)	1832 (0.36%)	45 (0.54%)
Cataracts ³	105 (4.85%)	685 (4.88%)	1951 (4.75%)	905 (4.53%)	23165 (5.41%)	395 (5.63%)
Pills for hypertension	98 (5.10%)	581 (4.18%)	1660 (6.14%)	886 (4.71%)	18043 (4.11%)	321 (4.71%)

¹ Inpatient DVT only.² "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.³ These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.6
First Reported Verified Outcomes Before and After AV-3¹ for OS Participants

Data as of September 12, 2005; Events through Study Closeout

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD ²	759	1712
CHD death ³	177	647
Clinical MI	639	1259
Angina	1270	1567
CABG/PTCA	1165	1971
Carotid artery disease	225	349
Congestive heart failure	719	1586
Stroke	596	1415
PVD	198	328
Coronary disease ⁴	2584	4182
Total cardiovascular disease	3469	5763
Cancer		
Breast cancer	1604	2502
Invasive breast cancer	1336	2090
Non-invasive breast cancer	274	427
Ovarian cancer	136	226
Endometrial cancer	214	337
Colorectal cancer	333	575
Other cancer ⁵	1433	2628
Total cancer	3643	5873
Fractures		
Hip fracture ⁶	295	837
Vertebral fracture ⁶	35	88
Other fracture ^{5,6}	275	422
Total fracture⁶	594	1284
Deaths		
Cardiovascular deaths	371	1431
Cancer deaths	620	2034
Deaths: other known cause	225	1159
Deaths: unknown cause	58	235
Deaths: not yet adjudicated	0	127
Total death	1274	4986

¹ AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.

² "CHD" includes clinical MI and CHD death.

³ "CHD death" includes definite and possible CHD death.

⁴ "Coronary disease" includes clinical MI, Evolving Q-wave MI, Possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁵ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

⁶ Hip fractures are adjudicated at all clinics, while other fractures are adjudicated only at a few clinics.

Table 5.7
Counts of Participants with Self-Reported Outcomes Before and After AV-3¹
for OS Participants who did not report a prevalent condition at baseline

Data as of September 12, 2005; Events through Study Closeout

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19160	25289
DVT ²	227	535
Pulmonary embolism	130	350
Diabetes (treated)	1740	3339
Gallbladder disease ³	2137	3553
Hysterectomy	1359	1981
Glaucoma	2755	5761
Osteoporosis	8703	12064
Osteoarthritis ⁴	6339	9280
Rheumatoid arthritis	1723	2884
Intestinal polyps	4397	8786
Lupus	348	653
Kidney stones ⁴	646	1681
Cataracts ⁴	9145	18061
Pills for hypertension	8141	13448

¹ AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.

² Inpatient DVT only.

³ "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

⁴ These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.1
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of September 12, 2005; Events through Study Closeout

	Participants with a self-report		Closed		Confirmed (%) ¹		Denied – related outcome found (%) ¹		Denied – no outcome found (%) ¹		Administrative denials (%) ¹	
	N	%	N	%	N	(%) ¹	N	(%) ¹	N	(%) ¹	N	(%) ¹
Cardiovascular												
Clinical MI	1457	95%	1387	95%	982	(71%)	219	(16%)	165	(12%)	21	(2%)
Angina ²	2675	97%	2594	97%	1225	(47%)	121	(5%)	1207	(47%)	41	(2%)
Congestive heart failure	1040	96%	995	96%	749	(75%)	53	(5%)	178	(18%)	15	(2%)
CABG/PTCA	3222	97%	3120	97%	2462	(79%)	268	(9%)	358	(11%)	32	(1%)
Carotid artery disease ³	432	96%	416	96%	354	(85%)	30	(7%)	27	(6%)	5	(1%)
Stroke/TIA ⁴	2450	96%	2354	96%	1798	(76%)	114	(5%)	401	(17%)	41	(2%)
PVD	313	97%	303	97%	176	(58%)	38	(13%)	83	(27%)	6	(2%)
DVT ⁵	462	96%	443	96%	301	(68%)	59	(13%)	75	(17%)	8	(2%)
Pulmonary embolism ⁵	239	96%	229	96%	196	(86%)	13	(6%)	19	(8%)	1	(<1%)
Cancers												
Breast cancer	2839	98%	2770	98%	2683	(97%)	2	(<1%)	69	(2%)	16	(1%)
Ovarian cancer	273	97%	265	97%	195	(74%)	52	(20%)	14	(5%)	4	(2%)
Endometrial cancer	343	98%	336	98%	268	(80%)	42	(13%)	23	(7%)	3	(1%)
Colorectal cancer	774	97%	752	97%	647	(86%)	54	(7%)	48	(6%)	3	(<1%)
Other cancer ⁶	3318	96%	3191	96%	2408	(75%)	166	(5%)	561	(18%)	56	(2%)
Fractures												
Hip fracture	828	95%	789	95%	641	(81%)	61	(8%)	77	(10%)	10	(1%)
Vertebral fracture	1192	97%	1153	97%	663	(58%)	49	(4%)	403	(35%)	38	(3%)
Other fracture	8998	98%	8816	98%	7254	(82%)	113	(1%)	1236	(14%)	213	(2%)

¹ Percentages between parentheses are relative to "closed."
² Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 316 such self-reports of angina are excluded from this table.
³ Carotid artery disease that is self-reported after a confirmed stroke is not adjudicated. In particular, 10 such self-reports of carotid artery disease are excluded from this table.
⁴ Stroke and TIA have a combined self-report. Only stroke is monitored. There were 546 participants who reported stroke/TIA for whom only TIA was confirmed.
⁵ HRT participants only.
⁶ Excludes non-melanoma skin cancer.

Table 6.2
Agreement of the Local Adjudications with Self-Reports — OS Participants

Data as of September 12, 2005; Events through Study Closeout

	Participants with a self-report		Closed		Confirmed (%) ¹		Denied – related outcome found (%) ¹		Denied – no outcome found (%) ¹		Administrative denials (%) ¹	
	N	%	N	%	N	(%) ¹	N	(%) ¹	N	(%) ¹	N	(%) ¹
Cardiovascular												
Clinical MI	1434	96%	1371	96%	926	(68%)	225	(16%)	189	(14%)	31	(2%)
Angina ²	3137	96%	3014	96%	1342	(45%)	201	(7%)	1400	(46%)	71	(2%)
Congestive heart failure	1275	96%	1223	96%	917	(75%)	73	(6%)	209	(17%)	24	(2%)
CABG/PTCA	3648	95%	3483	95%	2704	(78%)	317	(9%)	405	(12%)	57	(2%)
Carotid artery disease ³	504	97%	491	97%	412	(84%)	36	(7%)	36	(7%)	7	(1%)
Stroke/TIA ⁴	2996	95%	2856	95%	2104	(74%)	132	(5%)	536	(19%)	84	(3%)
PVD	418	97%	404	97%	245	(61%)	48	(12%)	103	(25%)	8	(2%)
Cancers												
Breast cancer	4110	97%	3987	97%	3663	(92%)	25	(1%)	235	(6%)	64	(2%)
Ovarian cancer	379	97%	366	97%	260	(71%)	61	(17%)	43	(12%)	2	(1%)
Endometrial cancer	453	96%	437	96%	333	(76%)	67	(15%)	28	(6%)	9	(2%)
Colorectal	939	96%	897	96%	750	(84%)	56	(6%)	74	(8%)	17	(2%)
Other cancer ⁵	4456	95%	4245	95%	2983	(70%)	291	(7%)	857	(20%)	114	(3%)
Fractures												
Hip fracture	1130	94%	1065	94%	854	(80%)	10	(1%)	175	(16%)	26	(2%)
Vertebral fracture	149	97%	144	97%	95	(66%)	8	(6%)	37	(26%)	4	(3%)
Other fracture	947	99%	935	99%	699	(75%)	21	(2%)	178	(19%)	37	(4%)

¹ Percentages between parentheses are relative to "closed."

² Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 341 such self-reports of angina are excluded from this table.

³ Carotid artery disease that is self-reported after a confirmed stroke is not adjudicated. In particular, 10 such self-reports of carotid artery disease are excluded from this table.

⁴ Stroke and TIA have a combined self-report. Only stroke is monitored. There were 649 participants who reported stroke/TIA for whom only TIA was confirmed.

⁵ Excludes non-melanoma skin cancer.

Table 6.3
Agreement of Central Adjudications with Local Adjudications — CT Participants

Data as of September 12, 2005; Events through Study Closeout

	Locally confirmed	Called forward for central adjudication		Centrally adjudicated		In agreement	
	N	N	% ¹	N	% ²	N	% ³
Cardiovascular							
Clinical MI	1610	1128	70%	1089	97%	982	90%
Angina ⁴	2363	1709	72%	1677	98%	1298	77%
Congestive heart failure	1667	1132	68%	1086	96%	877	81%
CABG/PTCA	2656	1851	70%	1801	97%	1756	98%
DVT ⁵	395	395	100%	382	97%	369	97%
Pulmonary embolism ⁵	267	267	100%	257	96%	248	96%
Stroke ⁶	1458	674	46%	642	95%	584	91%
Cancers							
Breast cancer	2720	2720	100%	2659	98%	2652	>99%
Invasive	2148	2148	100%	2097	98%	2055	98%
Non-invasive	572	572	100%	562	98%	488	87%
Ovarian cancer	237	237	100%	224	95%	179	80%
Endometrial cancer	334	334	100%	325	97%	314	97%
Colorectal cancer	713	713	100%	692	97%	666	96%
Fractures							
Hip fracture	778	775	>99%	740	95%	699	94%

¹ Percentage is relative to locally confirmed cases.

² Percentage is relative to cases called forward for central adjudication.

³ Percentage is relative to centrally adjudicated cases.

⁴ Participants with a confirmed MI no longer require adjudication of angina.

⁵ HRT only.

⁶ Stroke is locally adjudicated for the entire CT but only centrally adjudicated for HRT participants.

Table 6.4
Agreement of Central Adjudications with Local Adjudications — OS Participants

Data as of September 12, 2005; Events through Study Closeout

	Locally confirmed	Called forward for central adjudication		Centrally adjudicated		In agreement	
	N	N	% ¹	N	% ²	N	% ³
Cardiovascular							
Clinical MI	1783	772	43%	754	98%	620	82%
Angina ⁴	2725	1448	53%	1429	99%	1124	79%
Congestive heart failure	2162	898	42%	874	97%	702	80%
CABG/PTCA	2972	1385	47%	1362	98%	1304	96%
Cancers							
Breast cancer	3776	3776	100%	3670	97%	3604	98%
Invasive	3075	3075	100%	2986	97%	2865	96%
Non-Invasive	701	701	100%	684	98%	559	82%
Ovarian cancer	323	323	100%	305	94%	257	84%
Endometrial cancer	472	472	100%	456	97%	429	94%
Colorectal cancer	841	841	100%	797	95%	755	95%
Fractures							
Hip fracture	1071	1071	100%	987	92%	941	95%

¹ Percentage is relative to locally confirmed cases.

² Percentage is relative to cases called forward for central adjudication.

³ Percentage is relative to centrally adjudicated cases.

⁴ Participants with a confirmed MI no longer require adjudication of angina.

Table 6.5
Agreement of Locally and Centrally Adjudicated Cause of Death for All CT Participants

Data as of September 12, 2005; Events through Study Closeout

	Closed Local ¹	Closed Central N %	Confirmed Cause N % ²	Related Cause N % ²	Unrelated Cause N % ²
Final adjudicated death	3606	3506 97%	3044 (87%)	240 (7%)	222 (6%)
Cardiovascular					
Atherosclerotic cardiac ³	555	540 97%	496 (92%)	21 (4%)	23 (4%)
Cerebrovascular	264	253 96%	232 (92%)	8 (3%)	13 (5%)
Pulmonary embolism	29	28 97%	23 (82%)	0 (0%)	5 (18%)
Other cardiovascular	208	194 93%	109 (56%)	61 (31%)	24 (12%)
Unknown cardiovascular	45	44 98%	6 (14%)	27 (61%)	11 (25%)
Total cardiovascular deaths	1101	1059 96%	866 (82%)	117 (11%)	76 (7%)
Cancer					
Breast cancer	95	94 99%	91 (97%)	2 (2%)	1 (1%)
Ovarian cancer	130	126 97%	109 (87%)	16 (13%)	1 (1%)
Endometrial cancer	19	17 89%	16 (94%)	1 (6%)	0 (0%)
Colorectal cancer	154	153 99%	150 (98%)	2 (1%)	1 (1%)
Other cancer	1151	1132 98%	1074 (95%)	44 (4%)	14 (1%)
Unknown cancer site	68	68 100%	50 (74%)	16 (24%)	2 (3%)
Total cancer deaths	1617	1590 98%	1490 (94%)	81 (5%)	19 (1%)
Accident/injury					
Homicide	7	7 100%	6 (86%)	1 (14%)	0 (0%)
Accident	86	84 98%	79 (94%)	4 (5%)	1 (1%)
Suicide	11	11 100%	11 (100%)	0 (0%)	0 (0%)
Other injury	10	9 90%	1 (11%)	6 (67%)	2 (22%)
Total accidental deaths	114	111 97%	97 (87%)	11 (10%)	3 (3%)
Other					
Other known cause	672	647 96%	540 (83%)	16 (2%)	91 (14%)
Unknown cause	102	99 97%	51 (52%)	15 (15%)	33 (33%)
Total deaths - other causes	774	746 96%	591 (79%)	31 (4%)	124 (17%)

¹ Excludes temporary adjudications.

² Percentages are relative to closed central.

³ "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.6
Agreement of Locally and Centrally Adjudicated Cause of Death for All OS Participants

Data as of September 12, 2005; Events through Study Closeout

	Closed Local ¹	Closed Central N %	Confirmed Cause N % ²	Related Cause N % ²	Unrelated Cause N % ²
Final adjudicated death	6012	2462 41%	1998 (81%)	203 (8%)	261 (11%)
Cardiovascular					
Atherosclerotic cardiac ³	821	342 42%	276 (81%)	24 (7%)	42 (12%)
Cerebrovascular	461	158 34%	135 (85%)	6 (4%)	17 (11%)
Pulmonary embolism	48	15 31%	10 (67%)	1 (7%)	4 (27%)
Other cardiovascular	374	156 42%	68 (44%)	61 (39%)	27 (17%)
Unknown cardiovascular	85	34 40%	4 (12%)	22 (65%)	8 (24%)
Total cardiovascular deaths	1789	705 39%	493 (70%)	114 (16%)	98 (14%)
Cancer					
Breast cancer	380	159 42%	151 (95%)	5 (3%)	3 (2%)
Ovarian cancer	185	79 43%	73 (92%)	4 (5%)	2 (3%)
Endometrial cancer	49	20 41%	13 (65%)	7 (35%)	0 (0%)
Colorectal cancer	227	101 44%	93 (92%)	3 (3%)	5 (5%)
Other cancer	1650	750 45%	699 (93%)	25 (3%)	26 (3%)
Unknown cancer site	136	67 49%	48 (72%)	17 (25%)	2 (3%)
Total cancer deaths	2627	1176 45%	1077 (92%)	61 (5%)	38 (3%)
Accident/injury					
Homicide	10	6 60%	5 (83%)	1 (17%)	0 (0%)
Accident	117	57 49%	49 (86%)	2 (4%)	6 (11%)
Suicide	25	17 68%	14 (82%)	1 (6%)	2 (12%)
Other injury	13	4 31%	2 (50%)	1 (25%)	1 (25%)
Total accidental deaths	165	84 51%	70 (83%)	5 (6%)	9 (11%)
Other					
Other known cause	1197	392 33%	310 (79%)	7 (2%)	75 (19%)
Unknown cause	234	105 45%	48 (46%)	16 (15%)	41 (39%)
Total deaths - other causes	1431	497 35%	358 (72%)	23 (5%)	116 (23%)

¹ Excludes temporary adjudications.

² Percentages are relative to closed central.

³ "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.7
Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total		Age				
			50-54	55-59	60-69	70-79	
Number randomized	68132		9188	14661	31389	12894	
Mean follow-up (months)	96.1		102.9	99.1	94.4	92.0	
Cardiovascular							
CHD ¹	2198	(0.40%)	116 (0.15%)	251 (0.21%)	1003 (0.41%)	828 (0.84%)	
CHD death ²	620	(0.11%)	29 (0.04%)	44 (0.04%)	266 (0.11%)	281 (0.28%)	
Total MI ³	1772	(0.32%)	91 (0.12%)	218 (0.18%)	810 (0.33%)	653 (0.66%)	
Clinical MI	1692	(0.31%)	85 (0.11%)	210 (0.17%)	772 (0.31%)	625 (0.63%)	
Evolving Q-wave MI ⁴	84	(0.02%)	7 (0.01%)	8 (0.01%)	41 (0.02%)	28 (0.03%)	
Possible evolving Q-wave MI ⁴	390	(0.07%)	40 (0.05%)	54 (0.04%)	170 (0.07%)	126 (0.13%)	
Angina	2412	(0.44%)	129 (0.16%)	331 (0.27%)	1213 (0.49%)	739 (0.75%)	
CABG/PTCA	2740	(0.50%)	134 (0.17%)	362 (0.30%)	1382 (0.56%)	862 (0.87%)	
Carotid artery disease	461	(0.08%)	14 (0.02%)	53 (0.04%)	239 (0.10%)	155 (0.16%)	
Congestive heart failure	1743	(0.32%)	81 (0.10%)	172 (0.14%)	744 (0.30%)	746 (0.76%)	
Stroke	1589	(0.29%)	58 (0.07%)	159 (0.13%)	722 (0.29%)	650 (0.66%)	
PVD	410	(0.08%)	20 (0.03%)	50 (0.04%)	200 (0.08%)	140 (0.14%)	
CHD ¹ /Possible evolving Q-wave MI	2564	(0.47%)	155 (0.20%)	304 (0.25%)	1162 (0.47%)	943 (0.95%)	
Coronary disease ⁵	5925	(1.09%)	330 (0.42%)	748 (0.62%)	2823 (1.14%)	2024 (2.05%)	
Total cardiovascular disease	7720	(1.42%)	398 (0.51%)	954 (0.79%)	3684 (1.49%)	2684 (2.72%)	
Cancer							
Breast cancer	2790	(0.51%)	314 (0.40%)	595 (0.49%)	1321 (0.53%)	560 (0.57%)	
Invasive breast cancer	2242	(0.41%)	231 (0.29%)	489 (0.40%)	1059 (0.43%)	463 (0.47%)	
Non-invasive breast cancer	569	(0.10%)	86 (0.11%)	110 (0.09%)	271 (0.11%)	102 (0.10%)	
Ovary cancer	239	(0.04%)	22 (0.03%)	50 (0.04%)	114 (0.05%)	53 (0.05%)	
Endometrial cancer ⁶	372	(0.07%)	36 (0.05%)	87 (0.07%)	183 (0.07%)	66 (0.07%)	
Colorectal cancer	722	(0.13%)	40 (0.05%)	104 (0.09%)	359 (0.15%)	219 (0.22%)	
Other cancer ⁷	2970	(0.54%)	227 (0.29%)	482 (0.40%)	1466 (0.59%)	795 (0.80%)	
Total cancer	6789	(1.24%)	617 (0.78%)	1269 (1.05%)	3286 (1.33%)	1617 (1.64%)	
Fractures							
Hip fracture	791	(0.14%)	14 (0.02%)	50 (0.04%)	279 (0.11%)	448 (0.45%)	
Vertebral fracture	828	(0.15%)	30 (0.04%)	83 (0.07%)	353 (0.14%)	362 (0.37%)	
Other fracture ⁷	7691	(1.41%)	890 (1.13%)	1422 (1.17%)	3611 (1.46%)	1768 (1.79%)	
Total fracture	8848	(1.62%)	928 (1.18%)	1532 (1.27%)	4061 (1.64%)	2327 (2.36%)	
Deaths							
Cardiovascular deaths	1113	(0.20%)	46 (0.06%)	78 (0.06%)	449 (0.18%)	540 (0.55%)	
Cancer deaths	1627	(0.30%)	91 (0.12%)	219 (0.18%)	794 (0.32%)	523 (0.53%)	
Other known cause	735	(0.13%)	39 (0.05%)	80 (0.07%)	294 (0.12%)	322 (0.33%)	
Unknown cause	122	(0.02%)	6 (0.01%)	10 (0.01%)	57 (0.02%)	49 (0.05%)	
Not yet adjudicated	8	(<0.01%)	2 (<0.01%)	0 (0.00%)	3 (<0.01%)	3 (<0.01%)	
Total death	3605	(0.66%)	184 (0.23%)	387 (0.32%)	1597 (0.65%)	1437 (1.45%)	

¹ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

² "CHD death" includes definite and possible CHD death.

³ "Total MI" includes clinical MI and evolving Q-wave MI.

⁴ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁵ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁶ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

⁷ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.7 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of September 12, 2005; Events through Study Closeout

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	93.8	92.7	94.8	91.7	96.6	92.1
Cardiovascular						
CHD ¹	8 (0.35%)	26 (0.22%)	225 (0.41%)	48 (0.22%)	1857 (0.42%)	34 (0.47%)
CHD death ²	2 (0.09%)	8 (0.07%)	96 (0.17%)	13 (0.06%)	489 (0.11%)	12 (0.17%)
Total MI ³	7 (0.31%)	23 (0.20%)	159 (0.29%)	39 (0.18%)	1516 (0.34%)	28 (0.39%)
Clinical MI	7 (0.31%)	22 (0.19%)	154 (0.28%)	37 (0.17%)	1446 (0.32%)	26 (0.36%)
Evolving Q-wave MI ⁴	0 (0.00%)	2 (0.02%)	5 (0.01%)	2 (0.01%)	73 (0.02%)	2 (0.03%)
Possible evolving Q-wave MI ⁴	3 (0.13%)	9 (0.08%)	42 (0.08%)	13 (0.06%)	319 (0.07%)	4 (0.06%)
Angina	12 (0.53%)	30 (0.26%)	299 (0.54%)	80 (0.36%)	1961 (0.44%)	30 (0.42%)
CABG/PTCA	12 (0.53%)	24 (0.20%)	258 (0.47%)	71 (0.32%)	2344 (0.52%)	31 (0.43%)
Carotid artery disease	3 (0.13%)	2 (0.02%)	28 (0.05%)	4 (0.02%)	418 (0.09%)	6 (0.08%)
Congestive heart failure	5 (0.22%)	17 (0.14%)	244 (0.44%)	49 (0.22%)	1404 (0.31%)	24 (0.33%)
Stroke	7 (0.31%)	31 (0.26%)	212 (0.38%)	42 (0.19%)	1274 (0.28%)	23 (0.32%)
PVD	5 (0.22%)	3 (0.03%)	60 (0.11%)	4 (0.02%)	334 (0.07%)	4 (0.06%)
CHD ¹ /Possible evolving Q-wave MI	11 (0.48%)	34 (0.29%)	265 (0.48%)	60 (0.27%)	2156 (0.48%)	38 (0.53%)
Coronary disease ⁵	24 (1.05%)	70 (0.60%)	703 (1.27%)	169 (0.77%)	4882 (1.09%)	77 (1.07%)
Total cardiovascular disease	34 (1.49%)	101 (0.86%)	913 (1.65%)	212 (0.96%)	6361 (1.42%)	99 (1.38%)
Cancer						
Breast cancer	7 (0.31%)	63 (0.54%)	225 (0.41%)	72 (0.33%)	2394 (0.54%)	29 (0.40%)
Invasive breast cancer	6 (0.26%)	47 (0.40%)	175 (0.32%)	58 (0.26%)	1933 (0.43%)	23 (0.32%)
Non-invasive breast cancer	1 (0.04%)	16 (0.14%)	51 (0.09%)	14 (0.06%)	481 (0.11%)	6 (0.08%)
Ovary cancer	1 (0.04%)	6 (0.05%)	15 (0.03%)	7 (0.03%)	205 (0.05%)	5 (0.07%)
Endometrial cancer ⁶	1 (0.04%)	3 (0.03%)	24 (0.04%)	11 (0.05%)	327 (0.07%)	6 (0.08%)
Colorectal cancer	5 (0.22%)	12 (0.10%)	72 (0.13%)	23 (0.10%)	599 (0.13%)	11 (0.15%)
Other cancer ⁷	11 (0.48%)	50 (0.43%)	217 (0.39%)	73 (0.33%)	2586 (0.58%)	33 (0.46%)
Total cancer	24 (1.05%)	129 (1.10%)	531 (0.96%)	175 (0.80%)	5853 (1.31%)	77 (1.07%)
Fractures						
Hip fracture	3 (0.13%)	7 (0.06%)	24 (0.04%)	13 (0.06%)	738 (0.17%)	6 (0.08%)
Vertebral fracture	2 (0.09%)	16 (0.14%)	12 (0.02%)	13 (0.06%)	769 (0.17%)	16 (0.22%)
Other fracture ⁷	26 (1.14%)	112 (0.95%)	422 (0.76%)	205 (0.93%)	6831 (1.53%)	95 (1.32%)
Total fracture	29 (1.27%)	131 (1.12%)	452 (0.82%)	222 (1.01%)	7905 (1.77%)	109 (1.51%)
Deaths						
Cardiovascular deaths	5 (0.22%)	19 (0.16%)	165 (0.30%)	21 (0.10%)	889 (0.20%)	14 (0.19%)
Cancer deaths	9 (0.39%)	28 (0.24%)	140 (0.25%)	46 (0.21%)	1381 (0.31%)	23 (0.32%)
Other known cause	9 (0.39%)	9 (0.08%)	78 (0.14%)	13 (0.06%)	616 (0.14%)	10 (0.14%)
Unknown cause	0 (0.00%)	2 (0.02%)	28 (0.05%)	3 (0.01%)	87 (0.02%)	2 (0.03%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (<0.01%)	7 (<0.01%)	0 (0.00%)
Total death	23 (1.01%)	58 (0.49%)	411 (0.74%)	84 (0.38%)	2980 (0.67%)	49 (0.68%)

¹ "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.

² "CHD death" includes definite and possible CHD death.

³ "Total MI" includes clinical MI and evolving Q-wave MI.

⁴ Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

⁵ "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

⁶ Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

⁷ Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity
for CT Participants who did not report a prevalent condition at baseline

Data as of September 12, 2005; Events through Study Closeout

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	96.1	102.9	99.1	94.4	92.0
Hospitalizations					
Ever	34752 (6.37%)	3472 (4.41%)	6252 (5.16%)	16574 (6.71%)	8454 (8.56%)
Two or more	19193 (3.52%)	1561 (1.98%)	3053 (2.52%)	9255 (3.75%)	5324 (5.39%)
Other					
DVT ¹	803 (0.15%)	48 (0.06%)	116 (0.10%)	373 (0.16%)	266 (0.28%)
Pulmonary embolism	511 (0.09%)	34 (0.04%)	77 (0.06%)	255 (0.10%)	145 (0.15%)
Diabetes (treated)	5264 (1.01%)	724 (0.95%)	1103 (0.95%)	2458 (1.05%)	979 (1.05%)
Gallbladder disease ²	5248 (1.15%)	746 (1.07%)	1195 (1.15%)	2463 (1.21%)	844 (1.06%)
Hysterectomy	2075 (0.65%)	264 (0.58%)	454 (0.60%)	1013 (0.71%)	344 (0.62%)
Glaucoma	7565 (1.44%)	744 (0.96%)	1457 (1.23%)	3662 (1.55%)	1702 (1.86%)
Osteoporosis	14695 (2.86%)	1450 (1.88%)	2635 (2.25%)	7142 (3.08%)	3468 (3.93%)
Osteoarthritis ³	13026 (3.87%)	1858 (3.15%)	2923 (3.51%)	5952 (4.11%)	2293 (4.61%)
Rheumatoid arthritis	4009 (0.77%)	538 (0.70%)	866 (0.74%)	1822 (0.77%)	783 (0.84%)
Intestinal polyps	10620 (2.10%)	1271 (1.66%)	2215 (1.92%)	5299 (2.33%)	1835 (2.10%)
Lupus	732 (0.13%)	111 (0.14%)	166 (0.14%)	335 (0.14%)	120 (0.12%)
Kidney stones ³	1877 (0.41%)	241 (0.38%)	379 (0.38%)	898 (0.43%)	359 (0.43%)
Cataracts ³	21568 (5.21%)	1468 (2.26%)	3731 (3.72%)	11649 (6.14%)	4720 (8.05%)
Pills for hypertension	17885 (4.66%)	2230 (3.51%)	3784 (4.10%)	8356 (4.98%)	3515 (5.84%)

Outcomes	Race/Ethnicity					
	Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
	Number randomized	292	1519	6983	2875	55525
Mean follow-up (months)	93.8	92.7	94.8	91.7	96.7	92.1
Hospitalizations						
Ever	152 (6.66%)	558 (4.76%)	3551 (6.44%)	1176 (5.35%)	28875 (6.46%)	440 (6.11%)
Two or more	95 (4.16%)	250 (2.13%)	2044 (3.70%)	580 (2.64%)	15981 (3.57%)	243 (3.38%)
Other						
DVT ¹	3 (0.14%)	2 (0.02%)	78 (0.15%)	15 (0.07%)	697 (0.16%)	8 (0.11%)
Pulmonary embolism	4 (0.18%)	2 (0.02%)	48 (0.09%)	7 (0.03%)	445 (0.10%)	5 (0.07%)
Diabetes (treated)	25 (1.21%)	146 (1.33%)	913 (1.87%)	351 (1.71%)	3751 (0.87%)	78 (1.16%)
Gallbladder disease ²	22 (1.31%)	86 (0.81%)	420 (0.85%)	243 (1.45%)	4403 (1.18%)	74 (1.21%)
Hysterectomy	6 (0.59%)	36 (0.47%)	130 (0.54%)	72 (0.59%)	1815 (0.68%)	16 (0.38%)
Glaucoma	40 (1.85%)	153 (1.36%)	1005 (1.96%)	338 (1.59%)	5930 (1.38%)	99 (1.47%)
Osteoporosis	66 (3.04%)	389 (3.50%)	909 (1.71%)	639 (3.12%)	12483 (2.97%)	209 (3.11%)
Osteoarthritis ³	63 (4.60%)	307 (3.62%)	1301 (3.92%)	650 (4.31%)	10504 (3.83%)	201 (4.44%)
Rheumatoid arthritis	32 (1.55%)	74 (0.66%)	682 (1.33%)	357 (1.70%)	2787 (0.65%)	77 (1.13%)
Intestinal polyps	53 (2.53%)	215 (2.00%)	1125 (2.19%)	375 (1.78%)	8710 (2.10%)	142 (2.14%)
Lupus	6 (0.27%)	12 (0.10%)	96 (0.17%)	40 (0.18%)	570 (0.13%)	8 (0.11%)
Kidney stones ³	15 (0.81%)	47 (0.47%)	190 (0.41%)	100 (0.54%)	1501 (0.40%)	24 (0.39%)
Cataracts ³	92 (5.36%)	428 (4.74%)	2002 (4.73%)	828 (4.64%)	17925 (5.31%)	293 (5.31%)
Pills for hypertension	78 (5.27%)	380 (4.76%)	1748 (6.34%)	824 (5.03%)	14636 (4.49%)	219 (4.60%)

¹ Inpatient DVT only.

² "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

³ These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.9
Locally Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of September 12, 2005; Events through Study Closeout

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	96.1		91.0	
Ppts with other cancer	2970	(0.54%)	4061	(0.57%)
Accessory sinus	1	<0.01%	1	<0.01%
Adrenal gland	1	<0.01%	6	<0.01%
Anus	12	<0.01%	18	<0.01%
Appendix	6	<0.01%	9	<0.01%
Biliary tract, parts of (other/unspecified)	40	(0.01%)	42	(0.01%)
Bladder	176	(0.03%)	218	(0.03%)
Bones/joints/articular cartilage (limbs)	4	<0.01%	8	<0.01%
Bones/joints/articular cartilage (other)	5	<0.01%	2	<0.01%
Brain	79	(0.01%)	87	(0.01%)
Cervix	51	(0.01%)	44	(0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	3	<0.01%
Connective/subcutaneous/soft tissues	27	<0.01%	41	(0.01%)
Endocrine glands, related structures	6	<0.01%	7	<0.01%
Esophagus	34	(0.01%)	37	(0.01%)
Eye and adnexa	16	<0.01%	13	<0.01%
Genital organs	35	(0.01%)	25	<0.01%
Kidney	136	(0.02%)	182	(0.03%)
Larynx	15	<0.01%	11	<0.01%
Leukemia	139	(0.03%)	185	(0.03%)
Liver	33	(0.01%)	41	(0.01%)
Lung	593	(0.11%)	772	(0.11%)
Lymph nodes	12	<0.01%	9	<0.01%
Lymphoma,Hodgkins	17	<0.01%	17	<0.01%
Lymphoma,Non-Hodgkins	265	(0.05%)	380	(0.05%)
Melanoma of the skin	400	(0.07%)	510	(0.07%)
Multiple myeloma	106	(0.02%)	96	(0.01%)
Oral (mouth)	22	<0.01%	16	<0.01%
Palate	5	<0.01%	7	<0.01%
Pancreas	146	(0.03%)	186	(0.03%)
Parotid gland (Stensen's duct)	9	<0.01%	20	<0.01%
Peripheral nerves and autonomic nervous system	1	<0.01%	5	<0.01%
Pyriform sinus	0	(0.00%)	4	<0.01%
Respiratory system, intrathoracic, other	9	<0.01%	16	<0.01%
Salivary glands, major (other/unspecified)	3	<0.01%	11	<0.01%
Stomach	45	(0.01%)	56	(0.01%)
Thyroid	90	(0.02%)	106	(0.01%)
Tongue, part of (other/unspecified)	20	<0.01%	21	<0.01%
Urinary organs (other/unspecified)	12	<0.01%	25	<0.01%
Uterus, not otherwise specified	41	(0.01%)	81	(0.01%)
Other/unknown site of cancer	246	(0.05%)	309	(0.04%)
Other/unknown cancers reported on death form	209	(0.04%)	525	(0.07%)

Table 6.10
Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants

Data as of September 12, 2005; Events through Study Closeout

	CT	OS ¹
<u>Locally Verified</u>		
Number of participants	68132	6365
Mean follow-up time (months)	96.1	98.6
Ppts with other fractures²	7691 (1.41%)	697 (1.33%)
Ankle	1352 (0.25%)	129 (0.25%)
Carpal bone(s) in wrist	192 (0.04%)	13 (0.02%)
Clavicle or collar bone	147 (0.03%)	14 (0.03%)
Elbow, not otherwise specified	31 (0.01%)	1 (<0.01%)
Humerus, shaft/unspecified	86 (0.02%)	7 (0.01%)
Humerus, upper end	842 (0.15%)	71 (0.14%)
Humerus, lower end	104 (0.02%)	10 (0.02%)
Metacarpal bone(s)	272 (0.05%)	27 (0.05%)
Patella	358 (0.07%)	29 (0.06%)
Pelvis	361 (0.07%)	51 (0.10%)
Radius or ulna	2227 (0.41%)	210 (0.40%)
Sacrum and coccyx	107 (0.02%)	12 (0.02%)
Scapula	37 (0.01%)	6 (0.01%)
Shaft of femur	113 (0.02%)	10 (0.02%)
Tarsal/metatarsal bones	1291 (0.24%)	130 (0.25%)
Tibia and fibula	640 (0.12%)	32 (0.06%)
Tibial plateau	176 (0.03%)	10 (0.02%)
Upper radius/ulna	381 (0.07%)	34 (0.07%)
Unknown other fracture	1 (<0.01%)	0 (0.00%)
<u>Self-Reports</u>		
Number of participants		93676
Mean follow-up time (months)		91.0
Elbow		676 (0.10%)
Foot		2316 (0.33%)
Hand		450 (0.06%)
Knee		796 (0.11%)
Lower Arm		3357 (0.47%)
Lower Leg		2626 (0.37%)
Pelvis		682 (0.10%)
Tailbone		198 (0.03%)
Upper Arm		1444 (0.20%)
Upper Leg		433 (0.06%)
Vertebra		1708 (0.24%)
Other Fracture		2574 (0.36%)

¹ Locally verified other fractures for OS Participants are only confirmed in the three bone density clinics.

² "Other fractures" excludes fractures indicated as pathological.

Table 6.11
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of September 12, 2005; Events through Study Closeout

	CT-	OS
Number Randomized	68132	93676
Mean Follow-up Time (months)	96.1	91.0
Total death	3605 (0.66%)	6260 (0.88%)
Adjudicated death	3597 (0.66%)	6133 (0.86%)
Centrally adjudicated death	3439 (0.63%)	0 (0.00%)
Locally adjudicated death (final)	78 (0.01%)	5893 (0.83%)
Temporary adjudicated death	42 (0.01%)	120 (0.02%)
Identified by NDI search	38 (0.01%)	120 (0.02%)
Cardiovascular		
Atherosclerotic cardiac	620 (0.11%)	824 (0.12%)
CHD deaths locally adjudicated before 10/99	0 (0.00%)	82 (0.01%)
Definite CHD deaths	297 (0.05%)	336 (0.05%)
Possible CHD deaths	323 (0.06%)	406 (0.06%)
Cerebrovascular	271 (0.05%)	465 (0.07%)
Pulmonary embolism	38 (0.01%)	49 (0.01%)
Other cardiovascular	166 (0.03%)	377 (0.05%)
Unknown cardiovascular	18 (<0.01%)	87 (0.01%)
Total cardiovascular deaths	1113 (0.20%)	1802 (0.25%)
Cancer		
Breast cancer	98 (0.02%)	382 (0.05%)
Ovarian cancer	116 (0.02%)	189 (0.03%)
Endometrial cancer	26 (<0.01%)	49 (0.01%)
Colorectal cancer	154 (0.03%)	229 (0.03%)
Other cancer	1138 (0.21%)	1666 (0.23%)
Unknown cancer site	95 (0.02%)	139 (0.02%)
Total cancer deaths	1627 (0.30%)	2654 (0.37%)
Accident/injury		
Homicide	7 (<0.01%)	10 (<0.01%)
Accident	100 (0.02%)	117 (0.02%)
Suicide	14 (<0.01%)	25 (<0.01%)
Other injury	5 (<0.01%)	15 (<0.01%)
Total accidental deaths	126 (0.02%)	167 (0.02%)
Other		
Other known cause	609 (0.11%)	1217 (0.17%)
Unknown cause	130 (0.02%)	420 (0.06%)
Total deaths – other causes	739 (0.14%)	1637 (0.23%)

Table 7.1
WHI Core Studies

Ref #	Title	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
W1	CT Blood Subsample	CT	6% subsample at baseline, Year, 1, 3, and 6	Blood: α - and β -carotene; α and γ -tocopherol; β -cryptoxanthine; FVII Ag; FVIIIc; fibrinogen; glucose; insulin; lipids (cholesterol; HDL; HDL-2; HDL-3; LDL; Lp(a); triglyceride); lutein+zeaxanthin; lycopene; retinol	1995-2005
W2	Measurement Precision Study (OS-MPS)	OS	800 at baseline and 3 months	Blood: α - and β -carotene; α and γ -tocopherol; β -cryptoxanthine; FVII Ag; FVIIIc; fibrinogen; glucose; insulin; lipids (cholesterol; HDL; HDL-2; HDL-3; LDL; Lp(a); triglyceride); lutein+zeaxanthin; lycopene; retinol	2000
W4	National Validation and Quality Assurance of Vitamin D Absorption from CaD Tablets for the WHI	CaD	460 participants at Year 3	Blood: 25-OH-Vitamin D ₃	2000
W5	DM Hormones	DM	300 at baseline and Year 1	Blood: albumin; androstenedione; bioavailable estradiol; DHEA; DHES; DHT; estradiol; estrone; estrone-sulfate; progesterone; prolactin; SHBG; testosterone; DNA: CYP19; SHBG; HSD17B1; HSD17B2; HSD17B3; HSD17B4; CYP11A1; CYP11A2; CYP11B1; CYP3A4; COMT; SULT1A1; SULT1E1; UGT1A1; ESR1; ESR2; PGR; NCOA1; NCOA2; NCOA3	2000
W6 W14	CVD Biomarkers - Phase I	HT	402 CHD cases, 272 stroke cases, 223 VTE cases/ controls at baseline and Year 1	Blood: APC resistance; AIII; cholesterol; CRP; D-dimer; E-selectin; F1+2; FVII Ag; FVIIIc; FIXc; FXIc; fibrinogen; glucose; homocysteine; HDL; IL-1 beta; insulin; LDL; LDL particle size (12 measures); Lp(a); MMP-9; PAI-1 Ag; protein C; protein S total; protein S free; PAP; TAFI; TFB1; TGF-beta; triglyceride; vWF.; <i>Added in 2004:</i> APC-E1P; lipid subfractions and LDL particle size by NMR; Free TFP-1, Total TFP-1, TFP1 activity; (tests not done on all three types of cases and not done at both time points) DNA: ER α -PvuII4; ER α -I989/G; ER β -I730A/G; ER β -CA repeats; FXII val344eu; FV-HR2; FV-Leiden; GPIIb/IIIa-Kob.a; GPIIb/IIIa-VNTR; GPIIIa-PIA1-A2; Integrin α 2-807CT; MTHFR; PT19911; PT20210; PAI-1; MTHFR; <i>Added in 2004:</i> ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; ESR2 A1730G; GPIIba M145T; GPIIIa P1-P2; ITGA2 807	2000-2006

Table 7.1 (continued)
WHI Core Studies

Ref #	Title	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
W11	CVD Biomarkers - Phase II Stroke after Feb 2001	HT	108 new E+P cases up to July 2002, 174 E-alone cases up to March 2005	Blood: E-Selectin; IL-6; CRP; APC-ETP; Free TFFP-I, Total TFFP-I, TFFP-I activity; glucose, insulin; DNA: ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; ESR2 A1730G; GP1ba M145T; GPIIa P1-P2; ITGA2 807	2006
W7	HT Genome-Wide Scan on Breast Cancer, CHD, and Stroke	HT and OS	Stage I: 1000 breast cancer, 1000 CHD, 1000 stroke cases/ controls; Stage II: 800 breast cancer, 773 CHD, 613 stroke cases/ controls; Stage III: 349 breast, 335 CHD, 258 stroke cases/ controls	DNA: Stage I: 250,000 SNPs in OS DNA pools; Stage II: approx 4,000 individual SNPs in OS; Stage III: individual SNPs in CT	2005-2006
W8	Nutritional Biomarkers Study	DM	275 participants	Blood: BUN Urine: isotopes, nitrogen, PABA	2005
W9	Biological Markers of the Effect of HT on Risk of Fractures in the Women's Health Initiative Clinical Trial	HT	750 fracture cases, including 125 hip fractures and 625 non-spine fractures; DNA on all 3,600 fracture cases	Blood (750 cases): bioavailable estradiol, total estradiol; SHBG; testosterone; Blood (1500 cases/controls): P1NP; CTx DNA: CYP19; SHBG; HSD17B1; HSD17B2; HSD17B3; HSD17B4; CYP1A1; CYP1A2; CYP1B1; CYP3A4; COMT; SULT1A1; UGT1A1; ESR1; ESR2; PGR; NCOA1; NCOA2; NCOA3	2005-2006
W10	Biological Markers of the Effect of HT and ET on Risk of Breast Cancer in the Women's Health Initiative Clinical Trial	HT	927 breast cancer cases (blood at baseline and Year 1)	Blood: total estradiol, bioavailable estradiol, estradiol sulfate, estrone sulfate, estrone, SHBG; testosterone; insulin, glucose, IGF-1, IGFBP-3; MPA on subset DNA: ER-a, ER-b, PGR, SHBP, CYP19, CYP1A1, CYP1A2, CYP1B1, CYP3A4, COMT, HSD17B1, HSD17B2, HSD17B3, HSD17B4, SULT1A1, SULT1E1, UGT1A1, NCOA1, NCOA2, NCOA3	2005-2006

Table 7.1 (continued)
WHI Core Studies

Ref #	Title	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
W15	Vitamin D Levels in CaD Participants with Colorectal Cancer or Fractures	CaD	3,800 cases/controls of colorectal cancer or hip, spine, or lower arm/wrist fractures	Blood: 25-OH-Vitamin D3 using radioimmuno assay method	2005
W18	HT Hormone Pretest	HT	50 E+P and 50 E-Along active and placebo; baseline and Year 1	Blood: estradiol, estrone, SHBG on E+P and E-Along samples, progesterone and testosterone on E+P only samples	2005
W19	WHI Proteomic 'Pilot' Study	HT	50 E+P and 50 E-Along active/ placebo/ baseline/ Year 1, excluding WHI primary outcomes	Blood: intact proteins identified by 1) fractionation and quantified by dye labeling and 2) isotope labeling with shotgun peptide analysis of fractions	2006
W20	WHI-EDRN Pilot Study for the Identification of Circulating Biomarkers for Colon Cancer in Pre-Clinical Specimens	HT	100 colon cancer cases/ controls	Blood: intact proteins identified by 1) peptide shotgun, 2) tumor antigen/autoantibody, 3) peptide capture mass spectrometry, and 4) intact protein analysis system approaches	2006-2007
Ref #	Title	Study Population	Case/Controls	Other Data	Proposed Study Dates
-	Coronary Artery Calcium Study (CACS)	HT	950 E-Along participants	Coronary artery imaging	2005

**Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type**

Disease	AS #	Title	Study PI	WHI PI	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
Cancer								
Breast Cancer	129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Strickler	Smoller	OS	900 cases/controls	Blood: estradiol; glucose; IGF-1; IGFBP-3; insulin	02/01/02-12/31/05
Breast Cancer	134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Modugno	Kuller	OS	200 cases/controls	Blood: 2-OH estrone; 16a-OH estrone	07/01/02-06/30/04
Breast Cancer	152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Ho	Smoller	OS	900 cases/controls (same as AS129)	DNA: IGF-1; IGFBP-3; insulin; insulin receptor substrate 1	08/01/03-07/31/07
Breast Cancer	167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Cummings	Cummings	OS	400 cases/600 controls	Blood: estradiol total; SHBG; total testosterone	01/01/05-12/31/05
Breast Cancer	188*	Inflammation and the Risk of Hormonally-Linked Cancer	Modugno	Kuller	OS	500 cases/controls (add AS 129 cases)	Blood: EGF; EGFR; eot; FGF; GCSE; GMCSE; IFNs; IL-1 cluster; sIL-2r; IL-2; IL-4; IL-5; IL-6; sIL-6r; IL-8; IL-10; IL-12p40; IL-13; IL-15; IL-17; MCP; MIPs; TNFa; TNFa soluble receptors I and II; VEGF; CRP; estradiol DNA: IL-1B-31 (TT); IL-1B-511 (TT); IL-IRNVNTR*2; IL-6 -597/-572/-373/-174; IL-8-251-A-T; IGF-1 (CA)n 192/192; IL-10-1082/-819/-592 (GCC/GCC); TNFa-308 (AA); TGFBR1*6A; TGFBR1 29 (CC)	07/06-06/09
Breast Cancer	215*	UGTs, NSAIDs, and Breast Cancer Risk in the WHI Observational Study	Lampe	Prentice	OS	3398 cases/controls	DNA: UGT1A1*28; UGT1A3(W11R); UGT1A3(V47A); UGT1A3(M270V); UGT1A6*2; UGT1A6*3; UGT1A7*2; UGT1A7*3; UGT1A7*4; UGT1A8*2; UGT1A8*3; UGT1A9(T110); UGT1A9*3; UGT2B4(D458E); UGT2B7(H268Y); CYP2C9*2; CYP2C9*3	12/05-11-09
Colorectal Cancer	108	Gene-environment effects and Colorectal Cancer	Lin	Chlebowski	OS	50 cases/150 controls	DNA: PTGS2/Cox-2 val511ala; May 2005: added hematopoietic prostaglandin D synthase	04/01/03-03/31/04

Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type

Disease	AS #	Title	Study PI	WHI PI	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
Cancer (continued)								
Colorectal Cancer	129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Strickler	Smoller	OS	500 cases/ controls	Blood: estradiol; glucose; IGF-1; IGFBP-3; insulin	02/01/02- 12/31/05
Colorectal Cancer	152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Ho	Smoller	OS	500 cases/ controls (same as AS129)	DNA: IGF-1; IGFBP-3; insulin; insulin receptor substrate 1	08/01/03- 07/31/07
Colorectal Cancer	192*	Estrogen & progesterone-related genes and colorectal cancer risk	Zhang	Manson	OS	800 cases/ 1600 controls	DNA: ESR1 (PVI; XbaI); ESR2 (CA repeat; G1730A); PGR (G+331A); CYP1A1 (MspI; Ile462Val); CYP1B1 (Leu432Val; Asn453Ser); CYP17A1 (T-34C); CYP19A1 ([TTTA]n repeat; G240A); COMT (Val158Met); HSD17B2 (Ser312Gly); 100 SNPs for haplotype analyses	
Colorectal Cancer	195*	Candidate Pathways in Colorectal Carcinogenesis: One-carbon Metabolism and Inflammation	Ulrich	Prentice	OS	925 cases/ 1338 controls	Blood: CRP; serum-amyloid A; creatinine; homocysteine, folate, pyridoxal-5'-phosphate (vitamin B6), vitamin B12, and holotranscobalamin II. RBC: folate DNA: Candidate polymorphisms in one-carbon metabolism (MTHFR, thymidylate synthase, reduced folate carrier, trifunctional enzyme, gamma-glutamyl-hydroxylase, methionine synthase, methionine synthase reductase, serine hydroxyl-methyl-transferase, holotranscobalamin II, DNA methyltransferase, alcohol dehydrogenase II) and in prostaglandin synthesis/pro-inflammatory cytokines (Cyclooxygenases 1 and 2, 5-Lipoxygenase, Prostacyclin synthase, TGFbeta, CRP, TNFa, IL-6); global DNA methylation	03/06- 02/11
Colorectal Cancer	206*	Selenium, Genetic Variation in Selenoenzymes and Colorectal Cancer	Peters	Prentice	OS	925 Cases, 1338 Controls	Blood: selenium levels with atomic absorption spectrometry DNA: 40 tagging polymorphisms in the following 6 selenoenzymes: GPX1, GPX2, GPX3, GPX4, TXNRD1, SEPP1	03/01/06- 02/28/11
Colorectal Cancer	208*	Proinflammatory Markers and Colorectal Cancer	Ho	Smoller	OS	500 cases/ 900 controls	Blood: TNFa, IL-6, CRP DNA: TNFa, TNFR1, TNFR2, IkBa, IkBb, IKKBB, IL6, gp130, STAT3	

Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type

Disease	AS #	Title	Study PI	WHI PI	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
Cancer (continued)								
Endometrial Cancer	129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Strickler	Smoller	OS	300 cases/controls	Blood: estradiol; glucose; IGF-1; IGFBP-3; insulin	02/01/02-12/31/05
Endometrial Cancer	152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Ho	Smoller	OS	300 cases/controls (same as AS129)	DNA: IGF-1; IGFBP-3; insulin; insulin receptor substrate 1	08/01/03-07/31/07
Endometrial Cancer	188*	Inflammation and the Risk of Hormonally-Linked Cancer	Modugno	Kuller	OS	500 cases/controls (add AS 129 cases)	Blood: EGF; EGFR; cot; FGF; GCSF; GMCSF; IFNs; IL-1 cluster; sIL-2; IL-4; IL-5; IL-6; sIL-6r; IL-8; IL-10; IL-12p40; IL-13; IL-15; IL-17; MCP; MIPs; TNFa; TNFa soluble receptors I and II; VEGF; CRP; estradiol DNA: IL-1B-31 (TT); IL-1B-511 (TT); IL-IRNVNTR*2; IL-6-597/-572/-373/-174; IL-8-251-A-T; IGF-1 (CA)n 192/192; IL-10-1082/-819/-592 (GCC/GCC); TNFa-308 (AA); TGFβR1 *6A; TGFβ1 29 (CC)	7/06-6/09
Lung Cancer	182*	Genetic and Epigenetic Markers of Lung Cancer Risk in Post-Menopausal Women	Schlecht	Smoller	OS	550 cases/1100 controls	DNA: Dnmt1; Dnmt3b; MGMT; MS; MTHFR; MTRR; p16; p53; RASSF1A; RARBeta	07/06-06/07
Ovarian Cancer	97	Modeling serum markers for cost-effective ovarian cancer screening	Anderson	Anderson	OS	240 cases/480 controls	Blood: CA-125; M-CSF; OVX1	09/30/01-06/30/09
Ovarian Cancer	121	Hyperinsulinemia and Ovarian Cancer	Modugno	Kuller	OS	225 cases/controls	Blood: glucose; IGF-1; IGFBP-1; IGFBP-3; insulin	09/01/02-08/31/04
Ovarian Cancer	188*	Inflammation and the Risk of Hormonally-Linked Cancer	Modugno	Kuller	OS	350 cases/controls	Blood: EGF; EGFR; cot; FGF; GCSF; GMCSF; IFNs; IL-1 cluster; sIL-2; IL-4; IL-5; IL-6; sIL-6r; IL-8; IL-10; IL-12p40; IL-13; IL-15; IL-17; MCP; MIPs; TNFa; TNFa soluble receptors I and II; VEGF; CRP; estradiol DNA: IL-1B-31 (TT); IL-1B-511 (TT); IL-IRNVNTR*2; IL-6-597/-572/-373/-174; IL-8-251-A-T; IGF-1 (CA)n 192/192; IL-10-1082/-819/-592 (GCC/GCC); TNFa-308 (AA); TGFβR1 *6A; TGFβ1 29 (CC)	7/06-6/09

Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type

Disease	AS #	Title	Study PI	WHI PI	Study Population	Cases/ Controls	Blood Analytes	Proposed Study Dates
Cardiovascular								
Pancreatic Cancer	146	A Prospective Study of Pancreatic Cancer Pathogenesis	Fuchs	Manson	OS	106 cases/ 318 controls	Blood: B12; folate; GST; homocysteine; IGF-I; IGF-II; IGFBP-1; IGFBP-3; insulin; pyridoxal-5-phosphate; DNA: CYP1A1; GSTM1; NAT1; NAT2; MTHFR-667; MTHFR-1287	03/01/03- 12/31/04
Pancreatic Cancer	214*	Prospective Study of Pancreatic Cancer Pathogenesis	Fuchs	Manson	OS	200 cases/ 400 controls	EDTA: C-peptide, insulin, proinsulin, adiponectin, leptin, CRP, IL6, TNFaRII, H. pylori whole cell and CagA antibodies, gastrin, carotenoids, retinol, 25(OH)vitamin D; RBC: Hemoglobin A1c; DNA: IRS1; IRS2; IGF1; IGF-2; IGF1R; IGF2R; GH1; GHR; IGFBP1; IGFBP-3; adiponectin; IL1B; IL1RN; IL6; IL8; IL10; TNFa; TGFB1; PPARD; NFKB1; NFKBIA; NFKBIL1; COX-1 (PTGS1); COX-2 (PTGS2); VDR	
CHD	83	Thrombotic, Inflammatory and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Ridker	Manson	OS	650 cases/ controls	Blood: cholesterol; CRP; D-dimer; HDL; homocysteine; sICAM-1; IL-6; LDL; Lp(a); tPA; triglyceride	09/01/99- 08/31/03
CHD	110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Rexrode	Manson	OS	385 cases/ controls	Blood: DHES; estradiol; estrone sulfate; FVII Ag; FVIIc; fibrinogen; estrone sulfate; SHBG; testosterone; glucose, insulin, cholesterol; HDL; HDL-2; HDL-3; LDL; Lp(a); triglyceride	09/01/00- 08/31/03
CHD	137	Postmenopause CHD risk: platelet genes & hormone therapy	Bray	Hays	OS	1060 cases/ 2120 controls	DNA: GPIIIa (integrin beta3); integrin alpha2 (platelet GPIa); GPI b alpha; ER beta; ER alpha; alpha2-adrenergic receptor; beta 3 subunit of G protein; GPVI	09/27/03- 08/31/07
CHD	165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Hartman	Hetsis	OS	800 cases/ 1600 controls	Blood: TSH on all; free T4 and TPO-Ab on subset	09/01/04- 07/31/07
CHD	164*	The IGF System and Coronary Heart Disease	Kaplan	Smoller	OS	350 cases/ controls	Blood: IGF-I total; IGFBP-3	01/06- 12/06
CHD	189*	Biochemical and Anthropometric Heterogeneity among Morbid Obese Women in the Women's Health Initiative Observational Study	Kuller	Kuller	OS	150 cases/ 1300 controls	Blood: NMR lipoproteins, adiponectin; ghrelin; glucose; insulin; leptin	12/05- 11/08

**Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type**

Disease	AS #	Title	Study PI	WHI PI	Study Population	Cases/Controls	Blood Analytes	Proposed Study Dates
Cardiovascular (continued)								
CHD	209*	Red blood cell omega-3 and trans fatty levels and the risk of coronary heart disease death	Robinson	Wallace	OS	800 cases/controls	RBC: EPA, DHA, ALA, and trans fatty acids	
Stroke	126	Stroke Risk Factors and Molecular Markers in Postmenopausal Women	Smoller	Smoller	OS	1100 cases/controls	Blood: cholesterol; HDL, triglyceride; Lp(a), PAI-1 Ag, NMR lipoprotein particle size, Lp-PLA2, CRP; D-dimer; E-selectin; F1+2; FVII Ag, FVIIc; fibrinogen; glucose; homocysteine; IL-6; insulin; MMP-9; neopterin; tPA; TNF-alpha; VCAM-1; IL-6	08/01/03-07/31/06
Stroke	165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Hartman	Heiss	OS	750 cases/1500 controls	Blood: TSH on all; free T4 and TPO-Ab on subset	09/01/04-07/31/07
Stroke	169*	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Kaplan	Smoller	OS	330 cases/700 controls	Blood: fibrinogen, vWF; Elastase, MMP-2, MMP-3, MMP-9, MMP-12, MMP activity, MMP-2/TIMP-1 Complex (activated MMP2), MMP-9/TIMP-2 complex (activated MMP-9), TIMP-1; HDL; cholesterol, LDL; triglycerides, glucose, CRP DNA: ApoE genotype (e2, e3, e4)	4/06-7/10
Stroke	187*	Serum Fatty Acids and Salicylic Acid in Relation to Incidence of Ischemic Stroke in Postmenopausal Women	He	Van Horn	OS	1050 cases/controls	Blood: fatty acids: myristic acid, palmitic acid, trans-elaidic acid, trans-linoleic acid; alpha-linolenic acid, eicosapentaenoic acid, docosahexaenoic acid; salicylic acid	
Hypertension	133	Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women	Sesso	Manson	OS	800 cases/controls	Blood: CRP; sICAM-1; IL-6; IL-1β; MMP-9; TNF-α; DNA: CRP, sICAM-1, IL-6, TNF-alpha; IL-1beta; MMP-9, adiponectin, PPAR-gamma2	08/01/04-07/31/08
Fracture								
Hip Fracture	90	WHI Sex Hormone and Genetic Risk Factors for Hip Fracture	Cummings	Cummings	OS	400 cases/controls	Blood: cystatin-C; estradiol; homocysteine; IGF-1; SHBG; testosterone; TSH; DNA: androgen receptor (AR); ApoE4; aromatase (CYP19); Coil A1 Sp 1; ESR1; ESR2; LDL receptor-related protein 5 (LRP5); TGF-beta-1 (Leu10pro); SHBG; VDR/FOK1	04/01/04-03/31/06

Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type

Disease	AS #	Title	Study PI	WHI PI	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
Fracture (continued)								
Hip Fracture	181	Estradiol, Cytokines, and Bone Turnover: Effects on Hip Fracture	Cauley	Kuller	OS	400 cases/controls (same as AS90)	Blood: CTx; IL-6sR; OPG; PINP; RANKL; TNF-alpha-SR-1; TNF-alpha-SR-2	07/01/05-06/30/08
Any Fracture	211*	Risk of Fractures and Low Bone Mass in Women: Role of Homocysteine levels, Total Intake of Folate and Other B Vitamins, and Genetic Determinates of Homocysteine Metabolism	LeBoff	LaCroix	OS	2500 cases/controls for homocysteine (B+Y1) and DNA; 400 cases/controls for serum and urine	EDTA: Homocysteine; Serum: CTx, BSAP; osteocalcin, serum OPG; rank ligand DNA: MTHFR C677T and A1298C; CBS G919A and T833C; MTR A2756; MTRR G66A Urine: N-telopeptides	12/05-11/08
Any Fracture	212*	Biochemical Antecedents of Fracture in Minority Women	Cauley	Kuller	OS	1320 cases/controls	Blood: Total estradiol, total testosterone, SHBG; PINP, CTx, 25-OH Vitamin D	4/06-3/10
Other								
Diabetes	132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Liu	Manson	OS	2150 cases/controls	Blood: CRP; E-selectin; glucose; ICAM-1; IL-6; insulin; TNF-alpha; VCAM-1; DNA: AP2; CAPN10; E-selectin ser128arg; NOS3; PPAR-g2Pro12A1a; TNF alpha G308A; UCP2	08/01/02-07/30/07
Diabetes	180*	Macrovascular Complications of Diabetes in Postmenopausal Women	Li	Johnson	OS	3164 cases	DNA: ACE; ADRB2; AGT; AGTRI; GNB3; NOS3; PPARG; RETN; TNF; UCP3, LPL, APOE, LDLR	12/05-11/09
Eye Disease	105	Carotenoids in Age-Related Eye Disease Study	Mares-Perlman	Sarto	OS	1350 cases/controls	Blood: alpha- and beta-carotene; all trans-beta-carotene; 9-cis-beta-carotene; 13-cis-beta-carotene; alpha- and beta-cryptoxanthine; alpha-delta-; and gamma-tocopherol; alpha- and beta cryptoxanthine; all trans-lutein; lutein cis-isomer-1; lutein cis-isomer-2; lutein cis-isomer-3; all trans-lycopene; 5-cis-lycopene; 9-cis-lycopene; 13-cis-lycopene; 15-cis-lycopene; total lycopene (trans+cis); retinol; retinyl palmitate; zeaxanthin; zeaxanthin cis isomer; cholesterol; triglyceride; Dec. 2004: added CRP, 25-OH Vitamin D	06/01/00-04/30/04

**Table 7.2
Funded and Approved WHI Ancillary Studies
Using Blood Resources by Disease Type**

Disease	AS #	Title	Study PI	WHI PI	Study Population	Case/Controls	Blood Analytes	Proposed Study Dates
Other (continued)								
Frailty/ Disability	179	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women	LaCroix	LaCroix	OS	600 controls	Blood: CRP; D-dimer; FVII Ag; FVIIc; FVIII; FXI a1-antitrypsin; fibrinogen; IL-6; PAP complex; DNA: ACE gene insertion (I) polymorphism; two promoter polymorphisms (-174G/C and -572G/C) of IL-6 gene	07/01/05-06/30/08
Scarcopenia	191/199*	Biomarkers and Genetic Determinants for Sarcopenia	Chen	Bassford	OS BMD	800 cases/ 1600 controls	Blood: CRP; Insulin, leptin, Acid Labile Subunit (ALS), IL-1a, IL-1b, IL-1ra, IL-6, IL-6sR, IL-10, TNF-alpha, TNFRII, IGF-1, IGFBP-1, IGFBP-3 DNA: IL-6 (3 marker SNPs and 1 minisatellite); IL1beta, IL1alpha, and IL1ra gene cluster (5 SNPs); TNF-alpha (4 sites); IGF-1 (8 tag SNPs); GHI (3 SNPs)	07/06-06/11

* = Pending funding

Table 7.3
OS Blood Committed to Ancillary Studies (AS)
 Updated through 9-12-05

Disease ¹	Cases reported as of 9-05	AS #	Cases committed	Volume Committed (Baseline/Year 3)						
				Serum (ml)	Citrate Plasma (ml)	EDTA Plasma (ml)	DNA (µg)	Other (ml)		
Cancer										
Breast Cancer	4,106	129	900 ⁶	0.25						
		134	200	0.3						
		152	900 ⁶				3			
		167	400			1.0				
		188 ³	500	0.125			1			
		215 ³	3,398				1			
		Colorectal Cancer	908	108	50				1	
				129	500 ⁶	0.25				
				152	500 ⁶				3	
				192 ³	800				1	
195 ³	925			0.2 Base 0.2 AV3		0.8	0.8	0.2 RBC		
Endometrial Cancer	551	206 ³	925	0.08 on 725 0.16 on 200 0.08 AV3 on 100			0.8			
		208 ³	500			0.5	1			
		129	300 ⁶	0.25						
		152	300 ⁶				3			
Lung Cancer	772	188 ³	500	0.125			1			
		182 ³	550	1.25 Base 1.25 Yr 1			1			
Ovarian Cancer	362	97	264 Base, 132 Yr 3	1.0 Base 1.0 Yr 3						
		121	200	0.5						
		188 ³	350	0.125			1			
Pancreatic Cancer	152	146	106			0.6	3			
		214 ³	200	1.2			1	0.1 RBC		
Cardiovascular										
CHD	2,471	83	650		1.0	0.5	3			
		110	385	1.8 ²						
		137	1,060				3			
		165	800	0.25-0.55						
		164 ³	350			0.3				
		189 ³	150	0.32		0.1				
		209 ³	800					.25 RBC		
Stroke	2,011	126	1,100		1.5	1.5				
		165	750	0.25-0.55						
		169 ³	188	0.9	0.5		1			
		187 ³	1,050							
Hypertension	21,589	133	800			0.8	2			

Table 7.3 (continued)
 OS Blood Committed to Ancillary Studies (AS)
 Updated through 9-12-05

Disease ¹	Cases reported as of 2-04 9/05	AS #	Cases committed	Volume Committed (Baseline/Year 3)				
				Serum (ml)	Citrate Plasma (ml)	EDTA Plasma (ml)	DNA (µg)	Other (ml)
Fracture								
Hip Fracture	1,132	90	400 ⁴	1.7			3	
		181	400 ⁴	0.75 ⁵				
Any fracture	1,878	211 ³	2,500			0.5 Base 0.5 Yr 3	1	
			400	1.0				0.5 Urine
		212 ³	1,320	1.0				
Other								
Diabetes	5,079	132	2,150			0.75	3	
		180 ³	3,164				3	
Eye Disease	See note 7	105	1,350	0.6				
Frailty/Disability	See note 7	179	1,200		0.7	0.25	1	
Sarcopenia	See note 7	191/199 ³	800			0.3	1	

¹ Some ancillary studies include cases from more than one disease

² No more baseline sample available for selected cases

³ Pending funding

⁴ AS 90 and AS 181 share cases and controls

⁵ D&A approved exceeding limit of 1.8 ml sample for this AS

⁶ AS 129 and AS 152 share cases and controls

⁷ Cases determined by AS

Table 8.1
Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
1	Informed Consent in the Women's Health Initiative Clinical Trial and Observational Study	Gen	McTiernan, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	11	Journal of Women's Health, 1995; 4(5):519-29
4	The Women's Health Initiative: Overview of the Nutrition Component	Gen	Tinker, Burrows, Henry, Patterson, Van Horn, Rupp	11	Nutrition and Women's Health, 1996; pp. 510-542
5	Women Health Initiative: Why Now? What is it? What's New?	Gen	Matthews, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	11	American Psychologist, 1997 Feb; 52(2):101-116,
6	Low-fat Diet Practices of Older Women: "Prevalence and Implication for Dietary Assessment"	Gen	Patterson, Kristal, Coates, Ritenbaugh, Van Horn, Caggiula, Snetselaar, Tyllavsky	11	Journal of the American Dietetic Association, 1996 Jul; 96(7):670-9,
7	The Evolution of the Women's Health Initiative: Perspectives from the NIH	Gen	Rossouw, Finnegan, Harlan, Pinn, Clifford, McGowan	11	Journal of the American Medical Women's Association, 1995; 50(2):50-5, Mar-Apr
8	Design of the WHI Clinical Trial and Observational Study	Gen	Prentice, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	11	Control Clin Trials, 1998; 19:61-109
9	Approaches to Monitoring the Results of Long-term Disease Prevention Trials: Examples from the Women's Health Initiative	CT	Freedman, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	11	Control Clin Trials, 1996 Dec; 17(6):509-25
11	The Role of Randomized Controlled Trials in Assessing the Benefits and Risks of Long-term Hormone Replacement Therapy: Example of the Women's Health Initiative	CT	Prentice, Rossouw, Johnson, Freedman, McTiernan	11	Menopause, 1996; 3(2):71-76
12	Factors Associated with Insurance Status among Participants in the WHI	Gen	Hsia, Sofaer, Kiefe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington	11	Journal of Women's Health & Gender-Based Medicine, 2000; 9(8):881-889
13	Depression and Cardiovascular Sequelae in Post-Menopausal Women	Gen	Wassertheil-Smoller, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	11	Arch Intern Med, 2004; 164:289-298
16	Caloric Requirements and Dietary Self-report	Gen	Hebert, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	11	Ann Epidemiol, 2003 13: 1-9
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	CT	Valanis, Bowen, Bassford, Whitlock, Charney, Carter	11	Archives of Family Medicine, 2000 Sep-Oct; 9(9):843-53

Table 8.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
19	Ethnic, Socioeconomic, and Lifestyle Correlates of Obesity in U.S. Women: The Women's Health Initiative	Gen	Manson, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	11	Clinical Journal of Women's Health, 2001; Dec 1(5):225-34
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	OS	Wassertheil-Smoller, Anderson, Black, Psaty, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	11	Hypertension 2000; 36:780-89
22	Pelvic Organ Prolapse: Gravity and Gravidity	CT	Hendrix, Clark, Nygaard, Aragaki, Barnabei, McTiernan	11	Am J Obstet Gynecol 2002; 186:1160-6
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	Gen	Wang, Anderson, Prentice	11	Biometrics, (1999); 55, 711-717
25	Hormone Replacement Therapy and the QT Interval	CT	Kadish, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz	11	Annals of Noninvasive Electrocardiology, 2004 Oct; 9(4):366-74
26	Special Populations Recruitment for the WHI: Success and Limitations	Gen	Fouad, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	11	Control Clin Trials (2004); 335-352
27	The Effects of Insurance Coverage and Ethnicity on Mammography Utilization in a Postmenopausal Population	Gen	Bush, Langer	11	Western Journal of Medicine, 1998; 168:236-40
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	Gen	Patterson, Kristal, Carter, Tinker, Bolton, Agurs-Collins	11	Ann Epidemiol; 1999; 9:178-197
40	The Health Impact of Domestic Violence in Older Women	OS	Mouton, Furniss, Lasser, Rovi	11	Journal of Women's Health & Gender-Based Medicine, 1999; 8(9): 1173-1179
41	Cross Sectional Correlates of Fasting Hyperinsulinemia Among a Multi Ethnic Sample of Postmenopausal Women	Gen	Pradhan, Manson, Rodrigues, Johnson, Wagenknecht, Allen, LaCroix	11	Accepted, Diabetic Medicine
43	Sleep Complaints of Postmenopausal Women	CT	Kripke, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	11	Clinical Journal of Women's Health, 2001, Vol 1, Number 5:244-252
51	The Relationship of Social Support and Social Burden to Breast Cancer Screening in the	Gen	Messina, Lane, Glanz, Smith, Taylor, Frishman, Powell	11	Health Psychology, 2004, Vol 23, No 6, 582-594

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MS ID	Title	Data Focus	Authors	Stage	Reference
	Women's Health Initiative				
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	Gen	Levine, Shumaker, Naughton, Kaplan, Kripke, Bowen	11	Psychological Assessment, 2003, Vol.15, No. 2, 123-136
59	Risk Factors for Kidney Stones in Postmenopausal Women in the Southern United States	Gen	Hall, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	11	Am J Med Sci, 2001; 322 (1):1-7
60	WHIMS: A Trial of the Effect of Estrogen Therapy in Preventing and Slowing the Progression of Dementia	WHIMS	Shumaker, Reboussin, Espeland, Rapp, McBee, Dailey, Bowen, Terrell, Jones	11	Control Clin Trials, 1998; 19:604-621
62	Self-reported Urogenital Symptoms in Postmenopausal Women: The Women's Health Initiative	Gen	Pastore, Carter, Hulka, Wells	11	Maturitas 2004, 49(4):292-303
63	Health Insurance as a Determinant of Cancer Screening in WHI OS Participants	OS	Hsia, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	11	Preventive Medicine, 2000; 31:261-270
66	Walking Compared with Vigorous Exercise for the Prevention of Cardiovascular Events in Women	OS	Manson, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	11	N Engl J Med, 2002; Vol. 347, No. 10
67	Yogurt Consumption is Associated with Healthy Behavior in Postmenopausal Women	OS	Mossavar-Rahmani, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	11	Clinical Journal of Women's Health, 2002; 2(3)128-134
69	Correlates of Serum Lycopene in Older Women	CT	Casso, White, Patterson, Agurs-Collins, Kooperberg, Haines	11	Nutrition and Cancer, 2000; 36:163-69
70	Correlates of Serum Alpha- and Gamma-Tocopherol in the WHI	CT	White, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	11	Ann Epidemiol, 2001; 11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status.	Gen	Liu	11	Menopausal Medicine, 1998; Vol.6(2), p.1-4
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	Gen	Jeffcoat, Lewis, Reddy, Wang, Redford	11	Periodontol, 2000 June; 23(1):94-102
76	Labeling as a Predictor of Dietary Maintenance	CT	Hopkins, Burrows, Bowen, Tinker	11	J Nutr Educ, 2001; 33:278-283
78	Lack of a Relationship Between Antioxidants	Gen	Wolf, Cauley, Stone, Nevitt, Simon,	11	Am J Clin Nutr, 2005; 82: 581-

Table 8.1
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MS ID	Title	Data Focus	Authors	Stage	Reference
	and BMD: Results from the WHI		Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff		588.
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	Gen	Howard, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetsetlaar	11	Int Journal Obesity, 2004; Vol 28, No. 8, p1039-1047
83	A Prospective Study of Physical Activity and the Risk of Breast Cancer in Women Aged 50 - 79 Years	Gen	McTiernan, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	11	JAMA, 2003; 290:1331-1336
84	Research Staff Turnover and Participant Adherence in the WHI	CT	Jackson, Beriman, Snetsetlaar, Granek, Boe, Huber, Milas, Spivak, Chlebowski	11	Control Clin Trials, 24 (2003); 422-435
85	The Women's Health Initiative: Rationale, Design and Progress Report	CT	Johnson, Anderson, Barad, Stefanick	11	Journal of the British Menopause Society, 1995; 155-159
86	The Effects of Physical and Emotional Status on Adherence to a Low-fat Dietary Pattern in the Women's Health Initiative	CT	Tinker, Perri, Bowen, Patterson, Parker, Wodarski, McIntosh, Sevick	11	JADA, June 2002; 102:789-800
88	Estimating Normal Hemogram Values for Postmenopausal Women	Gen	Assaf, Carleton, Miller, Coccio	11	Clinical Journal of Women's Health, Vol. 1, December 2000; No. 1, 23-28
91	Compliance with National Cholesterol Education Program Dietary and Lifestyle Guidelines Among Older Women with Self-reported Hypercholesterolemia: The Women's Health Initiative	OS	Hsia, Rodabough, Rosal, Cochrane, Howard, Snetsetlaar, Frishman, Stefanick	11	Am J Med, 2002; 113:384-92, 2002
92	Comparison of Self-report, Discharge Diagnosis, and Adjudication of Cardiovascular Events in the WHI	Gen	Heckbert, Hsia, Kooperberg, McTiernan, Curb, Safford, Psaty, Frishman	11	Am J Epidemiol, 2004; 160:1152-1158, 2004
93	Fat Intake in Husbands of Participants in the Dietary Modification Component of the Women's Health Initiative	Gen	Shikany	11	Nutr Res, 2002; 22:577-86, 2002
95	The Effects of Widowhood on Physical Health, Mental Health, and Health Behaviors; the Women's Health Initiative	OS	Wilcox, Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger	11	Health Psychology, 2003; 22 (5), 513-522, 2003

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Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
98	Antioxidant Use in the Women's Health Initiative Participants	Gen	Shikany, Patterson, Agurs-Collins, Anderson, Wang	11	Preventive Medicine, Mar 2003; Vol. 36, Issue 3; 379-387
99	Risk Factor Clustering in the Insulin Resistance Syndrome and its Relationship to Cardiovascular Disease In White, Black, Hispanic, and Asian Postmenopausal Women	OS	Howard, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	11	Metabolism, 2003 Mar; 52(3):362-71
100	The Yield of Six-Month Recall Mammography on Screening Mammograms	Gen	Yasmeen, Romano, Pettinger, Chlebowski, Robbins, Lane, Hendrix	11	JNCI, March 2003; 95(6): 429-436
102	Association Between Cardiovascular Outcomes and Antihypertensive Drug Treatment in Older Women	OS	Wassertheil-Smoller, Psaty, Greenland, Margolis, Oberman, Kotchen, Mouton, Hilker, Black, Trevisan, Aragaki	11	JAMA, 2004; 292: 2849-2859
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	CT	Rossouw, Hurd	11	Journal of Women's Health, 1999; 8:3-5
104	Promoting Adherence and Retention to Clinical Trials in Special Populations: A Women's Health Initiative Workshop	Gen	Wilcox, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	11	Control Clin Trials, 22 (3), 279-289
107	Vigorous Leisure Activity Through Women's Adult Life: The Women's Health Initiative	OS	Evenson, Wilcox, Pettinger, Brunner, Daugherty, King, McTiernan	11	Am J Epidemiol, 2002; 156:-945-953
108	Cross-Sectional Geometry, Bone Strength, and Bone Mass in the Proximal Femur in Black and White Postmenopausal Women	CT	Nelson, Barondess, Hendrix, Beck TJ	11	J Bone Miner Res, 2000; 15(10):1992-1997
109	Recruitment of Women to the WHI: the Case of Embajadoras in Arizona	Gen	Larkey, Staten, Ritenbaugh, Hall, Buller, Bassford, Altmani	11	Control Clin Trials, 23(2002); 289-298
112	Results of an Adjunct Dietary Intervention Program in the Women's Health Initiative	OS	Bowen, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	11	JADA 2002; 102:1631-1637
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	Gen	Barad, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	11	Accepted, Fertility and Sterility
115	Prevalence and 3-year Incidence of Abuse in Older Women	OS	Mouton, Rodabough, Rovi, Hunt, Brzycki	11	Am J Public Health, April 2004; Vol. 94, No.4
120	Obesity, Body Size, and Risk of	OS	Morimoto, White, McTiernan,	11	Cancer Causes Control, 2002;

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Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
	Postmenopausal Breast Cancer: The Women's Health Initiative		Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez		13:741-751
122	Does Statin Use Reduce Risk of Osteoporotic Fracture or Improve Bone Density in Postmenopausal Women? Results from the Women's Health Initiative Observational Study	OS	LaCroix, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeely, Pasaro, Jackson	11	Annals of Internal Medicine, 2003; 129:97-104
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	CT	Kearney, Rosal, Ockene, Churchill	11	Psychosom Med, 2002 May-Jun; 64(3):450-7
128	Inflammatory Biomarkers, Hormone Replacement Therapy, and Incident Coronary Heart Disease: A Prospective Analysis from the Women's Health Initiative Observational Study	OS	Pradhan, Manson, Rossouw, Siscovick, Mouton, Wallace, Jackson, Pettinger, Ridker	11	JAMA, 2002; 288:980-987
129	Thrombotic Markers for Coronary Heart Disease in Women	OS	Pradhan, LaCroix, Trevisan, Lewis, Langer, Hsia, Oberman, Kotchen, Ridker	11	Circulation, 2004; 110:292-300
130	Cross-sectional Analysis of Association Between Hormone Replacement Therapy and Thrombotic and Inflammatory Markers for CHD in Women	OS	Langer, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker	11	Thromb Haemost, 2005; 93: 1108-16
132	Second Malignancy and Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	Gen	Rosenberg, Greenland, Khandekar, Ascensao, Lopez, Sparks	11	Cancer, 2004 Jan 1; 100(1): 130-8. PMID:14692033
134	Alternative Self-Monitoring Tools in the Dietary Modification Component of the Women's Health Initiative	CT	Mossavar-Rahmani, Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Soule, Vosburg	11	J Am Diet Assoc, 2004; 104:76-85
135	Radiographic Measurements, Bone Mineral Density and the Singh Index in the Proximal Femur of White and African-American Postmenopausal Women		Barondess, Singh, Hendrix, Nelson	11	Clin J Women's Health, 2001; 1992-1997
138	Baseline Experience with the Modified Mini-Mental State Exam: The Women's Health Initiative Memory Study	WHIMS	Rapp, Espeland, Hogan, Jones, Dugan	11	Aging Ment Health, 2003 May; 7(3):217-23

Table 8.1
Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
140	Hysterectomy is an Independent Predictor of Framingham Risk Score	Gen	Hsia, Rossouw, Rodabough, Wassertheil-Smoller, McGovern, Limacher, Oberman, Margolis	11	Am J Cardiol, 2003; 92: 264-9
142	Coronary Artery Calcification in Black and White Women	OS	Khurana, Rosenbaum, Howard, Adams-Campbell, Detrano, Klouj, Hsia	11	Am Heart J, 2003; 145 : 724-9
144	Hysterectomy With and Without Oophorectomy and Risk for Cardiovascular Disease: The Women's Health Initiative	OS	Howard, Assaf, Cochrane, Kuller, Lasser, Manson, Stefanick, Trevisan, Van Horn	11	Circulation, 2005; 111:1462-1470
145	Breast Cancer and Nonsteroidal Anti-inflammatory Drugs: Prospective Results from the Women's Health Initiative	OS	Harris, Chlebowski, Jackson, Frid, Ascensao, Anderson, Loar, Rodabough, White, McTiernan	11	Cancer Research, 63, 6096-6101. 2003
155	Changes in Food Sources of Dietary Fat in Response to an Intensive Low-Fat Dietary Intervention: Early Results from the Women's Health Initiative	CT	Patterson, Kristal, Rodabough, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, Van Horn	11	JADA, April 2003; Vol 103, Number 4, p. 454-459
163	Ethnicity and Breast Cancer: Factors Influencing Differences in Incidence and Outcome	OS	Chlebowski, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan, Anderson, Chen, Aragaki, McTiernan	11	JNCL, 2005; Vol. 97, No. 6, pp. 439-448
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	OS	Margolis, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	11	Archives of Internal Medicine, Vol 165, Mar 14, 2005; 500-508
166	Is Tea Drinking Related to Bone Mineral Density and Osteoporotic Fractures? ---Results from the Women's Health Initiative Observational Study	OS	Chen, Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakin	11	Am J Epidemiol, 2003; 158: 772-781
169	Reliability and Validity of the Women's Health Initiative Insomnia Rating Scale	Gen	Levine, Kaplan, Kripke, Bowen, Naughton, Shumaker	11	Psychological Assessment, 2003; Vol. 15, No. 2, 137-148
171	Prevalence and Correlates of Panic Attacks in Post-Menopausal Women: Results from the Women's Health Initiative	Gen	Smoller, Wassertheil-Smoller, Hendrix, Jackson, Oberman, Sheps	11	Arch Intern Med, 2003; 163:2041-2050
177	Validity of Self-Reports of Fractures Among Postmenopausal Women in a Prospective Study	Gen	Chen, Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok,	11	Menopause, 2004; 11(3):264-274

Table 8.1
Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
	Results from the Women's Health Initiative		Borne, Jackson		
179	The Natural History of Pelvic Organ Prolapse in a Cohort of Postmenopausal Women; Data from the UC Davis Site of the Women's Health Initiative	CT	Handa, Garret, Hendrix, Gold, Robbins	II	Am J Obstet Gynecol, 2004; 190: 27-32
186	Physical Activity and Diabetes Risk in Postmenopausal White, Black, Hispanic and Asian Women: The Women's Health Initiative Observational Study	Gen	Hsia, Howard, Limacher, Oberman, Safford, Allen, Torrens, Lawson	II	Am J Preventative Medicine, Jan 2005; V. 28 (1): 19-25
188	Electrocardiographic Repolarization Phenotypes and Mortality Risk in Postmenopausal Women	CT	Rautaharju, LaCroix, Kooperberg, Larson	II	Accepted, Circulation
189	Dietary Adherence in the WHI Dietary Modification Trial	CT	The Writing Group for the WHI Investigators	II	J Am Diet Assoc, 2004 Apr; 104(4):654-658
197	Predictors of Angina vs Myocardial Infarction: Prospective Analysis from the Women's Health Initiative	OS	Hsia, Rossouw, Brunner, LaCroix, Wallace	II	Am J Cardiology, 2004; Vol 93; No 6: 673-8
198	Aspects of the Management and Coordination of The Women's Health Initiative	Gen	Cochrane, Lund, Anderson, Prentice	II	Diversity in Health Care Research: Strategies for Multisite, Multidisciplinary and Multi-ethnic Projects. J.W. Hawkins, L.A. Haggerty (eds.); 2003; pp.181-207 Springer
200	Expression and Ambivalence Over Expression of Negative Emotion: Psychometric Analysis in the Women's Health Initiative	Gen	Michael, Perrin, O'Connor, Wisdom, Ritenbaugh, Bowen, Brzyski, Cochrane	II	Journal of Women & Aging, 2005; Volume 17(1/2), p5-18
202	Depressive Symptoms and Heart Rate Variability in Postmenopausal Women: An Ancillary Study to the Women's Health Initiative	Gen	Sheps, Kim, McGorray, Bartholomew, Marsh, Dicken, Wassertheil-Smoller, Curb, Oberman, Barton, McMahon	II	Arch Intern Med, 2005 Jun 13; 165(11):1239-44
203	Estrogen Plus Progestin Influence on Breast Cancer and Mammography in Healthy Postmenopausal Women	CT	Chebowski, Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich,	II	JAMA, 2003; 289:3243-3253

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MS ID	Title	Data Focus	Authors	Stage	Reference
			McTiernan		
204	Effect of Estrogen Plus Progesterin on Stroke in Postmenopausal Women. The Women's Health Initiative: A Randomized Trial	CT	Wassertheil-Smoller, Hendrix, Limacher, Heiss, Kooperberg, Rossouw, Kotchen, Curb, Black, Aragaki, Safford, Stein, Laowattana, Mysiw	11	JAMA, 2003 May 28; 289(20):2673-84
206	Fracture Risk Among Breast Cancer Survivors	Gen	Chen, Barad, Ritenbaugh, Gass, Lopez, LeBoff, Bassford, Maricic	11	Archives of Internal Medicine, 2005; Vol 165: 552-558
208	The Effects of Estrogen Plus Progesterin on the Risk of Fracture and Bone Mineral Density: The Women's Health Initiative Clinical Trial	CT	Cauley, Robbins, Chen, Cummings, Jackson, LaCroix, LeBoff, Lewis, McGowan, Neuner, Pettinger, Stefanick, Wactawski-Wende, Watts	11	JAMA, 2003; 290:1729-1738
209	Estrogen Metabolism, Body Mass Index, Hormone Replacement Therapy and Postmenopausal Breast Cancer Risk	OS	Modugno, Cochrane, Chlebowski, Kuller, Stefanick, Rohan, Lasser, Kip	11	Accepted, International Journal of Cancer
210	Estrogen Plus Progesterin and Risk of Coronary Heart Disease: Final Results From the Women's Health Initiative Randomized Clinical Trial	CT	Manson, Hsia, Johnson, Rossouw, Assaf, Lasser, Trevisan, Black, Heckbert, Detrano, Strickland, Wong, Crouse, Stein, Cushman	11	N Engl J Med, 2003; 349:523-34
211	Effects of Estrogen plus Progesterin on Health-Related Quality of Life: Results from the Women's Health Initiative Randomized Clinical Trial	CT	Hays, Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis	11	N Engl J Med, May 2003; 348:1839-1854
212	Effect of Estrogen Plus Progesterin on Cardiovascular Events and Risk Factors in Postmenopausal Women with Diabetes Mellitus	CT	Margolis, Bonds, Rodabough, Tinker, Phillips, Allen, Bassford, Burke, Torrens, Howard	11	Diabetologia, 2004; 47: 7: 1175-1187
221	Gynecologic Cancer Outcomes of the Women's Health Initiative Randomized Trial of Estrogen Plus Progesterin	CT	Anderson, Judd, Kaunitz, Barad, Beresford, Liu, Pettinger, McNeeley, Lopez	11	JAMA, 2003; 290:1739-1748
222	Venous Thromboembolism in the Estrogen plus Progesterin Trial of the Women's Health Initiative	CT	Cushman, Prentice, Kuller, Sidney, Stafford, Psaty, Rodabough, Rosendaal	11	JAMA, 2004; Vol 292, No 13; 1573 - 1580

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MS ID	Title	Data Focus	Authors	Stage	Reference
224	Estimation of Dependence Between Paired Correlated Failure Times in the Presence of Covariate Measurement Error	OS	Gorfine, Hsu, Prentice	11	J R Stat Soc [Ser B]. 65: August 2003; Issue 3, 633-661
225	Estrogen Plus Progesterin and the Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women: The Women's Health Initiative Memory Study (WHIMS)	CT	Shumaker, Legault, Rapp, Thal, Wallace, Ockene, Hendrix, Jones, Assaf, Jackson, Kotchen, Wassertheil-Smoller, Wactawski-Wende	11	JAMA, 2003; 289:2651-2662
226	The Effect of Estrogen With Progesterin Treatment on Global Cognitive Function in Postmenopausal Women: Results from the Women's Health Initiative Memory Study	CT	Rapp, Espeland, Shumaker, Henderson, Brunner, Manson, Gass, Stefanick, Lane, Hays, Johnson, Coker, Dailey, Bowen	11	JAMA, 2003; 289:2663-2672
229	Symptoms and Side Effects Associated with Combined Estrogen plus Menopausal Symptoms and Treatment-Related Effects of Estrogen and Progesterin in the WHI	CT	Barnabei, Cochrane, O'Sullivan, Schenken, Chen, Johnson, Laube, McGovern, Nygaard, Wells, Williams, Young, Aragaki	11	Obstet Gynecol, May 2005; Vol 105 No 5: 1063-1073
232	Women's Health Initiative: Statistical Aspects and Early Results	Gen	Prentice, Anderson	11	In press, Encyclopedia of Clinical Trials
233	Estrogen Plus Progesterin Influence on Colorectal Cancer Risk in Healthy Post-menopausal Women: Results from the Women's Health Initiative (WHI) Randomized Trial	CT	Chlebowski, Wactawski-Wende, Ritenbaugh, Hubbell, Ascensao, Rodabough, Rosenberg, Taylor, Harris, Chen, Adams-Campbell, White	11	N Engl J Med, 2004; 350: 991-1004
234	Postmenopausal Hormone Therapy and Body Composition: Results from the Women's Health Initiative E & P Clinical Trial	CT	Chen, Bassford, Green, Sylvan, LeBoff, LaCroix, Margolis, Jackson, Cauley, Stefanick	11	Am J Clin Nutr, 2005; 82:651-6
235	Hormone Replacement Therapy and Risk of Cardiovascular Disease	CT	Kuller	11	Arterioscler Thromb Vasc Biol, 2003; 23: 11-16
240	Risks and Benefits of Estrogen Plus Progesterin in Healthy Post-menopausal Women: Principal Results of the Women's Health Initiative Randomized Controlled Trial.	CT	The Writing Group for the WHI Investigators	11	JAMA, 2002; 288(3):321-333

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Ms ID	Title	Data Focus	Authors	Stage	Reference
242	Estrogen Deficiency Symptom Management in Breast Cancer Survivors in the Changing Context of Menopausal Hormone Therapy	CT	Chlebowski, Kim, Col	11	Semin Oncol, 2003 Dec; 30(6):776-88. Review
243	Combined Hormone Therapy and Coronary Heart Disease in the Women's Health Initiative Clinical Trial and Observational Study	CT	Prentice, Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende	11	Am J Epidemiol, 2005; 162:1-11
246	WHI Response to Goodman, Goldzieher and Ayala's Critique of the Women's Health Initiative Report on the Risks and benefits of Estrogen Plus Progestin	CT	Hendrix, Prentice	11	Menopausal Medicine, 11:1-4, 2003
248	Progression of Coronary Calcification in Postmenopausal Women	OS	Hsia, Klouj, Prasad, Burt, Adams-Campbell, Howard	11	BMC Cardiovascular Disorders, 2004; 4:21 doi:10.1186/1471-2261-4-21
249	Combined Hormone Therapy Effects on Urinary Incontinence in the WHI	CT	Hendrix, Handa, Aragaki, Barnabei, Cochrane, Iglesia, McNealey, Naughton, Nygaard, Wallace	11	JAMA, 2005; 293: 935-948
265	Comparing SF-36 scores of Participants in the Women's Healthy Eating and Living Study, Women's Health Initiative, and Medical Outcomes Study	Gen	Yost, Haan, Levine, Gold	11	Quality of Life Research, (2005); 14: 1251-1261
271	Factors Associated with Treatment Initiation After Screening and Diagnosis of Osteoporosis	CT	Brennan, Wactawski-Wende, Crespi, Dmochowski	11	Am J Epidemiol, 2004; 160:475-483
272	HT, Medications, and the Development of Gallstone Disease in Women in the WHI CT.	CT	Wallace, Cirillo, Greenland, LaCroix, Limacher, Rodabough	11	JAMA, January 19, 2005; Vol 293, No. 3, 330-339
273	Effects of Conjugated Equine Estrogen in Postmenopausal Women With Hysterectomy. The Women's Health Initiative Randomized Controlled Trial	CT	The Writing Group for the WHI Investigators	11	JAMA, 2004; 291: 1701-1712
274	Association Between Self-Reported Alcohol Intake and Changes in Cognition: Results from the Women's Health Initiative Memory Study	CT	Espeland, Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp	11	Am J Epidemiol; 2005 161(3):228-238

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Ms ID	Title	Data Focus	Authors	Stage	Reference
	(WHIMS)				
277	Peripheral Arterial Disease in the Randomized E+P Trial	CT	Hsia, Kotchen, Bonds, Allison, Phillips, Masaki, Langer, Resnick, Caralis	11	Circulation, 109(5):620-626, February 10, 2004
279	Symptom Experiences After Stopping Use of E+P in the WHI	CT	Ockene, Cochrane, Barad, Larson, Barnabei, Brzyski, Gass, Gold, Hays, Lane, Manson, Rosal, Wylie-Rosette	11	JAMA, 2005; 294, No.2:183-193.
282	Improving Dietary Self-Monitoring and Adherence with Hand-Held Computers: A Pilot Study	CT	Glanz, Murphy, Moylan, Evensen, Curb	11	In press, American Journal of Health Promotion, 2005
285	Estrogen Plus Progestin Influence on Mammogram Density in Healthy Postmenopausal Women in the Women's Health Initiative	CT	McTiernan, Martin, Peck, Pisano, Wang, Aragaki, Chlebowski	11	In press, JNCI
288	Insulin as Related to Physical Activity and Energy Intake in Postmenopausal Women: Breast Cancer Implications	Gen	Chlebowski, Pettinger, Stefanick, Howard, Mossavar-Rahmani, McTiernan	11	J Clin Oncol, 2004; 22: 4507-4513
289	Cutaneous Melanoma in Postmenopausal Women Following Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	OS	Rosenberg, Greenland, Khandekar, McTiernan, Rodabough	11	Accepted, Cancer
302	Frailty: Emergence and Consequences in WHI Participants	Gen	Woods, LaCroix, Brunner, Cochrane, Masaki, Murray, Newman	11	In press JAGS. Tentative August
317	Pelvic Organ Prolapse in Older Women: Prevalence and Risk Factors	CT	Nygaard, Bradley, Brandt	11	Obstet Gynecol, 2004; 104,3: 489-497.
332	The Effect of Estrogen on Global Cognitive Function In Postmenopausal Women: Results from the Women's Health Initiative Memory Study	WHIMS	Espeland, Rapp, Shumaker, Brunner, Manson, Hsia, Margolis, Wallace, Dailey, Freeman, Hays	11	JAMA, 2004; 291:2959-2968
336	The Effect of CEE and E+P on Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women: Results from WHIMS	WHIMS	Shumaker, Legault, Kuller, Rapp, Thal, Lane, Stefanick, Hendrix, Langer, Lewis, Masaki, Coker	11	JAMA, 2004; 291:2947-2958
348	Effects of CEE on Health Related QOL and	CT	Brunner, Ockene, Aragaki, Assaf,	11	Arch Intern Med, 2005; 165:

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MS ID	Title	Data Focus	Authors	Stage	Reference
	Psychosocial Factors in the WHI		Brzyski, Gass, Granek, LaCroix, Mason, Matthews, Wallace, Woods		1976-1986
367	The Women's Health Initiative: A Potential Resource for Future Studies of Autoimmune Diseases	Gen	Howard	11	Autoimmunity, 37:4 (June 2004), pp. 265-268
368	Postmenopausal Hormone Therapy in Relation to Cardiovascular Disease and Cognition.	CT	Prentice	11	Proceedings of the Forty Seventh Study Group of the Royal College of Obstetricians and Gynecologists, 2004
398	Osteoporosis and Rate of Bone Loss among Postmenopausal Survivors of Breast Cancer: Results from a subcohort of WHI OS	OS	Chen, Maricic, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff, Bassford	11	Cancer, 2005; 104:7: tba October 1, 2005
30	Completeness of Purchase Mailing Lists for Identifying Older Women	CT	Falkner, Wactawski-Wende, Trevisan	10	
39	Hormone Replacement Therapy and Dietary Fat Intake Influence on Blood Lipids and Insulin in Postmenopausal Women	Gen	Chlebowski, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan	10	
190	Predictors of LVH	CT	Oberman, Ko, Lasser, LaCroix, Wylie	10	Accepted, Am J Cardio
201	Normal Electrocardiographic Patterns in Older Adult Women. Depolarization and Repolarization Phenotypes	Gen	Rautaharju, Prineas, Hsia, Kadish, Lund	10	Submitted, Amer J Cardio
218	Psychological Effects of Physical and Verbal Abuse among Postmenopausal Women	OS	Mouton, Rodabough, Cochrane, Brzyski, Rovi, Talamantes, Burge, Katerndahl	10	Submitted to the J of Gerontology
275	Association of Prior Hormone Therapy With Cognition During the Women's Health Initiative Memory Study (WHIMS) Estrogen / Progestin Clinical Trial	CT	Espeland, Hogan, Dailey, Gass, Hendrix, Murphy, Rapp, Shumaker, Wactawski-Wende	10	Submitted, Archives of Internal Medicine
280	Diet, Physical Activity, Energy Balance and Endogenous Sex Hormone Concentrations in the WHI	CT	McTiernan, Wu, Chlebowski, Modugno, Mossavar-Rahmani, Petri, Stanczyk, Van Horn	10	Submitted, CEBP
298	Effect of Aspirin Supplementation on Rates of Colorectal Cancer	OS	Allison, Langer, Garland, Criqui, Wu	10	Submitted to Cancer Epi Biomarkers and Prevention

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Ms ID	Title	Data Focus	Authors	Stage	Reference
341	Race, Socioeconomic Status, and Morbidity Burden in the WHI Baseline Data	Gen	Gold, Hubbell, Mason, Michael, Rodrigues, Safford, Whitlock	10	Submitted, Social Science and Medicine
342	OtherC of height and Weight are better Predictors of BMD than BMI	OS	Robbins	10	Submitted, JBMR
343	Effects of CEE on Invasive Breast Cancer in Postmenopausal Women with Hysterectomy: The WHI Randomized CT	CT	Stefanick, Chlebowski, Anderson, Assaf, Hendrix, Hubbell, Lane, Lessin, Margolis, Paskett, Rodabough, Sarto, Schenken, Yasmeen	10	Submitted, JAMA
344	Postmenopausal Hormone Therapy Does Not Influence Hospitalization for Non-specific Chest Pain or Its Prognosis	Gen	Robinson, Wallace, Cochrane, Ko, Limacher, Ockene, Wassertheil-Smoller, Blanchette	10	Submitted, N Engl J Med
345	Postmenopausal CEE Therapy Reduces Coronary Heart Disease Risk	CT	Hsia, Langer, Caralis, Crawford, Heckbert, Hendrix, Johnson, Kostis, Kuller, Manson, Pettinger, Greep	10	Submitted, Archives of Internal Medicine
350	Hormone Therapy and Risk of Venous Thrombosis in the Women's Health Initiative Trial of Estrogen Alone in Women Without a Uterus	CT	Curb, Prentice, Barnabei, Bray, Cyr, Gass, Langer, Mattox, Rodabough, Sidney, Van Horn	10	Resubmitted, Archives of Internal Medicine
354	Effect of CEE on Bone Mass and Risk for Fractures	CT	Jackson, Wactawski-Wende, Bassford, Beresford, Ko, LaCroix, Lewis, Pettinger, Robbins, Satterfield, Watts	10	Submitting to JBMR
357	Effect of Conjugated Equine Estrogen in Women Without a Uterus on the Incidence of Diabetes in Postmenopausal Women	CT	Lasser, Bonds, Brzyski, Caan, Heiss, Limacher, Liu, Mason, Oberman, O'Sullivan, Phillips, Prineas, Tinker	10	In revision, Diabetologia
370	Performance of a Longitudinal Screening Program to Identify All-Cause Dementia: Results from the Women's Health Initiative Memory Study	CT	Espeland, Bassford, Granek, Rapp	10	Submitted, Clinical Trials
373	Unopposed Estrogen and the Risk of Peripheral Arterial Disease	CT	Hsia, Criqui, Heckbert, Herrington, Manson, Masaki, McDermott, Robinson	10	Submitted, Circulation
378	Expression and Ambivalence Over Expression of Negative Emotion: Cross-sectional	Gen	Michael, Bowen, Brzyski, Cochrane, O'Connor, Perrin, Ritenbaugh, Wisdom	10	Submitted, Journal of Psychosomatic Research

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MS ID	Title	Data Focus	Authors	Stage	Reference
	Associations with Ppsychosocial Factors and Health Related Quality of Life				
423	Extension of Women's Health Initiative Clinical Trial Results on Postmenopausal Hormone Treatment and Cardiovascular Disease Using Observational Study Data	Gen	Prentice, Anderson, Barad, Curb, Howard, Kotchen, Kuller, Langer, Limacher, Pettinger, Stefanick, Wactawski-Wende	10	
492	Older Women Discharged as Non-specific Chest Pain are at Increased Cardiovascular Risk	CT	Robinson, Wallace, Cochrane, Ko, Limacher, Ockene, Wassertheil-Smoller, Blanchette	10	Submitted, Circulation
34	The Relationship Between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	Gen	Johnson, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	9	
73	Innovative Strategies for Monitoring and Enhancing Clinic Performance in the WHI Clinical Trial: The Creation of the Performance Monitoring Committee	Gen	Pottern, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker	9	
87	Predictors of Total Hip Replacement in a Cohort of Older Women: Result from the WHI OS	Gen	Wallace, Chang, Nevitt, LaCroix, Kaplan, Sturm	9	
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	CT	Johnson, Williams, Fouad	9	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	OS	Bowen, Green, Vizenor, Vu, Kreuter, Rolls	9	
139	Cholesteryl Ester Transfer Protein and Lecithin: Cholesterol Acyltransferase Activities in Hispanic and Anglo Postmenopausal Women: Associations with Total and Regional Body Fat		Greaves	9	
147	Association of Hormone Replacement Therapy with Body Fat Distribution in Postmenopausal Women	CT	Mayo, Heimbürger, Gower, Goran, Fouad, Redden, Oberman, Lewis, McGwin	9	
149	Health Status of Postmenopausal White Women with Back and Leg Pain Living in the Community: A Pilot Study	OS	Vogt, Lauerma, Chirumbole, Kuller	9	

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MS ID	Title	Data Focus	Authors	Stage	Reference
173	Relationships Between Blood Pressure, Hypertension, and Hypertension Therapy and Measures of Cognition Among WHIMS Women At Baseline	WHIMS	Johnson, Espeland, Mouton, Margolis, Masaki, Murphy, Wassertheil-Smoller, Prineas	9	
187	Estrogens and Cardiovascular Disease	OS	Rossouw	9	
192	Bone Mineral Density of American Indian and Alaska Native Women: Results from the Women's Health Initiative Study	Gen	Whampller, Howard, Rossouw, Chen	9	
216	Effects of Combination Estrogen-Progestin Hormone Replacement Therapy on Cognition and Affect: The Women's Health Initiative Study of Cognitive Aging	CT	Resnick, Maki	9	
220	The Women's Health Initiative: A Glimpse Behind the Scenes	CT	Furniss	9	
287	Prior menopausal Hormone Therapy and Breast Cancer Risk in the WHI Trial of E+P Therapy	CT	Anderson, Chlebowski, Aggerwal, Hubbell, Khandekar, Lane, Lasser, Lopez, Potter, Ritenbaugh, Rossouw	9	
294	Weighted Estimators for Proportional Hazards Regression with Missing Covariates	OS	Qi, Wang, Prentice	9	
326	The Association Between Osteoporosis and Oral Bone Loss in Postmenopausal Women	CT	Wactawski-Wende, Hovey, Hausmann, Trevisan, Grossi, Genco	9	
38	Relationship of Select Dietary Components and Colorectal Cancer among Postmenopausal Women: The Women's Health Initiative	Gen	Frank, Pettinger, Paskett, Wylie-Rosette, Agurs-Collins	8	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	OS	Siscovick, Manson, Trevisan, Wallace, Howard, Burke, Ridker	8	
148	Outcomes of Pap Smears on Postmenopausal Women		Yasmeen, Romano, Hubbell, La Valluer, Johnson, Lane, McIntosh, Hendrix	8	
154	Does Acidogenic Diet Contribute to the Incidence of Hip Fracture?	OS	Barzel, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	8	

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MS ID	Title	Data Focus	Authors	Stage	Reference
174	HMG Co-A Reductase Inhibitor (Statin) Use and the Risk of Breast Cancer in the Women's Health Initiative Observational Study	OS	Caulley, LaCroix, Chlebowski, Margolis, McTiernan, Vitolins, Furberg, Bauer	8	
181	The Relationship Between Moderate Alcohol Use Folic Acid Intake and Breast Cancer in the Women's Health Initiative Observational Study	OS	Assaf, Coccio, Paskett, Lane, Rohan, McTiernan, Duffy, Burkholder	8	
217	Associations with Gun-related Threats and Household Fear in Postmenopausal Women	OS	Mouton, Tan, del Aguila	8	
228	Past Hysterectomy as a Risk Factor for Hypertension in the Women's Health Initiative Observational Study Participants	OS	Barad	8	
230	Use of Electric Blankets Increases Risk of Endometrial Cancer	OS	Abel, Johnson, Mohanka, Mossavar-Rahmani	8	
310	Relationship of Body Fat Level and Distribution to Age Related Maculopathy in the Carotenoids in Age Related Eye Disease Study (CAREDS)	OS	LaRowe, Gehrs, Wallace, Chappel	8	
312	Accuracy of Food Portion Estimation Among Postmenopausal Women	CT	Coy, Frank, Lee, Meyskens	8	
316	Coffee Consumption and Risk of Nonmelanoma Skin Cancer in Caucasian Women	OS	Abel, Fernandez, Johnson, Jones, Mossavar-Rahmani, Rosenberg, Vitolins, Wong	8	
323	Correlation Between Pelvic Organ Prolapse, Pelvic Floor Disorder, Urinary Incontinence, Defecation Disorder, Voiding Dysfunction	OS	Nygaard, Bradley	8	
325	Association of Alcohol Intake with Cognition during the WHISCA E+P CT	CT	Espeland, Coker, Limacher, Messina, Ockene, Powell, Rapp, Resnick, Wallace	8	
347	Effect of CEE & E+P on Stroke in the WHI	CT	Hendrix, Wassertheil-Smoller, Aragaki, Bray, Cricqui, Howard, Johnson, Kooperberg, Mouton, Rapp, Trevisan	8	

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Ms ID	Title	Data Focus	Authors	Stage	Reference
353	Effects of Conjugated Equine Estrogens on Colorectal Cancer in Post-Menopausal Women with Hysterectomy: The Women's Health Initiative Randomized Controlled Trial. [WHI Priority Paper]	CT	Ritenbaugh, Stanford, Ascensao, Chlebowski, Frank, Garland, Lane, Mason, McNeeley, Shikany, Stefanick, Taylor, Wu	8	
371	Associations between Age-Related Maculopathy and Lutein and Zeaxanthin in the Diet and Serum in the Carotenoids in Age-Related Eye Disease Study, an Ancillary Study of the Women's Health Initiative	OS	Moeller, Mares-Perlman	8	
440	Statistical Aspects of Monitoring and Reporting of the Women's Health Initiative Randomized Hormone Therapy Trials	CT	Anderson, Kooperberg, Rossouw, Pettinger, Prentice	8	
20	Relation of Demographic Factors, Menstrual History, Reproduction and Medication Use to Sex Hormones in Postmenopausal Women	CT	McTiernan, Chen, Rohan, Modugno, Hendrix, Wu	7	
29	Effects of Diet Intervention on Motivation to Make Other Health Related Changes	CT	Langer, Lo	7	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	Gen	Agurs-Collins, Dolan, Pasaro, Howard	7	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	OS	Paskett, Sherman, Andersen, Hays, McDonald, Naughton	7	
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	CT	Creech	7	
81	The Prevalence of Urinary Incontinence in WHI Women	Gen	Hendrix, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	7	

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Ms ID	Title	Data Focus	Authors	Stage	Reference
117	Correlates of Session Completion and Self-Monitoring of Food Intake Among Minority Participants Enrolled in the Women's Health Initiative (WHI) Dietary Modification Intervention During the First Year of Intervention		Rosal, Ockene, Mossavar-Rahmani, Margolis, Paskett, Thomson	7	
193	Predictors of Adherence to the Women's Health Initiative Clinical Trial Interventions: A Conceptual Framework	CT	Rosal, Shumaker, Snetselaar, Tinker, Cochrane, Bowen, Brunner, Ockene	7	
194	Predictors of Adherence to the Hormone Replacement Therapy Clinical Trial in the Women's Health Initiative	CT	Cochrane, Stefanick, Wallace, Granek, Lillington, Anderson, Woods, Naughton	7	
195	Predictors of Calcium/Vitamin D Supplementation Adherence in the Women's Health Initiative	CT	Brunner, Cauley, Snetselaar, Jackson, Cochrane, Granek, Wactawski-Wende	7	
196	Intrapersonal, Interpersonal, Treatment, and Organizational Adherence Predictors in the Women's Health Initiative Dietary Modification Clinical Trial	CT	Tinker, Van Horn, Perri, Rosal, Ockene, Patterson, Assaf, Hays, Young	7	
236	Women's Health Initiative Study of Cognitive Aging (WHISCA): Study Design, Implementation, and Data Management	CT	Coker, Espeland, Rapp, Resnick, Maki, Hege, Farmer, Shumaker	7	
237	The Women's Health Initiative Study of Cognitive Aging (WHISCA): Rationale, Objectives, and Description of a Randomized Clinical Trial of the Effects of Hormone Therapy on Age-Associated Cognitive Decline	CT	Resnick, Maki, Rapp, Espeland, Coker, Shumaker	7	
314	Aspirin Dose, Inflammation and Cardiovascular Disease	OS	Berger, Langer, Wong, Oberman, Burke, Kostis	7	
315	Urethral Changes in Postmenopausal Women	CT	Coughlin	7	

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Ms ID	Title	Data Focus	Authors	Stage	Reference
324	Extreme Obesity in a Large Sample of US Women: a Growing Threat	OS	McTigue, Kuller, Burke, Kotchen, Lewis, Stefanick, Van Horn	7	
327	Effects of a 7-yr Low Fat, High Carbohydrate Diet on Body Weight in Postmenopausal Women – the Women’s Health Initiative Dietary Modification Trial	CT	Howard, Beresford, Frank, Jones, Manson, Prentice, Snetselaar, Stefanick, Thomson, Tinker, Vitolins	7	
331	Pelvic Floor Symptoms in Older, Community-Dwelling Women	CT	Bradley, Kennedy, Nygaard	7	
359	Fractures and Osteoporosis in Diabetics	OS	Bonds, Johnson, Margolis, Robbins, Rodrigues, Strotmeyer	7	
361	Estrogen Therapy With and Without Progestin and the Risk of Hip and Knee Joint Replacement in Postmenopausal Women	CT	Wallace, Cirillio, Yood	7	
447	DM & CHD	CT	Howard, Van Horn, Hsia, Manson, Smoller, Stefanick, Tinker, Perri, Greenland and the WHI Investigators	7	
448	DM & Breast Cancer	CT	Prentice, Caan, Chlebowski, Kuller, Margolis, Caan, Ockene, Patterson Paskett Henderson and the WHI Investigators	7	
449	DM & Colorectal Cancer	CT	Beresford, Johnson, Black, Lasser, Ritenbaugh, Snetselaar, Ritenbaugh, Snetsalar, Bowen, Johnson and the WHI Investigators	7	
450	CaD & Fracture	CT	Jackson, LaCroix, Gass, Lewis, Robbins, Wallace, Cauley, McGowan, Cummings, and the WHI Investigators	7	
451	CaD & Colorectal Cancer	CT	Wactawski-Wende, Kotchen, Anderson, Assaf, Brunner, O’Sullivan, Cochrane, Garland, Kooperberg and the WHI Investigators	7	
352	Body size, weight cycling and risk of renal cell carcinoma among post-menopausal women.	Gen	Luo, Margolis	6	

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Ms ID	Title	Data Focus	Authors	Stage	Reference
418	Linear Measurement Error Models with restricted Sampling	CT	Gorfine, Prentice	6	
18	The Relationship of Dietary Phytoestrogens to Menopausal Symptoms and Major Morbidity in Postmenopausal Women	CT	Assaf, Cyr, Coccio, Hixson	5	
45	Socio-demographic Determinants of Folic Acid Intake	Gen	Beresford, Kritchevsky, Vitolins, Wodarski	5	
54	Current Treatment Patterns in Women with Hypercholesterolemia	Gen	Manson, Freed, Chae	5	
118	Association Between Depressive Symptomatology and Physical Activity in Postmenopausal Women	Gen	Ockene, Rosal, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson, Sato	5	
141	The Association of Food and Nutrient Intake with the Incidence of Stroke in the WHI Observational Study	OS	Beresford, Shikany, St. Jeor, Torrens, Mossavar-Rahmani, Heiss, Patterson, Van Horn	5	
151	History of Estrogen and Oral Contraceptive Use and Cognitive Function: Results from the Women's Health Initiative Memory Study	WHIMS	Rapp, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker	5	
152	The Impact of Magnesium Intake on Bone Mass and Risk of Fracture in the Women's Health Initiative Observational Study	OS	Jackson, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	5	
153	Metabolic Syndrome and Depression	CT	Wylie-Rosette, Cochrane, Perri, Rapp, Rosal	5	
156	Incidence of Systemic Lupus Erythematosus in the Women's Health Initiative	OS	Assaf, Cyr, Crowley, Coccio	5	
159	Endogenous Sex Steroid Hormone and Risk of Coronary Heart Disease in Postmenopausal Women	OS	Rexrode, Manson, Kuller, McTiernan, Stefanick, Heckbert, White	5	
160	Correlation of Endogenous Sex Steroid Hormones with Inflammatory and Thrombotic Markers in Postmenopausal Women	OS	Rexrode, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern	5	

Table 8.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
176	Validating and Improving the Gail and Colleagues Model Of Breast Cancer Risk in the WHI	Gen	Chlebowski, Anderson, McTiernan, Aragaki	5	
180	Alcohol Use and the Risk of Endometrial Cancer in the Women's Health Initiative Observational Study	OS	Assaf, Beresford, Ockene, Chen, Cyr, Coccio, Moulton, Duffy, Burkholder	5	
182	The Effect of Moderate Alcohol Consumption on the Incidence of Ovarian Cancer	OS	Assaf, Coccio, Anderson, Caan, Kaunitz, DeSantis, Duffy, Burkholder	5	
223	Physical Activity and Fracture in the Women's Health Initiative Observational Study	OS	Wactawski-Wende, Cauley, Jackson, LeBoff	5	
268	The Effects of Estrogen Plus Progestin on the Overall Health of Postmenopausal Women as Measured by a Global Index of Disease Events	CT	LaCroix, Anderson, Beresford, Cauley, Chlebowski, Curb, Hendrix, Hubbell, Jackson, Margolis, O'Sullivan, Phillips, Wallace, Aragaki	5	
284	The Effect of E+P on Bone Mineral Density	CT	Jackson, Cauley, Chen, LaCroix, Phillips, Robbins, Rodrigues, Tyllavsky, Wactawski-Wende, Pettinger	5	
296	Place of Birth and Migration within the United States and its effects on Health Behaviors and Cardiovascular Risk Factors in Post-Menopausal Women	OS	Johnson, Connelly, Allison, Goldman, Langer, Limacher, Michael, Polanco-Paula, Sato	5	
301	ACE-inhibitor Use and Occurrence of Frailty and Disability in Postmenopausal Women	Gen	Gray, LaCroix, Woods, Cochrane, McDermott, Murray, Rodrigues, Black	5	
303	Statin Use and Occurrence of Frailty and Disability in Postmenopausal Women	Gen	LaCroix, Gray, Woods, Allison, Black, Cochrane, Curb, Greenland, Newman	5	
304	The Effect of E+P Discontinuation on Risk for Fracture: The WHI	Gen	Jackson, Watts, Brzyski, Hubbell, Kuller, LaCroix, O'Sullivan, Sato, Stefanick	5	

Table 8.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
307	Determinants of Retinal Levels of Lutein and Zeaxanthin in Older Women Recruited to Participate in the Carotenoids in Age-Related Eye Disease Study (CAREDS)	OS	Mares-Perlman, Snodderly, Gruber, Moeller, Ficek, Klein, Wooten, Johnson, Chappel	5	
308	Relationship between Dietary Fat and Age Related Maculopathy in the CAREDS population	OS	Mehra, Blodi, Chappel, Moeller	5	
309	Correlates of Dietary Patterns in Older Women in the Carotenoids in Age Related Eye Disease Study (CAREDS)	OS	Moeller, Ritenbaugh, Tinker, Moeller, Blodi, Chappel	5	
311	Relationship of Supplement Use to Age Related Maculopathy	OS	Gruber, Mares-Perlman, Wallace, Moeller, Oxtan, Chappel	5	
320	Endometrial Cancer and NSAID Use in the Women's Health Initiative	OS	Modugno, Harris, Ness, Yasmeen, O'Sullivan, Rohan	5	
322	The Influence of Years Since Menopause on the Effect of HT on Cardiovascular Disease	CT	Rossouw, Barad, Barnabei, Ko, Manson, Margolis, Prentice, Stefanick, Wu	5	
328	Leukocyte Count as a Predictor of Cancer in Postmenopausal Women	OS	Margolis, Lopez, McTiernan, Thomson	5	
334	Sexual Function and the Effect of Discontinuation of E+P Therapy Among Participants in WHI	CT	Gass, Cochrane	5	
337	Joint Analyses of CT and OS Data on E+P Use and Cancers of the Breast	Gen	Prentice, Anderson, Chlebowski, Hendrix, Hubbell, Kooperberg, Kuller, Lane, Langer, Manson, McTiernan, O'Sullivan, Stefanick	5	
339	Validity of Self-Reported Diabetes Mellitus in the WHI	Gen	Margolis, Bonds, Brzyski, Howard, Phillips, Robinson, Safford, Tinker	5	
346	Estrogen + Progestin & CEE Influence on Breast Cancer Diagnosis	CT	Chlebowski, Anderson, Chen, Gilligan, Lane, Langer, McTiernan	5	

Table 8.1
Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
358	Estrogen only Influence on Mammogram Density in Healthy Postmenopausal Women in the Women's Health Initiative Randomized Trial	CT	Martin, McTiernan, Pisano, Chlebowski, Heiss	5	
362	Effects of Postmenopausal Hormone Therapy on Rheumatoid Arthritis and Systemic Lupus Erythematosus: The Women's Health Initiative Randomized Controlled trials	CT	Wallitt, Howard, Foster, Torner, Wasiko, Katz, Pettinger	5	
366	Association of Vasomotor Symptoms with Cardiovascular Outcomes	CT	Barad, Allison, Barnabei, Brunner, Cochran, Gass, Ockene, Robinson, Schatz, Stefanick, Woods, Rossouw	5	
372	Risk Factors for Hip Fracture, WHI Observational Study	OS	Robbins, Aragaki, Cauley, Chen, Jackson, Kooperberg, Lewis, Stefanick, Wactawski-Wende, Watts	5	
374	Tamoxifen and Coronary Heart Disease (CHD) Risk	Gen	Chlebowski, Allison, Brzyski, Greep, Kooperberg, O'Sullivan, Robinson	5	
375	Past Weight Cycling as a Cause of Immune Related Cancers	OS	DeRoos, Caan, McTiernan, Mossavar-Rahmani, Rosenberg, Thomson, Ulrich	5	
381	Estimating Ovarian Cancer Risk	Gen	Anderson, Chlebowski, Johnson, Kaunitz, Sato, Monk	5	
386	Dietary Predictors of Ovarian Cancer Risk in Postmenopausal Women Participating in WHI	Gen	Thomson, Caan, La Valluer, Modugno, Mossavar-Rahmani, Parker, Sarto, Shikany	5	
393	BMI as a Predictor of Body Image in Older Women, Controlling for Socio-demographic Correlates	OS	Carrigan, Robbins, Winward, Blanchette, Grosz, Hays, Hunt, Manson, Messina, Parker, Rosal	5	
409	Risk Factors for Fracture in Minority Women	OS	Cauley, Allison, Talavera	5	
417	Postmenopausal Hormone Therapy and CHD Risk: Interaction with COX-2 Inhibitors	CT	Hsia, Pettinger, Manson	5	
422	Part 2 of Ms289	Gen	Rosenberg, Greenland, Khandekar, McTiernan, Rodabough, Sharma	5	

Table 8.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
429	Biomarkers, Postmenopausal Hormone Therapy and the Risk of Stroke: The Women's Health Initiative Trials of Postmenopausal Hormone Therapy.	Gen		5	
124	Relationships Between Nutritional Intake and Measures of Cognition	WHIMS	Espeland, Bowen, Haan, Brunner, Snetselaar, Dunn	4	
183	Panic Attacks, Chest Pain and Ischemia in Post-Menopausal Women	Gen	Smoller, Wassertheil-Smoller, Sheps, Brunner, Curb, Oberman, Hendrix, Hsia	4	
185	Correlates of Dietary Lutein in Older Women Recruited to Participate in the Carotenoids in Age-Related Eye Disease Study (CAREDS)	OS	Mares-Perlman, Allen, Wallace, Ritenbaugh, Tinker	4	
215	Stress, Personality, and Social Support in the Development of Breast Cancer	OS	Michael, Ritenbaugh, Ockene, Weihs, Bowen, Chlebowski, Hays	4	
238	Effects of Timing of Initiation of Menopausal Hormone Therapy and Duration of Prior Use on Cognition and Affect (WHISCA)	CT	Maki, Resnick	4	
250	Treatment with Estrogen + Progestin and Age-related Maculopathy in the Women's Health Initiative Sight Exam Study (WHISE)	CT	Haan, Wallace, Klein, Klein, Hendrix, Seddon, Musch, Hyman	4	
251	History of Hormone Replacement Therapy use, Reproductive History and Age-Related Maculopathy in the Women's Health Initiative Sight Exam Study	CT	Haan, Wallace, Hendrix, Seddon, Klein, Klein, Musch, Langer, Brunner, Wactawski-Wende	4	
252	Dietary and Supplement intake of Antioxidants in Relation to Age Related Maculopathy Endpoints in the Women's Health Initiative Sight Exam Study	CT	Haan	4	
253	Cardiovascular Disease and Age Related Maculopathy in the Women's Health Initiative Sight Exam Study	CT	Klein, Klein, Hendrix, Seddon, Langer, Kuller, Brunner, Haan, Hyman, Tomany	4	

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Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
256	Inflammation and ARM in the WHISE Study	CT	Klein, Klein, Knudson, Seddon, Wallace, Hyman	4	
259	Alcohol, Caffeine and ARM in the WHISE Study	CT	Klein, Seddon, Klein, Johnson, Toman, Hyman, Musch, Johnson	4	
266	Correlation of Endogenous Sex Steroid Hormones with Fasting Glucose and Insulin Levels, HOMA Indices, and Incident Diabetes Mellitus in Postmenopausal Women.	OS	Weinstein, Rexrode, Ridker, Manson, Kuller, Hankinson, Cochrane	4	
267	Adherence to Dietary Modification: A Theoretical Framework	CT	Rosal, Ockene, Fletcher	4	
281	Prevalence of ST Segment Depression on Holter Monitoring in Women in the OS Relationship to HRT	OS	Sheps, Smoller, Wassertheil-Smoller	4	
283	Baseline Memory Impairment and HRT as Moderators of the Association between Change in Cognition and Dementia in WHIMS	OS	Royall	4	
318	The Association of Depressive Symptoms with BMD and Fracture: A Prospective Study form the WHI OS	OS	Scholes, Brunner, Ko, Robbins, Melville, Reed	4	
340	Postmenopausal HT and Hip Geometry	CT	Chen	4	
356	The Cross-sectional Relationship Between Relative Body Weight and Cognitive Function in Older Postmenopausal Women Participating in The Women's Health Initiative	CT	Kerwin, Kotchen, Kooperberg, McTigue, Robinson, Van Horn, Coker, Espeland	4	
360	Obesity and risk of Dementia in Postmenopausal Women	WHIMS	Kerwin, Kotchen, Chlebowski, Coker, Espeland, Kuller, Vitolins	4	
363	Air Pollution and Cardiovascular Disease Incidence in the Women's Health Initiative Observational Study	CT	Kaufman	4	

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Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
380	Coagulation Factors, Postmenopausal Hormone Replacement Therapy and the Risk of Venous Thrombosis: The Women's Health Initiative Clinical Trials of Postmenopausal Hormone Therapy	CT	Cushman, Rosendaal, Baird, Bray, Curb, Eaton, Heckbert, Howard, Phillips, Stafford	4	
387	Predictive Role of the Resting Electrocardiogram in the WHI HT	CT	Denes, Greenland, Limacher, Allison, Johnson, LaCroix, Larson, Oberman	4	
388	Accuracy of Commercial Geocoding in the Environmental Epidemiology of Arrhythmogenesis in WHI	CT	Whitsetl	4	
389	Error in Estimating Ambient Particulate Matter Health Effects in the Environmental Epidemiology of Arrhythmogenesis in the WHI	CT	Whitsetl	4	
390	Using Artificial Neural Networks to Assess Risks and Benefits for the Individual Postmenopausal Woman	WHIMS	Hogervorst	4	
396	Association Between Hypertension and Change in Cognitive Function in Postmenopausal Women: Results from the Women's Health Initiative Memory Study (WHIMS)	WHIMS	Margolis, Espeland, Johnson	4	
411	Application of GIS to Estimate Residential Daily Ambient Pollutant Concentrations		Liao, Whitsetl, Pequet, Dou, Lin, Smith	4	
415	Application of GIS to Estimate Residential Daily Ambient Pollutant Concentrations.	CT	Liao, Pequet, Dou, Lin, Smith, Whitsetl	4	
445	Interaction of Hormone Therapy With Biomarkers for Cardiovascular Outcomes.	Gen	Bray	4	
56	Psychometric Evaluation of the Urinary Incontinence Scale	Gen	Levine, Shumaker, Naughton, Kaplan, Bowen	3	
90	Passive Smoke Exposure in Childhood and Adulthood and Prevalent Coronary Heart Disease in Women Enrolled in the WHI	OS	Frishman, Wagenknecht, Wong, Ockene	3	
157	Type 2 Diabetes and Cognitive Functioning in	WHIMS	Haan, Wallace, Hogan, Coker, Ockene	3	

Table 8.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
	WHIMS				
161	Reproductive History and Cognitive Function in WHIMS	WHIMS	Haan, Frishman, Stefanick	3	
205	Risk Factors for Sarcopenia Among a Multiethnic Cohort of Postmenopausal Women	Gen	Chen, Cauley, Lewis, Phillips, Van Horn, Wallace	3	
207	Comparisons Between Never Smokers, Former Smokers and Current Smokers in the Observational Study of the WHI	OS	Brunner, Johnson, Hunt, Paskett, Stevens, Ockene, Bowen	3	
213	Body Composition, Ethnicity, and Breast Cancer Risk in Postmenopausal Women	OS		3	
245	Factors Associated with Self-Reported Severity of Constipation in the Women's Health Initiative	Gen	Morse, Ockene, Nygaard, Crawford	3	
297	Racial/Ethnic Differences in Menopausal Symptoms in Minority vs. White Women in the Oscohort of WHI at baseline	OS	Mossavar-Rahmani, Cochrane, Brzyski, Schenken, Murphy, O'Sullivan, Potter, Kempainen	3	
299	Association Between Hypertension and Change in Cognitive Function in Ppostmenopausal Women: Results from the Women's Health Initiative Memory Study (WHIMS)	WHIMS	Margolis, Espeland, Johnson	3	
349	The Effect of Hormone Replacement Therapy on the Disease Progression of Postmenopausal Osteoporosis	CT	Garnett, Chen, Ko, Robbins, Satterfield, Wang	3	
369	Markers of Inflammation as Predictors of Type 2 Diabetes Mellitus in a Multi-Racial Cohort of Women	OS	Liu, Bonds, Carnethon, Heiss, Howard, Margolis, Phillips, Robinson, Safford, Wylie-Rosette	3	
376	Markers of Endothelial Activation as predictors of Type 2 Diabetes Mellitus in a Multi-Racial Cohort of Women	OS	Liu, Manson, Cook, Hotamisligil, Hu, Levitan, Margolis, Oberman, Ridker, Rifai, Rodrigues, Tinker	3	
377	Medication Utilization for the Secondary Prevention of Cardiovascular Disease in Older Women	Gen	Robinson, Wallace, Cochrane, Black, Ko, Masaki, O'Sullivan, Petrovich	3	
383	The Role of Insulin and Insulin-like Growth	OS	Modugno, Anderson, Monk, Rohan,	3	

Table 8.1
Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
	Factors in Ovarian Cancer Risk		Shikany, Williams		
385	Development of a Glycemic Index Database for Food Frequency Questionnaires Used in Epidemiologic Studies	CT	Neuhouser, Tinker, Shikany, Beresford, Caan, Koh-Barnerjee, Parker, Patterson, Robinson, Snetsetlaar, Thomson, Van Horn	3	
392	Family Aggregation of Macrovascular Complications of Diabetes in Postmenopausal Women	OS	Li, Johnson, Curb, O'Sullivan, Robinson, Safford	3	
394	Smoking and Colorectal Cancer (CRC) Risk	Gen	Paskett, Allison, Hunt, Messina, Reeves, Rohan, Whitlock, Williams	3	
395	Hormone Therapy, Lean Mass, Falling and Fracture Risk among Postmenopausal Women: Results from the Women's Health Initiative Hormone Trials	CT	Chen, Bassford, Cauley, Jackson, LaCroix, Lewis	3	
397	Is There an Association Between Baseline Macronutrient Intake and Changes in Cognition? Results from the Women's Health Initiative Memory Study (WHIMS)	WHIMS	Espeland, Thomson, Mossavar-Rahmani	3	
399	Subtypes of Mild Cognitive Impairment: Prevalence, Course, and Effect of Hormone Therapy	WHIMS	Rapp	3	
406	Effect of HT on Incidence of Stroke in Older Women with Atrial Fibrillation	CT	Konety, Robinson	3	
414	The Impact of Prehypertension on Cardiovascular Disease Risk	CT	Hsia, Allison, Black, Eaton, LaCroix, Lasser, Margolis, Wenger	3	
427	Statin Use and Cognition in Postmenopausal Women: The Women's Health Initiative Memory Study (WHIMS)	CT	Espeland	3	
428	Pelvic Organ Prolapse as a Risk Factor for Postmenopausal Osteoporotic Fractures.	Gen	Pal, Barad, Wassertheil-Smoller, Barnabei, Kiperszok	3	
430	Sleep Quality and Cardiovascular Diseases of Postmenopausal Women	Gen		3	

Table 8.1
Publications

MS ID	Title	Data Focus	Authors	Stage	Reference
433	Hormone Therapy and Fracture: Biological Mechanisms in the Womens Health Initiative Hormone Trial	CT		3	
438	Walking Speed And Risk Of Strokes	Gen		3	
439	The Effect of Intentional and Unintentional Weight Loss on Stroke Risk in the Women's Health Initiative Observational Study.	OS		3	
463	Glycemic Load and Risk of Coronary Heart Disease in the Women's Health Initiative Observational Study	OS		3	

Stage

- 3=Writing group approved
- 4=Analysis proposed
- 5=Analysis in progress
- 6=Analysis completed
- 7=Draft manuscript
- 8=Final ms submitted to P&P & PO
- 9=Final ms approved
- 10=Submitted
- 11=In press/published

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
223	Women's Health Initiative Cancer Survivor Cohort: Biological, Psychosocial, and Behavioral Predictors of Survival	Paskett	Jackson	6/22/2005				Proposed
221	Dietary Modification, Calcium/Vitamin D Supplementation, and Change in Breast Density	Rohan	Smoller	1/31/2005				PO Approved
220	Coronary Heart Disease Incidence and the Built Environment: a Prospective Study in a Cohort of Postmenopausal Women	Lurie	Margolis	3/29/2005		no		D&A Approval
219	Diet And Eye Health In The WHI: End Of Trial Study	Mares	Sarto	12/27/2004		no		D&A Approval
218	WHI Nutrition and Physical Activity Assessment Study (NPAAS)	Prentice	Prentice	12/16/2004		no		PO Approved
217	Validation of the Self-Report of Rheumatoid Arthritis and Systemic Lupus Erythematosus: The Women's Health Initiative	Wallitt	Howard	3/10/2005		no		PO Approved
216	Decision-Making About Cancer Screening Among Older Women	Messina	Lane	9/28/2004		no		PO Approved
215	UGTs, NSAIDs, and Breast Cancer Risk in the WHI Observational Study	Lampe	Prentice	11/19/2004	all ppts diagnosed with breast cancer at least one year after their enrollment plus matched controls	yes	12/01/05-11/30/09	Submitted
214	A Prospective Study of Pancreatic Cancer Pathogenesis - Extension	Fuchs	Manson	11/19/2004		yes		SC Approved
212	Biochemical Antecedents of Fracture in Minority Women	Cauley	Kuller	1/28/2005		yes	04/01/06-03/31/10	SC Approved

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
211	Homocysteine Levels, B Vitamins and Bone Health in Women	LeBoff		11/19/2004	2500 cases/2500 controls for EDTA plasma (B+Y1) and DNA; 400 cases/400 controls for serum and urine	yes	12/01/05-11/30/08	Submitted
209	Red Blood Cell Omega-3 and Trans Fatty Levels and the Risk of Coronary Heart Disease Death	Harris	Wallace		cases are CHD deaths	yes		Proposed
208	Proinflammatory Markers and Colorectal Cancer	Ho	Smoller	11/19/2004	same cases/controls as AS 129	yes		SC Approved
206	Selenium, Genetic Variation in Selenoenzymes and Colorectal Cancer	Peters	Prentice	11/19/2004	Same cases/controls as AS195	yes	03/01/06-02/28/11	Submitted
205	Genome-Wide Scan of Cardiovascular Disease and Breast Cancer and Combined Postmenopausal Hormone Therapy	Prentice	Grimm	11/19/2004		yes		Tabled
199	Genetic Factors of Muscle Loss	Chen	Bassford			yes		SC Approved
198	Women's Thoughts and Feelings About Participating In a Clinical Trial	Furniss	Lasser	8/2/2004		no		PO Approved
197	Validity of Self-Reported Diabetes Mellitus in the Women's Health Initiative	Margolis	Margolis	4/28/2004		no		Funded
196	Heart Failure Evaluation in Post-Menopausal Women: the Women's Health Initiative Study	Klein	Van Horn	12/7/2004		no		PO Approved

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
195	Candidate Pathways in Colorectal Carcinogenesis: One-Carbon Metabolism and Inflammation	Ulrich		11/19/2004	Same cases/controls as AS 206	yes	03/01/06-02/28/11	Submitted
194	Genetic Epidemiology of Hip Fracture in WHI & SOF	Zmuda	Kuller	5/26/2004		yes		Proposed
192	Estrogen & Progesterone-Related Genes and Colorectal Cancer risk	Zhang	Manson	5/26/2004		yes		SC Approved
191	Cytokines, Hormones and Sarcopenia in Older Women	Chen	Bassford	5/26/2004	Identification of cases done in AS153	yes	07/01/06-06/30/11	Submitted
189	Biochemical and Anthropometric Heterogeneity Among Morbid Obese Women in the Women's Health Initiative Observational Study	Kuller		5/26/2004		yes	12/01/05-11/30/08	Submitted
188	Inflammation and the Risk of Hormonally-Linked Cancer	Modugno	Kuller	5/26/2004		yes	07/01/06-06/30/09	SC Approved
187	Serum Fatty Acids and Salicylic Acid in Relation to Incidence of Ischemic Stroke in Postmenopausal Women	He	Van Horn	3/18/2005	shares cases and controls with AS 126	yes		SC Approved
185	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly Stopping Hormone Replacement Study Pills	Ritenbaugh	Ritenbaugh	3/12/2004		no		Funded
184	Measures for Changes in Skeletal Muscle Mass	Chen	Bassford	1/9/2004		no		PO Approved
183	WHIMS MRI study	Shumaker				no		Funded
182	Genetic and Epigenetic Markers of Lung Cancer Risk in Postmenopausal Women	Schlecht	Smoller	5/26/2004		yes	07/01/06-06/30/07	Submitted
181	Estradiol, Cytokines, and Bone Turnover: Effects on Hip Fracture	Cauley	Kuller		same as AS90	yes	07/01/05-06/30/08	Funded

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
180	Macrovascular Complications of Diabetes in Postmenopausal Women	Li	Johnson			yes	12/01/05-11/30/09	Submitted
179	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women	LaCroix				yes	07/01/05-06/30/08	Submitted
178	Mammographic Density and Invasive Breast Cancer	Pisano	Heiss			no	03/12/04-02/28/07	Funded
177	Relative Risk Differences Between FFQs and Food Records	Subar	Patterson	7/31/2003		no		Funded
175	Physical Function Determinants in Minority Women	Nicholas	Bassford			no		Funded
171	Analysis of Heart Rate Variability from Ultra-short Records: The WHI Study	Michael	Ritenbaugh	12/11/2002		no		Analysis
169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Kaplan	Smoller			yes	04/01/06-07/30/10	Submitted
167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Cummings				yes	01/01/05-12/31/05	Funded
165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Hartman	Heiss			yes	09/01/04-07/31/07	Funded
164	The IGF System and Coronary Heart Disease	Kaplan	Smoller			yes	01/01/06-12/31/06	SC Approved
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Hays	Hays	9/4/2003		no		SC Approved
162	Interactive Telephone Strategy to Maintain Diet Change	Beresford				no		Tabled
161	Bone Mass Response to Termination of Estrogen + Progestin	Cauley	Kuller	8/10/2002		no		Funded

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
160	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly stopping Hormone Replacement Study Pills	Valanis	Ritenbaugh	7/31/2002		no		Complete
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Mouton	Schenken	2/27/2002		no		PO Approved
153	Longitudinal Changes in Hip Geometry and Skeletal Muscle	Chen	Bassford			no	08/15/03-06/30/08	Funded
152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Ho	Smoller		Same as AS129	yes	08/01/03-07/31/07	Funded
150	Effect of Airborne Particulate Matter and Other Air Pollutants on the Incidence of Cardiovascular Events in the Women's Health Initiative Observational Study	Kaufman				no	05/01/02-05/31/05	Funded
147	Gene-Gene and Gene-Environment Interactions and Breast Cancer Risk	Eng	Jackson			yes		Dropped
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Fuchs	Manson			yes	03/01/03-12/31/04	Analysis
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Dorn	Trevisan	5/23/2001		no		Complete
140	Air Pollution and Electrocardiographic Abnormalities	Whitsel	Heiss			no	09/01/03-05/31/08	Funded
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Paskett	Burke	8/2/2001		no		Analysis
137	Postmenopause CHD Risk: Platelet Genes & Hormone Therapy	Bray	Hays			yes	09/27/03-08/31/07	Funded
135	Natural History of Pelvic Organ Prolapse in WHI Women	Nygaard	Wallace	10/20/2000		no		Funded

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Modugno	Kuller			yes	07/01/02-06/30/04	Analysis
133	Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women	Sesso	Manson			yes	08/01/04-07/31/08	Funded
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Liu	Manson			yes	08/01/02-07/30/07	Funded
130	Randomized Controlled Trial of Fat Reduction, Calcium/Vitamin D Supplementation, Hormone Replacement Therapy, and risk of Proliferative Forms of Benign Breast Disease	Rohan	Smoller			no	07/01/01-06/30/06	Funded
129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Strickler	Smoller		same as AS152	yes	02/01/02-12/31/05	Funded
127	CHD Risk Perception Study	Barnhart	Wassertheil-Smoller	8/16/2000		no		Funded
126	Stroke Risk Factors and Molecular Markers in Postmenopausal Women	Smoller				yes	08/01/03-07/31/06	Funded
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Namie	Langer	12/11/2000		no		Complete
122	Feasibility Study of Computerized Tailored Dietary Feedback	Glanz	Curb	3/15/2000		no		Complete
121	Hyperinsulinemia and Ovarian Cancer	Modugno	Kuller		originally a subset of AS97	yes	09/01/02-08/31/04	Analysis

Table 8.2
Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Coy	Hubble	11/17/1999		no		Complete
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Nichols	Jackson	9/17/1999		no		Analysis
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Hakim	Bassford	5/19/1999		no		Complete
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Rexrode	Manson		79 matched cases-ontrols and 92 cases (but not controls) overlap with AS83.	yes	09/01/00-08/31/03	Funded
108	Gene-environment effects and Colorectal Cancer	Lin	Chlebowski			yes	04/01/03-03/31/04	Funded
105	Carotenoids in Age-Related Eye Disease Study	Mares-Perlman	Sarto			yes	06/01/00-04/30/04	Funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	MeNikow	Robbins	2/17/1999		no		Complete
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Shumaker	Shumaker	10/16/1998		no		Funded
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Fouad	Oberman			no		Complete
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Hays	Hays	8/12/1998		no		Funded
99	GENNID Study	Chlebowski	Chlebowski	6/10/1998		no		Complete
98	Bone mineral density as a predictor for periodontitis	Wactawski-Wende	Trevisan	6/10/1998		no		Funded

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Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
97	Modeling serum markers for cost-effective ovarian cancer screening	Anderson	Anderson			yes	09/30/01-06/30/09	Funded
95	Work organization, psychological distress, and health among minority older women	Rodriguez	Curb	11/12/1997		no		Complete
93	The Epidemiology of Venous Disease	Criqui	Langer	3/11/1998		no		Complete
92	Fasting glucose in baseline plasma from all CT participants	Howard	Howard			no		Tabled
90	WHI Sex Hormone and Genetic Risk Factors for Hip Fracture	Cummings	Cummings		same as AS181	yes	04/01/04-03/31/06	Funded
86	A Pilot Study to Determine the Sensitivity of Form 39 to Impaired Executive Control Function (ECF) as measured by the CLOX: an Executive Clock-Drawing Task	Polk	Schenken			no		Complete
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Dunn	Van Horn	5/21/1997		no		Funded
83	Thrombotic, Inflammatory and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Ridker				yes	09/01/99-08/31/03	Complete
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Chen	Ritenbaugh	10/1/1997		no		Complete
78	Community Strategy to Retain Women Enrolled in Research	Fouad	Oberman	7/9/1997		no		Complete
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Chlebowski	Chlebowski	8/17/1997		no		Complete

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Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
75	Adherence to Dietary Modification in the WHI	Rosal	Ockene	4/4/2001		no		Analysis
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Wodarski	Trevisan			no		Complete
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Ritenbaugh	Langer			no		Complete
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Chen	Ritenbaugh	4/23/1997		no		Analysis
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status: WHI	Sheps	Heiss			no		Complete
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Hsia	Hsia	1/30/1997		no		Complete
67	Prevalence and Natural History of Autoimmune Thyroid Disease in Postmenopausal Women	Zakarija	O'Sullivan	5/15/1996		no		Funded
65	Benign Breast Disease	Rohan				no	04/01/98-06/30/99	Complete
63	Development and Evaluation of Eating Style Index	Haines	Heiss	9/18/1996		no		Complete
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Haan	Robbins	9/1/1996		no		Funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Ober	Robbins	6/19/1996		no		Funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	Shikany	Oberman			no		Complete
57	Hispanic Women's Advocacy and Retention Strategies	Ritenbaugh	Ritenbaugh	5/15/1996		no		Complete

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Ancillary Studies

AS #	Title	Study PI	WHI PI	D&A Approval	Cases/Controls	OS Blood Specimen?	Proposed Study Dates	Funding Status
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Pleuss	Burke	4/17/1996		no		Complete
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Burrows	Grimm	4/17/1996		no		Complete
48	Prostate Ca Survey of Spouses of WHI Screened Women	Smoller	Smoller			no		Complete
47	Effect of diet intervention on motivation to make other health-related changes		Langer			no		Complete
40	Ethnic and age differences in use of Mammography	Wassertheil-Smoller	Wassertheil-Smoller	9/20/1995		no		Complete
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Shumaker				no	06/01/96-04/30/05	Funded
36	HRT and changes in Mammographic Density	Hulka	Heiss			no	01/31/98-12/31/02	Complete
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Nelson	Hendrix	7/17/1995		no		Complete
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Mayo	Oberman	6/14/1995		no		Complete
25	Ankle-Arm Blood Pressure Index Measurement	Masaki	Curb	3/14/1995		no		Complete
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Schneider	Langer	2/14/1995		no		Complete
17	Domestic Violence in Older Women	Mouton	Lasser	3/14/1995		no		Complete
15	The Relationship between Osteopenia and Periodontitis	Wactawski-Wende	Trevisan	2/14/1995		no		Complete

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14	High Density Lipoprotein Metabolism	Going	Moon	1/10/1995		no		Complete
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Vogt	Kuller	1/10/1995		no		Complete
11	Validation and Exploration of Sleep and Mood Predictors	Kripke	Langer	3/23/1994		no		Complete
9	Oral Bone Loss	Jeffcoat	Lewis			no	05/29/95-11/30/04	Analysis
5	Explanations for the Development of Fat Distaste	Green	Bowen	1/21/1994		no		Complete