Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
March 1, 2004 to August 31, 2004

Prepared by
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WHI Semi-Annual Progress Report

Contents Page

Executive Summary

This report, summarizing data accumulated through August 31, 2004 presents the current status of the three clinical trial components and the Observational Study of the Women's Health Initiative (WHI). The focus of this report is adherence to the interventions, completeness of follow-up, safety and event rate comparisons for each clinical trial component.

Both arms of the Hormone Therapy (HT) trial component have been terminated and the initial results have been published. The current report shows intermediate endpoints and clinical events rates by age, race/ethnicity, and hysterectomy status.

For the Dietary Modification (DM) component, 48,835 women were randomized. Intervention adherence is monitored by the difference between the Intervention and Control arms in Food Frequency Questionnaire (FFQ) percent energy from fat (C-I). Studywide, the FFQ mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.4% at AV-9. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing by 0.25% per year. For fruit and vegetable intake, the mean difference between the arms remains consistently in excess of 1 more serving per day for Intervention vs. Control women. Similarly women in the Intervention arm consumed almost 1 more serving per day of grains at AV-1 than women in the Control arm, decreasing to one-third serving at AV-9. Currently, 4.1% of the DM participants are lost-to-follow-up or have stopped follow-up and 4.3% of participants are deceased. The average follow-up time for DM women is approximately 7.5 years. After adjustment for age, the current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 115%, 70%, and 65%, respectively, of what was assumed in the study design. Cumulative event rates for all monitored outcomes are provided by age and race/ethnicity.

The Calcium and Vitamin D (CaD) component randomized 36,282 women previously recruited to the trial. Adherence to CaD supplements, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report at 53-64%. In the latest interval (Aug. 03- Feb. 04), the adherence summary remained stable for all annual visits. About 20-35% of women on study medication takes less than 80% of their CaD pills, but nonetheless, continue to be partially adherent. Follow-up rates for CaD participants are better than for the other CT components in part because of the delayed randomization into this trial component; only 2.3% of participants are lost-to-follow-up or have stopped follow-up, and 3.3% of the participants are known to be deceased. With an average of 6.5 years of follow-up, the current rates of hip fractures, colorectal cancer and invasive breast cancer in the placebo arm are approximately 45%, 75%, and 115% respectively, of what was assumed in the study design. As above, cumulative event rates are provided for all monitored outcomes by age and race/ethnicity.

Observational Study recruitment ended with 93,676 women enrolled. Follow-up rates suggest strong retention overall as response rates to mailings exceed 93% through year 8. Only 3.7% of OS participants have been lost or have stopped follow-up. Event rates by age, race/ethnicity and follow-up time (pre- vs. post-year 3 visit) are presented for all adjudicated outcomes.

Information on the timeliness and quality of outcomes ascertainment, clinical center performance is provided. Finally, a summary of the current status of laboratory activities, publications, and ancillary study activities is included.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) through August 31, 2004. Topics include intervention adherence, follow-up, safety, outcomes, and specialized scientific efforts. Updates are provided for each study component separately with a separate section on outcomes devoted to data quality, processing and timeliness issues.

During the past 6 months, the major scientific activities of the WHI investigators have related to publishing the initial report from the Estrogen Alone (ERT) trial and developing additional disease-specific reports of the both the ERT and combined estrogen plus progestin (PERT) trial. Recent clinical trial publications include:

- Women's Health Initiative Steering Committee. Effects of Conjugated Equine Estrogen in Postmenopausal Women with Hysterectomy: the Women's Health Initiative Randomized Trial. JAMA 2004:291:1701-1712

- Margolis KL, Bonds DE, Rodabough RJ, Tinker L, Phillips LS, Allen C, Bassford T, Burke G, Torrens J, Howard BV. Effect of oestrogen plus progestin on the incidence of diabetes in postmenopausal women: results from the Women's Health Initiative Hormone Trial. Diabetologia 2004;47:1175-1187.

- Cushman M, Kuller L, Prentice R, Rodabough R, Psaty B, Stafford R, Sidney S, Rosendaal F. Estrogen Plus Progestin and Risk of Venous Thrombosis. JAMA 2004; 292(13); 1573-1580.

- Chen, Z, Kooperberg, C; Pettinger, MB; Bassford, T; Cauley, JA; LaCroix, AZ; Lewis, CE; Kipersztok, S; Borne, C; Jackson, R. Validity of self-report for fractures among a multiethnic cohort of postmenopausal women: results from the Women's Health Initiative observational study and clinical trials. Menopause. 11(3):264-274, 2004.

WHI investigators continue to analyze observational data. A recent example is

- Hsia J, Rossouw JE, Brunner R, LaCroix AZ, Wallace R. Predictors of Angina vs Myocardial Infarction: Prospective Analysis from the Women's Health Initiative. Am J Cardiology, 2004. Vol 93; No 6: 673-8

In addition, the WHI Memory Study investigators have published two articles from the ERT trial:

- Espeland M, Rapp S, Shumaker S, Brunner R, Manson J, Sherwin B, Hsia J, Margolis K, Hogan P, Wallace R, Dailey M, Freeman R, Hays J. Conjugated equine estrogens and global cognitive function in postmenopausal women. JAMA 2004;291:2959-2968.

- Shumaker S, Legault C, Kuller L, Rapp S, Thal L, Lane D, Fillit H, Stefanick M, Hendrix S, Lewis CB, Masaki K, Coker L. Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women. JAMA. 2004;291:2947-2958.

Analyses of cardiovascular disease biomarkers in the hormone trials are substantially completed and reports of these results will be developed over the next few months. Analysis of blood specimens for fracture related outcomes is beginning. Some additional work towards identifying biomarkers for cancer outcomes is proceeding. A proposal for a genome-wide scan for the outcomes of coronary heart disease, stroke and breast cancer in the PERT trial has been approved by the Steering Committee and has been submitted to the NHLBI for review. Discussions of proteomic studies are also underway.

Preparation for closeout was completed. A timeline for all key aspects of completing follow-up and data collection, unblinding participants to their intervention status, and providing participants with final trial results has been developed. Clinical trial participants will have their last clinic visit between October 1, 2004 and March 31, 2005, with publication of the primary results for the Dietary Modification and Calcium + Vitamin D trials expected by November 2005.

In preparation for the reporting and interpretation of Dietary Modification Trial results a Nutritional Biomarker Study has been proceeded. The 12 participating WHI clinical centers have recruited 543 DM women (50% intervention) each of whom has completed the NBS protocol. The protocol will be repeated in a 20% reliability subsample during close-out. In this substudy, done in collaboration with Dr. Dale Schoeller at the University of Wisconsin, energy consumption is measured using a doubly labeled water technique, and protein consumption is measured using urinary nitrogen. Blood concentrations are also assessed for various other nutrients. These objective measures will be used to calibrate food frequency estimates of energy consumption. The calibrated values are expected to play a fundamental role in the analysis and interpretation of DM trial data.

The NHLBI has authorized WHI centers to proceed with preparations for extended follow-up of all WHI participants through 2010. This will involve a streamlined version of the existing outcomes collection protocol, following the basic elements of the previously approved 2-year follow-up of women in the HRT program. The protocol and consent forms have been approved by the Steering Committee and relevant institutional review boards. Thirty-nine Clinical Centers are expected to participate. Clinical trial women will be consented for extended follow-up at their close-out visit. Observational study participants will be consented through mail contact or in-person contact based on local requirements. An additional, supplemental consent will be administered to all participants requesting permission to allow commercial entities access to WHI specimens.

Additional special efforts of the last few months included:

- Intensive performance monitoring and targeted support of Clinical Centers with regard to outcomes data processing to reduce backlogs and to assure rapid completion of the final trial database upon close-out. Outcomes processing at one Clinical Center with persistently low performance has been absorbed by the Clinical Coordinating Center.

- Initiation of the first competition among WHI investigators for access to serum and plasma specimens from women in the CT.

All reports summarize Clinical Center (CC) data provided to the CCC by August 31, 2004. All data presented are derived from WHILMA, the study database. Data managed in WHILMA are those defined by standardized data collection procedures and instruments (see *WHI Manuals, Vol. 2 - Procedures* and *Vol. 3 - Forms*).

The WHI Clinical Coordinating Center (CCC) is located at Fred Hutchinson Cancer Research Center, in Seattle, WA. Several other groups contribute to the coordinating center effort through a contractual relationship with the CCC: University of Washington (Bruce Psaty, PI) for cardiovascular expertise; Wake Forest University (Sally Shumaker, PI) for clinical facilitation and behavioral expertise; Wake Forest University (Ron Prineas, PI) for centralized ECG reading; University of California, San Francisco (Steve Cummings, PI) for centralized bone densitometry reading and osteoporosis expertise; McKesson Bioservices (Frank Cammarata, PI) for drug distribution on specimen repository; Medical Research Laboratories (Evan Stein, PI), biospecimen analysis.

Clinical Center locations and Principal Investigators (PI) are listed in *Table 1.1*. We note that Dr. Evelyn Whitlock is the new the Principal Investigator for the Portland CC, taking over from Dr. Cheryl Ritenbaugh who returned to Arizona where she remains a WHI Investigator.

Table 1.1
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
Albert Einstein College of Medicine	Sylvia Smoller, PhD	Bronx, NY
Baylor College of Medicine	Jennifer Hays, PhD	Houston, TX
Brigham and Women's Hospital	Joann Manson, MD DrPH	Boston, MA
Emory University	Larry Phillips, MD	Atlanta, GA
Fred Hutchinson Cancer Research Center	Shirley Beresford, PhD	Seattle, WA
George Washington University	Judith Hsia, MD	Washington, DC
Kaiser Foundation Research Institute	Bette Caan, PhD	Oakland, CA
Kaiser Foundation Research Institute	Evelyn Whitlock, MD	Portland, OR
Medical College of Wisconsin	Jane Kotchen MD MPH	Milwaukee, WI
MedStar Research Institute	Barbara Howard, PhD	Washington, D.C.
Memorial Hospital of Rhode Island	Annlouise Assaf, PhD	Pawtucket, RI
Northwestern University	Linda Van Horn, PhD RD	Chicago and Evanston, IL
Ohio State University	Rebecca Jackson, MD	Columbus, OH
Research Foundation SUNY, Stony Brook	Dorothy Lane, MD MPH	Stony Brook, NY
Rush Presbyterian/St. Luke's Medical Ctr	Henry Black, MD	Chicago, IL

Table 1.1 (continued)
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
Stanford University	Marcia Stefanick, PhD	San Jose, CA
State University of New York, Buffalo	Jean Wactawski-Wende, PhD	Buffalo, NY
University of Alabama at Birmingham	Cora Lewis, MD MSP	Birmingham, AL
University of Arizona	Tamsen Bassford, MD	Tucson and Phoenix, AZ
University of California, Davis	John Robbins, MD	Sacramento, CA
University of California, Irvine	Allan Hubbell, MD	Irvine, CA
University of California, Los Angeles	Howard Judd, MD	Los Angeles, CA
University of California, Los Angeles	Rowan Chlebowski, MD PhD	Torrance, CA
University of California, San Diego	Robert Langer, MD MPH	La Jolla/Chula Vista, CA
University of Cincinnati	Margery Gass, MD	Cincinnati, OH
University of Florida	Marian Limacher, MD	Gainesville/ Jacksonville, FL
University of Hawaii	David Curb, MD	Honolulu, HI
University of Iowa	Robert Wallace, MD	Iowa City/Bettendorf, IA
University of Massachusetts	Judith Ockene, PhD	Worcester, MA
University of Medicine and Dentistry	Norman Lasser, MD PhD	Newark, NJ
University of Miami	Mary-Jo O'Sullivan, MD	Miami, FL
University of Minnesota	Karen Margolis, MD	Minneapolis, MN
University of Nevada	Robert Brunner, PhD	Reno, NV
University of North Carolina, Chapel Hill	Gerardo Heiss, MD MPH	Chapel Hill, NC
University of Pittsburgh	Lewis Kuller, MD DrPH	Pittsburgh, PA
University of Tennessee	Karen Johnson, MD	Memphis, TN
University of Texas	Robert Brzyski, MD	San Antonio, TX
University of Wisconsin	Gloria Sarto, MD	Madison, WI
Wake Forest University	Denise Bonds, MD	Winston-Salem/Greensboro, NC
Wayne State University	Susan Hendrix, DO	Detroit, MI

2. HRT Component

Intervention activities of both hormone trials were terminated, the estrogen alone trial (ERT) on February 29, 2004 and the estrogen plus progestin trial (PERT) on July 7, 2002, based on interim findings of adverse effects. Follow-up of these participants without further intervention is proceeding through the planned trial duration according to most other aspects of the protocol. The only notable change in follow-up is the cessation of endometrial biopsies in the PERT trial.

2.1 Recruitment

Between 1993 and 1998, 27,347 women were randomized into the HRT component (99.4% of goal). Of these, 10,739 women had a prior hysterectomy (39%) and were randomized to ERT or placebo in equal proportions. The remaining 16,608 women with an intact uterus were randomized to PERT or its placebo, again in equal proportions for most of the recruitment period. *Table 2.1 – Hormone Replacement Therapy Component Age - Specific Recruitment* documents the age distribution for each trial.

2.2 Intermediate Outcomes

Bone mineral density (BMD) measures, collected in three clinical centers (Pittsburgh, Birmingham, and Tucson) at baseline and at follow-up years 1, 3, 6, and 9, continue to reflect the beneficial effects of hormones. *Table 2.2 – Bone Mineral Density Analysis: HRT Participants* does not separate the post-intervention measures from those obtained while women were taking study medications. The apparent reduction in BMD in the hip, especially in women with a uterus, is partially attributable to the cessation of hormone use. *Table 2.3 – Bone Mineral Density Analysis: HRT Participants by Race/Ethnicity* presents BMD data for Black/African American, Hispanic/Latino, and White women participating in the HRT component at these three centers.

2.3 Vital Status

Table 2.4 – Lost-to-Follow-up and Vital Status presents data on the vital status and the participation status of participants in the HRT trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing.* For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, 4.5% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 5.2% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or dead. Currently, the average follow-up for HRT participants is about 7.3 years, suggesting that approximately 20.0% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

2.4 Outcomes

Table 2.5 – Verified Outcomes (Annualized Percentages) contains counts of the number of verified, major WHI outcomes for HRT participants by age and race/ethnicity. We are reporting centrally adjudicated outcomes for those outcomes that are centrally adjudicated for all participants in a component and locally verified outcomes for events for which central adjudication has not yet been completed. Thus, for the HRT component we are using centrally

adjudicated outcomes for clinical MI, DVT, PE, breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, hip fractures, and death. The estimates of annualized incidence rates for many event types in several racial/ethnic subgroups should be viewed with caution as the small number of events observed to-date results in unstable estimates. Approximately 3% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound of the actual number of outcomes that have occurred.

Compared to the design assumptions, we have observed about 75% of the expected number of CHD events, 90% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, and about 45% of the expected number of hip fractures.

The central adjudicators have classified the strokes among HRT participants in one of six classes of the Glasgow scale, based on the condition of the participant at discharge:

1. Good recovery – participant can lead a full and independent life with or without minimal neurological deficit.

2. Moderately disabled – participant has neurological or intellectual impairment but is independent.

3. Severely disabled – participant conscious but totally dependent on others to get through daily activities.

4. Vegetative survival – participant has no obvious cortical functioning.

5. Dead. (All participants who died within one month of their stroke were classified in this category, irrespective of their actual cause of death.)

6. Unable to categorize based on available documentation.

The subclass *Non-disabling stroke* contains strokes with Glasgow scale classes 1 and 2; *Fatal/ disabling stroke* contains strokes with Glasgow scale classes 3 through 5; *Unknown status from stroke* contains strokes with Glasgow scale class 6 and strokes for which the Glasgow classification was not yet complete.

Table 2.6 – Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus compares the rates of the same verified outcomes according to baseline hysterectomy strata. For most cardiovascular outcomes the event rates are slightly larger for the women without a uterus, while for cancers of the female organs, the rates are slightly larger for women with a uterus. The differences in cardiovascular disease rates are consistent with the risk profile differences we have previously observed.

Table 2.7 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes contains counts of the number of self-reports by age and race/ethnicity for some outcomes that are not verified in WHI. As most of the self-reported outcomes are somewhat over-reported (see *Section 6.4 – Outcomes Data Quality*), the numbers in this table should be taken as an upper bound on the number of events that have occurred in HRT participants.

2.5 Issues

With the termination of both hormone trials, WHI investigators are engaged in many efforts to bring forward the best possible information from this resource. WHI investigators are preparing disease-specific manuscripts on the completed Estrogen alone trial database, describing the ERT effects in more detail.

Efforts to examine potential biomarkers continue to develop. Most of the cardiovascular biomarkers have been measured and it is anticipated that efforts toward publishing these results will begin soon. To follow-up on the possible prevention of CHD in younger women with ERT, a proposal has also been developed to examine intermediate cardiovascular endpoints using imaging technologies for coronary artery calcification and carotid IMT. The fracture biomarker proposal has been approved and is in the early stages of study implementation. The breast cancer and colorectal cancer proposals are still under development.

The monitoring of post-intervention effects in the PERT trial continues, to determine the degree of carry-over or diminution of effects. Too little time has passed since the stopping of the ERT trial to be able to provide reliable post-intervention effects. The 5-year extension of follow-up is intended to provide additional clarity on the duration of post-intervention effects, particularly for the ERT trial.

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

Data as of August 31, 2004

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3,420	125%	13%	10%
55-59	5,411	99%	20%	20%
60-69	12,364	100%	45%	45%
70-79	6,152	90%	22%	25%
Without Uterus	**10,739**			
50-54	1,396	113%	13%	10%
55-59	1,916	78%	18%	20%
60-69	4,852	88%	45%	45%
70-79	2,575	84%	24%	25%
With Uterus	**16,608**			
50-54	2,024	135%	12%	10%
55-59	3,495	116%	21%	20%
60-69	7,512	111%	45%	45%
70-79	3,577	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
Bone Mineral Density[1] Analysis: HRT Participants

Data as of August 31, 2004

	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	249	1.05	0.13	274	1.04	0.12
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]	168	3.48	7.75	190	3.01	6.56
Spine Scan						
Baseline	906	0.97	0.16	987	0.95	0.16
AV1	817	0.99	0.16	889	0.97	0.16
AV3	757	1.00	0.17	829	0.99	0.17
AV6	658	1.01	0.17	722	0.99	0.17
AV9	239	1.00	0.17	259	0.98	0.17
AV1 % Change from baseline BMD[2]	814	1.90	4.56	887	2.07	4.35
AV3 % Change from baseline BMD[2]	754	3.51	6.19	825	4.09	6.05
AV6 % Change from baseline BMD[2]	650	4.40	7.62	709	4.81	7.57
AV9 % Change from baseline BMD[2]	159	5.29	9.56	178	5.59	8.66
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	0.15	860	0.86	0.14
AV6	688	0.87	0.14	757	0.84	0.13
AV9	247	0.86	0.15	274	0.84	0.13
AV1 % Change from baseline BMD[2]	838	0.71	3.31	925	0.64	3.17
AV3 % Change from baseline BMD[2]	769	2.18	4.83	854	2.16	4.77
AV6 % Change from baseline BMD[2]	678	0.17	5.89	737	0.60	5.78
AV9 % Change from baseline BMD[2]	166	-1.32	6.96	189	-1.36	6.74

[1] Measured in (g/cm^2).
[2] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 2.3
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of August 31, 2004

	Black/African American						Hispanic/Latino						White					
	Without Uterus			With Uterus			Without Uterus			With Uterus			Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	174	1.06	0.10	99	1.08	0.11	66	1.03	0.10	61	1.02	0.11	686	0.99	0.10	843	0.98	0.09
AV1	153	1.07	0.11	86	1.08	0.11	44	1.04	0.10	50	1.03	0.10	635	1.00	0.10	775	0.99	0.09
AV3	150	1.09	0.11	87	1.10	0.12	51	1.05	0.12	45	1.06	0.11	566	1.01	0.12	708	1.00	0.10
AV6	131	1.08	0.11	69	1.08	0.12	48	1.09	0.11	43	1.09	0.14	502	1.02	0.12	619	1.01	0.11
AV9	43	1.12	0.14	32	1.14	0.13	11	1.08	0.15	7	1.19	0.23	193	1.04	0.12	229	1.02	0.10
AV1 % Change from baseline BMD[2]	153	0.75	2.95	86	0.91	2.86	44	-0.16	2.30	49	-0.07	2.42	633	0.40	2.80	773	0.21	2.27
AV3 % Change from baseline BMD[2]	150	2.06	3.45	87	2.15	3.18	51	1.66	4.58	44	3.15	5.43	564	2.24	4.63	704	1.88	3.77
AV6 % Change from baseline BMD[2]	131	0.60	3.99	68	0.44	4.05	48	5.79	6.55	42	5.87	6.53	495	2.80	5.92	608	2.57	5.37
AV9 % Change from baseline BMD[2]	14	-0.83	4.51	9	0.21	3.67	11	7.32	7.03	7	10.81	6.67	142	3.51	7.85	171	2.85	6.52
Spine Scan																		
Baseline	170	1.04	0.15	98	1.08	0.19	65	0.96	0.13	59	0.92	0.13	659	0.95	0.16	808	0.93	0.15
AV1	149	1.05	0.16	85	1.09	0.19	44	0.97	0.11	47	0.94	0.14	613	0.97	0.16	740	0.95	0.16
AV3	146	1.07	0.17	86	1.11	0.20	51	0.95	0.13	43	0.95	0.14	552	0.99	0.17	683	0.97	0.16
AV6	116	1.08	0.17	67	1.08	0.19	48	0.98	0.14	40	0.93	0.15	486	1.00	0.17	600	0.98	0.17
AV9	42	1.08	0.18	32	1.11	0.21	11	0.94	0.15	5	0.96	0.14	184	0.99	0.16	216	0.96	0.15
AV1 % Change from baseline BMD[2]	149	1.88	4.38	85	1.74	4.81	44	-0.70	4.46	47	1.74	6.95	610	2.11	4.56	738	2.13	4.10
AV3 % Change from baseline BMD[2]	146	3.42	6.18	86	2.92	6.37	51	-0.35	5.62	43	3.14	6.89	549	3.91	6.10	679	4.30	5.94
AV6 % Change from baseline BMD[2]	116	3.30	6.92	66	2.29	7.16	48	1.84	6.68	40	2.81	8.85	478	5.01	7.81	588	5.17	7.47
AV9 % Change from baseline BMD[2]	14	0.12	7.15	9	1.76	8.22	11	4.60	7.65	5	5.24	10.5	133	5.97	9.79	161	5.83	8.71
Hip Scan																		
Baseline	174	0.96	0.13	98	0.97	0.15	65	0.87	0.11	61	0.84	0.13	683	0.83	0.13	843	0.82	0.12
AV1	153	0.97	0.13	86	0.97	0.14	43	0.87	0.11	50	0.85	0.12	634	0.83	0.13	775	0.83	0.12
AV3	150	0.98	0.14	87	0.99	0.15	50	0.89	0.13	45	0.88	0.13	567	0.85	0.14	711	0.84	0.13
AV6	132	0.95	0.14	70	0.94	0.14	47	0.89	0.13	43	0.86	0.11	501	0.84	0.13	629	0.83	0.12
AV9	43	0.95	0.13	31	0.94	0.13	11	0.83	0.18	7	0.84	0.16	191	0.84	0.14	230	0.82	0.12
AV1 % Change from baseline BMD[2]	153	1.14	2.96	86	1.12	3.46	43	0.31	3.62	49	1.06	3.48	631	0.64	3.38	773	0.56	3.13
AV3 % Change from baseline BMD[2]	150	1.85	3.89	87	1.36	3.94	50	2.76	5.28	44	4.57	6.04	561	2.23	5.00	706	2.07	4.75
AV6 % Change from baseline BMD[2]	132	-1.54	5.33	68	-2.44	5.11	47	2.44	6.02	42	4.15	6.47	491	0.46	5.91	612	0.68	5.67
AV9 % Change from baseline BMD[2]	14	-3.29	6.87	9	-3.17	6.97	11	2.51	8.06	7	1.73	7.12	140	-1.37	6.82	171	-1.38	6.75

[1] Measured in (g/cm^2).
[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 August 31, 2004

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	633	5.9	798	4.8	1431	5.2
Alive: Current Participation[1]	9508	88.5	14947	90.0	24455	89.4
Alive: Recent Participation[2]	31	0.3	196	1.2	227	0.8
Alive: Past/Unknown Participation[3]	3	<0.1	5	<0.1	8	<0.1
Stopped Follow-Up[4]	377	3.5	450	2.7	827	3.0
Lost to Follow-Up[5]	187	1.7	212	1.3	399	1.5

[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 August 31, 2004

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3420		5411		12364		6152	
Mean follow-up (months)	88.0		93.5		90.5		87.1		84.5	
Cardiovascular										
CHD[1]	897	(0.45%)	45	(0.17%)	95	(0.23%)	407	(0.45%)	350	(0.81%)
CHD death[2]	236	(0.12%)	10	(0.04%)	20	(0.05%)	94	(0.10%)	112	(0.26%)
Total MI[3]	732	(0.37%)	37	(0.14%)	79	(0.19%)	334	(0.37%)	282	(0.65%)
Clinical MI	699	(0.35%)	36	(0.14%)	77	(0.19%)	318	(0.35%)	268	(0.62%)
Evolving Q-wave MI[4]	34	(0.02%)	1	(<0.01%)	2	(<0.01%)	17	(0.02%)	14	(0.03%)
Possible evolving Q-wave MI[4]	168	(0.08%)	17	(0.06%)	21	(0.05%)	69	(0.08%)	61	(0.14%)
Angina	1001	(0.50%)	46	(0.17%)	128	(0.31%)	478	(0.53%)	349	(0.81%)
CABG/PTCA	1111	(0.55%)	50	(0.19%)	137	(0.34%)	543	(0.60%)	381	(0.88%)
Carotid artery disease	201	(0.10%)	4	(0.02%)	18	(0.04%)	112	(0.12%)	67	(0.15%)
Congestive heart failure	704	(0.35%)	35	(0.13%)	71	(0.17%)	289	(0.32%)	309	(0.71%)
Stroke	652	(0.33%)	24	(0.09%)	64	(0.16%)	287	(0.32%)	277	(0.64%)
Non-disabling stroke	335	(0.17%)	19	(0.07%)	39	(0.10%)	141	(0.16%)	136	(0.31%)
Fatal/disabling stroke	217	(0.11%)	2	(0.01%)	15	(0.04%)	95	(0.11%)	105	(0.24%)
Unknown status from stroke	100	(0.05%)	3	(0.01%)	10	(0.02%)	51	(0.06%)	36	(0.08%)
PVD	187	(0.09%)	7	(0.03%)	17	(0.04%)	96	(0.11%)	67	(0.15%)
DVT	369	(0.18%)	21	(0.08%)	49	(0.12%)	168	(0.19%)	131	(0.30%)
Pulmonary embolism	254	(0.13%)	17	(0.06%)	37	(0.09%)	124	(0.14%)	76	(0.18%)
CHD[1]/Possible evolving Q-wave MI	1055	(0.53%)	62	(0.23%)	116	(0.28%)	473	(0.53%)	404	(0.93%)
Coronary disease[5]	2429	(1.21%)	128	(0.48%)	287	(0.70%)	1123	(1.25%)	891	(2.06%)
DVT/PE	503	(0.25%)	28	(0.11%)	67	(0.16%)	243	(0.27%)	165	(0.38%)
Total cardiovascular disease	3584	(1.79%)	182	(0.68%)	422	(1.03%)	1669	(1.86%)	1311	(3.03%)
Cancer										
Breast cancer	856	(0.43%)	81	(0.30%)	154	(0.38%)	409	(0.46%)	212	(0.49%)
Invasive breast cancer	686	(0.34%)	60	(0.23%)	127	(0.31%)	319	(0.36%)	180	(0.42%)
Non-invasive breast cancer	175	(0.09%)	21	(0.08%)	28	(0.07%)	93	(0.10%)	33	(0.08%)
Ovarian cancer	68	(0.03%)	2	(0.01%)	13	(0.03%)	37	(0.04%)	16	(0.04%)
Endometrial cancer[6]	73	(0.04%)	3	(0.01%)	17	(0.04%)	37	(0.04%)	16	(0.04%)
Colorectal cancer	294	(0.15%)	19	(0.07%)	28	(0.07%)	151	(0.17%)	96	(0.22%)
Other cancer[7]	1118	(0.56%)	83	(0.31%)	157	(0.38%)	524	(0.58%)	354	(0.82%)
Total cancer	2319	(1.16%)	183	(0.69%)	360	(0.88%)	1111	(1.24%)	665	(1.54%)
Fractures										
Hip fracture	324	(0.16%)	3	(0.01%)	15	(0.04%)	97	(0.11%)	209	(0.48%)
Vertebral fracture	310	(0.15%)	10	(0.04%)	34	(0.08%)	117	(0.13%)	149	(0.34%)
Other fracture[7]	3016	(1.50%)	338	(1.27%)	479	(1.17%)	1405	(1.57%)	794	(1.83%)
Total fracture	3458	(1.72%)	348	(1.31%)	516	(1.26%)	1555	(1.73%)	1039	(2.40%)
Deaths										
Cardiovascular deaths	432	(0.22%)	16	(0.06%)	33	(0.08%)	168	(0.19%)	215	(0.50%)
Cancer deaths	603	(0.30%)	29	(0.11%)	75	(0.18%)	284	(0.32%)	215	(0.50%)
Other known cause	264	(0.13%)	12	(0.05%)	34	(0.08%)	103	(0.11%)	115	(0.27%)
Unknown cause	80	(0.04%)	5	(0.02%)	11	(0.03%)	31	(0.03%)	33	(0.08%)
Not yet adjudicated	52	(0.03%)	4	(0.02%)	3	(0.01%)	24	(0.03%)	21	(0.05%)
Total death	1431	(0.71%)	66	(0.25%)	156	(0.38%)	610	(0.68%)	599	(1.38%)

[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 August 31, 2004

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)	85.2	83.8	87.3	85.2	88.5	84.1
Cardiovascular						
CHD[1]	5 (0.54%)	11 (0.30%)	91 (0.46%)	28 (0.26%)	745 (0.46%)	17 (0.63%)
CHD death[2]	2 (0.22%)	5 (0.14%)	43 (0.22%)	4 (0.04%)	179 (0.11%)	3 (0.11%)
Total MI[3]	4 (0.43%)	9 (0.24%)	60 (0.30%)	24 (0.22%)	620 (0.38%)	15 (0.56%)
Clinical MI	4 (0.43%)	8 (0.22%)	59 (0.30%)	22 (0.20%)	592 (0.36%)	14 (0.52%)
Evolving Q-wave MI[4]	0 (0.00%)	1 (0.03%)	1 (0.01%)	2 (0.02%)	29 (0.02%)	1 (0.04%)
Possible evolving Q-wave MI[4]	0 (0.00%)	2 (0.05%)	17 (0.09%)	8 (0.07%)	139 (0.09%)	2 (0.07%)
Angina	6 (0.65%)	14 (0.38%)	112 (0.56%)	40 (0.37%)	819 (0.50%)	10 (0.37%)
CABG/PTCA	7 (0.76%)	11 (0.30%)	97 (0.49%)	42 (0.38%)	941 (0.58%)	13 (0.48%)
Carotid artery disease	1 (0.11%)	1 (0.03%)	7 (0.04%)	1 (0.01%)	189 (0.12%)	2 (0.07%)
Congestive heart failure	3 (0.33%)	7 (0.19%)	88 (0.44%)	25 (0.23%)	574 (0.35%)	7 (0.26%)
Stroke	5 (0.54%)	13 (0.35%)	87 (0.44%)	20 (0.18%)	516 (0.32%)	11 (0.41%)
Non-disabling stroke	3 (0.33%)	7 (0.19%)	38 (0.19%)	12 (0.11%)	270 (0.17%)	5 (0.19%)
Fatal/disabling stroke	2 (0.22%)	5 (0.14%)	34 (0.17%)	4 (0.04%)	168 (0.10%)	4 (0.15%)
Unknown status from stroke	0 (0.00%)	1 (0.03%)	15 (0.08%)	4 (0.04%)	78 (0.05%)	2 (0.07%)
PVD	2 (0.22%)	1 (0.03%)	20 (0.10%)	2 (0.02%)	162 (0.10%)	0 (0.00%)
DVT	1 (0.11%)	2 (0.05%)	35 (0.18%)	5 (0.05%)	324 (0.20%)	2 (0.07%)
Pulmonary embolism	3 (0.33%)	1 (0.03%)	30 (0.15%)	3 (0.03%)	215 (0.13%)	2 (0.07%)
CHD[1]/Possible evolving Q-wave MI	5 (0.54%)	13 (0.35%)	107 (0.54%)	36 (0.33%)	875 (0.54%)	19 (0.70%)
Coronary disease[5]	11 (1.19%)	28 (0.76%)	269 (1.35%)	90 (0.82%)	1999 (1.23%)	32 (1.19%)
DVT/PE	4 (0.43%)	2 (0.05%)	52 (0.26%)	7 (0.06%)	435 (0.27%)	3 (0.11%)
Total cardiovascular disease	18 (1.95%)	42 (1.14%)	391 (1.96%)	116 (1.06%)	2975 (1.83%)	42 (1.56%)
Cancer						
Breast cancer	3 (0.33%)	20 (0.54%)	78 (0.39%)	27 (0.25%)	721 (0.44%)	7 (0.26%)
Invasive breast cancer	3 (0.33%)	15 (0.41%)	62 (0.31%)	20 (0.18%)	579 (0.36%)	7 (0.26%)
Non-invasive breast cancer	0 (0.00%)	5 (0.14%)	16 (0.08%)	7 (0.06%)	147 (0.09%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	62 (0.04%)	1 (0.04%)
Endometrial cancer[6]	1 (0.11%)	0 (0.00%)	2 (0.01%)	3 (0.03%)	67 (0.04%)	0 (0.00%)
Colorectal cancer	1 (0.11%)	8 (0.22%)	27 (0.14%)	12 (0.11%)	240 (0.15%)	6 (0.22%)
Other cancer[7]	6 (0.65%)	19 (0.52%)	89 (0.45%)	35 (0.32%)	956 (0.59%)	13 (0.48%)
Total cancer	11 (1.19%)	47 (1.28%)	192 (0.96%)	73 (0.67%)	1972 (1.21%)	24 (0.89%)
Fractures						
Hip fracture	0 (0.00%)	4 (0.11%)	9 (0.05%)	5 (0.05%)	304 (0.19%)	2 (0.07%)
Vertebral fracture	2 (0.22%)	3 (0.08%)	5 (0.03%)	5 (0.05%)	291 (0.18%)	4 (0.15%)
Other fracture[7]	12 (1.30%)	40 (1.09%)	160 (0.80%)	102 (0.93%)	2665 (1.64%)	37 (1.37%)
Total fracture	13 (1.41%)	45 (1.22%)	172 (0.86%)	107 (0.98%)	3081 (1.90%)	40 (1.48%)
Deaths						
Cardiovascular deaths	3 (0.33%)	9 (0.24%)	77 (0.39%)	6 (0.05%)	333 (0.21%)	4 (0.15%)
Cancer deaths	4 (0.43%)	12 (0.33%)	54 (0.27%)	18 (0.16%)	509 (0.31%)	6 (0.22%)
Other known cause	4 (0.43%)	2 (0.05%)	25 (0.13%)	3 (0.03%)	227 (0.14%)	3 (0.11%)
Unknown cause	0 (0.00%)	1 (0.03%)	13 (0.07%)	4 (0.04%)	60 (0.04%)	2 (0.07%)
Not yet adjudicated	0 (0.00%)	1 (0.03%)	8 (0.04%)	1 (0.01%)	40 (0.02%)	2 (0.07%)
Total Death	11 (1.19%)	25 (0.68%)	177 (0.89%)	32 (0.29%)	1169 (0.72%)	17 (0.63%)

[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 August 31, 2004

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	87.6		88.2	
Cardiovascular				
CHD[1]	417	(0.53%)	480	(0.39%)
CHD death[2]	122	(0.16%)	114	(0.09%)
Total MI[3]	335	(0.43%)	397	(0.33%)
Clinical MI	321	(0.41%)	378	(0.31%)
Evolving Q-wave MI[4]	14	(0.02%)	20	(0.02%)
Possible evolving Q-wave MI[4]	61	(0.08%)	107	(0.09%)
Angina	528	(0.67%)	473	(0.39%)
CABG/PTCA	531	(0.68%)	580	(0.47%)
Carotid artery disease	110	(0.14%)	91	(0.07%)
Congestive heart failure	374	(0.48%)	330	(0.27%)
Stroke	294	(0.37%)	358	(0.29%)
Non-disabling stroke	150	(0.19%)	185	(0.15%)
Fatal/disabling stroke	99	(0.13%)	118	(0.10%)
Unknown status from stroke	45	(0.06%)	55	(0.05%)
PVD	88	(0.11%)	99	(0.08%)
DVT	144	(0.18%)	225	(0.18%)
Pulmonary embolism	92	(0.12%)	162	(0.13%)
CHD[1]/Possible evolving Q-wave MI	476	(0.61%)	579	(0.47%)
Coronary disease[5]	1183	(1.51%)	1246	(1.02%)
DVT/PE	198	(0.25%)	305	(0.25%)
Total cardiovascular disease	1685	(2.15%)	1899	(1.55%)
Cancer				
Breast cancer	289	(0.37%)	567	(0.46%)
Invasive breast cancer	235	(0.30%)	451	(0.37%)
Non-invasive breast cancer	56	(0.07%)	119	(0.10%)
Ovarian cancer	20	(0.03%)	48	(0.04%)
Endometrial cancer[6]	0	N/A	73	(0.06%)
Colorectal cancer	124	(0.16%)	170	(0.14%)
Other cancer[7]	436	(0.56%)	682	(0.56%)
Total cancer	845	(1.08%)	1474	(1.21%)
Fractures				
Hip fracture	121	(0.15%)	203	(0.17%)
Vertebral fracture	115	(0.15%)	195	(0.16%)
Other fracture[7]	1156	(1.47%)	1860	(1.52%)
Total fracture	1320	(1.68%)	2138	(1.75%)
Deaths				
Cardiovascular deaths	204	(0.26%)	228	(0.19%)
Cancer deaths	258	(0.33%)	345	(0.28%)
Other known cause	105	(0.13%)	159	(0.13%)
Unknown cause	45	(0.06%)	35	(0.03%)
Not yet adjudicated	21	(0.03%)	31	(0.03%)
Total death	633	(0.81%)	798	(0.65%)

[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 August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5411	12364	6152
Mean follow-up (months)	88.0	93.5	90.5	87.1	84.5
Hospitalizations					
Ever	13343 (6.65%)	1187 (4.45%)	2121 (5.20%)	6216 (6.92%)	3819 (8.82%)
Two or more	7363 (3.67%)	558 (2.09%)	1045 (2.56%)	3419 (3.81%)	2341 (5.41%)
Other					
Diabetes (treated)	2143 (1.13%)	298 (1.17%)	411 (1.06%)	998 (1.18%)	436 (1.07%)
Gallbladder disease[1]	1982 (1.19%)	267 (1.16%)	418 (1.20%)	923 (1.24%)	374 (1.06%)
Hysterectomy	662 (0.54%)	59 (0.37%)	121 (0.46%)	334 (0.61%)	148 (0.59%)
Glaucoma	2962 (1.54%)	259 (0.99%)	509 (1.28%)	1402 (1.63%)	792 (1.98%)
Osteoporosis	5725 (3.01%)	438 (1.67%)	889 (2.24%)	2766 (3.25%)	1632 (4.18%)
Osteoarthritis[2]	4620 (3.71%)	582 (2.88%)	926 (3.25%)	2107 (3.92%)	1005 (4.56%)
Rheumatoid arthritis	1583 (0.83%)	196 (0.76%)	325 (0.83%)	713 (0.83%)	349 (0.86%)
Intestinal polyps	3734 (2.00%)	385 (1.49%)	663 (1.70%)	1897 (2.27%)	789 (2.06%)
Lupus	277 (0.14%)	34 (0.13%)	58 (0.14%)	127 (0.14%)	58 (0.13%)
Kidney stones[2]	697 (0.41%)	83 (0.38%)	130 (0.38%)	319 (0.42%)	165 (0.45%)
Cataracts[2]	8112 (5.43%)	453 (2.06%)	1219 (3.60%)	4341 (6.36%)	2099 (8.28%)
Pills for hypertension	7052 (4.95%)	784 (3.65%)	1357 (4.30%)	3228 (5.19%)	1683 (6.20%)

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)	85.2	83.8	87.3	85.2	88.5	84.1
Hospitalizations						
Ever	67 (7.26%)	185 (5.03%)	1382 (6.94%)	592 (5.43%)	10939 (6.74%)	178 (6.60%)
Two or more	43 (4.66%)	86 (2.34%)	781 (3.92%)	273 (2.50%)	6088 (3.75%)	92 (3.41%)
Other						
Diabetes (treated)	12 (1.50%)	49 (1.46%)	343 (1.97%)	197 (1.96%)	1510 (0.97%)	32 (1.28%)
Gallbladder disease[1]	12 (1.71%)	29 (0.87%)	174 (0.97%)	119 (1.46%)	1622 (1.20%)	26 (1.17%)
Hysterectomy	2 (0.51%)	6 (0.24%)	40 (0.49%)	35 (0.56%)	573 (0.56%)	6 (0.36%)
Glaucoma	16 (1.85%)	56 (1.58%)	372 (2.03%)	174 (1.65%)	2301 (1.47%)	43 (1.71%)
Osteoporosis	28 (3.21%)	131 (3.71%)	311 (1.62%)	310 (3.05%)	4860 (3.16%)	85 (3.32%)
Osteoarthritis[2]	29 (4.65%)	98 (3.77%)	464 (3.84%)	325 (4.29%)	3630 (3.63%)	74 (4.25%)
Rheumatoid arthritis	12 (1.47%)	29 (0.82%)	257 (1.41%)	203 (1.96%)	1055 (0.68%)	27 (1.06%)
Intestinal polyps	19 (2.23%)	58 (1.72%)	383 (2.06%)	187 (1.79%)	3050 (2.02%)	37 (1.49%)
Lupus	2 (0.22%)	4 (0.11%)	31 (0.16%)	18 (0.17%)	221 (0.14%)	1 (0.04%)
Kidney stones[2]	8 (1.09%)	24 (0.76%)	72 (0.43%)	50 (0.55%)	535 (0.39%)	8 (0.35%)
Cataracts[2]	41 (5.77%)	137 (4.95%)	743 (4.96%)	411 (4.66%)	6675 (5.55%)	105 (5.22%)
Pills for hypertension	42 (6.46%)	129 (5.01%)	644 (6.53%)	445 (5.44%)	5710 (4.78%)	82 (4.68%)

[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.

3. DM Component

3.1 Recruitment

WHI randomized 48,835 women into the Dietary Modification component, 102% of goal. Age- and race/ethnicity- specific DM recruitment data are presented in *Table 3.1 – Dietary Modification Component Age – and Race/Ethnicity- Specific Recruitment.* The age fractions exceeded the design assumptions for ages 50-54, 55-59, and 60-69. For the age category 70-79, recruitment was lower than designed. Minority recruitment accounted for 19% of randomized DM participants.

3.2 Adherence

Nutrient intake data for adherence monitoring are presented in *Table 3.2 – Nutrient Intake Monitoring* and *Figure 3.1 – Nutrient Intake.* Studywide, the Food Frequency Questionnaire (FFQ) mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.4% at AV-9. This report presents comparisons of the primary DM nutrients and food groups separately for each racial/ethnic group (*Figure 3.2*). Because of sparse data, some of these results are highly variable. The C-I value in minority women is roughly 1-3 percentage points lower compared to white women. All C-I analyses are based on only those women providing a food frequency questionnaire at the designated visit. Percent of missing FFQs has remained fairly constant over time: 7.9% missing at AV-1, 10.3% at AV-3, 11.4% at AV-5, 12.0% at AV-8, and 12.0% at AV-9.

For fruit and vegetable intake, the mean difference between the arms of the trial remains consistently in excess of 1 more serving per day for Intervention vs. Control women. For grain intake, Intervention women, compared to Control women, consumed almost 1 more serving per day of grains at AV-1, decreasing to one-third serving at AV-9. Generally, the C-I for fruit and vegetable intake, as well as grain intake, are similar across race/ethnicity groups.

Multivariate analyses were conducted to identify factors associated with C-I differences in percent energy from fat based on FFQs collected in the last year and controlling for visit year and clinic effect (*Table 3.3 – Control – Intervention Difference in % Energy from Fat in WHI DM Participants Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year*). Separate analyses were conducted to examine session attendance, completion, and fat score provision variables in relation to C-I because these measures are highly correlated. For example, self-monitoring scores are almost always provided at sessions, and therefore session attendance (and completion) is closely associated with self-monitoring. The participant characteristics that are consistently associated with a lower C-I difference are being 70-79 years compared to 60-69 years at randomization, being Black compared to White, being Hispanic compared to White, and having lesser education or family income. Length of time in the study, measured by "Visit," e.g., AV-7 compared to AV-6, indicates that adherence decreases with the length of time participants have been in the Dietary Study. However, the higher adherence at AV-9 compared to AV-6 is intriging. The three intervention participation variables – session attendance, completion, and self-monitoring – are all significantly associated with much higher (i.e., better) C-I values.

Body weight data are presented in *Figure 3.3 – Mean Body Weight for DM Participants Stratified by Treatment Arm.* In the lower graph we describe the paired differences in weight change from

baseline. From baseline to AV-1, women in the intervention arm reduced body weight by an average of 2.2 kg in comparison to no change for women in the control arm. Although women in the intervention arm have gradually experienced a return to mean baseline weight by about AV-8, control women have gained weight over time and hence the difference between the arms of the trial is statistically significant at every annual visit ($p<0.01$).

Table 3.4 – Reasons for Stopping DM give reasons for stopping DM Intervention activities categorized by general type. Overall, the major reasons for stopping given by participants were family illness, emergency, or other family demands (9.7%), issues of interest in the study (9.1%), and demands of work (8.2%). Issues specifically related to the DM intervention were seldom mentioned.

3.3 Blood Specimen Analyses

Data are not presented as AV-6 analyses are not yet complete and thus data have not changed since the previous Semi-annual Progress Report.

3.4 Bone Density Analyses

Tables 3.5 and *3.6 – Bone Mineral Density Analysis* present blinded bone mineral density data from the DM bone density subsample overall and by race/ethnicity. Changes from baseline to AV-1, AV-3, and AV-6 occurred with increases in mean bone mineral density in the whole body scan as well as the spine. There were, generally, similar trends by race/ethnicity. An increase in BMD is not expected from this intervention. Possible reasons for these increases include use of calcium supplements or hormone therapy, selection of health-conscious women, incomplete BMD data (e.g., 12.6% missing at AV-3), or measurement issues.

3.5 Vital Status

Table 3.7 – Lost-to-Follow-up and Vital Status: DM Participants presents data on the vital status and the participation status of participants in the DM trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, about 4.1% of the DM participants are lost-to-follow-up or have stopped follow-up, and 4.3% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for DM participants is about 7.5 years, suggesting that approximately 20.5% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.8 – Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for Dietary Modification contains counts of the number of verified major WHI outcomes for DM participants by race/ethnicity and age. We are reporting centrally adjudicated data for those outcomes that are centrally adjudicated for all participants in a component. Thus, for the DM component we are using centrally adjudicated outcomes for breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, hip fractures, and death. Locally verified outcomes for events for which central

adjudication has not yet been completed are included in the counts. Approximately 3% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound to the actual number of outcomes that have occurred. Compared to the design assumptions, we have observed almost 115% of the expected number of breast cancers, 70% of the expected number of colorectal cancers, about 65% of the expected number of CHD events, and about 35% of the expected number hip fractures.

Table 3.9 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants contains counts of the number of self-reports for some outcomes that are not verified in WHI. As most of the locally verified outcomes are somewhat over reported (see *Section 6.4 – Outcomes Data Quality)*, the number in this table should be taken as an upper bound to the number of events that have occurred in DM participants.

3.7 Issues

As noted above, the C-I percent energy from fat difference is less than the design assumptions. The WHI investigators and staff have repeatedly undertaken regular, annual initiatives to improve adherence including the Intensive Intervention Program (IIP) in 2000, the Targeted Message Campaign in 2001 and in 2002, and the Personalized Evaluation of Fat Intake (PEFI). In 2003, we conducted a centralized "self-help" PEFI protocol that provided women the opportunity to participate in a second round of assessment and feedback. Clinical Centers also implemented locally developed augmented interventions. The active intervention phase has ended with the last group sessions occurring in August 2004. Approximately three months before their close-out visit, DM-Intervention participants will receive a motivational adherence postcard reminding them of the importance to continue following the DM dietary change eating style until their close-out contact.

3.8 Nutritional Biomarkers Substudy (NBS), a Substudy within the WHI DM

In late 2003, the DM Committee proposed conducting a study of nutritional biomarkers in a subset of DM study participants. Shortly thereafter, in January 2004, the WHI Steering Committee approved the WHI Nutritional Biomarkers Substudy (NBS), to be funded from internal (CCA-WG) monies that have been reserved for explanatory analyses in the WHI trials. The principal aim of the NBS is to collect biomarkers of energy expenditure and nutrient intake in about 550 DM participants, with actual recruitment of 543 women, about 50% of whom are in the DM intervention group. The biomarker data will be used to calibrate the dietary assessment (FFQ) measurements, thus refining our ability to interpret the DM results in relation to dietary intake. The principal biomarkers being collected are doubly labeled water (DLW) measures of energy expenditure, and urinary nitrogen (UN) measures of protein consumption. Because energy and protein expenditures act as surrogates for intake of energy and protein, participant eligibility is restricted to weight-stable women. In addition to energy and protein measures, biomarkers of micronutrient intake will be collected, e.g., blood tocopherols, folate, carotenoids, B-vitamins, selenium, and urinary potassium, calcium and sodium.

Twelve WHI CCs were selected to participate in the NBS based on their interest, experience with nutrition studies involving biological specimen protocols and dietary assessment, investigator involvement with the DM study, and WHI DM performance. Each participating clinic worked especially hard to meet recruitment goals and complete enrollment by September 30, 2004. The

participating CCs recruited participants according to substrata matching WHI's age and race/ethnicity distribution. Ten of the CCs recruited approximately 50 women, half DM-intervention and half DM-control. Two CCs recruited only minority participants, approximately 25 participants each. These recruitment strategies were successful as 18% of all NBS participants were minority women. The study design consisted of two visits to the local CC, two weeks apart. The protocol activities included the doubly labeled water protocol and follow-up measurement of urinary isotope output (for energy expenditure), collection of one 24-hour urine collection (for UN and protein intake, and urinary sodium, calcium and potassium), a fasting blood draw (for micronutrient analysis), completion of an FFQ, vitamin/mineral supplement use interview, self-report of physical activity, and measurement of height and weight. Three CCs added indirect calorimetry to the protocol to obtain measures of resting energy expenditure by working with their local General Clinical Research Centers. A 20% reliability subsample (approximately 110 participants) will repeat the entire protocol approximately 6 months after their initial participation (between October 2004 and March 2005 during the WHI close-out window) and will also complete two 24-hour dietary recalls. Laboratory analyses are underway and we expect results in the spring of 2005 for use in manuscript preparation of the primary DM Trials results.

A copy of the NBS protocol is available, upon request.

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

Data as of: August 31, 2004

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6,961	149%	14%	10%
55-59	11,039	118%	23%	20%
60-69	22,717	108%	47%	45%
70-79	8,118	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: August 31, 2004

	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	8669	36.3	7.0	9.9	0.1	<.01
FFQ Year 3[5]	3241	27.7	7.9	4889	37.3	7.1	9.6	0.2	<.01
FFQ Year 4[6]	5056	28.6	8.1	7879	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]	7120	29.8	8.3	10811	38.0	7.2	8.2	0.1	<.01
FFQ Year 7[9]	4506	30.5	8.5	7032	38.3	7.4	7.8	0.2	<.01
FFQ Year 8[10]	2571	30.9	8.6	4205	38.6	7.4	7.7	0.2	<.01
FFQ Year 9[11]	1450	31.4	8.4	2174	38.8	7.8	7.4	0.3	<.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	177	27.6	9.7	209	35.1	8.3	7.5	0.9	<.01
24 Hr Recall, Year 6 Cohort	735	26.7	9.1	1118	33.9	7.8	7.3	0.4	<.01
24 Hr Recall, Year 7	116	27.6	9.6	119	34.5	8.6	6.9	1.2	<.01
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	8669	1575.8	625.5	96.3	9.9	<.01
FFQ Year 3	3241	1476.1	538.0	4889	1571.6	644.3	95.4	13.7	<.01
FFQ Year 4	5056	1443.0	536.5	7879	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	7120	1411.1	552.5	10811	1533.3	634.3	122.2	9.2	<.01
FFQ Year 7	4506	1397.4	534.2	7032	1529.6	636.3	132.2	11.4	<.01
FFQ Year 8	2571	1386.8	538.9	4205	1529.3	632.2	142.5	15.0	<.01
FFQ Year 9	1450	1392.2	593.2	2174	1489.0	604.2	96.8	20.3	<.01
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	1383.8	466.9	248	1563.0	508.8	179.2	46.9	<.01
24 Hr Recall, Year 6	177	1371.5	448.3	209	1663.0	558.1	291.5	52.2	<.01
24 Hr Recall, Year 6 Cohort	735	1386.3	392.0	1118	1543.1	480.0	156.8	21.2	<.01
24 Hr Recall, Year 7	116	1360.4	397.6	119	1523.0	503.6	162.6	59.3	0.02

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.
9 464 (10%) Intervention women had <=20% energy from fat at year 7.
10 252 (10%) Intervention women had <=20% energy from fat at year 8.
11 100 (7%) Intervention women had <=20% energy from fat at year 9.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: August 31, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
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	8669	64.5	31.3	21.0	0.5	<.01
FFQ Year 3	3241	45.8	23.7	4889	66.0	32.5	20.2	0.7	<.01
FFQ Year 4	5056	46.2	23.9	7879	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	7120	47.0	24.7	10811	65.6	32.5	18.6	0.5	<.01
FFQ Year 7	4506	47.8	25.2	7032	66.1	33.0	18.3	0.6	<.01
FFQ Year 8	2571	47.9	25.2	4205	66.5	32.7	18.5	0.8	<.01
FFQ Year 9	1450	49.0	27.4	2174	65.0	31.7	15.9	1.0	<.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	41.4	23.5	248	60.5	27.4	19.1	2.5	<.01
24 Hr Recall, Year 6	177	42.6	22.4	209	66.6	30.3	24.0	2.8	<.01
24 Hr Recall, Year 6 Cohort	735	41.5	20.0	1118	59.7	26.2	18.3	1.1	<.01
24 Hr Recall. Year 7	116	43.1	23.0	119	58.8	24.9	15.7	3.1	<.01
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	8669	22.5	11.7	7.7	0.2	<.01
FFQ Year 3	3241	15.5	8.9	4889	22.9	12.2	7.4	0.2	<.01
FFQ Year 4	5056	15.7	8.9	7879	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	7120	15.9	9.1	10811	22.9	12.3	6.9	0.2	<.01
FFQ Year 7	4506	16.4	9.5	7032	23.1	12.6	6.7	0.2	<.01
FFQ Year 8	2571	16.3	9.2	4205	23.3	12.6	7.0	0.3	<.01
FFQ Year 9	1450	16.8	10.2	2174	22.8	11.9	5.9	0.4	<.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	177	13.5	7.9	209	21.7	11.5	8.2	1.0	<.01
24 Hr Recall, Year 6 Cohort	735	13.1	7.1	1118	19.6	9.7	6.5	0.4	<.01
24 Hr Recall, Year 7	116	13.3	7.5	119	19.4	9.4	6.2	1.1	<.01

(continues)

[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: August 31, 2004

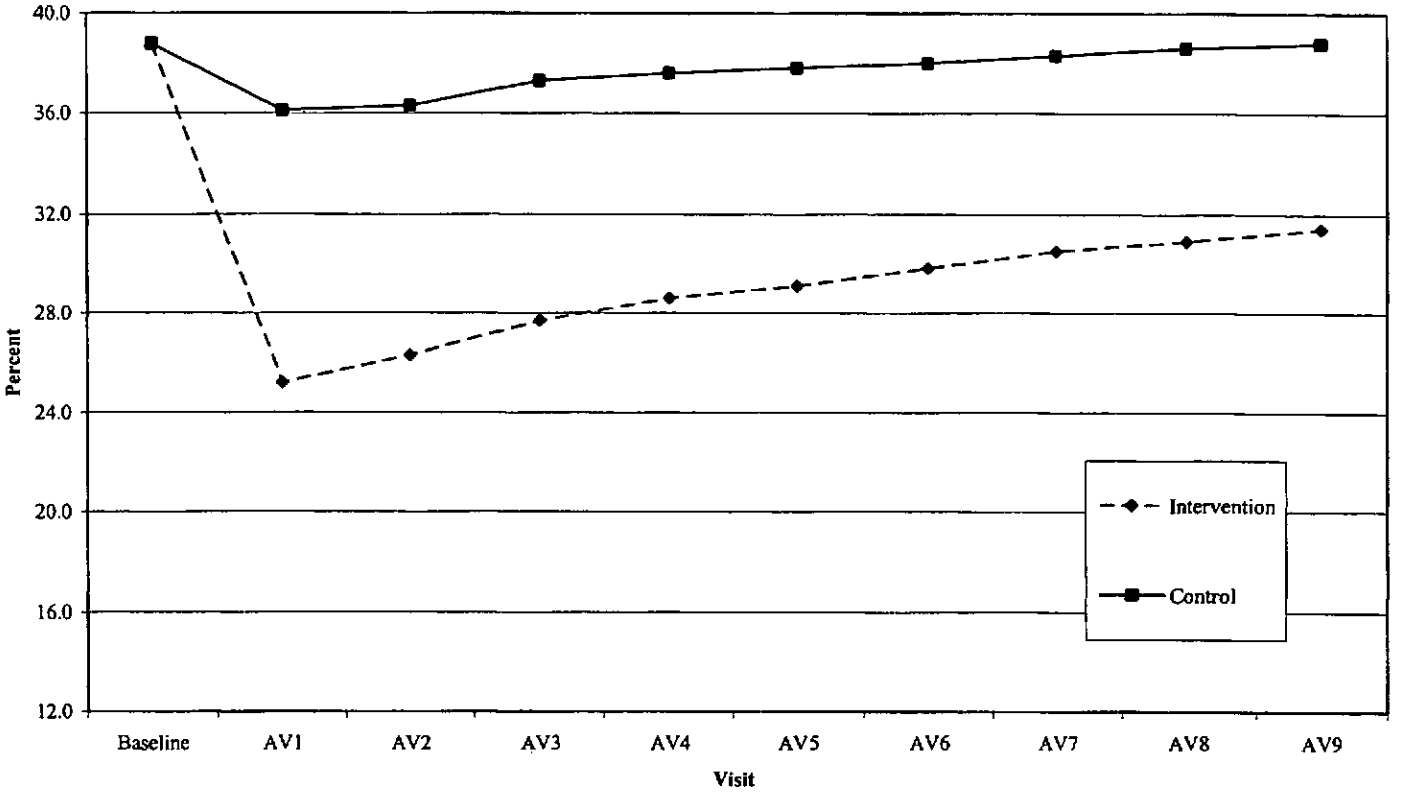
	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19541	15.3	7.6	29294	15.3	7.6	0.0	0.1	0.79
FFQ Year 1	18099	7.9	4.4	26776	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	5929	8.3	4.5	8669	12.4	6.5	4.1	0.1	<.01
FFQ Year 3	3241	8.8	4.7	4889	12.8	6.8	4.0	0.1	<.01
FFQ Year 4	5056	9.0	4.9	7879	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	7120	9.2	5.1	10811	12.7	6.7	3.5	0.1	<.01
FFQ Year 7	4506	9.2	5.1	7032	12.8	6.7	3.6	0.1	<.01
FFQ Year 8	2571	9.3	5.1	4205	12.7	6.6	3.5	0.2	<.01
FFQ Year 9	1450	9.4	5.5	2174	12.5	6.7	3.1	0.2	<.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	3.2	0.7	<.01
24 Hr Recall, Year 6	177	9.2	6.0	209	14.1	7.4	4.8	0.7	<.01
24 Hr Recall, Year 6 Cohort	735	8.8	4.7	1118	12.3	6.1	3.5	0.3	<.01
24 Hr Recall, Year 7	116	9.6	6.8	119	12.1	6.3	2.5	0.9	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	19470	3.6	1.8	29216	3.6	1.8	0.0	0.0	0.69
FFQ Year 1	18018	5.0	2.3	26694	3.8	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	4875	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	5046	5.1	2.4	7865	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	5792	5.1	2.5	8975	3.8	2.1	1.2	0.0	<.01
FFQ Year 6	7096	4.9	2.5	10786	3.8	2.0	1.2	0.0	<.01
FFQ Year 7	4486	4.8	2.4	7016	3.8	2.0	1.0	0.0	<.01
FFQ Year 8	2557	4.8	2.4	4188	3.8	2.0	1.1	0.1	<.01
FFQ Year 9	1436	4.8	2.4	2159	3.7	2.0	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	0.42
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	4870	4.0	2.2	0.7	0.1	<.01
FFQ Year 4	5042	4.4	2.4	7853	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	7093	4.1	2.3	10770	3.7	2.1	0.4	0.0	<.01
FFQ Year 7	4483	3.9	2.2	7006	3.6	2.0	0.3	0.0	<.01
FFQ Year 8	2555	3.8	2.2	4177	3.6	2.1	0.2	0.1	<.01
FFQ Year 9	1434	3.7	2.2	2155	3.4	1.9	0.3	0.1	<.01

[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: August 31, 2004

% Energy from Fat[1]

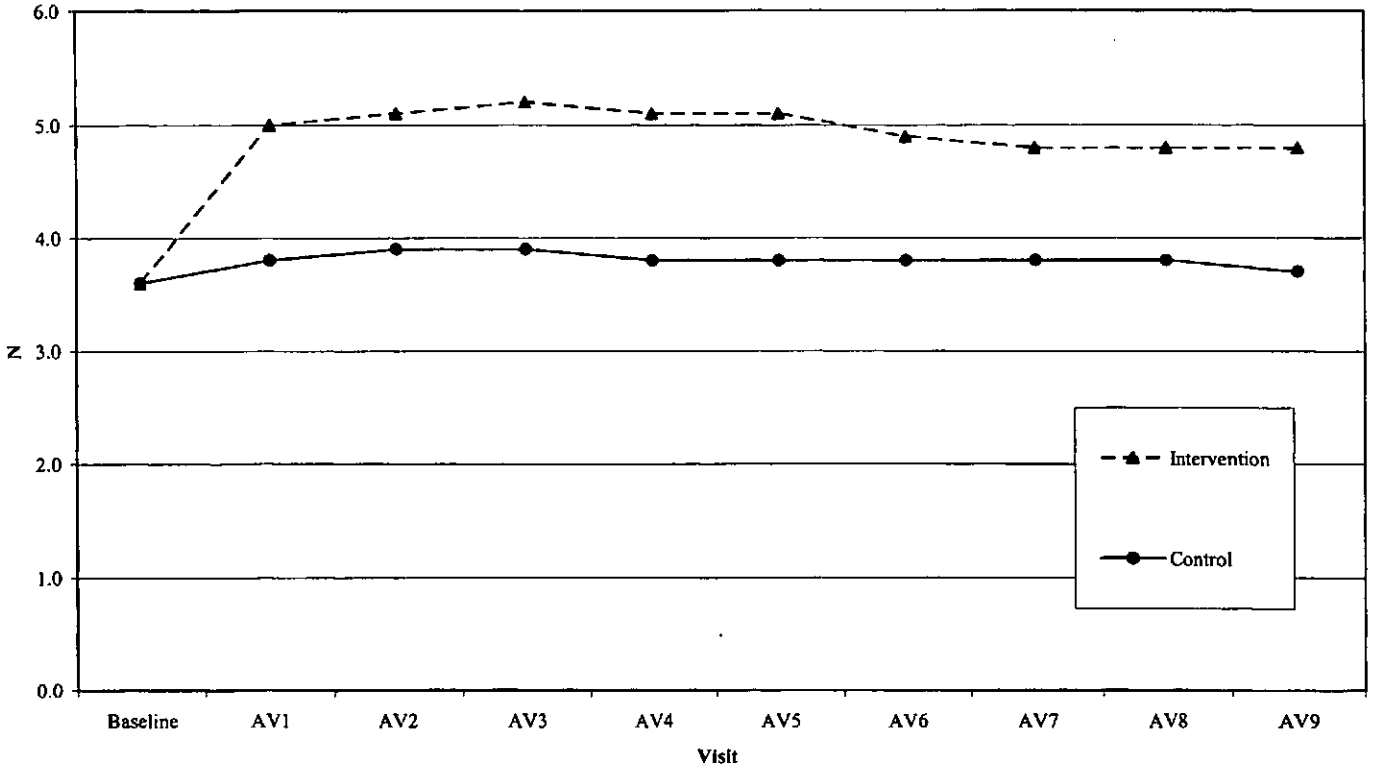


(continues)

Figure 3.1 (continued)
Nutrient Intake

Data as of: August 31, 2004

Fruit & Vegetable Servings per Day



Grain Servings per Day

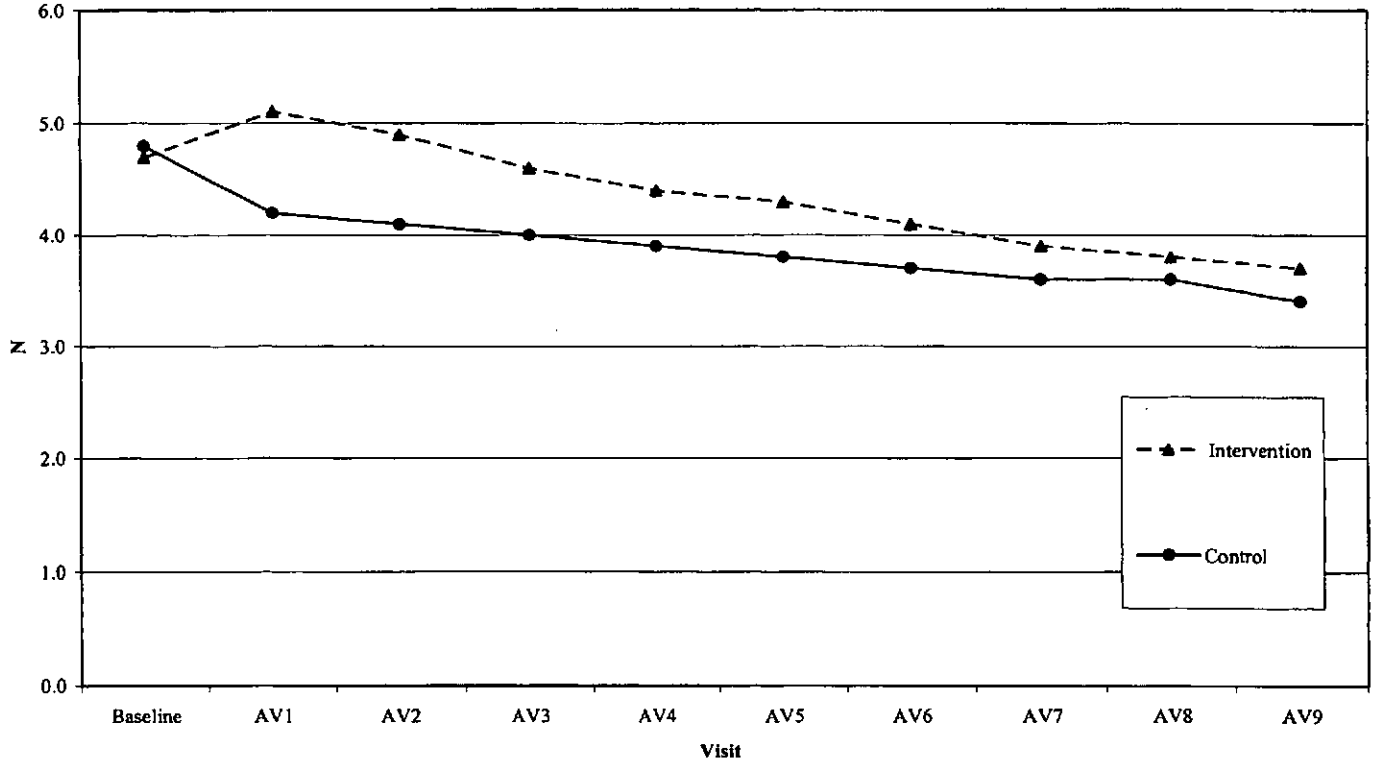
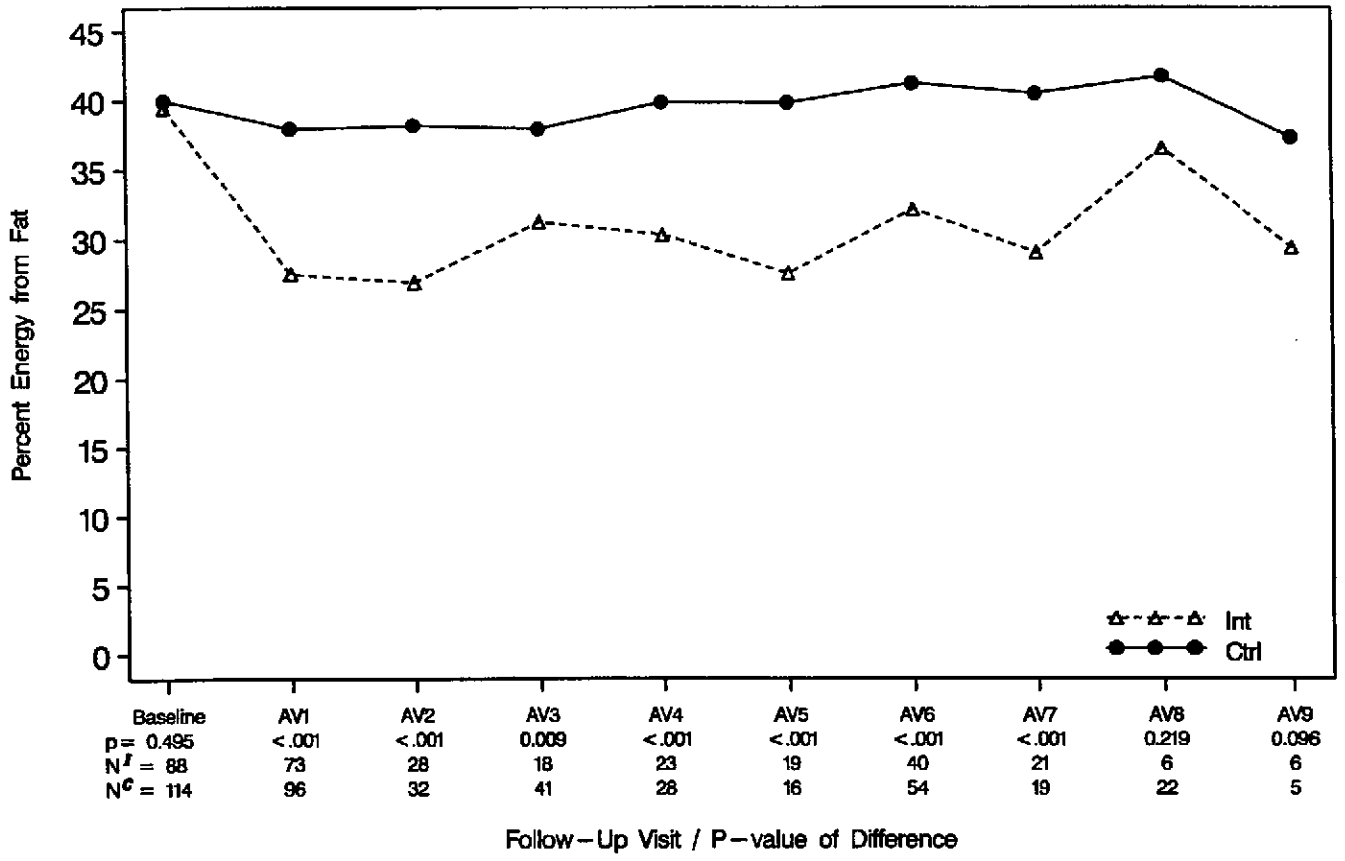


Figure 3.2
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: August 31, 2004



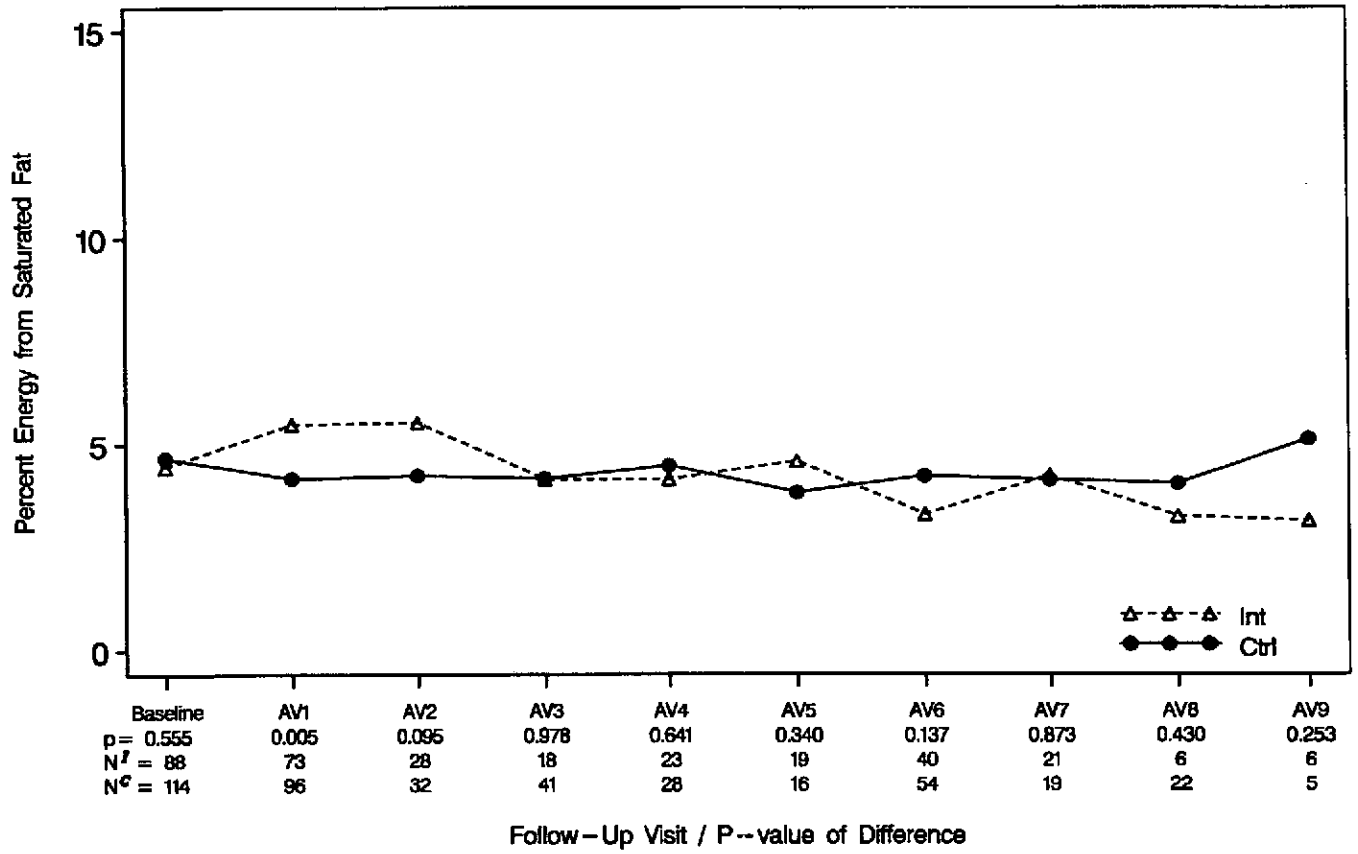
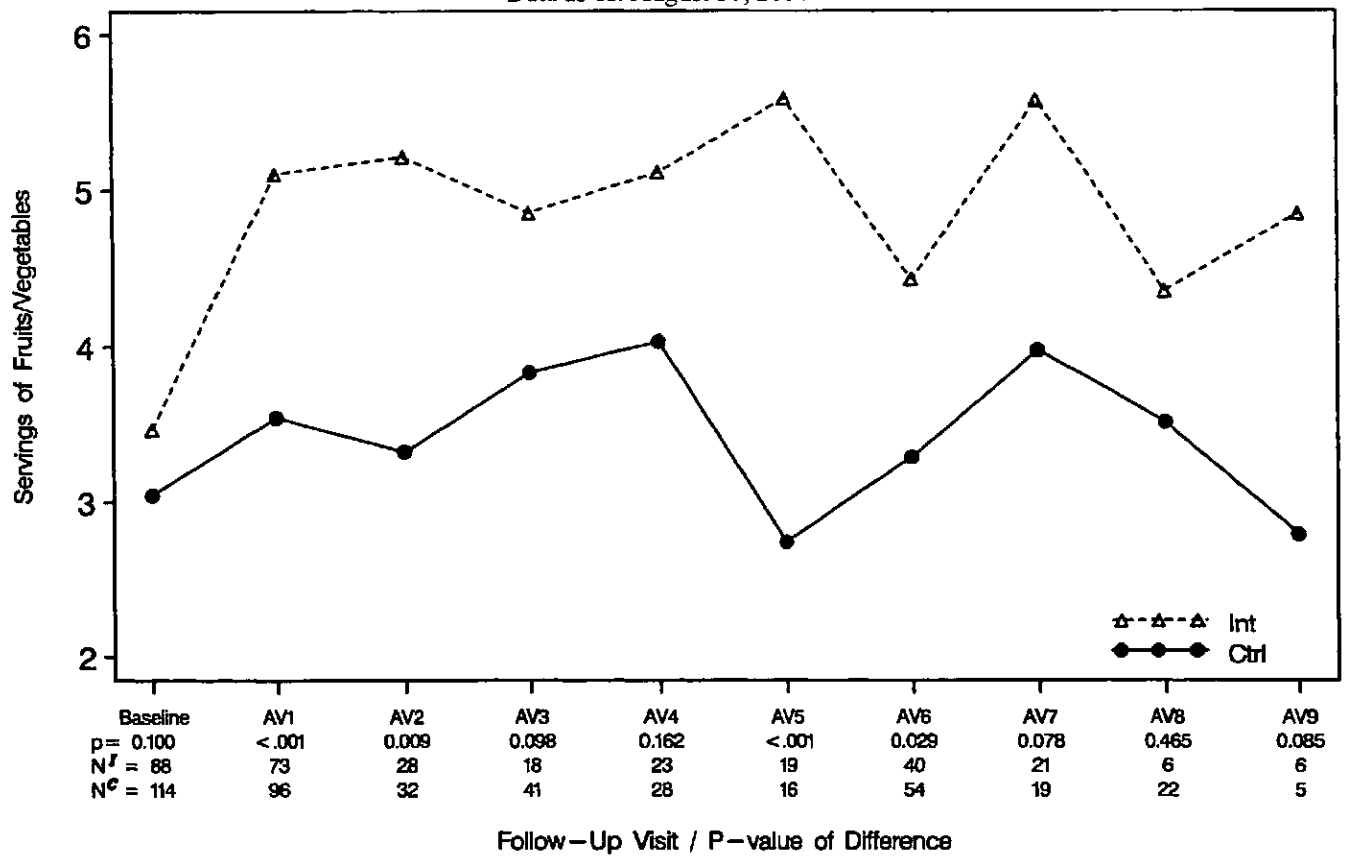
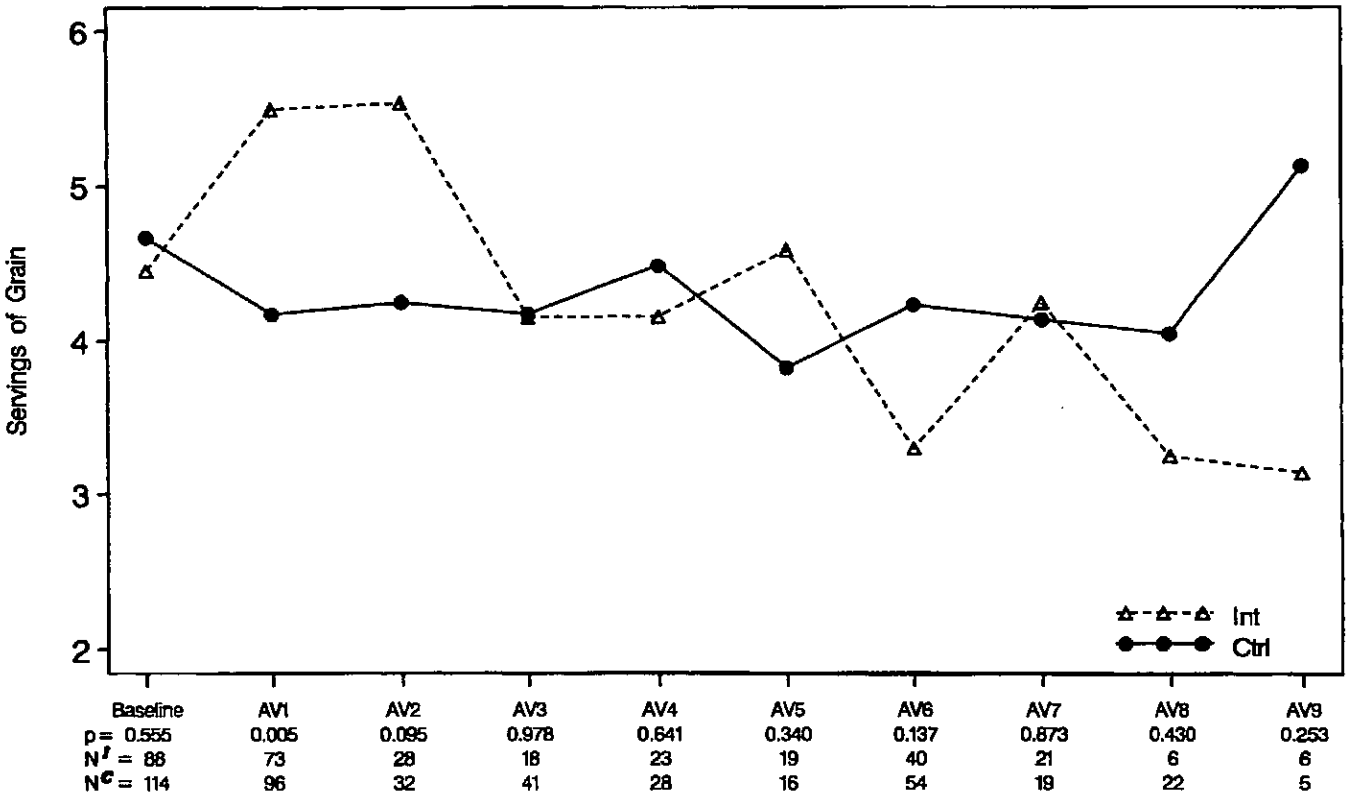


Figure 3.2 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women
Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.100	<.001	0.009	0.098	0.162	<.001	0.029	0.078	0.465	0.085
N^I =	88	73	28	18	23	19	40	21	6	6
N^C =	114	96	32	41	28	16	54	19	22	5

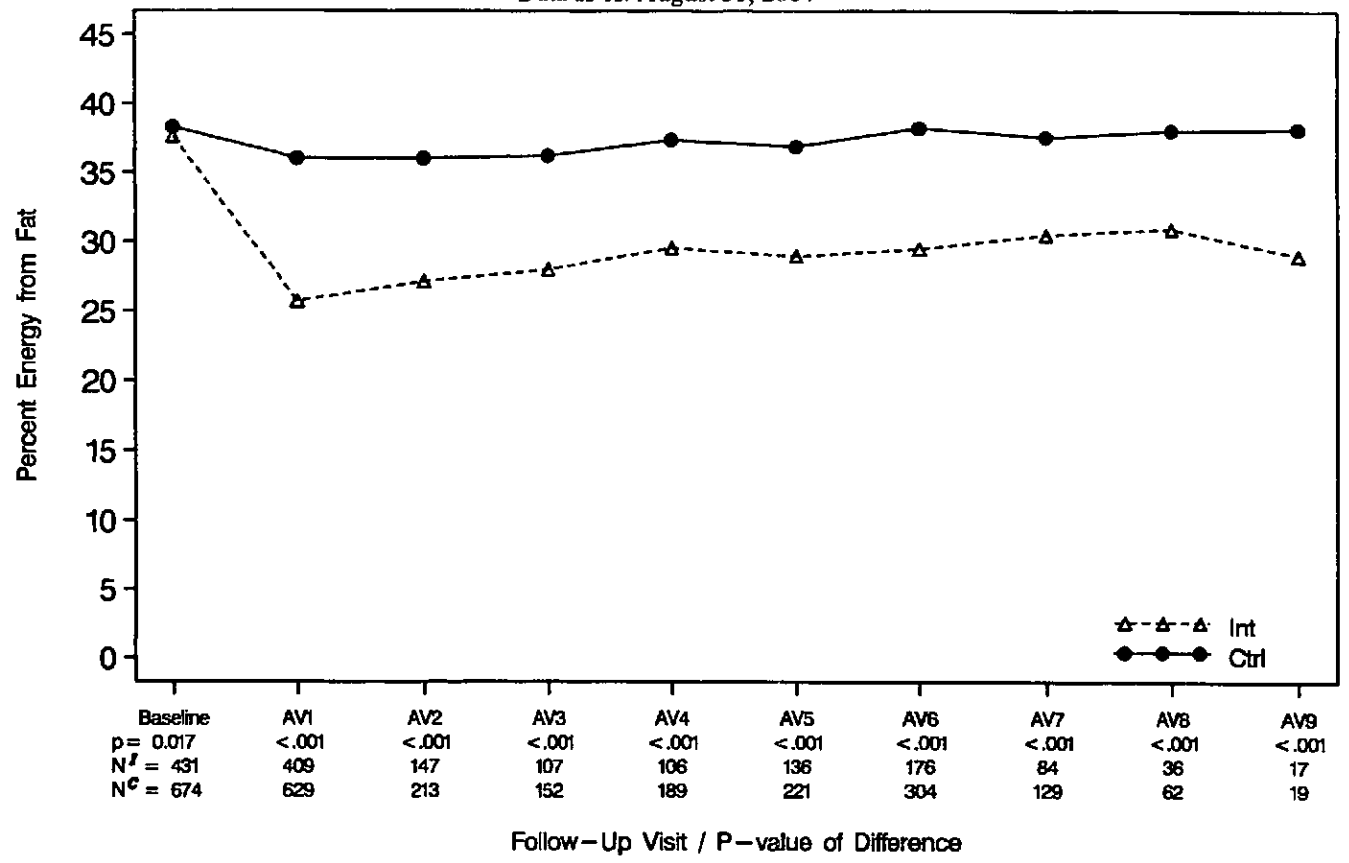
Follow–Up Visit / P–value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.555	0.005	0.095	0.978	0.641	0.340	0.137	0.873	0.430	0.253
N^I =	88	73	28	18	23	19	40	21	6	6
N^C =	114	96	32	41	28	16	54	19	22	5

Follow–Up Visit / P–value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women
Data as of: August 31, 2004



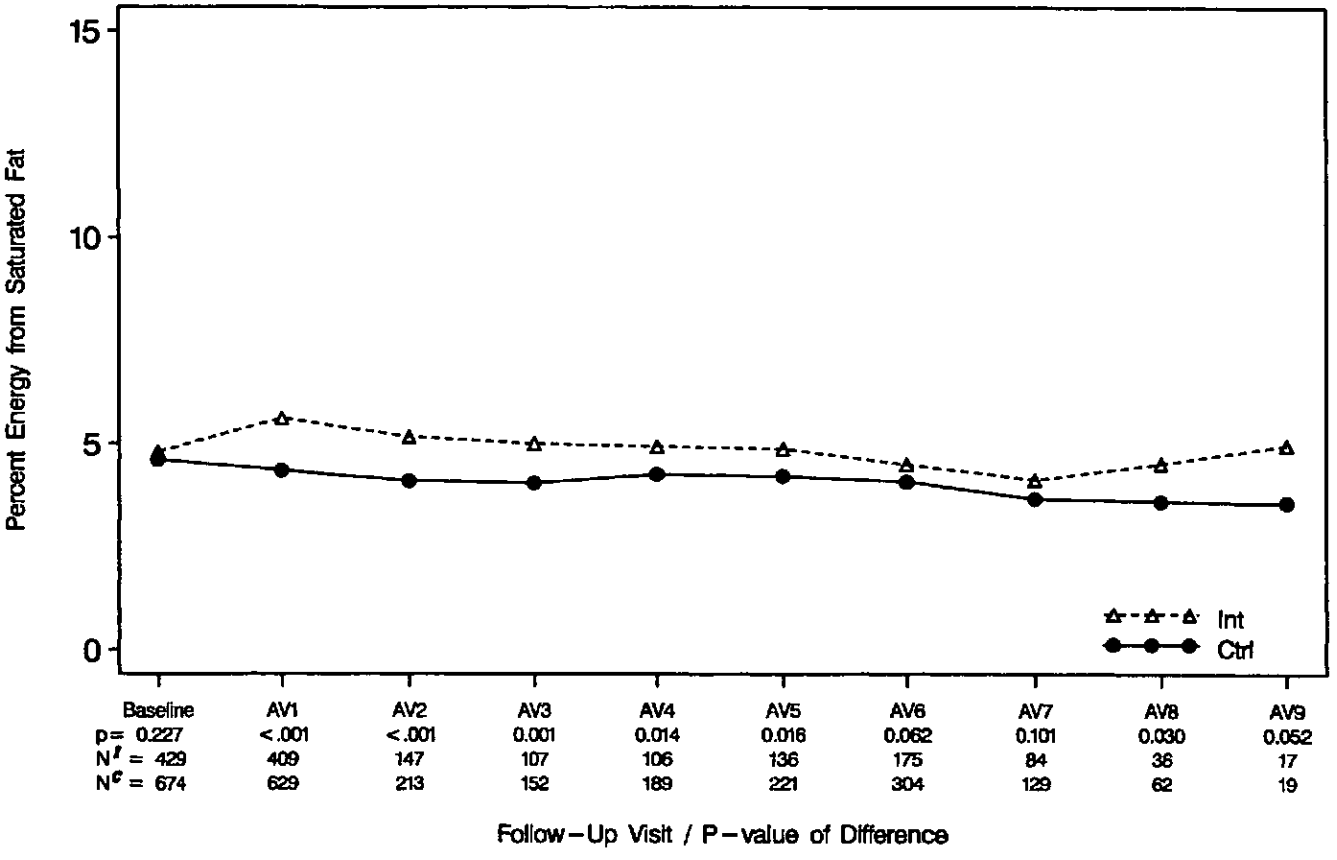
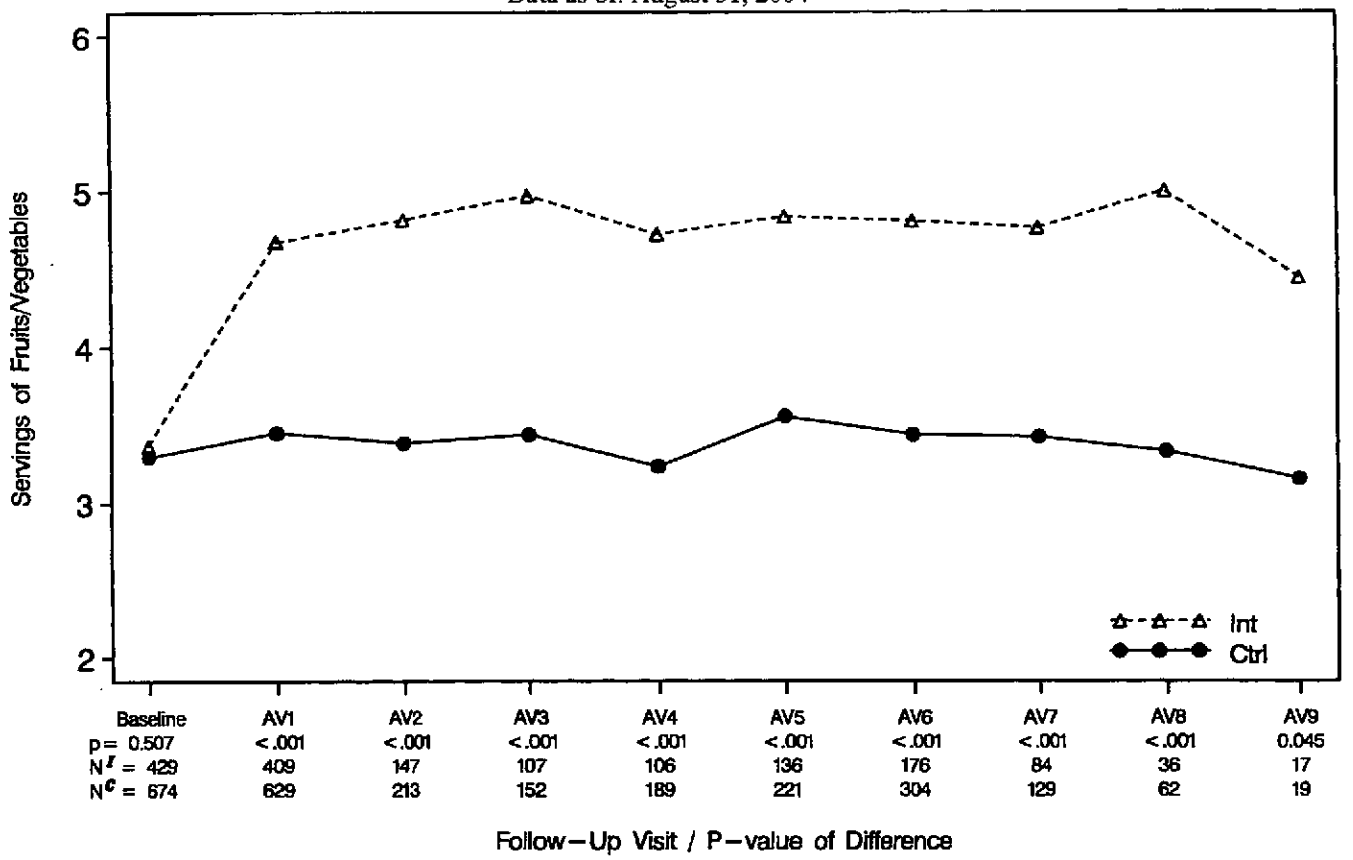
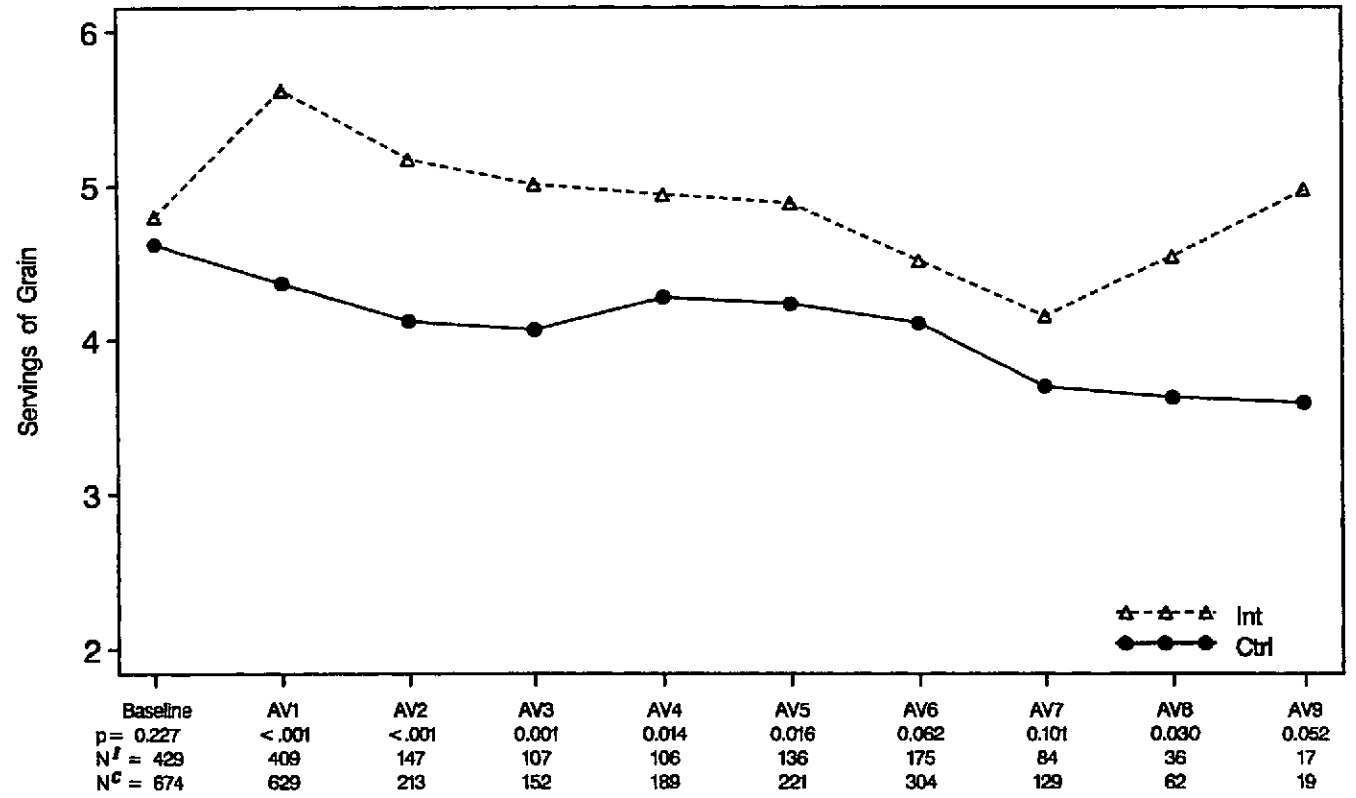


Figure 3.2 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women
Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.507	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.045
N^I =	429	409	147	107	106	136	176	84	36	17
N^C =	674	629	213	152	189	221	304	129	62	19

Follow–Up Visit / P–value of Difference

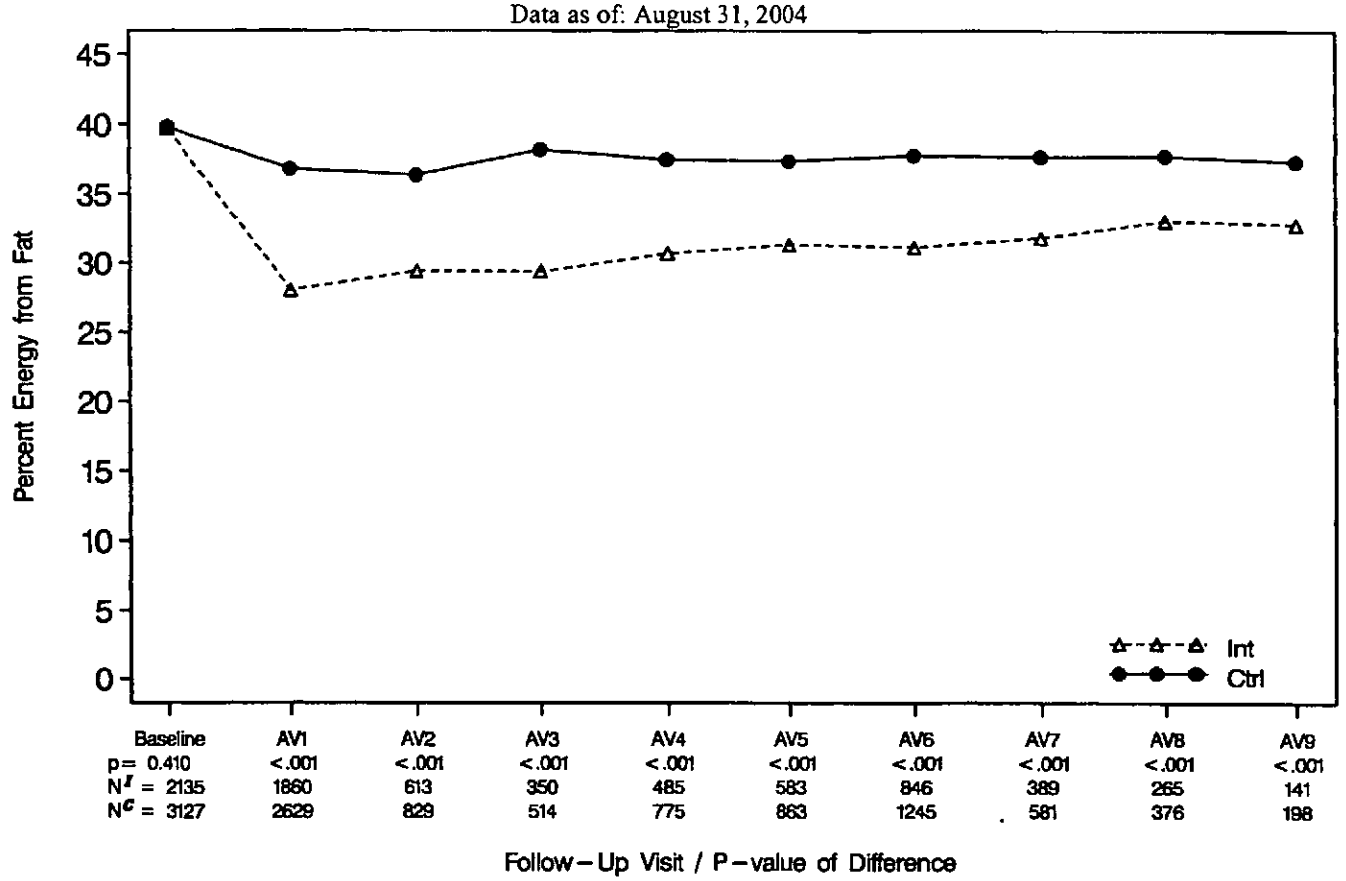


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.227	<.001	<.001	0.001	0.014	0.016	0.062	0.101	0.030	0.052
N^I =	429	409	147	107	106	136	175	84	36	17
N^C =	674	629	213	152	189	221	304	129	62	19

Follow–Up Visit / P–value of Difference

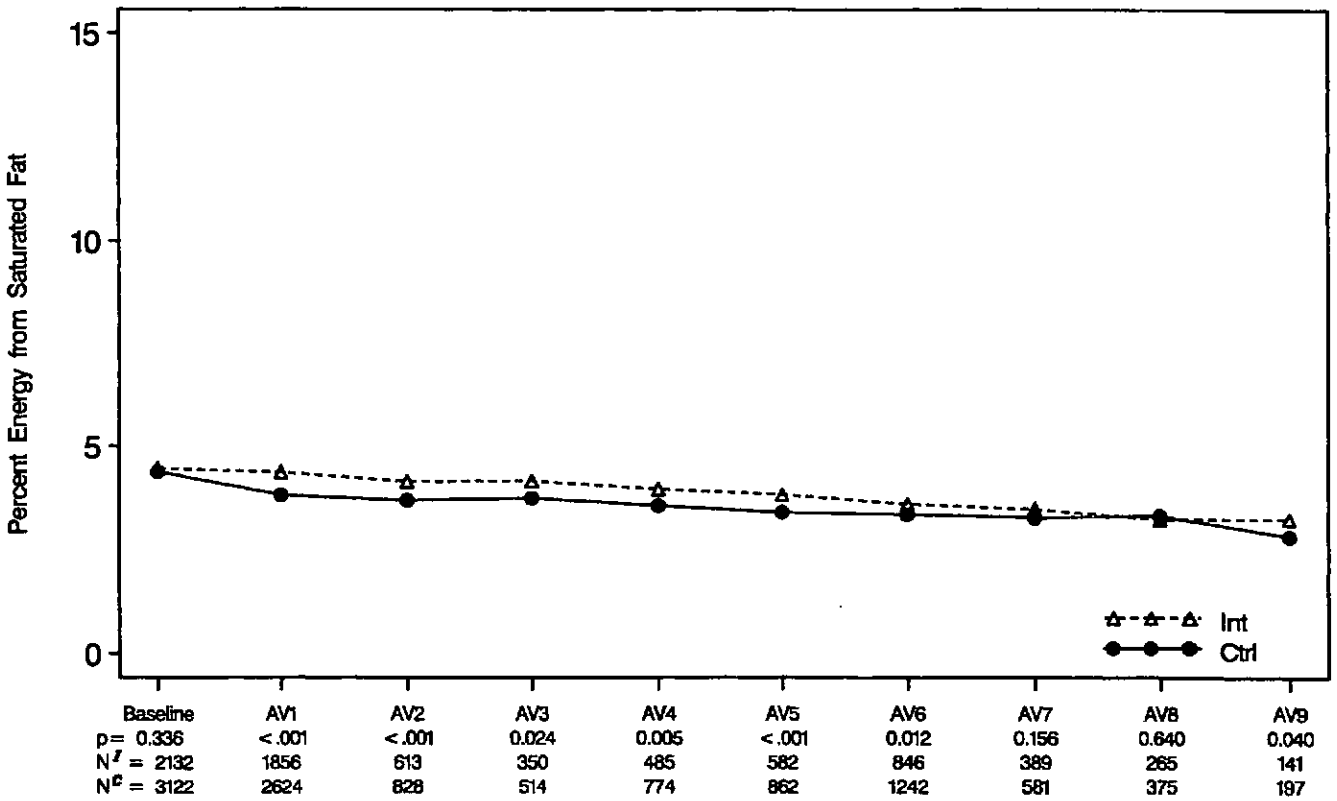
Figure 3.2 (continued)
Nutrient Intake Monitoring in Black Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.410	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	2135	1860	613	350	485	583	846	389	265	141
N^C =	3127	2629	829	514	775	863	1245	581	376	198

Follow-Up Visit / P-value of Difference

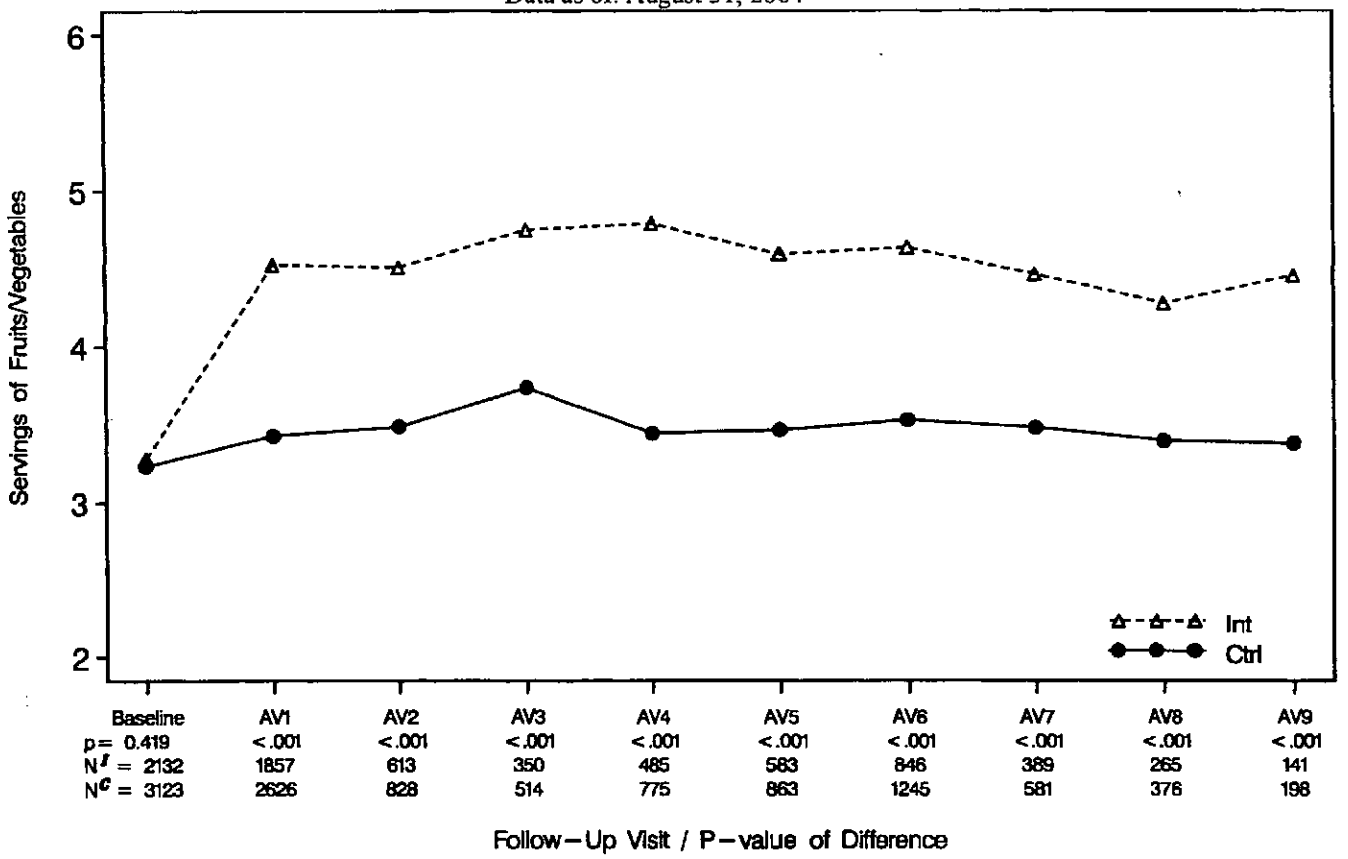


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.336	<.001	<.001	0.024	0.005	<.001	0.012	0.156	0.640	0.040
N^I =	2132	1856	613	350	485	582	846	389	265	141
N^C =	3122	2624	828	514	774	862	1242	581	375	197

Follow-Up Visit / P-value of Difference

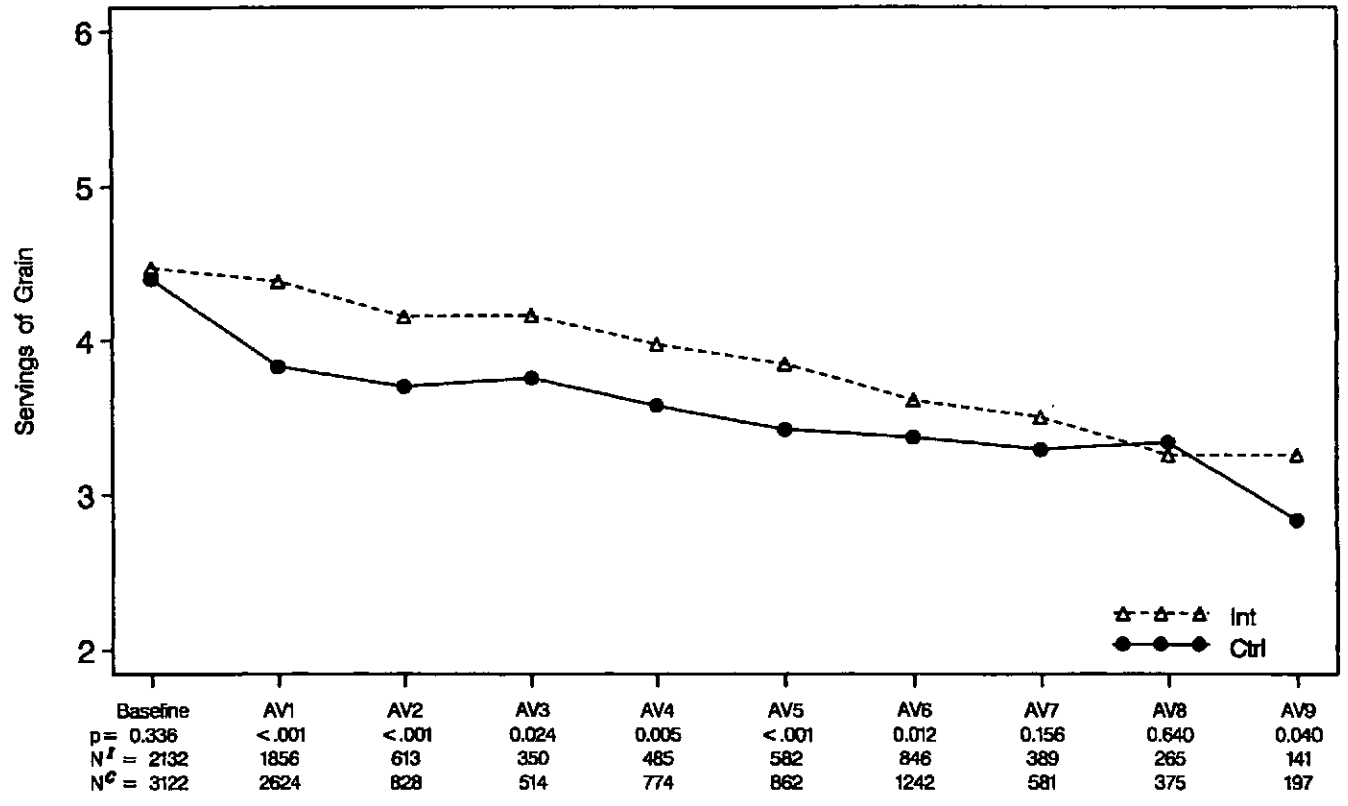
Figure 3.2 (continued)
Nutrient Intake Monitoring in Black Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.419	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	2132	1857	613	350	485	583	846	389	265	141
N^C =	3123	2626	828	514	775	863	1245	581	376	198

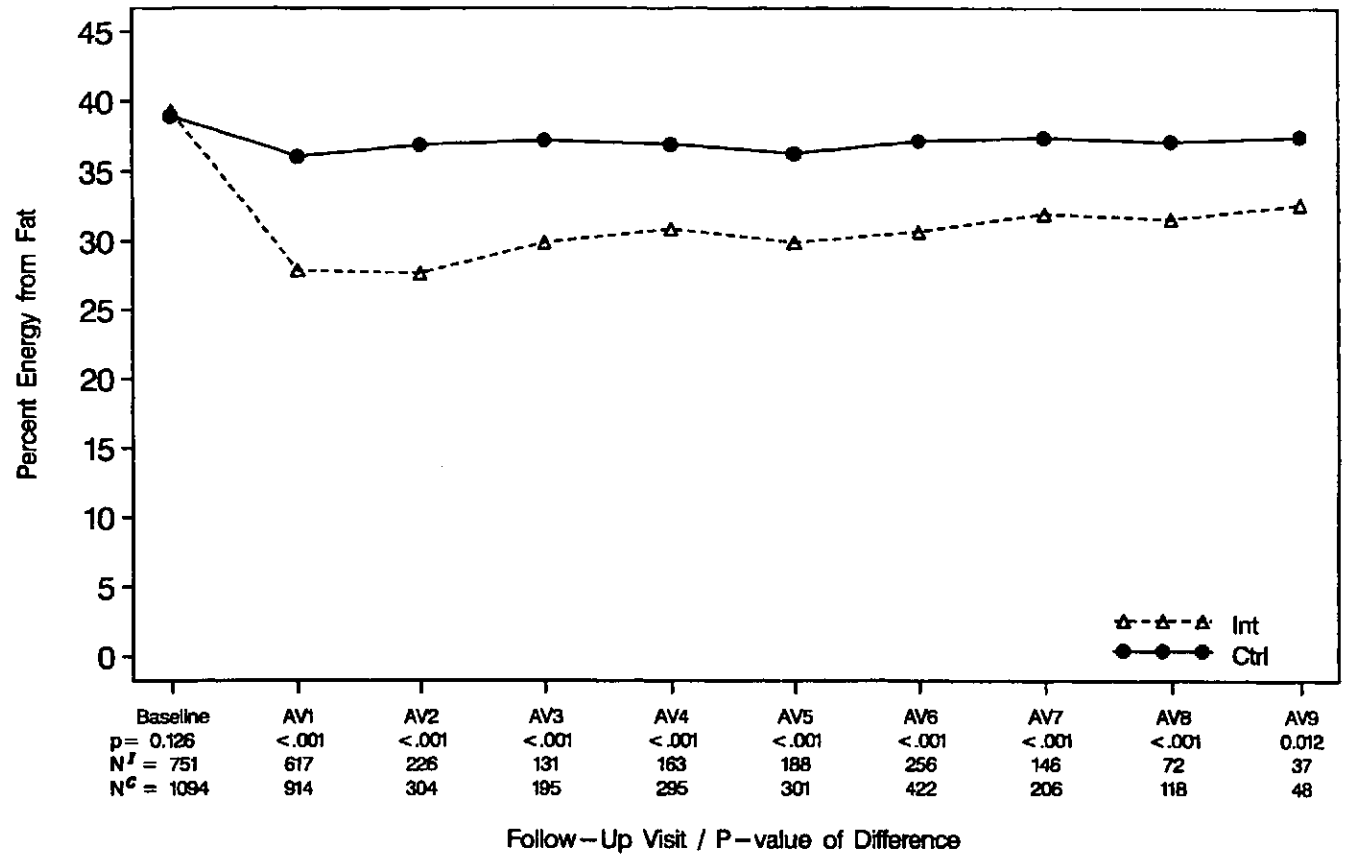
Follow–Up Visit / P–value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.336	<.001	<.001	0.024	0.005	<.001	0.012	0.156	0.640	0.040
N^I =	2132	1856	613	350	485	582	846	389	265	141
N^C =	3122	2624	828	514	774	862	1242	581	375	197

Follow–Up Visit / P–value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women
Data as of: August 31, 2004



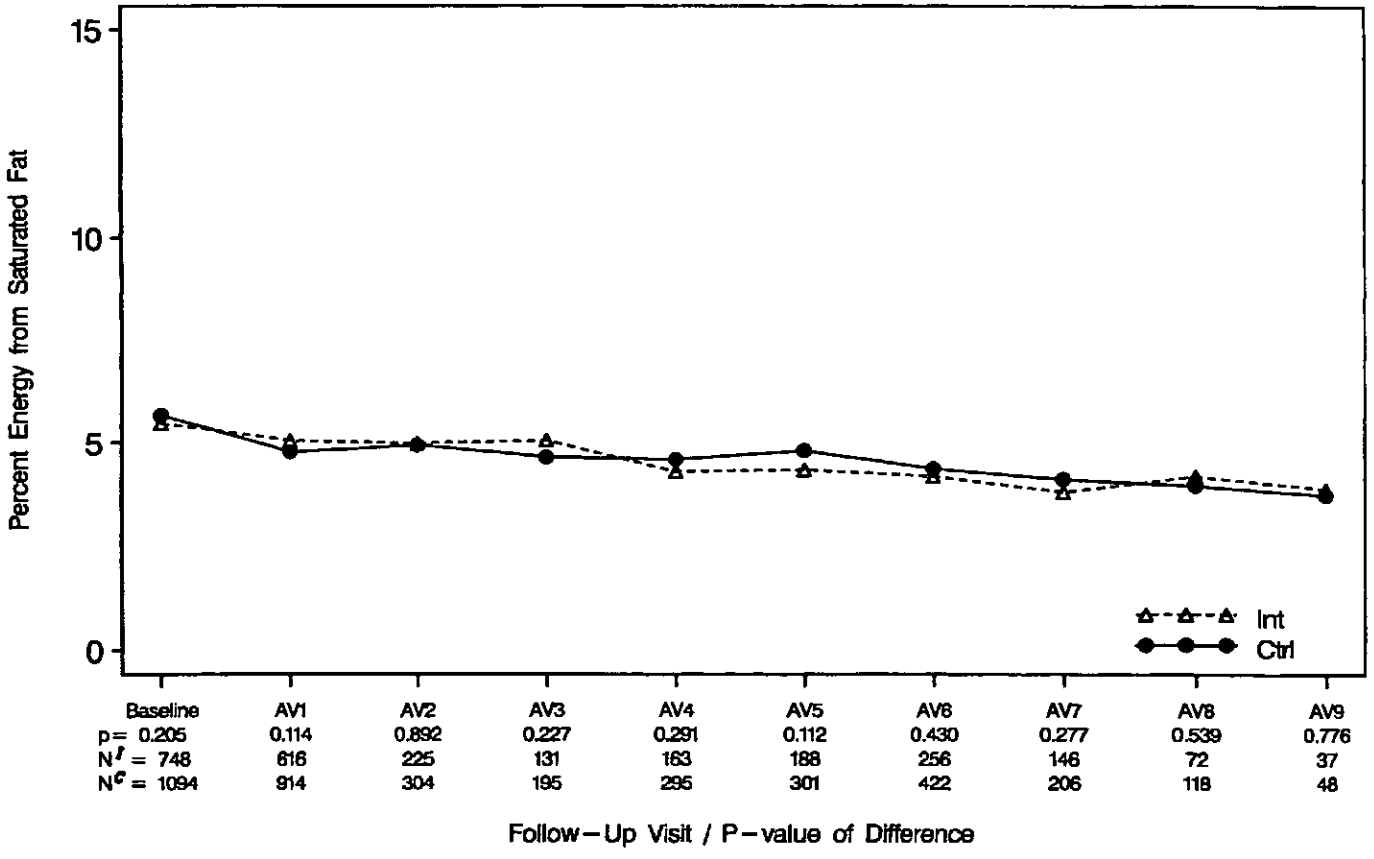
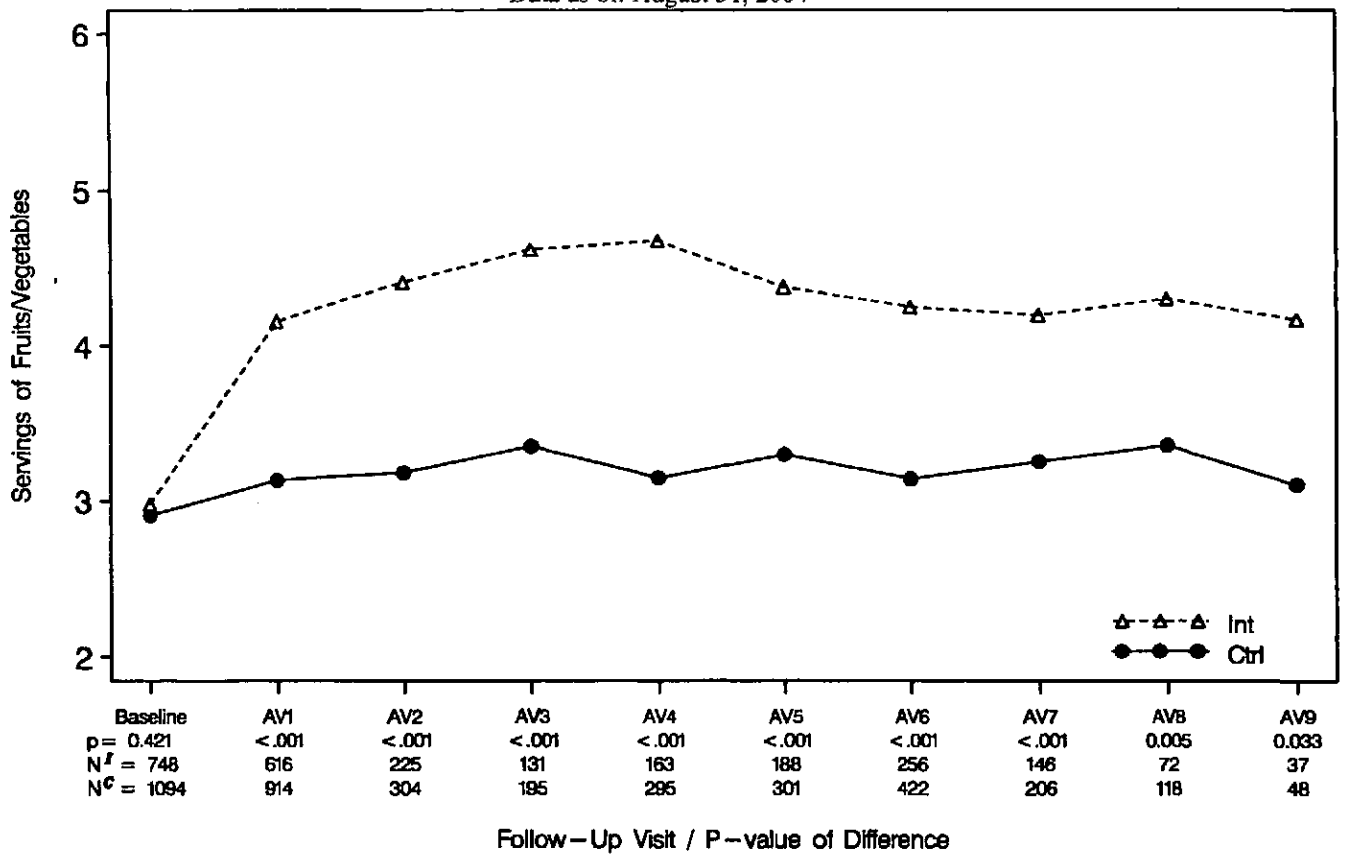


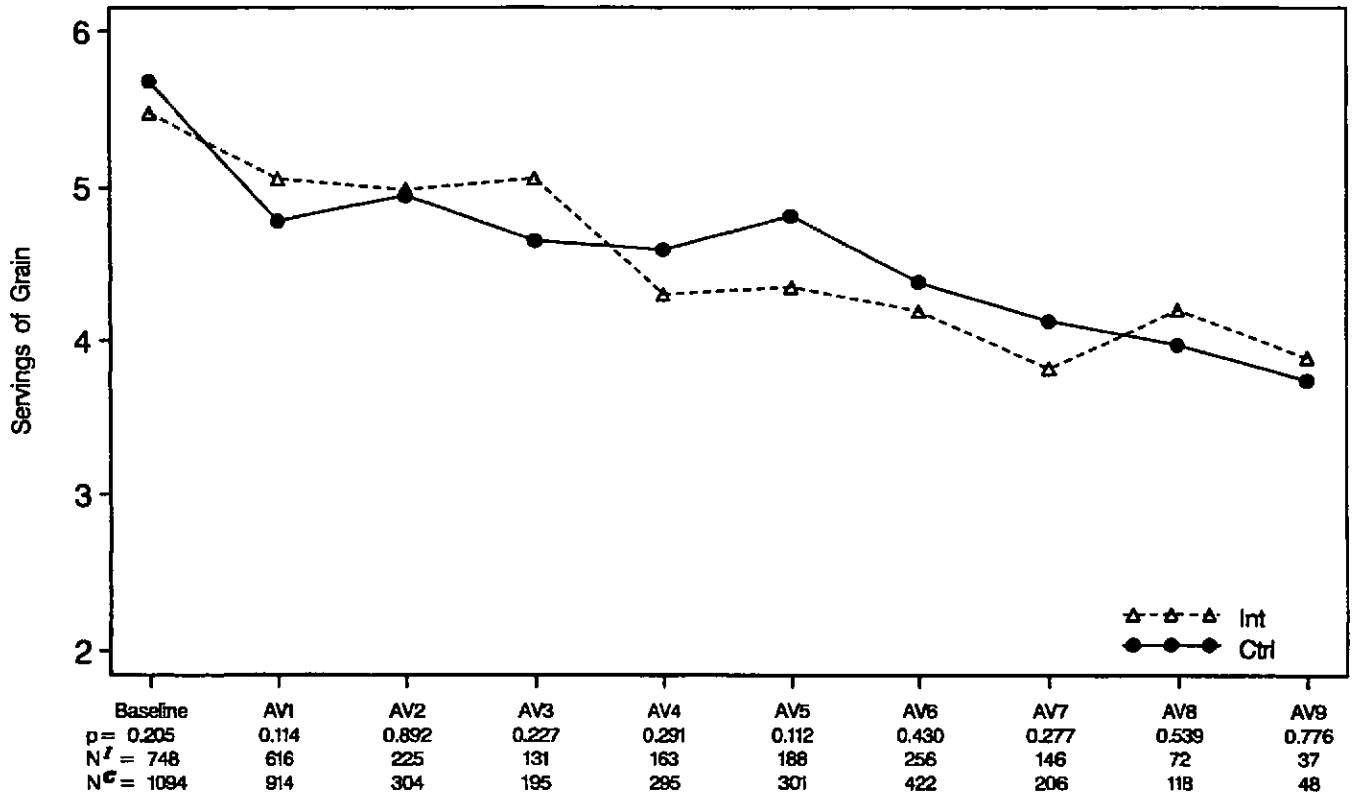
Figure 3.2 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.421	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.005	0.033
N^I =	748	616	225	131	163	188	256	146	72	37
N^C =	1094	914	304	195	295	301	422	206	118	48

Follow–Up Visit / P–value of Difference

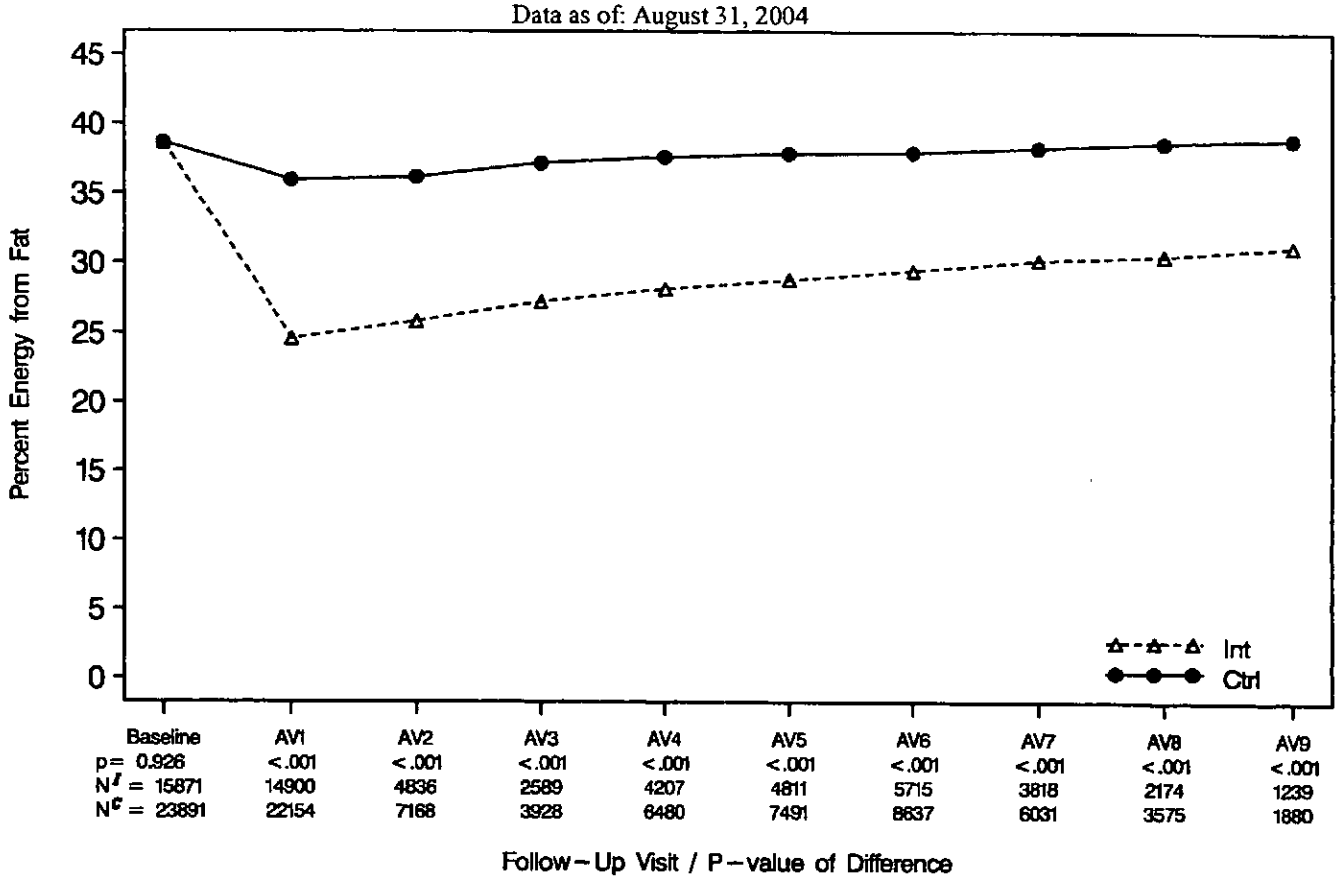


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.205	0.114	0.892	0.227	0.291	0.112	0.430	0.277	0.539	0.776
N^I =	748	616	225	131	163	188	256	146	72	37
N^C =	1094	914	304	195	295	301	422	206	118	48

Follow–Up Visit / P–value of Difference

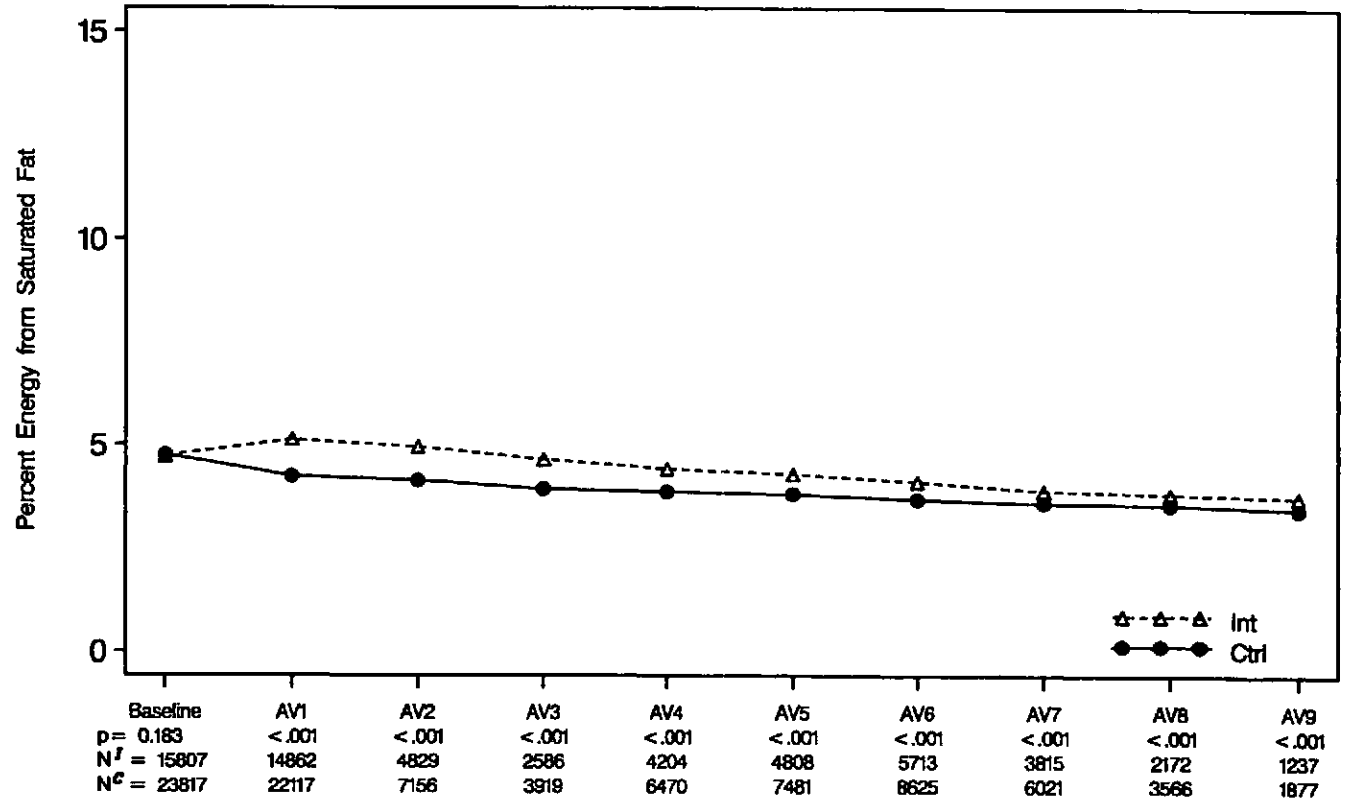
Figure 3.2 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.926	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	15871	14900	4836	2589	4207	4811	5715	3818	2174	1239
N^C =	23891	22154	7168	3928	6480	7491	8637	6031	3575	1880

Follow–Up Visit / P–value of Difference

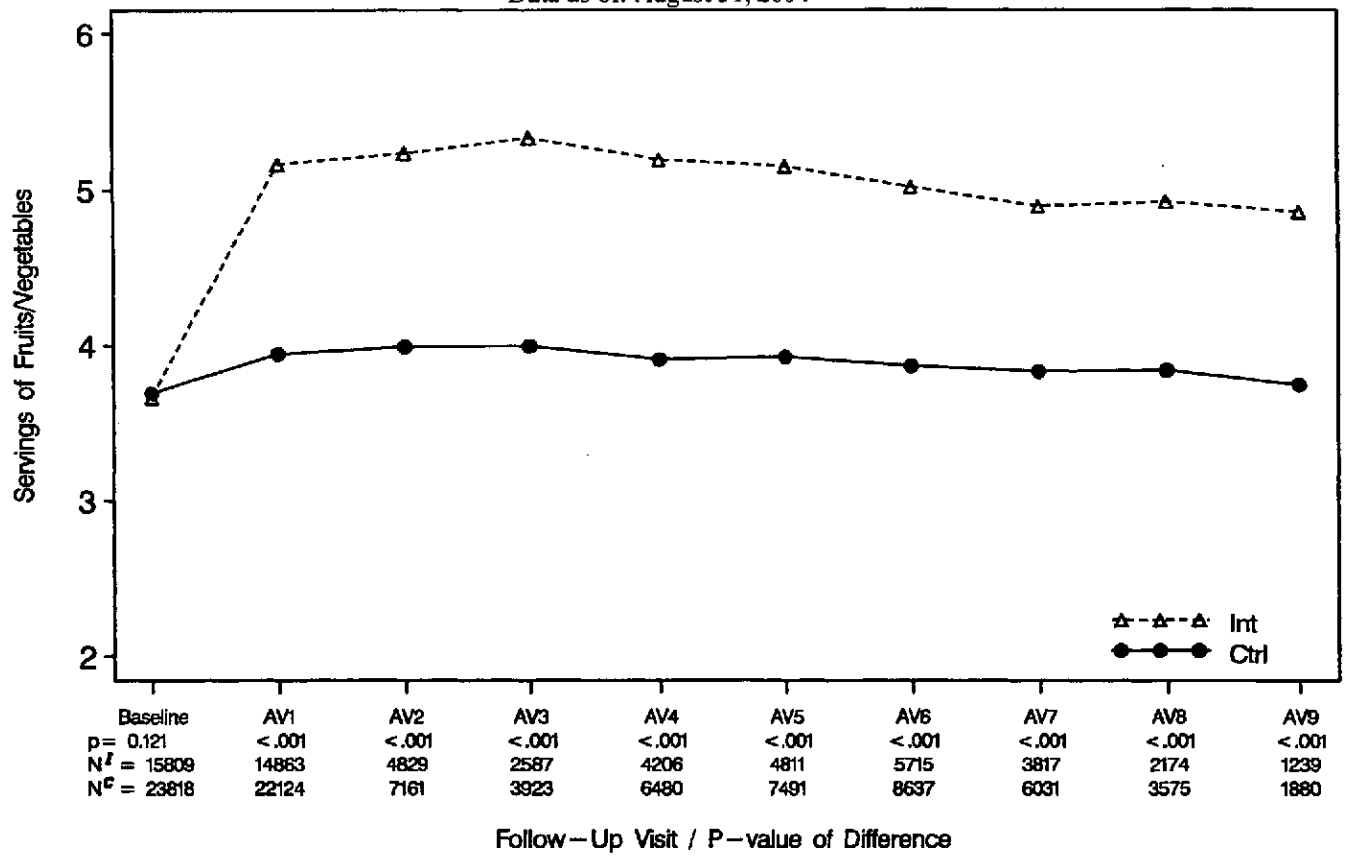


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.183	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	15807	14862	4829	2586	4204	4808	5713	3815	2172	1237
N^C =	23817	22117	7156	3919	6470	7481	8625	6021	3566	1877

Follow–Up Visit / P–value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2004



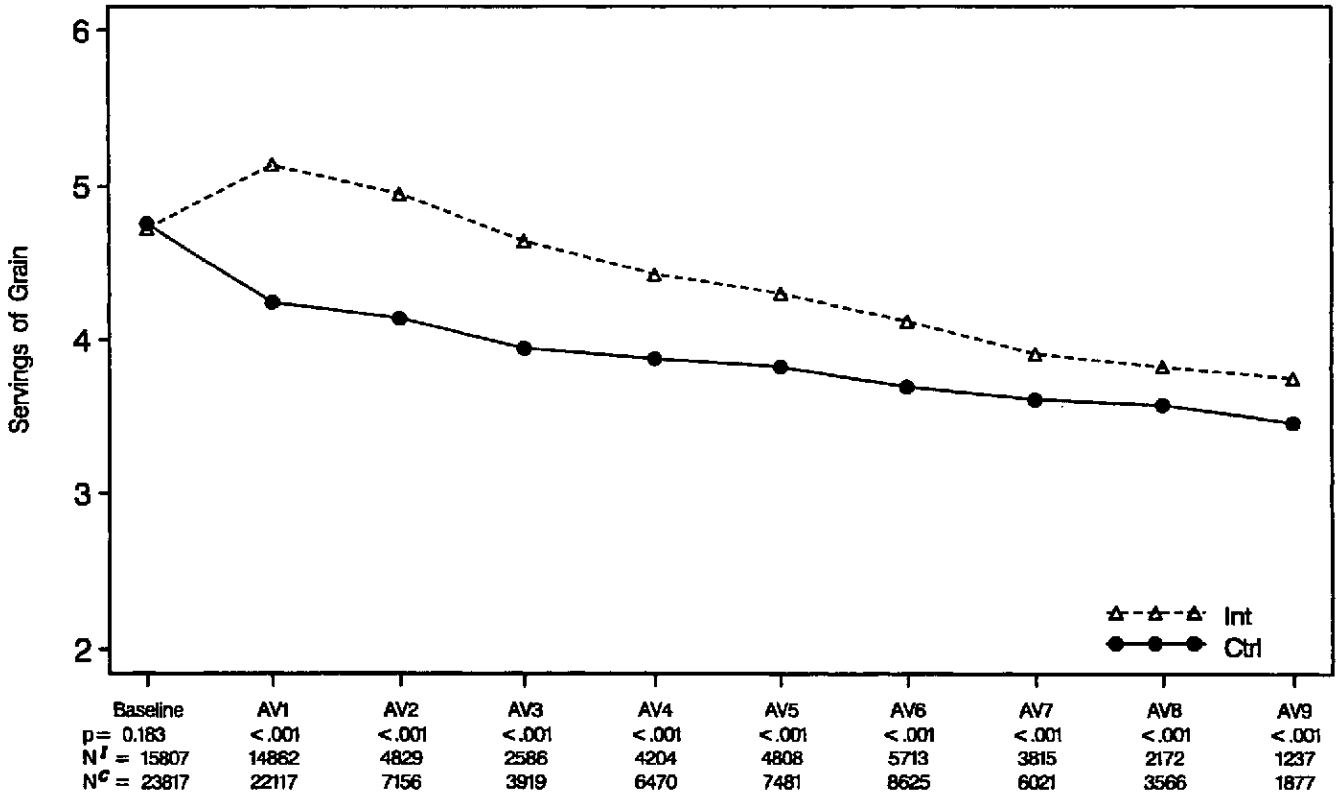
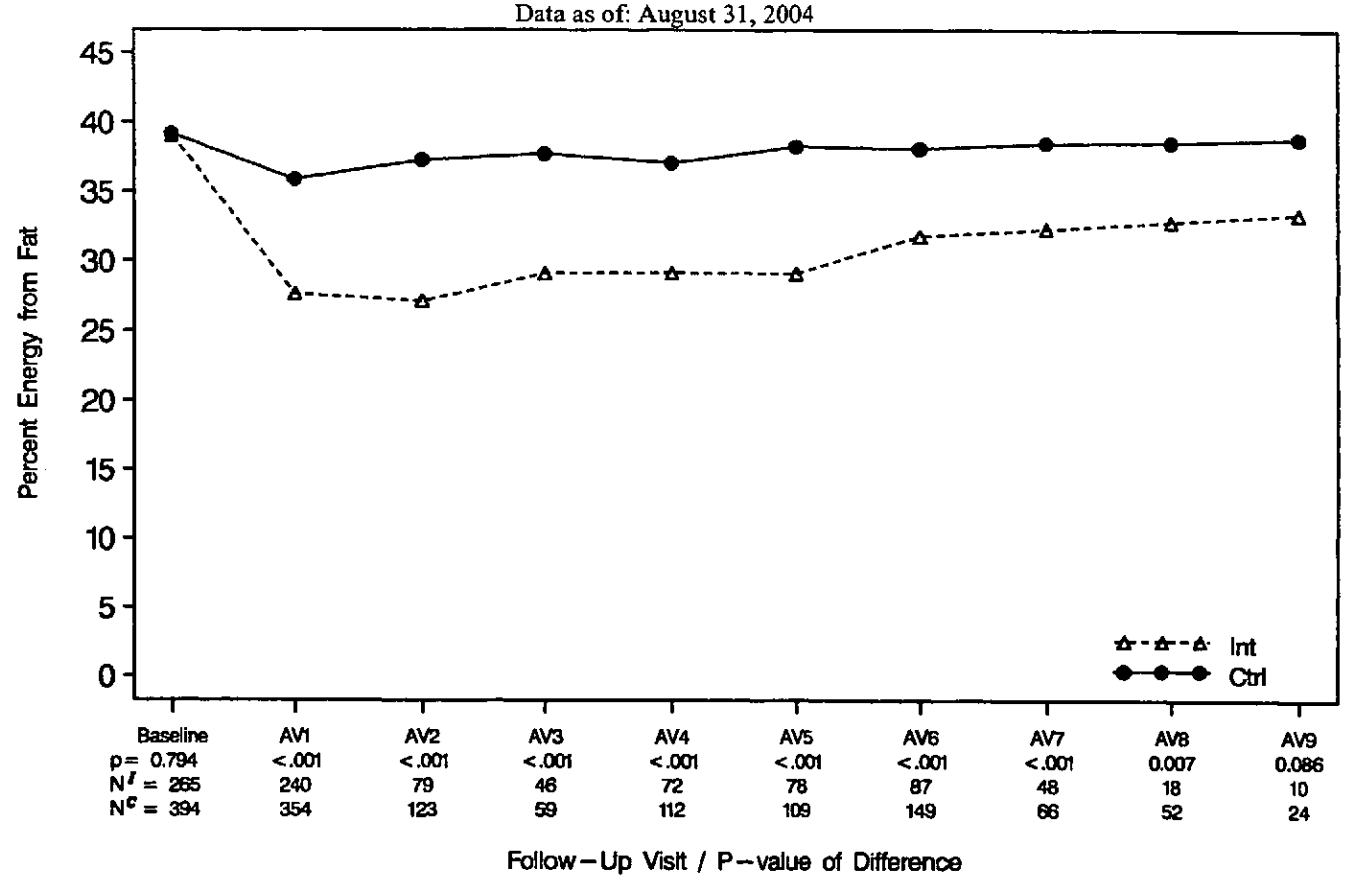


Figure 3.2 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity Women

Data as of: August 31, 2004



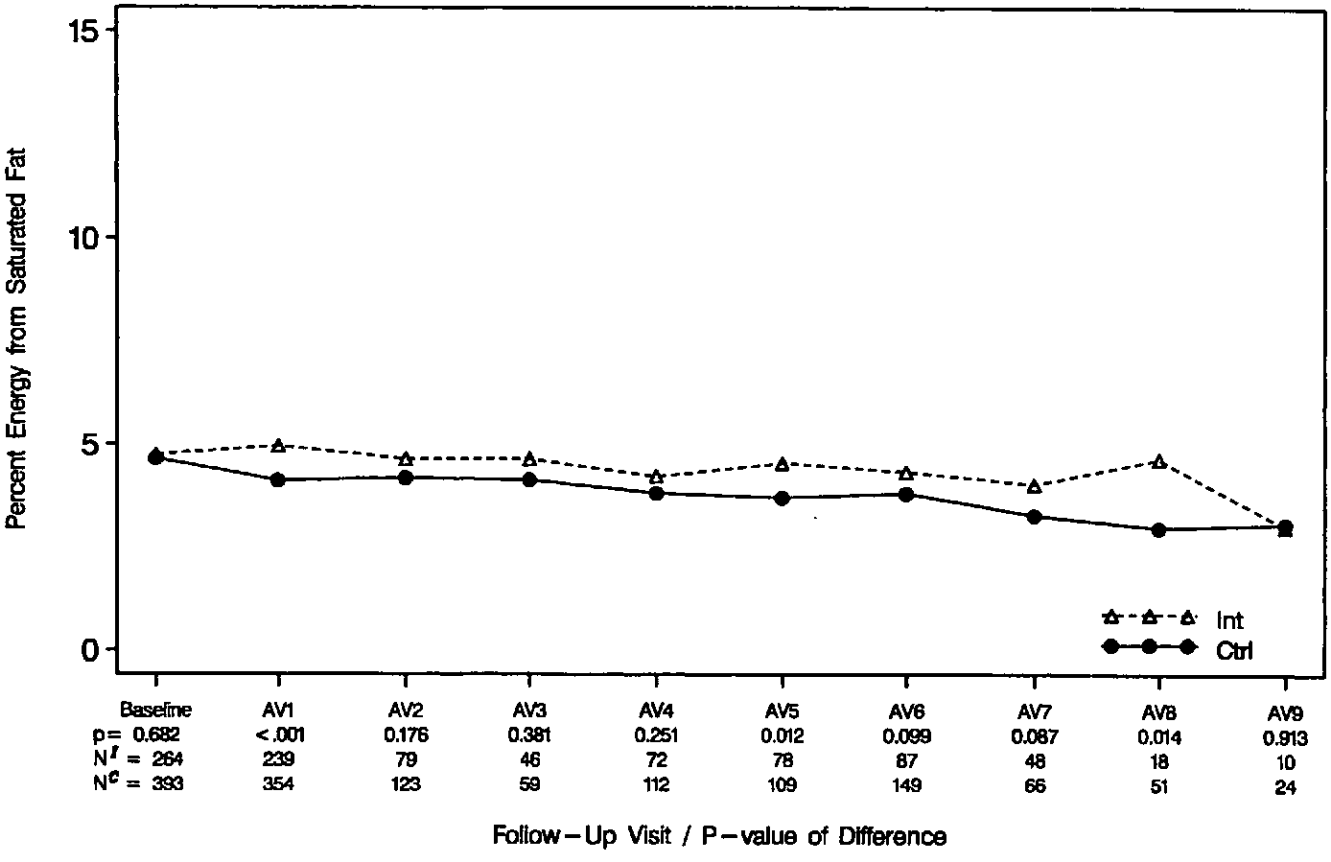
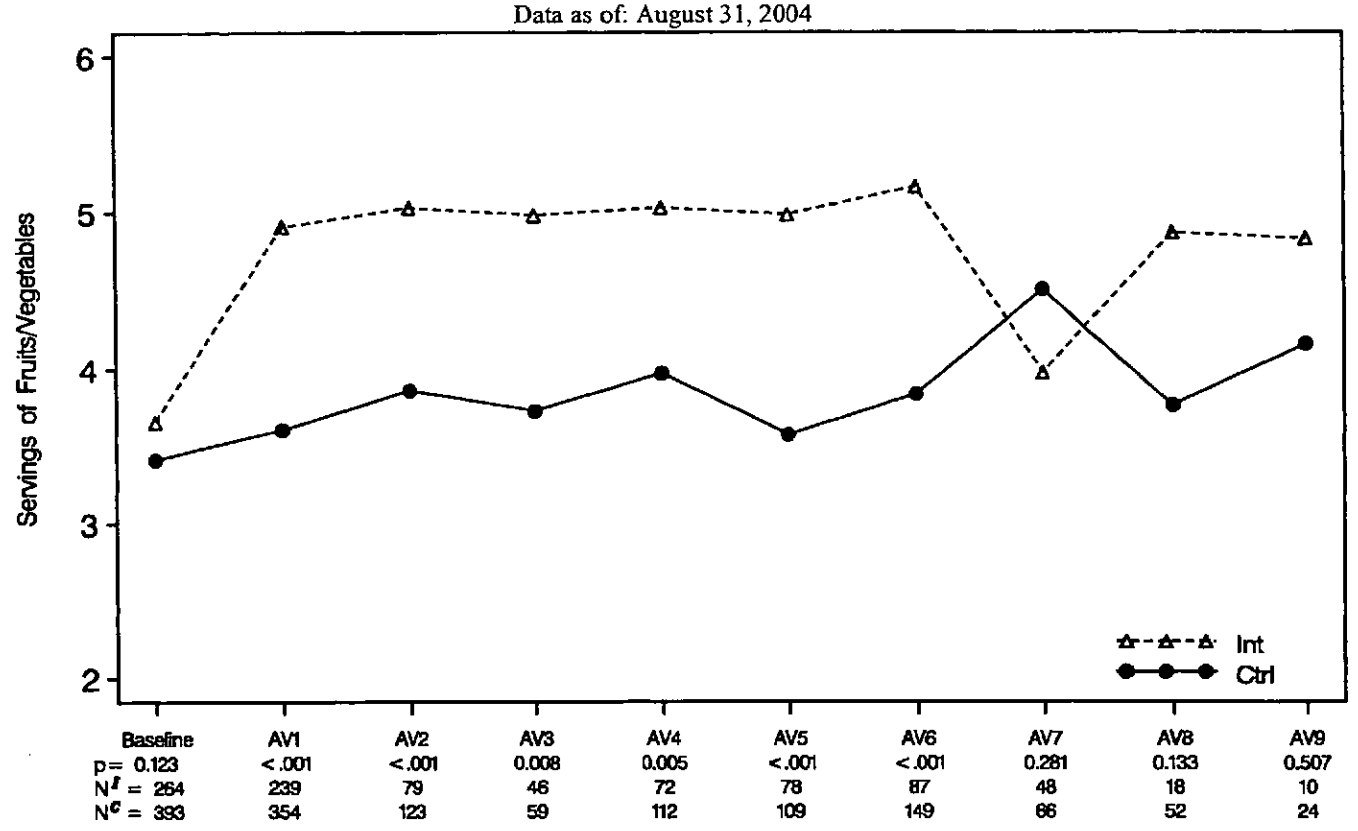


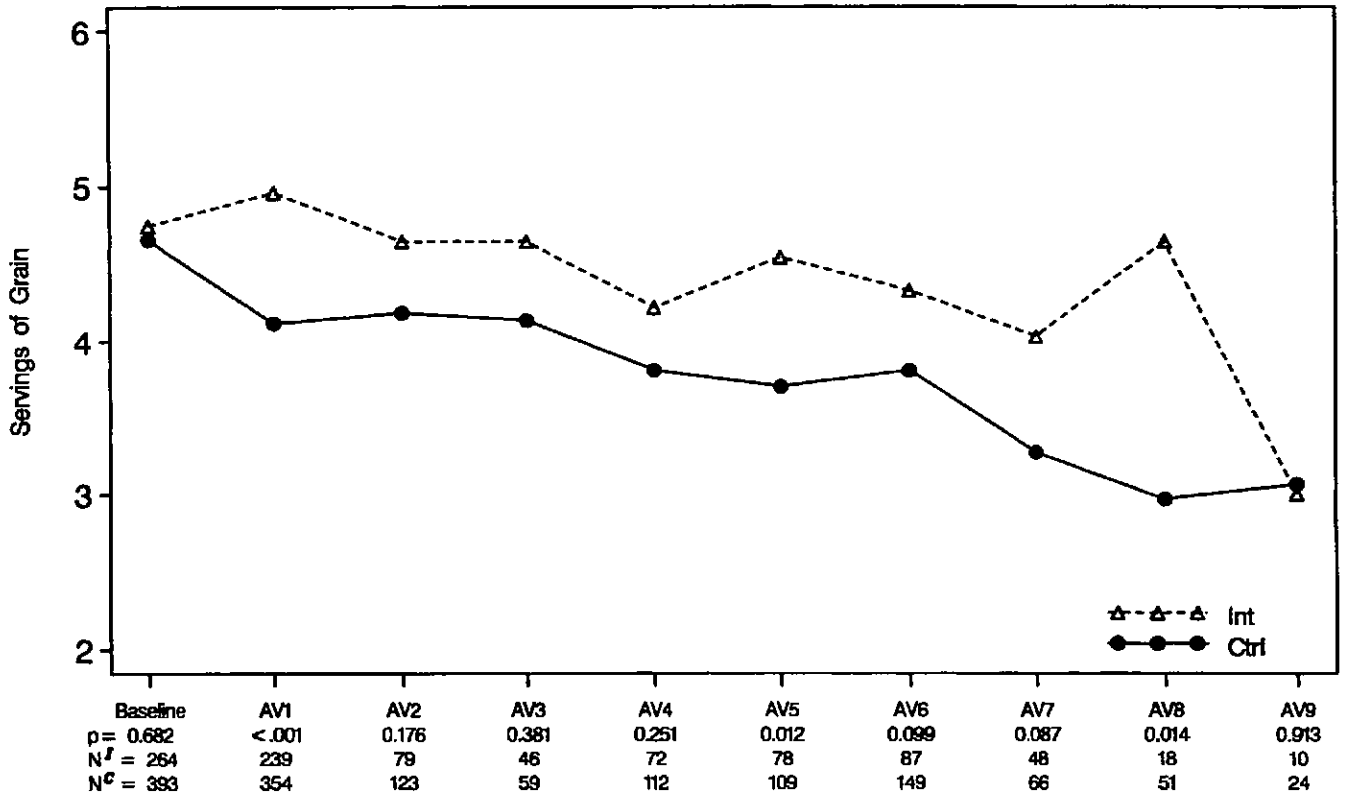
Figure 3.2 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.123	<.001	<.001	0.008	0.005	<.001	<.001	0.281	0.133	0.507
N^I =	264	239	79	46	72	78	87	48	18	10
N^C =	393	354	123	59	112	109	149	66	52	24

Follow−Up Visit / P−value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.682	<.001	0.176	0.381	0.251	0.012	0.099	0.087	0.014	0.913
N^I =	264	239	79	46	72	78	87	48	18	10
N^C =	393	354	123	59	112	109	149	66	51	24

Follow−Up Visit / P−value of Difference

Table 3.3
Control - Intervention Difference in % Energy from Fat in WHI DM Participants
Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year[1]

Data as of: August 31, 2004

	Model Including Attendance				Model Including Completion				Model Including Fat Scores			
	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion
Demographics			15.5%				15.5%				15.5%	
Age												
60-69	6645				6645				6645			
50-54 vs. 60-69	2003	0.48			2003	0.58			2003	0.44		
55-59 vs. 60-69	3149	-0.17			3149	-0.20			3149	-0.21		
70-79 vs. 60-69	2154	-1.37 **			2154	-1.20 **			2154	-1.26 **		
Ethnicity												
White	11513				11513				11513			
American Indian vs. White	53	3.31			53	3.81			53	3.80		
Asian/Pacific Islander vs. White	310	0.18			310	0.26			310	0.28		
Black vs. White	1431	-1.44 **			1431	-1.50 **			1431	-1.00		
Hispanic vs. White	469	-2.07 *			469	-2.13 *			469	-1.99 *		
Unknown vs. White	175	-2.50			175	-2.35			175	-2.23		
Education												
Post H.S.	10972				10972				10972			
0-8 Years vs. Post H.S.	126	0.08			126	0.63			126	0.74		
Some H.S. or Diploma vs. Post H.S.	2853	-0.87 *			2853	-0.76 *			2853	-0.78 *		
Family Income												
>75K	2499				2499				2499			
<20K vs. >75K	2366	-1.15 *			2366	-1.10 *			2366	-1.15 *		
20-35K vs. >75K	3304	-0.74			3304	-0.53			3304	-0.53		
35-50K vs. >75K	2919	-0.99 *			2919	-0.86			2919	-0.86		
50-75K vs. >75K	2863	-0.32			2863	-0.29			2863	-0.28		
HRT Randomized												
No	11696				11696				11696			
Yes vs. No	2255	0.73			2255	0.80 *			2255	0.84 *		
Visit			15.9%	(0.4%)			15.9%	(0.4%)			15.9%	(0.4%)
Visit Year												
AV-6	3155				3155				3155			
AV-7 vs. AV-6	3826	-0.83 **			3826	-0.85 **			3826	-0.81 **		
AV-8 vs. AV-6	3389	-0.83 *			3389	-0.94 **			3389	-0.74 *		
AV-9 vs. AV-6	3532	2.95 **			3532	4.57 **			3532	3.24 **		
Clinic Effect			20.6%	(4.7%)			20.6%	(4.7%)			20.6%	(4.7%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			23.9%	(3.3%)								
None	11392											
1 vs. None	496	4.19 **										
2 vs. None	649	5.80 **										
3 vs. None	748	6.52 **										
4+ vs. None	666	7.75 **										
# Sessions Completed in Previous 12 Months							24.1%	(3.5%)				
None					10743							
1 vs. None					282	3.39 **						
2 vs. None					324	4.38 **						
3 vs. None					587	6.19 **						
4+ vs. None					2015	8.27 **						
# Fat Scores Provided in Previous 12 Months											25.2%	(4.6%)
None									11585			
1 vs. None									409	4.08 **		
2 vs. None									398	5.93 **		
3 vs. None									463	6.75 **		
4+ vs. None									1096	8.81 **		

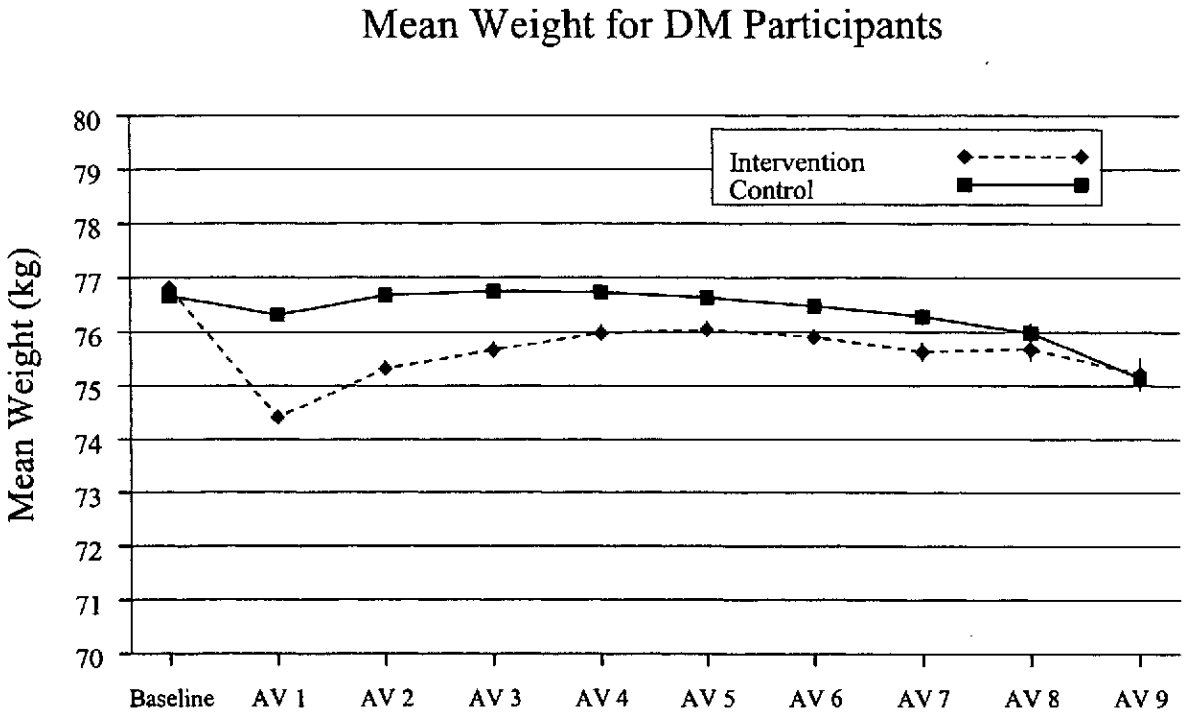
[1] Model adjusted for clinic effects.

* P-value <0.05 from a two-sided test.

** P-value <0.01 from a two-sided test.

Figure 3.3
Mean Body Weight for DM Participants
Stratified by Treatment Arm

Data as of: August 31, 2004



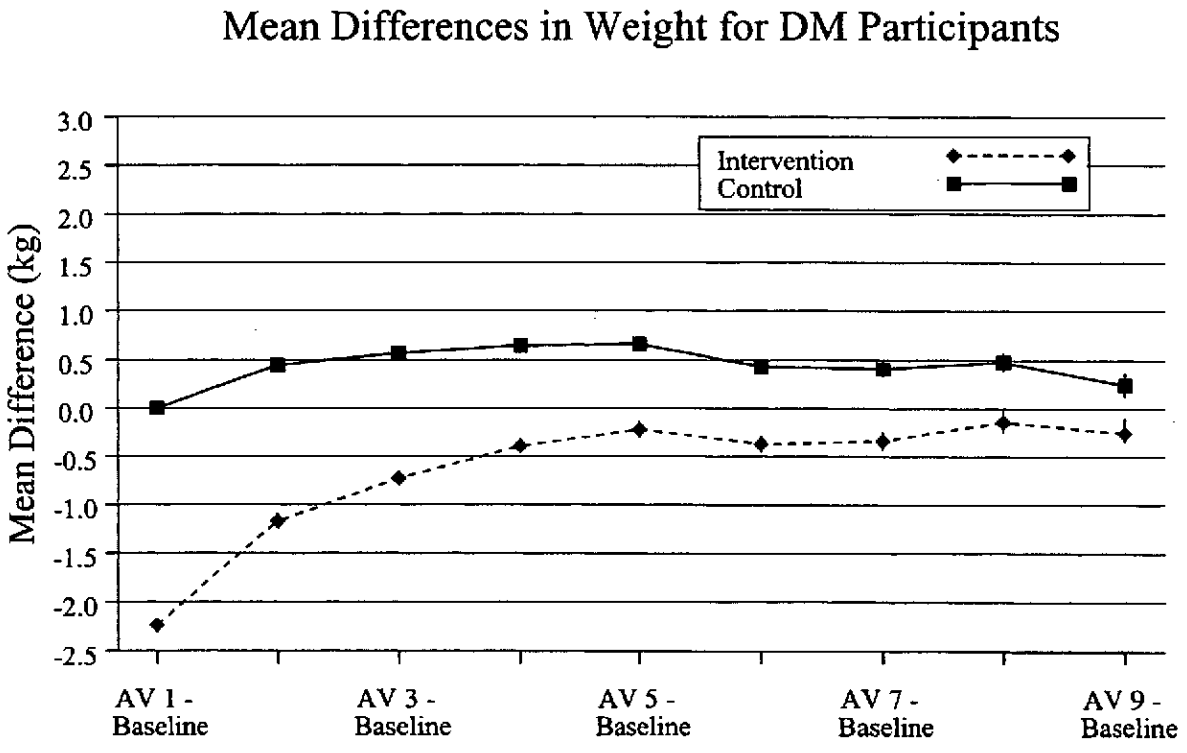


Table 3.4
Reasons for Stopping DM[1]

Data as of: August 31, 2004

Reasons[2]	(N = 2845)	
Personal/family		
Demands of work	232	8.2%
Family illness, emergency, or other family demands[3]	276	9.7%
Financial problems	9	0.3%
Lack of cooperation/support from family/friends[4]	49	1.7%
Living in nursing home	29	1.0%
Issues of interest in study[5]	260	9.1%
Travel		
Too far to CC	116	4.1%
Moved out of area or refuses to be followed at another CC	28	1.0%
Other travel issues[6]	64	2.2%
Visits & Procedures		
Doesn't like visits/calls	57	2.0%
Doesn't like required forms or safety procedures[7]	46	1.6%
Problems with other procedures[8]	12	0.4%
Worried about health effects of medical tests/procedures	3	0.1%
Wants test results[9]	1	< 0.1%
Problems with the CC[10]	30	1.1%

(continues)

1 Does not include reasons reported by women who stopped and later restarted DM Intervention.
2 Multiple reasons may be reported for a woman.
3 Combines "Family illness, emergency or other family demands," "Death in the family or of a close friend," and "Caregiver responsibilities demanding time, effort, lifestyle changes."
4 Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw."
5 Combines "Conflicting priorities other than work or family," "Feels discouraged regarding participation overall," "Loss of interest, boredom," "Feels it is not an important study," and "In another study in conflict with WHI intervention."
6 Combines "Transportation problems (other than distance)," "Traffic," "Parking at CC," and "CC neighborhood/safety."
7 Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
8 Combines "Doesn't like mammograms," "Cost of mammograms," "Doesn't like having blood drawn", "Doesn't like ECG," "Doesn't like gynecologic procedures," and "Doesn't like other procedures (other than those required for safety)."
9 Combines "Wants results of blood analyses," and "Wants results of bone mineral density measurement."
10 Combines "Problem with the CC," "Problem with CC staff person (other than DM Group Nutritionist)," and "Staff change/turnover."

Table 3.4 (continued)
Reasons for Stopping DM[1]

Data as of: August 31, 2004

Reasons[2]	(N = 2845)	
Symptoms		
GI problems[3]	3	0.1%
Hair/skin changes	1	< 0.1%
Weight loss/gain	5	0.2%
HRT related symptoms[4]	4	0.1%
Other[5]	8	0.3%
Health Conditions		
Disease and/or health conditions[6]	111	3.9%
Communication difficulties[7]	77	2.7%
Intervention		
Doesn't like randomized nature of intervention	11	0.4%
Expected some benefit from intervention	32	1.1%
Feels guilty/unhappy or like a failure for not meeting study goals	21	0.7%
Pill issues[8]	7	0.2%
CaD issues[9]	1	< 0.1%
HRT issues[10]	2	< 0.1%
Problem with DM group nutritionist or group members	30	1.1%
Doesn't like attending DM intervention classes	73	2.6%
Doesn't like self-monitoring	49	1.7%
Doesn't like budgeting fat grams	10	0.4%
Health concerns regarding long-term risk/benefits of low fat diet	24	0.8%
Unhappy that not losing weight	21	0.7%
Not in control of meal preparation	16	0.6%
Too difficult to meet or maintain dietary goals	53	1.9%
Doesn't like eating low fat diet	36	1.3%
Doesn't like eating 5 vegetables/fruits per day	2	< 0.1%
Doesn't like eating 6 grains per day	8	0.3%
Feels fat gram goal is unrealistic	8	0.3%
Eating pattern conflicts with personal health beliefs	31	1.1%
Other Health Issues		
Worried about costs if adverse effects occur	1	< 0.1%
Expected more health care	14	0.5%
Advised not to participate by health care provider[11]	21	0.7%
Study conflicts with other health issues[12]	30	1.1%
Other		
Other reasons not listed above	519	18.2%
Refuses to give a reason	102	3.6%

1 Does not include reasons reported by women who stopped and later restarted DM Intervention.
2 Multiple reasons may be reported for a woman.
3 Combines "Bloating/Gas," "Constipation," and "Other gastrointestinal problems."
4 Combines "Vaginal bleeding," "Breast tenderness," "Other breast changes," "Vaginal changes (e.g., dryness)," and "Hot flashes/night sweats."
5 Combines "Headaches," "Low energy/too tired," "Possible allergic reaction," and "Other symptoms not listed above."
6 Combines "Breast cancer," "Complex or atypical hyperplasia," "Endometrial cancer," "Deep vein thrombosis," "Pulmonary embolism," "Gallbladder disease," "Hypercalcemia," "Kidney failure/dialysis," "Renal calculi," "High triglycerides (> 1000 mg/dl)," "Malignant melanoma," "Meningioma," "Heart attack," "Stroke," "Arthritis," "Diabetes," "Depression," "Cholesterol (high or concern about levels)," "Osteoporosis," and "Other health conditions not listed above."
7 Combines "Communication problem," "Loss of vision and/or hearing," and "Cognitive/memory changes."
8 Combines "Doesn't like taking pills," "Doesn't like taste of pills," "Unable to swallow pills," and "Takes too many pills."
9 Combines "Wants to take her own calcium," "Feels diet is already sufficient in calcium/Vitamin D," "Taking more than the maximum allowable IU of Vit D," and "Taking Calcitriol."
10 Combines "Has made a personal decision to go on active HRT," "Has made a personal decision that she does not want to be on HRT," "Advised to go on active HRT by health care provider," "Advised to not be on active HRT by health care provider," "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)," "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider," and "Taking testosterone medications."
11 Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
12 Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 3.5
Bone Mineral Density[1] Analysis: DM Participants

Data as of: August 31, 2004

	N	Mean	S.D.
Whole Body Scan			
Baseline	3620	1.03	0.11
AV1	3276	1.03	0.11
AV3	3100	1.04	0.11
AV6	2783	1.05	0.12
AV9	1266	1.07	0.13
AV1 % Change from baseline BMD[2]	3247	0.18	2.50
AV3 % Change from baseline BMD[2]	3072	1.30	3.62
AV6 % Change from baseline BMD[2]	2741	2.10	5.33
AV9 % Change from baseline BMD[2]	993	2.71	6.60
Spine Scan			
Baseline	3502	0.99	0.17
AV1	3169	1.00	0.17
AV3	3009	1.01	0.17
AV6	2684	1.02	0.18
AV9	1205	1.01	0.17
AV1 % Change from baseline BMD[2]	3148	0.73	3.82
AV3 % Change from baseline BMD[2]	2984	2.12	5.20
AV6 % Change from baseline BMD[2]	2649	3.28	6.89
AV9 % Change from baseline BMD[2]	947	3.41	8.27
Hip Scan			
Baseline	3619	0.87	0.14
AV1	3274	0.87	0.14
AV3	3098	0.88	0.14
AV6	2809	0.88	0.14
AV9	1252	0.86	0.14
AV1 % Change from baseline BMD[2]	3253	-0.04	2.76
AV3 % Change from baseline BMD[2]	3070	0.98	4.18
AV6 % Change from baseline BMD[2]	2763	0.18	5.25
AV9 % Change from baseline BMD[2]	982	-1.04	6.31

[1] Measured in (g/cm^2).
[2] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 3.6
Bone Mineral Density[1] Analysis: DM 679Participants by Race/Ethnicity

Data as of: August 31, 2004

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
Baseline	583	1.08	0.11	195	1.05	0.11	2785	1.01	0.11
AV1	513	1.09	0.11	152	1.05	0.11	2568	1.01	0.10
AV3	496	1.10	0.12	152	1.05	0.12	2410	1.03	0.11
AV6	445	1.09	0.12	148	1.09	0.14	2145	1.04	0.12
AV9	121	1.13	0.12	55	1.09	0.18	1066	1.06	0.13
AV1 % Change from baseline BMD[2]	507	0.98	2.96	151	-0.33	2.24	2547	0.06	2.38
AV3 % Change from baseline BMD[2]	491	2.02	2.94	151	0.65	4.45	2389	1.20	3.68
AV6 % Change from baseline BMD[2]	433	0.39	3.39	148	4.39	7.55	2116	2.29	5.38
AV9 % Change from baseline BMD[2]	43	1.24	6.18	55	4.24	8.40	877	2.65	6.50
Spine Scan									
Baseline	576	1.07	0.18	188	0.97	0.15	2681	0.97	0.16
AV1	506	1.08	0.18	146	0.98	0.16	2474	0.98	0.16
AV3	491	1.09	0.19	147	0.96	0.15	2329	1.00	0.17
AV6	418	1.10	0.19	145	0.98	0.16	2076	1.01	0.17
AV9	117	1.08	0.18	53	0.95	0.15	1011	1.00	0.17
AV1 % Change from baseline BMD[2]	501	0.80	4.31	145	0.15	4.38	2460	0.75	3.67
AV3 % Change from baseline BMD[2]	487	2.10	5.25	146	0.08	5.92	2310	2.28	5.12
AV6 % Change from baseline BMD[2]	407	2.14	6.76	145	1.01	6.99	2053	3.68	6.86
AV9 % Change from baseline BMD[2]	43	0.07	7.29	53	0.91	7.83	833	3.80	8.26
Hip Scan									
Baseline	584	0.97	0.15	195	0.88	0.14	2783	0.85	0.13
AV1	514	0.98	0.15	152	0.88	0.14	2565	0.85	0.13
AV3	496	0.99	0.15	152	0.88	0.14	2408	0.86	0.13
AV6	451	0.97	0.15	150	0.89	0.14	2163	0.86	0.13
AV9	120	0.95	0.14	55	0.86	0.14	1053	0.85	0.13
AV1 % Change from baseline BMD[2]	510	0.84	2.87	151	-0.62	2.94	2550	-0.18	2.67
AV3 % Change from baseline BMD[2]	492	1.40	3.84	150	0.79	5.76	2387	0.90	4.10
AV6 % Change from baseline BMD[2]	439	-1.43	4.74	148	1.81	6.13	2132	0.39	5.19
AV9 % Change from baseline BMD[2]	43	-3.48	7.14	54	-0.77	5.67	868	-0.90	6.24

[1] Measured in (g/cm^2).
[2] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 3.7
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 31, 2004

	DM Participants (N = 48,835)	
	N	%
Vital Status/Participation		
Deceased	2092	4.3
Alive: Current Participation[1]	44189	90.5
Alive: Recent Participation[2]	575	1.2
Alive: Past/Unknown Participation[3]	7	<0.1
Stopped Follow-Up[4]	1309	2.7
Lost to Follow-Up[5]	663	1.4

[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 3.8
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11039	22717	8118
Mean follow-up (months)	90.4	97.1	93.1	88.3	86.5
Cancer					
Breast cancer	1939 (0.53%)	229 (0.41%)	435 (0.51%)	922 (0.55%)	353 (0.60%)
Invasive breast cancer	1559 (0.42%)	168 (0.30%)	355 (0.41%)	751 (0.45%)	285 (0.49%)
Non-invasive breast cancer	394 (0.11%)	64 (0.11%)	82 (0.10%)	176 (0.11%)	72 (0.12%)
Ovarian cancer	163 (0.04%)	19 (0.03%)	33 (0.04%)	74 (0.04%)	37 (0.06%)
Endometrial cancer[1]	272 (0.07%)	30 (0.05%)	63 (0.07%)	130 (0.08%)	49 (0.08%)
Colorectal cancer	468 (0.13%)	28 (0.05%)	75 (0.09%)	236 (0.14%)	129 (0.22%)
Other cancer[2]	1832 (0.50%)	161 (0.29%)	313 (0.37%)	918 (0.55%)	440 (0.75%)
Total cancer	4488 (1.22%)	451 (0.80%)	881 (1.03%)	2184 (1.31%)	972 (1.66%)
Cardiovascular					
CHD[3]	1252 (0.34%)	71 (0.13%)	147 (0.17%)	592 (0.35%)	442 (0.76%)
CHD death[4]	320 (0.09%)	17 (0.03%)	23 (0.03%)	145 (0.09%)	135 (0.23%)
Total MI[5]	1036 (0.28%)	56 (0.10%)	129 (0.15%)	495 (0.30%)	356 (0.61%)
Clinical MI	982 (0.27%)	50 (0.09%)	123 (0.14%)	469 (0.28%)	340 (0.58%)
Evolving Q-wave MI[6]	57 (0.02%)	7 (0.01%)	6 (0.01%)	28 (0.02%)	16 (0.03%)
Possible evolving Q-wave MI[6]	246 (0.07%)	25 (0.04%)	36 (0.04%)	118 (0.07%)	67 (0.11%)
Angina	1483 (0.40%)	83 (0.15%)	208 (0.24%)	777 (0.46%)	415 (0.71%)
CABG/PTCA	1611 (0.44%)	77 (0.14%)	213 (0.25%)	844 (0.50%)	477 (0.81%)
Carotid artery disease	253 (0.07%)	8 (0.01%)	29 (0.03%)	130 (0.08%)	86 (0.15%)
Congestive heart failure	989 (0.27%)	46 (0.08%)	101 (0.12%)	446 (0.27%)	396 (0.68%)
Stroke	932 (0.25%)	40 (0.07%)	96 (0.11%)	430 (0.26%)	366 (0.63%)
PVD	229 (0.06%)	10 (0.02%)	28 (0.03%)	107 (0.06%)	84 (0.14%)
CHD[3]/Possible evolving Q-wave MI	1484 (0.40%)	95 (0.17%)	182 (0.21%)	701 (0.42%)	506 (0.86%)
Coronary disease[7]	3541 (0.96%)	203 (0.36%)	463 (0.54%)	1760 (1.05%)	1115 (1.90%)
Total cardiovascular disease	4597 (1.25%)	247 (0.44%)	585 (0.68%)	2273 (1.36%)	1492 (2.55%)
Fractures					
Hip fracture	412 (0.11%)	11 (0.02%)	28 (0.03%)	158 (0.09%)	215 (0.37%)
Vertebral fracture	483 (0.13%)	18 (0.03%)	52 (0.06%)	216 (0.13%)	197 (0.34%)
Other fracture[2]	4861 (1.32%)	607 (1.08%)	986 (1.15%)	2276 (1.36%)	992 (1.69%)
Total fracture	5524 (1.50%)	634 (1.13%)	1055 (1.23%)	2549 (1.52%)	1286 (2.20%)
Deaths					
Cardiovascular deaths	588 (0.16%)	27 (0.05%)	39 (0.05%)	257 (0.15%)	265 (0.45%)
Cancer deaths	947 (0.26%)	64 (0.11%)	142 (0.17%)	452 (0.27%)	289 (0.49%)
Other known cause	366 (0.10%)	21 (0.04%)	40 (0.05%)	160 (0.10%)	145 (0.25%)
Unknown cause	103 (0.03%)	1 (<0.01%)	10 (0.01%)	48 (0.03%)	44 (0.08%)
Not yet adjudicated	88 (0.02%)	3 (0.01%)	6 (0.01%)	46 (0.03%)	33 (0.06%)
Total death	2092 (0.57%)	116 (0.21%)	237 (0.28%)	963 (0.58%)	776 (1.33%)

[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 3.8 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 31, 2004

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)	87.9	87.1	88.6	85.5	91.0	86.1
Cancer						
Breast cancer	4 (0.27%)	44 (0.55%)	152 (0.39%)	50 (0.38%)	1665 (0.55%)	24 (0.51%)
Invasive breast cancer	4 (0.27%)	34 (0.42%)	113 (0.29%)	41 (0.31%)	1347 (0.45%)	20 (0.42%)
Non-invasive breast cancer	0 (0.00%)	10 (0.12%)	40 (0.10%)	9 (0.07%)	331 (0.11%)	4 (0.08%)
Ovarian cancer	1 (0.07%)	4 (0.05%)	10 (0.03%)	5 (0.04%)	140 (0.05%)	3 (0.06%)
Endometrial cancer[1]	0 (0.00%)	3 (0.04%)	18 (0.05%)	7 (0.05%)	239 (0.08%)	5 (0.10%)
Colorectal cancer	4 (0.27%)	7 (0.09%)	50 (0.13%)	16 (0.12%)	384 (0.13%)	7 (0.15%)
Other cancer[2]	5 (0.34%)	25 (0.31%)	139 (0.36%)	40 (0.30%)	1600 (0.53%)	23 (0.49%)
Total cancer	14 (0.95%)	79 (0.99%)	352 (0.91%)	112 (0.85%)	3875 (1.29%)	56 (1.18%)
Cardiovascular						
CHD[3]	4 (0.27%)	13 (0.16%)	138 (0.36%)	22 (0.17%)	1060 (0.35%)	15 (0.32%)
CHD death[4]	0 (0.00%)	3 (0.04%)	52 (0.13%)	6 (0.05%)	251 (0.08%)	8 (0.17%)
Total MI[5]	4 (0.27%)	12 (0.15%)	104 (0.27%)	18 (0.14%)	887 (0.29%)	11 (0.23%)
Clinical MI	4 (0.27%)	12 (0.15%)	99 (0.25%)	17 (0.13%)	840 (0.28%)	10 (0.21%)
Evolving Q-wave MI[6]	0 (0.00%)	1 (0.01%)	5 (0.01%)	1 (0.01%)	49 (0.02%)	1 (0.02%)
Possible evolving Q-wave MI[6]	3 (0.20%)	7 (0.09%)	28 (0.07%)	7 (0.05%)	199 (0.07%)	2 (0.04%)
Angina	4 (0.27%)	16 (0.20%)	193 (0.50%)	43 (0.33%)	1206 (0.40%)	21 (0.44%)
CABG/PTCA	3 (0.20%)	12 (0.15%)	154 (0.40%)	30 (0.23%)	1398 (0.46%)	14 (0.30%)
Carotid artery disease	2 (0.14%)	1 (0.01%)	20 (0.05%)	2 (0.02%)	225 (0.07%)	3 (0.06%)
Congestive heart failure	1 (0.07%)	6 (0.07%)	156 (0.40%)	27 (0.21%)	785 (0.26%)	14 (0.30%)
Stroke	4 (0.27%)	19 (0.24%)	129 (0.33%)	22 (0.17%)	746 (0.25%)	12 (0.25%)
PVD	2 (0.14%)	2 (0.02%)	42 (0.11%)	2 (0.02%)	178 (0.06%)	3 (0.06%)
CHD[3]/Possible evolving Q-wave MI	7 (0.47%)	19 (0.24%)	165 (0.42%)	28 (0.21%)	1248 (0.41%)	17 (0.36%)
Coronary disease[7]	11 (0.74%)	37 (0.46%)	458 (1.18%)	86 (0.65%)	2904 (0.96%)	45 (0.95%)
Total cardiovascular disease	18 (1.22%)	57 (0.71%)	591 (1.52%)	108 (0.82%)	3764 (1.25%)	59 (1.25%)
Fractures						
Hip fracture	1 (0.07%)	1 (0.01%)	10 (0.03%)	6 (0.05%)	390 (0.13%)	4 (0.08%)
Vertebral fracture	1 (0.07%)	11 (0.14%)	7 (0.02%)	8 (0.06%)	448 (0.15%)	8 (0.17%)
Other fracture[2]	17 (1.15%)	73 (0.91%)	287 (0.74%)	119 (0.91%)	4301 (1.43%)	64 (1.35%)
Total fracture	18 (1.22%)	85 (1.06%)	301 (0.77%)	129 (0.98%)	4917 (1.63%)	74 (1.57%)
Deaths						
Cardiovascular deaths	3 (0.20%)	9 (0.11%)	86 (0.22%)	10 (0.08%)	471 (0.16%)	9 (0.19%)
Cancer deaths	6 (0.41%)	10 (0.12%)	86 (0.22%)	27 (0.21%)	803 (0.27%)	15 (0.32%)
Other known cause	6 (0.41%)	4 (0.05%)	46 (0.12%)	8 (0.06%)	297 (0.10%)	5 (0.11%)
Unknown cause	1 (0.07%)	1 (0.01%)	12 (0.03%)	3 (0.02%)	86 (0.03%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	2 (0.02%)	14 (0.04%)	2 (0.02%)	67 (0.02%)	3 (0.06%)
Total death	16 (1.08%)	26 (0.32%)	244 (0.63%)	50 (0.38%)	1724 (0.57%)	32 (0.68%)

[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 3.9
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: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11039	22717	8118
Mean follow-up (months)	90.4	97.1	93.1	88.3	86.5
Hospitalizations					
Ever	23469 (6.38%)	2491 (4.42%)	4481 (5.23%)	11419 (6.83%)	5078 (8.67%)
Two or more	12385 (3.37%)	1077 (1.91%)	2100 (2.45%)	6085 (3.64%)	3123 (5.33%)
Other					
DVT[1]	478 (0.13%)	28 (0.05%)	70 (0.08%)	232 (0.14%)	148 (0.27%)
Pulmonary embolism	323 (0.09%)	21 (0.04%)	48 (0.06%)	171 (0.10%)	83 (0.14%)
Diabetes (treated)	3445 (0.98%)	485 (0.88%)	763 (0.92%)	1602 (1.01%)	595 (1.07%)
Gallbladder disease[2]	3605 (1.17%)	541 (1.08%)	845 (1.16%)	1694 (1.23%)	525 (1.11%)
Hysterectomy	1471 (0.70%)	217 (0.68%)	338 (0.65%)	696 (0.75%)	220 (0.69%)
Glaucoma	4888 (1.38%)	509 (0.92%)	1003 (1.20%)	2383 (1.49%)	993 (1.84%)
Osteoporosis	9622 (2.77%)	1042 (1.89%)	1834 (2.22%)	4737 (3.03%)	2009 (3.84%)
Osteoarthritis[3]	9064 (4.00%)	1354 (3.23%)	2123 (3.64%)	4166 (4.28%)	1421 (4.86%)
Rheumatoid arthritis	2667 (0.75%)	370 (0.67%)	594 (0.72%)	1246 (0.78%)	457 (0.82%)
Intestinal polyps	7250 (2.12%)	917 (1.68%)	1615 (1.99%)	3615 (2.35%)	1103 (2.12%)
Lupus	464 (0.13%)	73 (0.13%)	107 (0.13%)	220 (0.13%)	64 (0.11%)
Kidney stones[3]	1188 (0.39%)	159 (0.35%)	261 (0.37%)	581 (0.41%)	187 (0.38%)
Cataracts[3]	14437 (5.20%)	1033 (2.26%)	2587 (3.70%)	7934 (6.23%)	2883 (8.33%)
Pills for hypertension	11872 (4.63%)	1563 (3.45%)	2656 (4.11%)	5621 (5.02%)	2032 (5.85%)

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)	87.9	87.1	88.6	85.5	91.0	86.1
Hospitalizations						
Ever	90 (6.09%)	366 (4.56%)	2507 (6.45%)	728 (5.54%)	19481 (6.46%)	297 (6.28%)
Two or more	55 (3.72%)	154 (1.92%)	1376 (3.54%)	352 (2.68%)	10288 (3.41%)	160 (3.38%)
Other						
DVT[1]	1 (0.07%)	0 (0.00%)	43 (0.11%)	7 (0.05%)	420 (0.14%)	7 (0.15%)
Pulmonary embolism	2 (0.14%)	1 (0.01%)	33 (0.09%)	2 (0.02%)	281 (0.09%)	4 (0.09%)
Diabetes (treated)	17 (1.23%)	94 (1.24%)	640 (1.86%)	194 (1.57%)	2451 (0.84%)	49 (1.09%)
Gallbladder disease[2]	13 (1.23%)	55 (0.76%)	286 (0.83%)	146 (1.47%)	3059 (1.22%)	46 (1.14%)
Hysterectomy	4 (0.57%)	29 (0.57%)	96 (0.55%)	45 (0.64%)	1287 (0.73%)	10 (0.38%)
Glaucoma	25 (1.77%)	93 (1.21%)	705 (1.95%)	177 (1.39%)	3827 (1.31%)	61 (1.37%)
Osteoporosis	41 (2.91%)	250 (3.30%)	610 (1.63%)	375 (3.07%)	8216 (2.90%)	130 (2.97%)
Osteoarthritis[3]	41 (4.86%)	205 (3.54%)	933 (4.01%)	389 (4.36%)	7360 (3.97%)	136 (4.68%)
Rheumatoid arthritis	20 (1.51%)	48 (0.62%)	472 (1.30%)	209 (1.67%)	1869 (0.64%)	49 (1.09%)
Intestinal polyps	38 (2.77%)	157 (2.14%)	792 (2.18%)	229 (1.82%)	5932 (2.12%)	102 (2.35%)
Lupus	3 (0.21%)	5 (0.06%)	63 (0.16%)	18 (0.14%)	368 (0.12%)	7 (0.15%)
Kidney stones[3]	8 (0.68%)	21 (0.31%)	124 (0.38%)	54 (0.49%)	966 (0.39%)	15 (0.38%)
Cataracts[3]	57 (5.28%)	283 (4.60%)	1392 (4.69%)	486 (4.61%)	12026 (5.31%)	193 (5.37%)
Pills for hypertension	40 (4.23%)	250 (4.66%)	1252 (6.44%)	493 (5.05%)	9687 (4.44%)	150 (4.73%)

[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.

4. CaD Component

4.1 Recruitment

Table 4.1 – Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment presents the final sample size for number of women randomized in the Calcium and Vitamin D component of the WHI Clinical Trial. A total of 36,282 women have been randomized which is 80.6% of the overall goal of 45,000. The age distribution of the CaD trial participants is somewhat younger than anticipated in the design assumptions for the trial. Seventeen percent of women randomized are aged 70-79 years compared with the design assumption of 25%. Eighty-three percent of participants are white, 9% are African American, and 4% are Hispanic.

4.2 Adherence

Table 4.2 – CaD Adherence Summary presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report (see *Figure 4.1 – CaD Adherence Summary*) at 55-62%. In the most recent time interval, March 2004 – August 2004, adherence rates edged slightly up at AV-6 to AV-8. About 20-39% of women on study medication take less than 80% of their CaD pills, but nonetheless remain partially adherent.

Table 4.3 – CaD Drop-out Rates by Follow-up Time summarizes interval and cumulative drop-out rates in comparison to the original design assumptions. The original power calculations for CaD assumed a 6% drop-out rate in year 1 and a 3% per year drop-out rate thereafter. An independent lost-to-follow-up rate of 3% per year was also incorporated, resulting in approximately 8.8% stopping intervention in year 1 and 5.9% in subsequent years. Drop-out rates in this report account for re-starting CaD, which results in lower rates than seen in early reports. At every annual visit, the observed drop-out rates are lower than design assumptions. Interval drop-out rates at AV-3 and beyond range from 3.1-5.3%, which compares favorably to the 5.9% design assumption. At AV-5, the cumulative drop-out rate was 20.0% (design assumption was 24.0%). From AV-6 through AV-8, observed cumulative rates are below the design assumption by about 4-7%.

Table 4.4 summarizes the frequency of reported reasons for stopping CaD. The majority of women stopping study supplements do so of their own accord. Only 7.8% have indicated that they were advised by their physician to discontinue these supplements. 1168 women (10.9%) reported other health problems or diseases, 2963 women (27.5%) reported symptoms, and 550 women (5.1%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (10.5%) followed by want to take her own calcium (4.1%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 19.9% of women.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of August 31, 2004, 3252 (9.0%) of women were taking alendronate, 599 (1.7%) were taking risendronate, 274 (0.8%) were taking calcitonin, and 848 (2.3%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.5 – Bone Mineral Density Analysis: CaD Participants presents the mean bone mineral density levels at AV-1, AV-3, AV-6, and AV-9 and percent change in BMD during these intervals among women randomized at the three BMD measurement sites (Pittsburgh, Arizona, Birmingham). At the three skeletal sites examined (hip, spine, and whole body), BMD increased between AV-1 and AV-3 from 1.3-1.6%, with the greatest change occurring at the spine. The percent changes between AV-6 and AV-1 were approximately two times as large as those observed at AV-3 for the spine and whole body. At the hip, BMD change from AV-6 to AV-1 was 0.23%, less than the 1.27% increase observed at AV-3. For those few participants who have an AV-9 BMD measurement, spine and whole body BMD increased by 3-4%, whereas hip BMD declined by 0.48%.

Table 4.6 – Bone Mineral Density Analysis: CaD Participants presents the mean bone mineral density levels and percent change according to race/ethnicity. At AV-3 the rates of change relative to AV-1 were generally in the range of 1-2% gains for all skeletal sites. At AV-6, white and Hispanic/Latino women experienced BMD gains of approximately 0.4-6% at the various skeletal sites, whereas African American women had negative percent changes in BMD at the hip and whole body.

4.4 Vital Status

Table 4.7 – Lost-to-Follow-up and Vital Status presents data on the vital status and the participation status of participants in the CaD trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, 2.4% of the participants are lost-to-follow-up or have stopped follow-up, and 3.7% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for CaD participants is about 6.5 years, suggesting that approximately 17.9% could be expected to be dead or lost-to-follow-up. Our overall rates compare very favorably to design assumptions.

4.5 Outcomes

Table 4.8 – Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for Calcium and Vitamin D contains counts of the number of verified major WHI outcomes for CaD participants. For the CaD component we are using centrally adjudicated outcomes for breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, hip fractures, and death. Locally verified outcomes for events for which central adjudication has not yet been completed are included in the counts. In this table, only outcomes that took place after randomization in the CaD trial are included. Approximately 3% of the self-reported outcomes have not yet been verified, so the numbers in this table should thus be seen as a lower bound to the actual number of outcomes that have taken place. Currently, with 312 cases of hip fracture locally verified, we have observed only about 45% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (307 cases) is

approximately 75%, the number of invasive breast cancer cases (983 cases) is approximately 115%, and the number of CHD cases (852 cases) is about 75% of what was expected.

Table 4.9 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the self-reported outcomes are somewhat over reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred in CaD participants.

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

Data as of: August 31, 2004

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5,153	118%	14%	10%
55-59	8,270	95%	23%	20%
60-69	16,521	84%	46%	45%
70-79	6,338	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
CaD Adherence Summary
All CaD Participants

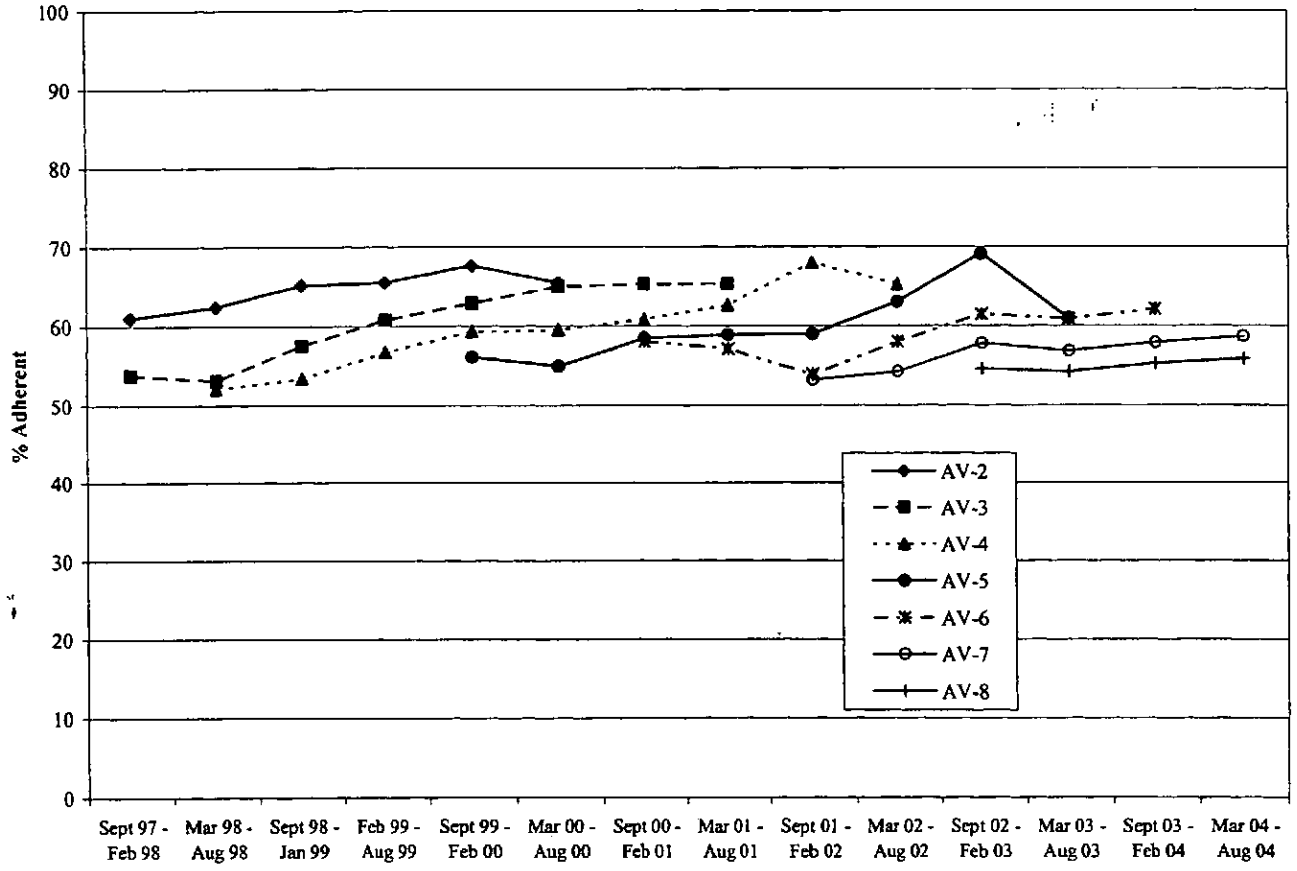
Data as of: August 31, 2004

	Due	Conducted[1]		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[2,3] <50%		Medication Rate[2,3] 50%-80%		Medication Rate[2,3] 80% +		Adherence Summary[4]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Annual Visit - 2	33070	32260	98	25858	78	2368	7	116	0	32684	100	5772	18	6998	21	19914	61	60
Annual Visit - 3	36282	35243	97	26514	74	1918	5	343	1	33432	99	5393	16	5714	17	22325	66	62
Annual Visit - 4	36282	34767	96	24601	69	1575	4	378	1	31467	99	4311	14	4810	15	22346	70	62
Annual Visit - 5	36282	34517	95	23101	65	1396	4	346	1	29917	99	3740	12	4199	14	21978	73	62
Annual Visit - 6	36246	34367	95	21243	60	1239	4	375	1	28456	99	3185	11	3875	13	21396	74	60
Annual Visit - 7	28799	26876	93	15791	56	874	3	364	2	21527	98	2217	10	2875	13	16435	75	59
Annual Visit - 8	16560	15303	92	8517	53	492	3	243	2	11889	98	1169	10	1606	13	9114	75	57
Annual Visit - 9	7297	6682	92	3690	53	246	4	127	2	5021	98	507	10	684	13	3830	74	55
Annual Visit - 10	1966	1743	89	977	52	59	3	42	3	1297	97	113	8	166	12	1018	76	55

[1] Based on *Form 33* collection.
[2] Medication rate calculated as the number of pills taken divided by the number of days since bottle(s) were dispensed.
[3] Percentage calculated based on denominator of total dispensation which is the sum of missed pill collection and total with collection.
[4] Adherence summary calculated as the number of women consuming ≥80% of pills divided by the number due for a visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Figure 4.1
CaD Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills[1]

Data as of: August 31, 2004



[1] Adherence calculations changed as of the September 2001 – February 2002 interval.

Table 4.3
CaD Drop-Out Rates by Follow-Up Time

Data as of: August 31, 2004

	Design		Observed			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-2	8.8	8.8	7.2	0.2	7.2	7.1
AV-3	5.9	14.2	5.3	0.4	5.3	12.0
AV-4	5.9	19.2	4.4	0.6	4.4	16.2
AV-5	5.9	24.0	3.9	0.6	3.9	20.0
AV-6	5.9	28.5	3.5	0.7	3.5	23.5
AV-7	5.9	32.7	3.1	0.7	3.1	26.5
AV-8	5.9	36.7	3.1	0.8	3.1	29.5

[1] Estimated rate of stopping CaD in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] The first event of stopping or death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping or death or lost to follow-up. Cumulative rates calculated as Kaplan-Meier estimates.
[5] Drop-out rates derived from Form 7 by date.

Table 4.4
Reasons for Stopping CaD[1]

Data as of: August 31, 2004

Reasons[2]	(N = 10763)	
Personal/family		
Demands of work	210	2.0%
Family illness, emergency or other family demands[3]	403	3.7%
Financial problems	16	0.1%
Lack of cooperation/support from family/friends[4]	87	0.8%
Living in nursing home	85	0.8%
Issues of interest in study[5]	406	3.8%
Travel		
Too far to CC	261	2.4%
Moved out of area or refuses to be followed at another CC	105	1.0%
Other travel issues[6]	105	1.0%
Visits & Procedures		
Doesn't like visits, calls	98	0.9%
Doesn't like required forms or safety procedures[7]	89	0.8%
Problems with other procedures[8]	35	0.3%
Worried about health effects of medical tests/procedures	34	0.3%
Wants results of blood analyses	4	0.0%
Wants results of bone mineral density	2	0.0%
Problems with CC[9]	59	0.5%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands," "Death in the family or of a close friend," and "Caregiver responsibilities demanding time, effort, lifestyle changes."
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw."
[5] Combines "Conflicting priorities other than work or family," "Feels discouraged regarding participation overall," "Loss of interest, boredom," "Feels it is not an important study," and "In another study in conflict with WHI intervention."
[6] Combines "Transportation problems (other than distance)," "Traffic," "Parking at CC," and "CC neighborhood/safety."
[7] Combines "Doesn't like filling out forms (other than those required for safety)," and "Doesn't like required safety forms and/or procedures."
[8] Combines "Doesn't like mammograms," "Cost of mammograms," "Doesn't like having blood drawn," "Doesn't like ECG," "Doesn't like gynecologic procedures" and "Doesn't like other procedures (other than those required for safety)."
[9] Combines "Problem with the CC," "Problem with CC staff person (other than DM Group Nutritionist)," and "Staff change/turnover".

Table 4.4 (continued)
Reasons for Stopping CaD[1]

Data as of: August 31, 2004

Reasons[2]	(N = 10763)	
Symptoms		
Bloating/gas	215	2.0%
Constipation	237	2.2%
Other gastrointestinal problems	284	2.6%
HRT Related Symptoms[3]	36	0.3%
Other[4]	2191	20.4%
Health Conditions		
Hypercalcemia	349	3.2%
Renal calculi	290	2.7%
Osteoporosis	107	1.0%
Other Diseases/Health Conditions[5]	1168	10.9%
Communication difficulties[6]	190	1.8%
Intervention		
Doesn't like randomized nature of intervention	369	3.4%
Expected some benefit from intervention	58	0.5%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	22	0.2%
Takes too many pills	389	3.6%
Other pill issues[7]	1130	10.5%
HRT Issues[8]	166	1.5%
DM Issues[9]	17	0.2%
Wants to take her own calcium	444	4.1%
Feels diet is already sufficient in calcium/Vit D	56	0.5%
Taking more than the max allowable IU of Vit D	56	0.5%
Taking Calcitrol	25	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	11	0.1%
Expected more health care	25	0.2%
Advised not to participate by health care provider[10]	836	7.8%
Study conflicts with other health issues[11]	550	5.1%
Other		
Other reasons not listed above	2146	19.9%
Refuses to give a reason	163	1.5%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Vaginal bleeding," "Breast tenderness," "Other breast changes," "Vaginal changes (e.g., dryness)," and "Hot flashes/night sweats."
[4] Combines "Experiencing health problems or symptoms not due to intervention," "Reports other health problems or symptoms from the WHI intervention", "Reports health problems or symptoms from the WHI intervention," "Hair/skin changes," "Headaches," "Weight loss/gain," "Low energy/too tired," "Possible allergic reaction," and "Other symptoms not listed above."
[5] Combines "Removed from intervention due to WHI symptom management," "Removed from intervention due to adverse health event", "Breast cancer", "Complex or atypical hyperplasia," "Endometrial cancer," "Deep vein thrombosis," "Pulmonary embolism," "Gallbladder disease," "Kidney failure/dialysis," "High triglycerides (> 1000 mg/dl)," "Malignant melanoma," "Meningioma," "Heart attack," "Stroke," "Arthritis," "Diabetes," "Depression," "Cholesterol (high or concern about levels)," and "Other health conditions not listed above."
[6] Combines "Communication problem," "Loss of vision and/or hearing," and "Cognitive/memory changes."
[7] Combines "Doesn't like taking pills," "Doesn't like taste of pills," and "Unable to swallow pills."
[8] Combines "Has made a personal decision to go on active HRT," "Has made a personal decision that she does not want to be on HRT," "Advised to go on active HRT by health care provider," "Advised to not be on active HRT by health care provider," "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)," "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider," and "Taking testosterone medications."
[9] Combines "Doesn't like DM requirements," "Problem with DM Group Nutritionist or group members", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes," "Doesn't like self-monitoring," "Doesn't like budgeting fat grams," "Has concerns regarding long-term risks/benefits of low fat diet," "Unhappy that not losing weight", "Not in control of meal preparation", "Too difficult to meet or maintain dietary goals," "Doesn't like eating low fat diet," "Doesn't like eating 5 vegetables/fruits per day," "Doesn't like eating 6 grains per day," "Feels fat gram goal is unrealistic," and "Eating pattern conflicts with personal health beliefs."
[10] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
[11] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 4.5
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: August 31, 2004

	N	Mean	S.D.
Whole Body Scan			
AV1	2440	1.02	0.11
AV3	2284	1.03	0.11
AV6	2038	1.05	0.12
AV9	908	1.07	0.14
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]	679	3.36	6.72
Spine Scan			
AV1	2349	0.99	0.16
AV3	2220	1.01	0.17
AV6	1967	1.02	0.17
AV9	866	1.01	0.17
AV3 % Change from AV1 BMD[2]	2151	1.58	4.21
AV6 % Change from AV1 BMD[2]	1887	2.72	6.00
AV9 % Change from AV1 BMD[2]	644	2.95	7.19
Hip Scan			
AV1	2431	0.86	0.14
AV3	2285	0.87	0.14
AV6	2055	0.87	0.14
AV9	898	0.86	0.14
AV3 % Change from AV1 BMD[2]	2211	1.27	3.55
AV6 % Change from AV1 BMD[2]	1964	0.23	5.05
AV9 % Change from AV1 BMD[2]	670	-0.48	5.97

[1] Measured in (g/cm^2).
[2] AVX % Change from AV1 BMD is defined as ((AVX-AV1)/AV1)x100.

Table 4.6
Bone Mineral Density[1] Analysis: CaD Participants by Race/Ethnicity

Data as of: August 31, 2004

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
AV1	279	1.08	0.11	123	1.04	0.12	2000	1.01	0.10
AV3	264	1.10	0.12	116	1.05	0.12	1868	1.03	0.11
AV6	228	1.08	0.12	115	1.10	0.15	1661	1.04	0.12
AV9	67	1.14	0.15	42	1.12	0.20	784	1.06	0.13
AV3 % Change from AV1 BMD[2]	260	1.23	3.01	104	2.20	4.36	1813	1.45	3.38
AV6 % Change from AV1 BMD[2]	221	-0.33	3.76	97	5.94	7.25	1607	2.40	5.21
AV9 % Change from AV1 BMD[2]	26	2.92	6.28	32	5.87	7.75	609	3.21	6.67
Spine Scan									
AV1	274	1.07	0.18	118	0.98	0.16	1919	0.98	0.16
AV3	260	1.08	0.19	113	0.97	0.15	1811	1.00	0.17
AV6	213	1.08	0.18	113	0.98	0.16	1607	1.01	0.17
AV9	65	1.09	0.17	41	0.96	0.15	745	1.01	0.16
AV3 % Change from AV1 BMD[2]	256	1.15	4.40	101	0.38	3.99	1760	1.74	4.17
AV6 % Change from AV1 BMD[2]	206	1.01	6.16	95	1.29	5.76	1555	3.04	5.96
AV9 % Change from AV1 BMD[2]	26	1.71	6.91	31	2.26	6.68	575	3.01	7.23
Hip Scan									
AV1	279	0.98	0.14	123	0.87	0.14	1991	0.85	0.13
AV3	264	0.98	0.15	116	0.88	0.13	1869	0.86	0.13
AV6	232	0.96	0.14	117	0.89	0.14	1672	0.86	0.13
AV9	66	0.97	0.13	42	0.88	0.16	775	0.85	0.13
AV3 % Change from AV1 BMD[2]	260	0.85	3.16	103	1.74	4.74	1814	1.30	3.51
AV6 % Change from AV1 BMD[2]	224	-1.97	4.35	98	2.79	5.30	1611	0.42	5.00
AV9 % Change from AV1 BMD[2]	26	-1.51	4.57	32	2.06	4.26	601	-0.59	6.08

[1] Measured in (g/cm^2).
[2] AVX % Change from AV1 BMD is defined as ((AVX-AV1)/AV1)x100.

Table 4.7
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: August 31, 2004

	CaD Participants (N = 36,282)	
	N	%
Vital Status/Participation		
Deceased	1359	3.7
Alive: Current Participation[1]	33742	93.0
Alive: Recent Participation[2]	303	0.8
Alive: Past/Unknown Participation[3]	3	<0.1
Stopped Follow-Up[4]	554	1.5
Lost to Follow-Up[5]	321	0.9

[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 4.8
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5153	8270	16521	6338
Mean follow-up (months)	77.8	83.8	80.3	76.1	74.2
Fractures					
Hip fracture	312 (0.13%)	5 (0.01%)	27 (0.05%)	104 (0.10%)	176 (0.45%)
Vertebral fracture	324 (0.14%)	12 (0.03%)	37 (0.07%)	135 (0.13%)	140 (0.36%)
Other fracture[1]	3351 (1.42%)	410 (1.14%)	679 (1.23%)	1542 (1.47%)	720 (1.84%)
Total fracture	3821 (1.62%)	425 (1.18%)	734 (1.33%)	1711 (1.63%)	951 (2.43%)
Cancer					
Colorectal cancer	307 (0.13%)	22 (0.06%)	42 (0.08%)	152 (0.15%)	91 (0.23%)
Breast cancer	1235 (0.52%)	146 (0.41%)	288 (0.52%)	582 (0.56%)	219 (0.56%)
Invasive breast cancer	983 (0.42%)	106 (0.29%)	234 (0.42%)	467 (0.45%)	176 (0.45%)
Non-invasive breast cancer	260 (0.11%)	40 (0.11%)	55 (0.10%)	118 (0.11%)	47 (0.12%)
Ovarian cancer	108 (0.05%)	12 (0.03%)	29 (0.05%)	45 (0.04%)	22 (0.06%)
Endometrial cancer[2]	163 (0.07%)	19 (0.05%)	38 (0.07%)	75 (0.07%)	31 (0.08%)
Other cancer[1]	1230 (0.52%)	110 (0.31%)	207 (0.37%)	602 (0.57%)	311 (0.79%)
Total cancer	2940 (1.25%)	301 (0.84%)	590 (1.07%)	1399 (1.34%)	650 (1.66%)
Cardiovascular					
CHD[3]	852 (0.36%)	49 (0.14%)	104 (0.19%)	392 (0.37%)	307 (0.78%)
CHD death[4]	218 (0.09%)	11 (0.03%)	19 (0.03%)	84 (0.08%)	104 (0.27%)
Total MI[5]	701 (0.30%)	40 (0.11%)	88 (0.16%)	338 (0.32%)	235 (0.60%)
Clinical MI	651 (0.28%)	36 (0.10%)	83 (0.15%)	315 (0.30%)	217 (0.55%)
Evolving Q-wave MI[6]	52 (0.02%)	4 (0.01%)	5 (0.01%)	25 (0.02%)	18 (0.05%)
Possible evolving Q-wave MI[6]	204 (0.09%)	23 (0.06%)	29 (0.05%)	90 (0.09%)	62 (0.16%)
Angina	999 (0.42%)	53 (0.15%)	147 (0.27%)	506 (0.48%)	293 (0.75%)
CABG/PTCA	1117 (0.47%)	61 (0.17%)	149 (0.27%)	566 (0.54%)	341 (0.87%)
Carotid artery disease	185 (0.08%)	8 (0.02%)	16 (0.03%)	103 (0.10%)	58 (0.15%)
Congestive heart failure	672 (0.29%)	27 (0.08%)	73 (0.13%)	314 (0.30%)	258 (0.66%)
Stroke	639 (0.27%)	29 (0.08%)	66 (0.12%)	284 (0.27%)	260 (0.66%)
PVD	172 (0.07%)	5 (0.01%)	22 (0.04%)	81 (0.08%)	64 (0.16%)
CHD[3]/Possible evolving Q-wave MI	1045 (0.44%)	72 (0.20%)	132 (0.24%)	474 (0.45%)	367 (0.94%)
Coronary disease[7]	2449 (1.04%)	141 (0.39%)	334 (0.60%)	1172 (1.12%)	802 (2.05%)
Total cardiovascular disease	3205 (1.36%)	175 (0.49%)	419 (0.76%)	1542 (1.47%)	1069 (2.73%)
Deaths					
Cardiovascular deaths	389 (0.17%)	19 (0.05%)	30 (0.05%)	159 (0.15%)	181 (0.46%)
Cancer deaths	613 (0.26%)	47 (0.13%)	92 (0.17%)	291 (0.28%)	183 (0.47%)
Other known cause	223 (0.09%)	9 (0.03%)	28 (0.05%)	105 (0.10%)	81 (0.21%)
Unknown cause	63 (0.03%)	2 (0.01%)	12 (0.02%)	24 (0.02%)	25 (0.06%)
Not yet adjudicated	71 (0.03%)	4 (0.01%)	5 (0.01%)	40 (0.04%)	22 (0.06%)
Total death	1359 (0.58%)	81 (0.23%)	167 (0.30%)	619 (0.59%)	492 (1.25%)

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

Data as of: August 31, 2004

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)	77.6	74.1	76.5	75.8	78.2	74.1
Fractures						
Hip fracture	1 (0.10%)	4 (0.09%)	6 (0.03%)	2 (0.02%)	299 (0.15%)	0 (0.00%)
Vertebral fracture	1 (0.10%)	5 (0.11%)	4 (0.02%)	7 (0.07%)	299 (0.15%)	8 (0.29%)
Other fracture[1]	16 (1.66%)	39 (0.88%)	163 (0.77%)	83 (0.87%)	3010 (1.53%)	40 (1.47%)
Total fracture	18 (1.87%)	47 (1.06%)	171 (0.81%)	92 (0.97%)	3446 (1.75%)	47 (1.73%)
Cancer						
Colorectal cancer	3 (0.31%)	5 (0.11%)	27 (0.13%)	8 (0.08%)	261 (0.13%)	3 (0.11%)
Breast cancer	3 (0.31%)	24 (0.54%)	85 (0.40%)	35 (0.37%)	1076 (0.55%)	12 (0.44%)
Invasive breast cancer	3 (0.31%)	16 (0.36%)	64 (0.30%)	29 (0.31%)	859 (0.44%)	12 (0.44%)
Non-invasive breast cancer	0 (0.00%)	8 (0.18%)	22 (0.10%)	6 (0.06%)	224 (0.11%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	3 (0.07%)	7 (0.03%)	3 (0.03%)	94 (0.05%)	1 (0.04%)
Endometrial cancer[2]	1 (0.11%)	2 (0.05%)	5 (0.02%)	3 (0.03%)	150 (0.08%)	2 (0.07%)
Other cancer[1]	3 (0.31%)	19 (0.43%)	80 (0.38%)	27 (0.28%)	1089 (0.55%)	12 (0.44%)
Total cancer	10 (1.04%)	51 (1.15%)	197 (0.93%)	71 (0.75%)	2582 (1.31%)	29 (1.07%)
Cardiovascular						
CHD[3]	5 (0.52%)	5 (0.11%)	83 (0.39%)	20 (0.21%)	727 (0.37%)	12 (0.44%)
CHD death[4]	1 (0.10%)	3 (0.07%)	36 (0.17%)	3 (0.03%)	170 (0.09%)	5 (0.18%)
Total MI[5]	5 (0.52%)	3 (0.07%)	56 (0.26%)	18 (0.19%)	609 (0.31%)	10 (0.37%)
Clinical MI	5 (0.52%)	3 (0.07%)	53 (0.25%)	17 (0.18%)	564 (0.29%)	9 (0.33%)
Evolving Q-wave MI[6]	0 (0.00%)	0 (0.00%)	3 (0.01%)	1 (0.01%)	47 (0.02%)	1 (0.04%)
Possible evolving Q-wave MI[6]	1 (0.10%)	5 (0.11%)	23 (0.11%)	8 (0.08%)	167 (0.08%)	0 (0.00%)
Angina	2 (0.21%)	10 (0.22%)	106 (0.50%)	38 (0.40%)	830 (0.42%)	13 (0.48%)
CABG/PTCA	4 (0.42%)	8 (0.18%)	98 (0.46%)	33 (0.35%)	960 (0.49%)	14 (0.52%)
Carotid artery disease	1 (0.10%)	1 (0.02%)	8 (0.04%)	2 (0.02%)	171 (0.09%)	2 (0.07%)
Congestive heart failure	2 (0.21%)	4 (0.09%)	86 (0.41%)	25 (0.26%)	548 (0.28%)	7 (0.26%)
Stroke	5 (0.52%)	18 (0.40%)	67 (0.32%)	16 (0.17%)	523 (0.27%)	10 (0.37%)
PVD	2 (0.21%)	2 (0.04%)	24 (0.11%)	1 (0.01%)	142 (0.07%)	1 (0.04%)
CHD[3]/Possible evolving Q-wave MI	6 (0.62%)	10 (0.22%)	104 (0.49%)	27 (0.28%)	886 (0.45%)	12 (0.44%)
Coronary disease[7]	8 (0.83%)	21 (0.47%)	268 (1.27%)	74 (0.78%)	2050 (1.04%)	28 (1.03%)
Total cardiovascular disease	13 (1.35%)	38 (0.85%)	344 (1.63%)	92 (0.97%)	2679 (1.36%)	39 (1.44%)
Deaths						
Cardiovascular deaths	2 (0.21%)	10 (0.22%)	58 (0.27%)	7 (0.07%)	307 (0.16%)	5 (0.18%)
Cancer deaths	1 (0.10%)	12 (0.27%)	48 (0.23%)	14 (0.15%)	530 (0.27%)	8 (0.29%)
Other known cause	5 (0.52%)	2 (0.04%)	22 (0.10%)	4 (0.04%)	186 (0.09%)	4 (0.15%)
Unknown cause	0 (0.00%)	1 (0.02%)	9 (0.04%)	2 (0.02%)	50 (0.03%)	1 (0.04%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	11 (0.05%)	2 (0.02%)	56 (0.03%)	2 (0.07%)
Total death	8 (0.83%)	25 (0.56%)	148 (0.70%)	29 (0.31%)	1129 (0.57%)	20 (0.74%)

[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 4.9
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: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8270	16521	6338
Mean follow-up (months)	77.8	83.8	80.3	76.1	74.2
Hospitalizations					
Ever	15936 (6.77%)	1643 (4.57%)	3038 (5.49%)	7616 (7.27%)	3639 (9.28%)
Two or more	7949 (3.38%)	668 (1.86%)	1362 (2.46%)	3832 (3.66%)	2087 (5.32%)
Other					
DVT[1]	348 (0.15%)	20 (0.06%)	59 (0.11%)	162 (0.16%)	107 (0.28%)
Pulmonary embolism	221 (0.09%)	17 (0.05%)	40 (0.07%)	116 (0.11%)	48 (0.12%)
Diabetes (treated)	2507 (1.11%)	379 (1.08%)	546 (1.02%)	1156 (1.15%)	426 (1.15%)
Gallbladder disease[2]	2303 (1.16%)	345 (1.08%)	562 (1.18%)	1066 (1.23%)	330 (1.03%)
Hysterectomy	909 (0.66%)	128 (0.62%)	218 (0.64%)	420 (0.69%)	143 (0.65%)
Glaucoma	3391 (1.49%)	355 (1.00%)	692 (1.28%)	1623 (1.61%)	721 (1.97%)
Osteoporosis	6607 (2.95%)	667 (1.89%)	1244 (2.31%)	3209 (3.23%)	1487 (4.17%)
Osteoarthritis[3]	6197 (4.21%)	930 (3.46%)	1452 (3.82%)	2803 (4.51%)	1012 (5.04%)
Rheumatoid arthritis	1734 (0.77%)	248 (0.71%)	403 (0.75%)	776 (0.77%)	307 (0.82%)
Intestinal polyps	4844 (2.21%)	609 (1.75%)	1054 (1.99%)	2378 (2.45%)	803 (2.29%)
Lupus	314 (0.13%)	52 (0.14%)	71 (0.13%)	136 (0.13%)	55 (0.14%)
Kidney stones[3]	717 (0.36%)	96 (0.32%)	164 (0.35%)	335 (0.37%)	122 (0.36%)
Cataracts[3]	10371 (5.82%)	735 (2.51%)	1903 (4.19%)	5571 (6.95%)	2162 (9.25%)
Pills for hypertension	8859 (5.27%)	1173 (3.99%)	1969 (4.61%)	4097 (5.69%)	1620 (6.72%)

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)	77.6	74.1	76.5	75.8	78.2	74.1
Hospitalizations						
Ever	66 (6.85%)	224 (5.03%)	1491 (7.05%)	539 (5.68%)	13430 (6.83%)	186 (6.85%)
Two or more	44 (4.57%)	91 (2.04%)	780 (3.69%)	240 (2.53%)	6697 (3.41%)	97 (3.57%)
Other						
DVT[1]	3 (0.32%)	1 (0.02%)	30 (0.15%)	6 (0.06%)	305 (0.16%)	3 (0.11%)
Pulmonary embolism	3 (0.31%)	0 (0.00%)	20 (0.10%)	2 (0.02%)	193 (0.10%)	3 (0.11%)
Diabetes (treated)	11 (1.23%)	69 (1.65%)	381 (2.02%)	177 (1.98%)	1832 (0.96%)	37 (1.46%)
Gallbladder disease[2]	10 (1.37%)	35 (0.86%)	157 (0.82%)	110 (1.51%)	1964 (1.19%)	27 (1.18%)
Hysterectomy	2 (0.49%)	15 (0.52%)	46 (0.51%)	34 (0.65%)	807 (0.68%)	5 (0.33%)
Glaucoma	19 (2.07%)	54 (1.26%)	424 (2.14%)	158 (1.72%)	2707 (1.42%)	29 (1.13%)
Osteoporosis	26 (2.83%)	144 (3.35%)	360 (1.77%)	271 (3.04%)	5733 (3.06%)	73 (2.88%)
Osteoarthritis[3]	34 (5.59%)	121 (3.73%)	552 (4.30%)	305 (4.69%)	5097 (4.17%)	88 (4.95%)
Rheumatoid arthritis	16 (1.87%)	27 (0.63%)	281 (1.44%)	141 (1.56%)	1246 (0.66%)	23 (0.90%)
Intestinal polyps	29 (3.27%)	82 (2.00%)	477 (2.41%)	161 (1.77%)	4044 (2.21%)	51 (2.04%)
Lupus	4 (0.42%)	1 (0.02%)	34 (0.16%)	12 (0.13%)	261 (0.13%)	2 (0.07%)
Kidney stones[3]	6 (0.74%)	14 (0.36%)	63 (0.35%)	37 (0.46%)	590 (0.35%)	7 (0.30%)
Cataracts[3]	47 (6.30%)	166 (4.87%)	846 (5.23%)	407 (5.35%)	8779 (5.92%)	126 (5.99%)
Pills for hypertension	34 (5.62%)	160 (5.23%)	821 (7.49%)	418 (5.72%)	7330 (5.07%)	96 (5.59%)

[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.

5. Observational Study

5.1 Recruitment

Recruitment into the OS component, completed in December of 1998, reached 93,717, approximately 94% of the expected sample size. After removing duplicate enrollments and a few enrollments with insufficient data, the final analytic cohort was established with 93,676 participants. *Table 5.1 – Observation Study Age and Race/Ethnicity Specific Recruitment* documents the age distribution and the racial/ethnic composition of this cohort.

5.2 Overview of Follow-up

OS follow-up is conducted by annual mailed self-administered questionnaires except for year 3, when participants attended a clinic follow-up visit. Participants at the three bone density sites also attended clinic visits at years 6 and 9 for a bone density scan. For all other years, the CCC mails the *Medical History Update* and the *OS Exposure Update* questionnaires approximately two months prior to the anniversary of the participants' enrollment. Participants mail their completed questionnaires to their local CC for data entry and outcomes processing. Non-respondents receive up to two additional mailings from the CCC. For odd numbered follow-up years, CCs attempt to complete follow-up of non-responders by local contacts, usually telephone reminders or interviews.

The "regular" annual mailings ended in March 2004 and "close-out" mailings started in April 2004. Close-out mailings will continue through Spring 2005. During the close-out year, CCs attempt to complete follow-up of non-responders for all OS participants, regardless of which follow-up year they are in.

The year 3 clinic visit assessed change in physical measures, blood analytes, diet, and use of medications and supplements. These visits, which occurred at all CCs, started in 1997 and ended in late 2001. Year 6 visits at the three bone density sites started in 2000 and year 9 visits started in 2003. Bone density clinic visits by OS participants ended October 1, 2004, with the start of the CT close-out visits.

5.3 Completeness of Annual Mail Follow-up

Table 5.2 – Response Rates to OS Follow-up Procedures shows completeness of OS mail follow-up by follow-up year, type of contact, and clinic group. These rates include participants for whom the full sequence of mailings is complete and there has been at least two months for CC follow-up of non-responders, as of 8/31/04.

The overall response of 95.7% for year 1 data collection, which includes mailings plus CC follow-up of non-responders, slightly exceeds the 95% goal for completion of *Form 48 – OS Exposure Update*, but falls short of the optimal goal (98%) for completion of *Form 33 – Medical History Update*. For years 2, 4, 5, 6, 7, and 8 the rates of 94.0% (Y2), 93.6% (Y4), 94.5% (Y5), 93.4% (Y6), 94.5% (Y7), and 94.1% (Y8) exceed or meet the 94% (Y2), 92% (Y4), 91% (Y5), 90% (Y6), 90% (Y7), and 90% (Y8) goals for the *Exposure Update*. These rates fall slightly short of the optimal goals (98% at Y1 with a 0.5% annual decline to 94.5% by Y8) for the *Medical History Update*.

5.4 Completeness of Clinic Visits (Years 3, 6, and 9)

Table 5.3 – OS Annual Visit 3/6 Task Completeness shows completeness of activities conducted at the year 3 clinic visit for all participants and at the year 6 visit for bone density participants. By the end of the year 3 clinic visits, 96.1% participants overall had completed *Form 33 – Medical History Update* and 82.7% had provided *Form 100 – Blood Collection*. Of those participants at the 3 bone densitometry substudy clinics due for the year 6 visit as of 8/31/04, 87.6% completed *Form 33 – Medical History Updates* and 76.9% completed *Form 87 – Bone Densitometry*. Rates for the year 9 visit are not yet available.

5.5 Bone Mineral Density

Bone scans are given to all enrolled WHI participants in three Clinical Centers: Birmingham, Pittsburgh, and Tucson. The choice of three centers was based on reducing the variability associated with multiple sites and operators while achieving adequate sample size. The selection of these three clinical centers was based both on their previous experience in bone densitometry and the expected enrollment of minorities which allows us to address hypotheses regarding racial/ethnic differences. Bone scans were given at baseline and years 1, 3, 6, and 9 in these centers. Bone scans for OS year 9 participants ended October 1, 2004, with the start of CT close-out visits.

Table 5.4 – Bone Mineral Density Analysis (OS participants) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline, AV-3, AV-6, and AV-9, along with % change from baseline for the three types of scans available: whole body, spine, and hip. Baseline and % change at AV-3 is given using only those women who have an AV-3 bone scan; this is also the case for AV-6 and AV-9 data. The current data suggest overall a small increase in bone density, as measured by the whole body scan, over three, six, and nine years in this group of women. In general, we would have expected a small decrease in BMD over time. As with the corresponding DM results, this increase could be related to some selection of health conscious women who may be taking hormone replacement therapy or calcium supplements of their own, or could be due to measurement issues.

5.6 Vital Status

Table 5.6 – Lost-to-Follow-up and Vital Status: OS Participants presents data on the vital status and the participation status of participants in the OS. A detailed description of CC and CCC activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define OS participants to be lost-to-follow-up if there is no outcomes information from the participant for 24 months. Currently, 1.7% of the participants are lost-to-follow-up, and an additional 2.0% of the participants have stopped follow-up. 5.3% of the OS participants are deceased.

5.7 Outcomes

Table 5.7 – Verified Outcomes (Annualized Percentages) for OS Participants contains counts of the number of verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 4% of the self-reported outcomes have not yet been verified, the numbers in this table can be seen as a lower bound to the actual number of outcomes that took place. For the OS component we are using centrally adjudicated outcomes for breast cancer, ovarian cancer,

endometrial cancer, colorectal cancer, and hip fractures. Locally verified outcomes for events for which central adjudication has not yet been completed are included in the counts. Compared to the incidence rates used in the CT design, we have about 125% of the expected number of breast cancers, 60% of the expected number of colorectal cancers, about 55% of the expected number of CHD events, and about 40% of the expected number hip fractures.

Table 5.8 – Counts (Annualized Percentages) of Participants with Self Reported Outcomes by Age and Race/Ethnicity for OS Participants contains counts of the number of self-reports for some outcomes that are not verified in WHI. As most of the locally verified outcomes are somewhat over-reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred among OS participants.

Tables 5.9 – First Reported Verified Outcomes and *5.10 – Counts of Participants with Self-Reported Outcomes,* contain counts of outcomes relative to AV-3. These tables count the *first* event of a particular type, thus a participant who reports, say, a myocardial infarction at AV-1 and another one at AV-4 gets only counted in the "Before AV-3" category. These tables may be useful for investigators who want to propose ancillary studies or papers.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of: August 31, 2004

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12,384	13%
55-59	17,323	18%
60-69	41,199	44%
70-79	22,770	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
Response Rates to OS Follow-up Procedures

Data as of: August 31, 2004

	# Due[1]	Mailings Initiated[2]		Response to Mailings		Response to CC follow-up		Total Responses	
		N	%	N	%[3]	N	%[4]	N	%[5]
Year 1	93,479	93,294	99.8%	86,610	92.8%	2,813	42.1%	89,423	95.7%
VCC	41,642	41,608	99.9%	38,400	92.3%	1,678	52.3%	40,078	96.2%
NCC	51,837	51,686	99.7%	48,210	93.3%	1,135	32.7%	49,345	95.2%
Year 2	93,039	91,400	98.2%	86,193	94.3%	N/A		87,463	94.0%
VCC	41,458	40,711	98.2%	38,417	94.4%	N/A		39,026	94.1%
NCC	51,581	50,689	98.3%	47,776	94.3%	N/A		48,437	93.9%
Year 4	91,810	90,071	98.1%	84,001	93.3%	N/A		85,897	93.6%
VCC	40,919	40,133	98.1%	37,254	92.8%	N/A		38,034	92.9%
NCC	50,891	49,938	98.1%	46,747	93.6%	N/A		47,863	94.1%
Year 5	90,217	88,309	97.9%	83,152	94.2%	2,096	40.6%	85,248	94.5%
VCC	40,522	39,828	98.3%	37,264	93.6%	900	35.1%	38,164	94.2%
NCC	49,695	48,481	97.6%	45,888	94.7%	1,196	46.1%	47,084	94.7%
Year 6[6]	58,082	56,538	97.3%	52,878	93.5%	N/A		54,245	93.4%
VCC	24,233	23,667	97.7%	22,016	93.0%	N/A		22,528	93.0%
NCC	33,849	32,871	97.1%	30,862	93.9%	N/A		31,717	93.7%
Year 7	40,845	39,537	96.8%	37,656	95.2%	925	49.2%	38,581	94.5%
VCC	19,730	19,147	97.0%	18,064	94.3%	432	39.9%	18,496	93.7%
NCC	21,115	20,390	96.6%	19,592	96.1%	493	61.8%	20,085	95.1%
Year 8	13,417	12,971	96.7%	12,385	95.5%	N/A		12,621	94.1%
VCC	8,433	8,165	96.8%	7,723	94.6%	N/A		7,874	93.4%
NCC	4,984	4,806	96.4%	4,662	97.0%	N/A		4,747	95.2%

[1] Excludes women who are deceased.
[2] Mailings are not sent to women who have requested no follow-up, who are deceased, who have a non-deliverable address at the time of mailing, or who have a *Form 33* completed within the previous 3 months.
[3] Percent response of those initiated.
[4] Percent response from OS participants not responding to mailings. CC follow-up not required in even numbered follow-up years.
[5] Percent response of those due.
[6] Does not include bone density sites.

Table 5.3
OS Annual Visit 3/6 Task Completeness

Data as of: August 31, 2004

	Task	# Due[1]	# Done[2]	% Done
Year 3	Form 33 - Medical History Update	92,475	88,854	96.1%
	Form 38 - Daily Life	92,475	82,339	89.0%
	Form 44 - Current Medications	92,475	79,266	85.7%
	Form 45 - Current Supplements	92,475	79,165	85.6%
	Form 60 - Food Frequency Quest	92,475	82,499	89.2%
	Form 80 - Physical Measures	92,475	77,386	83.7%
	Form 100 - Blood Collection	92,475	76,487	82.7%
	Form 143 - Follow-up	92,475	81,975	88.6%
Year 6[3]	Form 33 - Medical History Update	5,647	4,945	87.6%
	Form 80 - Physical Measures	5,647	4,365	77.3%
	Form 87 - Bone Densitometry	5,647	4,344	76.9%
	Form 146 - Follow-up	5,647	4,676	82.8%

[1] Includes all Year 3/6 contacts due through 10/31/03. Excludes women who are deceased.
[2] Tasks completed within the -6/+15 month window for Year 3 and –2/+10 month window for Year 6.
[3] Includes bone density sites only.

Table 5.4
Bone Mineral Density[1] Analysis: OS Participants

Data as of: August 31, 2004

	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)	4469	1.01	0.11
Baseline (for ppts. with an AV9 scan)	1686	1.02	0.10
AV3	5158	1.02	0.11
AV6	4515	1.04	0.12
AV9	1699	1.04	0.13
AV3 % Change from baseline BMD[2]	5096	0.95	3.70
AV6 % Change from baseline BMD[2]	4211	1.97	5.61
AV9 % Change from baseline BMD[2]	1456	1.73	6.71
Spine Scan			
Baseline	6237	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4994	0.97	0.17
Baseline (for ppts. with an AV6 scan)	4301	0.97	0.17
Baseline (for ppts. with an AV9 scan)	1642	0.98	0.16
AV3	5034	0.99	0.18
AV6	4337	1.00	0.18
AV9	1647	1.02	0.18
AV3 % Change from baseline BMD[2]	4986	1.67	5.15
AV6 % Change from baseline BMD[2]	4044	3.33	6.97
AV9 % Change from baseline BMD[2]	1414	5.02	8.54
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)	4506	0.85	0.14
Baseline (for ppts. with an AV9 scan)	1695	0.84	0.13
AV3	5186	0.85	0.14
AV6	4542	0.84	0.14
AV9	1700	0.83	0.13
AV3 % Change from baseline BMD[2]	5114	0.48	4.34
AV6 % Change from baseline BMD[2]	4215	-0.07	5.51
AV9 % Change from baseline BMD[2]	1447	-1.78	6.12

[1] Measured in (g/cm^2).
[2] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 5.5
Bone Mineral Density[1] Analysis: OS Participants by Race/Ethnicity

Data as of: August 31, 2004

	American Indian/ Alaskan Native			Asian/Pacific Islander			Black/African American			Hispanic/Latino			White			Unknown		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	108	1.01	0.12	25	1.02	0.09	828	1.05	0.11	464	1.01	0.11	4944	1.01	0.10	46	1.01	0.12
Baseline (for ppts. with an AV3 scan)	77	1.02	0.12	22	1.03	0.09	572	1.05	0.11	323	1.01	0.10	4073	1.01	0.10	36	1.00	0.11
Baseline (for ppts. with an AV6 scan)	53	1.02	0.12	16	1.03	0.08	519	1.05	0.11	308	1.02	0.10	3547	1.01	0.10	26	1.00	0.12
Baseline (for ppts. with an AV9 scan)	6	1.15	0.12	6	1.01	0.09	120	1.06	0.11	36	1.06	0.10	1505	1.01	0.10	13	0.99	0.09
AV3	81	1.03	0.13	22	1.03	0.11	580	1.06	0.12	338	1.03	0.11	4100	1.01	0.11	37	1.01	0.10
AV6	55	1.03	0.13	16	1.05	0.13	526	1.05	0.12	322	1.06	0.13	3569	1.03	0.12	27	1.01	0.12
AV9	6	1.15	0.14	6	1.02	0.14	122	1.11	0.14	36	1.08	0.15	1516	1.04	0.12	13	0.99	0.09
AV3 % Change from baseline BMD[2]	77	0.70	4.45	22	-0.03	5.44	572	1.52	3.35	322	1.51	4.43	4067	0.84	3.65	36	0.42	2.92
AV6 % Change from baseline BMD[2]	51	0.83	5.88	15	1.60	6.69	492	0.00	3.90	304	3.50	6.40	3326	2.15	5.67	23	0.03	3.85
AV9 % Change from baseline BMD[2]	6	0.16	5.02	6	0.89	6.11	52	1.54	6.22	36	1.49	7.05	1345	1.77	6.75	11	-0.44	4.48
Spine Scan																		
Baseline	109	0.99	0.17	24	0.95	0.12	819	1.04	0.18	450	0.95	0.16	4790	0.97	0.17	45	0.99	0.19
Baseline (for ppts. with an AV3 scan)	77	0.99	0.15	21	0.96	0.12	576	1.04	0.17	315	0.95	0.16	3971	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	54	0.99	0.17	15	0.96	0.12	491	1.04	0.17	299	0.96	0.16	3416	0.97	0.16	26	0.97	0.22
Baseline (for ppts. with an AV9 scan)	6	1.14	0.14	5	0.93	0.09	118	1.06	0.16	34	1.01	0.17	1466	0.97	0.16	13	0.97	0.19
AV3	81	1.00	0.16	21	0.96	0.12	579	1.05	0.19	328	0.95	0.16	3990	0.98	0.17	35	0.95	0.17
AV6	56	1.00	0.17	15	0.98	0.12	494	1.05	0.19	314	0.96	0.17	3431	1.00	0.18	27	0.99	0.22
AV9	6	1.15	0.13	5	0.95	0.03	118	1.08	0.18	34	1.02	0.19	1471	1.02	0.18	13	1.03	0.22
AV3 % Change from baseline BMD[2]	77	0.16	5.83	21	0.42	4.57	576	1.15	5.59	314	0.27	5.39	3964	1.90	5.03	34	0.84	5.17
AV6 % Change from baseline BMD[2]	52	0.96	8.42	14	2.16	4.64	464	1.53	6.57	295	1.15	6.93	3196	3.84	6.93	23	3.09	7.29
AV9 % Change from baseline BMD[2]	6	1.45	7.50	5	2.74	7.62	52	4.83	8.61	34	1.62	6.94	1306	5.13	8.58	11	6.83	8.55
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	464	0.83	0.13	4948	0.83	0.13	46	0.85	0.14
Baseline (for ppts. with an AV3 scan)	78	0.88	0.15	22	0.82	0.10	582	0.93	0.15	324	0.83	0.12	4104	0.83	0.13	36	0.83	0.12
Baseline (for ppts. with an AV6 scan)	53	0.89	0.16	16	0.81	0.11	522	0.94	0.15	312	0.84	0.12	3576	0.83	0.13	27	0.83	0.15
Baseline (for ppts. with an AV9 scan)	6	1.02	0.04	6	0.81	0.08	122	0.92	0.14	36	0.87	0.14	1512	0.83	0.13	13	0.81	0.12
AV3	82	0.88	0.15	22	0.82	0.09	588	0.94	0.15	338	0.85	0.13	4119	0.83	0.13	37	0.82	0.13
AV6	55	0.88	0.17	16	0.82	0.11	528	0.91	0.15	327	0.85	0.13	3588	0.83	0.13	28	0.82	0.15
AV9	6	1.00	0.05	6	0.83	0.09	122	0.90	0.15	36	0.85	0.15	1517	0.82	0.13	13	0.79	0.13
AV3 % Change from baseline BMD[2]	77	-0.36	4.85	22	0.51	4.28	582	0.36	4.00	322	1.68	4.99	4075	0.43	4.30	36	-0.81	4.76
AV6 % Change from baseline BMD[2]	50	-1.21	7.56	15	2.00	5.27	493	-2.38	4.86	307	1.20	6.22	3326	0.17	5.40	24	-1.51	6.61
AV9 % Change from baseline BMD[2]	6	-2.23	4.96	6	1.53	4.37	52	-2.23	5.96	36	-1.75	6.22	1336	-1.78	6.13	11	-1.90	6.59

[1] Measured in (g/cm^2).
[2] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 5.6
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: August 31, 2004

	OS Participants (N = 93,676)	
	N	%
Vital Status/Participation		
Deceased	4969	5.3
Alive: Current Participation[1]	82839	88.4
Alive: Recent Participation[2]	2206	2.4
Alive: Past/Unknown Participation[3]	184	0.2
Stopped Follow-Up[4]	1846	2.0
Lost to Follow-Up[5]	1632	1.7

[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 5.7
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12384	17323	41199	22770
Mean follow-up (months)	83.2	87.7	86.2	82.4	80.0
Cardiovascular					
CHD[1]	2012 (0.31%)	70 (0.08%)	165 (0.13%)	802 (0.28%)	975 (0.64%)
CHD death[2]	614 (0.09%)	15 (0.02%)	33 (0.03%)	194 (0.07%)	372 (0.25%)
Clinical MI	1592 (0.25%)	60 (0.07%)	142 (0.11%)	663 (0.23%)	727 (0.48%)
Angina	2534 (0.39%)	109 (0.12%)	277 (0.22%)	1185 (0.42%)	963 (0.63%)
CABG/PTCA	2693 (0.41%)	100 (0.11%)	273 (0.22%)	1281 (0.45%)	1039 (0.68%)
Carotid artery disease	498 (0.08%)	25 (0.03%)	37 (0.03%)	204 (0.07%)	232 (0.15%)
Congestive heart failure	1935 (0.30%)	70 (0.08%)	151 (0.12%)	745 (0.26%)	969 (0.64%)
Stroke	1677 (0.26%)	45 (0.05%)	131 (0.11%)	644 (0.23%)	857 (0.56%)
PVD	450 (0.07%)	17 (0.02%)	40 (0.03%)	187 (0.07%)	206 (0.14%)
Coronary disease[3]	5819 (0.90%)	237 (0.26%)	555 (0.45%)	2504 (0.89%)	2523 (1.66%)
Total cardiovascular disease	7923 (1.22%)	311 (0.34%)	726 (0.58%)	3329 (1.18%)	3557 (2.34%)
Cancer					
Breast cancer	3627 (0.56%)	378 (0.42%)	642 (0.52%)	1680 (0.59%)	927 (0.61%)
Invasive breast cancer	3044 (0.47%)	309 (0.34%)	528 (0.42%)	1409 (0.50%)	798 (0.53%)
Non-invasive breast cancer	599 (0.09%)	72 (0.08%)	116 (0.09%)	278 (0.10%)	133 (0.09%)
Ovarian cancer	309 (0.05%)	33 (0.04%)	50 (0.04%)	141 (0.05%)	85 (0.06%)
Endometrial cancer[4]	488 (0.07%)	39 (0.04%)	72 (0.06%)	226 (0.08%)	151 (0.10%)
Colorectal cancer	774 (0.12%)	42 (0.05%)	88 (0.07%)	345 (0.12%)	299 (0.20%)
Other cancer[5]	3464 (0.53%)	249 (0.28%)	437 (0.35%)	1593 (0.56%)	1185 (0.78%)
Total cancer	8291 (1.28%)	721 (0.80%)	1243 (1.00%)	3810 (1.35%)	2517 (1.66%)
Fractures					
Hip fracture	888 (0.14%)	21 (0.02%)	64 (0.05%)	275 (0.10%)	528 (0.35%)
Vertebral fracture[6]	108 (0.22%)	5 (0.07%)	8 (0.09%)	40 (0.19%)	55 (0.48%)
Other fracture[5, 6]	639 (1.33%)	79 (1.12%)	103 (1.16%)	266 (1.29%)	191 (1.68%)
Total fracture[7]	1581 N/A	103 N/A	171 N/A	562 N/A	745 N/A
Deaths					
Cardiovascular deaths	1353 (0.21%)	36 (0.04%)	80 (0.06%)	432 (0.15%)	805 (0.53%)
Cancer deaths	2121 (0.33%)	121 (0.13%)	250 (0.20%)	921 (0.33%)	829 (0.55%)
Other known cause	945 (0.15%)	43 (0.05%)	94 (0.08%)	350 (0.12%)	458 (0.30%)
Unknown cause	334 (0.05%)	16 (0.02%)	26 (0.02%)	127 (0.04%)	165 (0.11%)
Not yet adjudicated	216 (0.03%)	4 (<0.01%)	16 (0.01%)	89 (0.03%)	107 (0.07%)
Total death	4969 (0.76%)	220 (0.24%)	466 (0.37%)	1919 (0.68%)	2364 (1.56%)

[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 5.7 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: August 31, 2004

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)	78.1	80.6	78.5	75.3	84.2	80.5
Cardiovascular						
CHD[1]	11 (0.40%)	36 (0.20%)	188 (0.38%)	35 (0.15%)	1710 (0.31%)	32 (0.36%)
CHD death[2]	4 (0.15%)	14 (0.08%)	87 (0.17%)	9 (0.04%)	488 (0.09%)	12 (0.14%)
Clinical MI	8 (0.29%)	27 (0.15%)	121 (0.24%)	29 (0.13%)	1382 (0.25%)	25 (0.28%)
Angina	16 (0.58%)	39 (0.22%)	216 (0.43%)	71 (0.31%)	2163 (0.40%)	29 (0.33%)
CABG/PTCA	13 (0.47%)	42 (0.23%)	168 (0.34%)	71 (0.31%)	2360 (0.43%)	39 (0.44%)
Carotid artery disease	3 (0.11%)	5 (0.03%)	23 (0.05%)	10 (0.04%)	448 (0.08%)	9 (0.10%)
Congestive heart failure	13 (0.47%)	22 (0.12%)	202 (0.40%)	41 (0.18%)	1625 (0.30%)	32 (0.36%)
Stroke	11 (0.40%)	41 (0.23%)	169 (0.34%)	31 (0.14%)	1403 (0.26%)	22 (0.25%)
PVD	2 (0.07%)	4 (0.02%)	48 (0.10%)	5 (0.02%)	380 (0.07%)	11 (0.12%)
Coronary disease[3]	34 (1.24%)	91 (0.51%)	534 (1.07%)	140 (0.62%)	4943 (0.90%)	77 (0.87%)
Total cardiovascular disease	42 (1.53%)	138 (0.77%)	737 (1.48%)	178 (0.79%)	6714 (1.23%)	114 (1.28%)
Cancer						
Breast cancer	10 (0.36%)	75 (0.42%)	234 (0.47%)	88 (0.39%)	3186 (0.58%)	34 (0.38%)
Invasive breast cancer	9 (0.33%)	64 (0.36%)	193 (0.39%)	76 (0.34%)	2672 (0.49%)	30 (0.34%)
Non-invasive breast cancer	1 (0.04%)	12 (0.07%)	43 (0.09%)	13 (0.06%)	525 (0.10%)	5 (0.06%)
Ovarian cancer	1 (0.04%)	5 (0.03%)	16 (0.03%)	10 (0.04%)	276 (0.05%)	1 (0.01%)
Endometrial cancer[4]	0 (0.00%)	7 (0.04%)	15 (0.03%)	7 (0.03%)	449 (0.08%)	10 (0.11%)
Colorectal cancer	2 (0.07%)	12 (0.07%)	93 (0.19%)	16 (0.07%)	641 (0.12%)	10 (0.11%)
Other cancer[5]	14 (0.51%)	63 (0.35%)	215 (0.43%)	67 (0.30%)	3054 (0.56%)	51 (0.57%)
Total cancer	27 (0.99%)	155 (0.86%)	551 (1.10%)	183 (0.81%)	7277 (1.33%)	98 (1.10%)
Fractures						
Hip fracture	5 (0.18%)	10 (0.06%)	21 (0.04%)	10 (0.04%)	831 (0.15%)	11 (0.12%)
Vertebral fracture[6]	1 (0.15%)	0 (0.00%)	3 (0.05%)	5 (0.15%)	99 (0.26%)	0 (0.00%)
Other fracture[5, 6]	9 (1.39%)	3 (1.63%)	40 (0.65%)	36 (1.10%)	545 (1.45%)	6 (1.90%)
Total fracture[7]	14 N/A	13 N/A	61 N/A	49 N/A	1427 N/A	17 N/A
Deaths						
Cardiovascular deaths	9 (0.33%)	35 (0.19%)	164 (0.33%)	27 (0.12%)	1095 (0.20%)	23 (0.26%)
Cancer deaths	11 (0.40%)	41 (0.23%)	186 (0.37%)	53 (0.23%)	1805 (0.33%)	25 (0.28%)
Other known cause	14 (0.51%)	17 (0.09%)	86 (0.17%)	43 (0.19%)	776 (0.14%)	9 (0.10%)
Unknown cause	2 (0.07%)	5 (0.03%)	57 (0.11%)	14 (0.06%)	250 (0.05%)	6 (0.07%)
Not yet adjudicated	1 (0.04%)	7 (0.04%)	18 (0.04%)	4 (0.02%)	185 (0.03%)	1 (0.01%)
Total death	37 (1.35%)	105 (0.58%)	511 (1.02%)	141 (0.62%)	4111 (0.75%)	64 (0.72%)

[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 5.8
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: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12384	17323	41199	22770
Mean follow-up (months)	83.2	87.7	86.2	82.4	80.0
Hospitalizations					
Ever	41339 (6.36%)	3805 (4.20%)	6048 (4.86%)	18575 (6.57%)	12911 (8.50%)
Two or more	20330 (3.13%)	1532 (1.69%)	2535 (2.04%)	9068 (3.21%)	7195 (4.74%)
Other					
DVT[1]	688 (0.11%)	51 (0.06%)	83 (0.07%)	311 (0.11%)	243 (0.17%)
Pulmonary embolism	433 (0.07%)	37 (0.04%)	59 (0.05%)	190 (0.07%)	147 (0.10%)
Diabetes (treated)	4569 (0.73%)	569 (0.65%)	835 (0.69%)	2089 (0.77%)	1076 (0.74%)
Gallbladder disease[2]	5218 (0.95%)	773 (0.96%)	1052 (0.98%)	2342 (0.99%)	1051 (0.85%)
Hysterectomy	3078 (0.47%)	432 (0.48%)	578 (0.46%)	1402 (0.50%)	666 (0.44%)
Glaucoma	7643 (1.23%)	761 (0.86%)	1208 (1.00%)	3512 (1.30%)	2162 (1.55%)
Osteoporosis	19423 (3.27%)	1937 (2.22%)	3124 (2.64%)	8953 (3.47%)	5409 (4.13%)
Osteoarthritis[3]	14425 (3.81%)	1865 (2.85%)	2626 (3.22%)	6463 (4.09%)	3471 (4.75%)
Rheumatoid arthritis	4222 (0.69%)	586 (0.67%)	808 (0.68%)	1731 (0.65%)	1097 (0.77%)
Intestinal polyps	11948 (2.03%)	1396 (1.62%)	2292 (1.97%)	5567 (2.19%)	2693 (2.06%)
Lupus	920 (0.14%)	126 (0.14%)	187 (0.15%)	410 (0.15%)	197 (0.13%)
Kidney stones[3]	2085 (0.38%)	265 (0.36%)	392 (0.38%)	889 (0.37%)	539 (0.42%)
Cataracts[3]	24908 (5.39%)	1511 (2.04%)	3653 (3.64%)	12936 (6.27%)	6808 (8.35%)
Pills for hypertension	19875 (4.28%)	2282 (3.04%)	3545 (3.65%)	8728 (4.44%)	5320 (5.59%)

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)	78.1	80.6	78.5	75.3	84.2	80.5
Hospitalizations						
Ever	206 (7.52%)	738 (4.11%)	3227 (6.46%)	1191 (5.26%)	35427 (6.47%)	550 (6.20%)
Two or more	112 (4.09%)	285 (1.59%)	1593 (3.19%)	481 (2.12%)	17589 (3.21%)	270 (3.04%)
Other						
DVT[1]	3 (0.12%)	4 (0.02%)	62 (0.13%)	10 (0.05%)	601 (0.11%)	8 (0.09%)
Pulmonary embolism	1 (0.04%)	3 (0.02%)	35 (0.07%)	2 (0.01%)	388 (0.07%)	4 (0.05%)
Diabetes (treated)	45 (1.93%)	164 (0.96%)	706 (1.60%)	285 (1.35%)	3296 (0.62%)	73 (0.86%)
Gallbladder disease[2]	29 (1.34%)	71 (0.44%)	342 (0.77%)	216 (1.22%)	4490 (0.98%)	70 (0.94%)
Hysterectomy	12 (0.44%)	58 (0.32%)	201 (0.40%)	138 (0.61%)	2618 (0.48%)	51 (0.57%)
Glaucoma	43 (1.70%)	237 (1.38%)	893 (1.95%)	279 (1.30%)	6081 (1.16%)	110 (1.30%)
Osteoporosis	86 (3.43%)	589 (3.59%)	967 (2.04%)	682 (3.27%)	16795 (3.37%)	304 (3.74%)
Osteoarthritis[3]	55 (3.59%)	452 (3.58%)	1180 (4.08%)	670 (4.50%)	11848 (3.76%)	220 (4.08%)
Rheumatoid arthritis	36 (1.43%)	93 (0.54%)	619 (1.36%)	358 (1.70%)	3038 (0.58%)	78 (0.94%)
Intestinal polyps	45 (1.79%)	303 (1.89%)	949 (2.07%)	360 (1.70%)	10134 (2.05%)	157 (1.97%)
Lupus	8 (0.30%)	15 (0.08%)	92 (0.19%)	49 (0.22%)	743 (0.14%)	13 (0.15%)
Kidney stones[3]	16 (0.71%)	37 (0.24%)	239 (0.56%)	115 (0.60%)	1640 (0.36%)	38 (0.51%)
Cataracts[3]	93 (4.80%)	626 (4.96%)	1792 (4.89%)	821 (4.62%)	21215 (5.48%)	361 (5.72%)
Pills for hypertension	89 (5.09%)	541 (4.29%)	1554 (6.36%)	820 (4.84%)	16579 (4.12%)	292 (4.70%)

[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 5.9
First Reported Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of: August 31, 2004

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	758	1254
CHD death[3]	177	437
Clinical MI	638	954
Angina	1269	1265
CABG/PTCA	1164	1529
Carotid artery disease	223	275
Congestive heart failure	718	1217
Stroke	564	1113
PVD	198	252
Coronary disease[4]	2582	3237
Total cardiovascular disease	3439	4484
Cancer		
Breast cancer	1596	2031
Invasive breast cancer	1338	1706
Non-invasive breast cancer	264	335
Ovarian cancer	135	174
Endometrial cancer	212	276
Colorectal cancer	332	442
Other cancer[5]	1428	2036
Total cancer	3629	4662
Fractures		
Hip fracture[6]	294	594
Vertebral fracture[6]	35	73
Other fracture[5, 6]	275	364
Total fracture[6]	593	988
Deaths		
Cardiovascular deaths	371	982
Cancer deaths	618	1503
Deaths: other known cause	223	722
Deaths: unknown cause	58	276
Deaths: not yet adjudicated	1	215
Total death	1271	3698

[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 5.10
Counts of Participants with Self-Reported Outcomes Before and After AV-3[1]
for OS Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2004

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19161	22178
DVT[2]	227	461
Pulmonary embolism	130	303
Diabetes (treated)	1740	2829
Gallbladder disease[3]	2137	3081
Hysterectomy	1359	1719
Glaucoma	2755	4888
Osteoporosis	8703	10720
Osteoarthritis[4]	6339	8086
Rheumatoid arthritis	1724	2498
Intestinal polyps	4397	7551
Lupus	348	572
Kidney stones[4]	646	1439
Cataracts[4]	9145	15763
Pills for hypertension	8141	11734

[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.

6. Outcomes Processing

6.1 Overview

Most outcomes are initially ascertained by self-report on *Form 33 – Medical History Update*. CT participants complete this form every six months; OS participants complete this form every year. Those participants who report an outcome requiring documentation and adjudication are asked to complete a more detailed form (*Form 33D – Medical History Update - Detail*) that collects the information needed to request the associated medical records.

After these forms are completed and entered into the database, the CCs identify adjudication cases based on the *Form 33D* information. CCs then request hospital and related records. Once the cases are documented, clinic staff sends the charts having potential cardiovascular, cancer, and fracture outcomes to the local physician adjudicator for evaluation and classification. Key cardiovascular outcomes are further adjudicated by a central committee process. The investigators at UCSF (Steve Cummings, PI) subcontract to the CCC to adjudicate all hip fractures. Staff at the CCC code and adjudicate all cancers of major interest in the study (breast, colon, rectum, ovary, and endometrium) using standardized SEER guidelines. Outcomes for selected other diseases, such as diabetes, gallbladder disease, and hysterectomy, are collected as self-reports only.

6.2 Terminology

When a particular outcome, say MI, is investigated, all participants can be divided into five groups:

1. Those who have no self-report of an MI and have no locally confirmed MI.

2. Those who have a self-report of an MI and a locally confirmed MI. We refer to these participants' cases as *confirmed (with self-report).*

3. Those who have no self-report of an MI but do have a locally confirmed MI usually as a result of an investigation of a self-report of another outcome. We refer to these participants' cases as *confirmed (without self-report).*

4. Those who have a self-report of an MI but do not have a locally confirmed MI, and for whom all relevant adjudication cases are closed. We refer to these participants' self-reports as *denied.*

5. Those who have a self-report of an MI, but do not have a locally confirmed MI, while some of the relevant adjudication cases are still open. We refer to these participants' self-reports as *open.*

The *confirmed cases* are the cases of participants in categories 2 and 3; the *self-reports* are the cases of participants in categories 2, 4, and 5; the *closed self-reports* are the cases of participants in categories 2 and 4. For some analyses we divide the *denied* self-reports into three groups:

4a. The reports of the participants for which the self-reported outcome was denied, but for whom a related outcome (e.g., an angina based on an MI self-report) was found. We refer to those

participants' self-reports as *denied - related outcome found.* For the outcome tables, we consider all cardiovascular outcomes to be related, all cancer outcomes to be related, and all fracture outcomes to be related.

4b. The reports of the participants for which the self-reported outcome was denied after review of the relevant documentation. We refer to those participants' self-reports as *denied - no (related) outcome found.*

4c. The reports of the participants for which the self-report was *denied* for *administrative reasons.* Self-reports can only be denied if they satisfy one of several narrowly defined rules. Usually this means that no documentation was obtained after several attempts over a one-year period.

6.3 Central Adjudication

The following outcomes are centrally adjudicated:

- Clinical MI, angina, CHF, CABG/PTCA, self reports of MI that are denied locally: all cases that occurred before 1/1/2001, all cases for HRT participants, and 10% of the cases that occurred after 1/1/2001 for other participants are centrally adjudicated. Note that many of the self-reports of MI that are denied locally are already centrally adjudicated because another centrally adjudicated outcome, such as CHF or angina, was found.

- Stroke, PE, DVT, and self reports of stroke, PE, and DVT that are denied locally: all cases for HRT participants are centrally adjudicated.

- Primary cancers (breast, colorectal, ovary, endometrium), hip fracture, and self-reports of primary cancer and hip fracture that are denied locally: all cases are centrally adjudicated.

- Death: all cases that occurred before 1/1/2001, all cases for CT participants, and 10% of the cases that occurred after 1/1/2001 for OS participants are centrally adjudicated.

We used data from central adjudicated cases for those outcomes where 100% of all self-reports and the locally verified outcomes are centrally adjudicated in the outcomes tables in *Sections 2, 3, 4,* and *5.* In particular, those outcomes are death (and the various death classifications), breast, colorectal, endometrial, and ovarian cancer, and hip fracture for all trials, and clinical MI, stroke, PE, and DVT for the HRT trials. These central adjudicated data are supplemented with local verified outcomes for cases for which the central adjudication is not yet completed (see *Tables 6.5* and *6.6*). The main reason why we use central adjudication is that this data is thought to be of higher quality. The Morbidity and Mortality committee has mandated that all papers using outcomes that for which central adjudicated data are available on all participants should use such data.

6.4 Outcomes Data Quality

Tables 6.1 and *6.2 – Timeliness and Completeness of Local Adjudications* display the distribution of time required to locally adjudicate a self-reported outcome by month on *Form 33* for the CT and the OS, respectively. This table is based on the day on which the form was received by the clinic, which may not be the same as the day on which the form was entered in the database. Overall

97% of self-reported outcomes in the CT and 97% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 61% of the outcomes in the CT and 62% of the outcomes in the OS have been closed within 90 days of self-report and 80% (CT) and 81% (OS) within 180 days. (Note: the fact that the percentages for the OS appear better is because most of the outcomes in 1996 and earlier, when outcomes processing was considerably slower, are CT outcomes.)

Figures 6.1 and *6.2 – Timeliness per Period of Self-Report* display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed per year of self-report separately for the CT and OS. Both figures clearly show that improvements in the processing of outcomes have happened throughout the study.

Tables 6.3 and *6.4 – Agreement of Local Adjudications with Self-Reports* show condition types that the participant can indicate on *Form 33* or *Form 33D* and the fraction of time that the local adjudicator agrees with that self-report. Because of the complications of the adjudication process, it is not straightforward to define an appropriate estimate of the accuracy of individual self-reports. For example, for most outcome types, second occurrences do not need to be adjudicated, but if the participant reports a second occurrence before the first is confirmed, an adjudication case will be opened. This case will be closed without a locally confirmed outcome when the first self-report is confirmed. To circumvent this and similar problems, the unit in *Tables 6.3* and *6.4* is defined to be a *participant* rather than an outcome event. For some participants whose self-report is denied, related outcomes may be found. We also note that on *Form 33* and *Form 33D* participants report a "stroke or transient ischemic attack (TIA)," while for monitoring purposes only the outcome "stroke" is used. Thus, the number of confirmed cases in *Tables 6.3* and *6.4,* which include TIA, is substantially larger than that in some of the outcomes tables in other sections of this report.

A self-reported outcome may be denied for the following reasons: (i) the outcome did take place, but could not be verified because insufficient evidence was available to the WHI adjudicator; (ii) the outcome did not take place, but a related outcome (which may or may not be of interest to WHI) occurred; (iii) the outcome took place before enrollment in WHI; and (iv) the current self-report was a duplicate report of a previous self-report.

The accuracy of self-reports varies considerably by outcome. For many outcomes the agreement rates for the CT are a few percentage points higher than for the OS. The accuracy of cancer and fracture self-reports may be higher than that for cardiovascular disease because more cardiovascular self-reports result in a related outcome. If those related outcomes are included with the confirmed self-reports, cardiovascular outcomes have a 76% agreement rate between self-reports and locally confirmed outcomes (84% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 86% (91% for the primary cancers), and fracture outcomes have an agreement rate of 81% for the CT and OS combined.

Note that the accuracy of self-reports for *other fractures* (*other cancers*) reflects the percentage of people who reported an *other fracture* (*other cancer*) for whom any of the fractures (cancers) in the other category was found, even if the participant indicated the wrong skeletal site (cancer site).

Tables 6.5 and *6.6 – Agreement of Central Adjudications with Local Adjudications* show that there is good agreement between local and central adjudications for all outcomes. Often angina and

congestive heart failure occur in conjunction with an MI. Disagreement on angina or CHF, when there is agreement about the MI is not considered very serious. Some self-reports are locally adjudicated as one type of outcome, while they are centrally adjudicated as another outcome. Data regarding such cross-classification are not shown.

We note that, thanks to the effort of the central adjudicators and the CCC cancer coders the fraction of outcomes that were called forward for central adjudication that have been centrally adjudicated has increased considerably. Now about 97% of the cardiovascular outcomes have been centrally adjudicated and about 97% of the cancer outcomes have been centrally adjudicated.

For some of the outcomes there appears to be a large difference in agreement rate between the CT and the OS. This is an artifact. For CT participants disagreements between local and central adjudicators are further investigated. As a result of that a number of the central adjudications involved are subsequently recoded to agree with the local adjudication. The result of this second central adjudication is an apparent higher agreement rate between local and central adjudication.

Tables 6.5 and *6.6* show how many outcomes were identified by local adjudicators, but denied centrally. *Tables 6.7* and *6.8 – Source of Outcomes Identified by Central Adjudications* show outcomes that were identified by the central adjudicators, but not by the local adjudicators. Approximately 14% (CT)-20% (OS) of the MIs that were identified by central adjudicators were not found by local adjudicators. Most of these MIs were identified on cases that were called forward for "related" events, such as angina, CHF, and CABG/PTCA. Most of the cases of endometrial cancer that were identified based on a locally confirmed other outcome, were identified because of a locally confirmed case of cancer of the uterus; most of the cases of hip fracture that were identified based on a locally confirmed other outcome, were identified because of a locally confirmed case of fractures of the upper leg; and most of the cases of stroke that were identified because of a locally confirmed other outcome were identified because of a locally confirmed case of TIA. Cancer of the uterus, upper leg fractures, and TIA are reviewed centrally specifically for this reason.

Tables 6.9 and *6.10 – Agreement of Locally and Centrally Adjudicated Cause of Death.* We note that in general there is good agreement between the local and central assessment of the cause of death. For most causes the agreement is about 90%. Notable exceptions are the "other" and "unknown" categories of all types: central adjudication seems to be able to determine the cause of death more frequently than local adjudication. In this table artherosclerotic death includes both definite and possible CHD death, as early on in the study these two categories were a combined cause of death.

6.5 Outcomes Data Summary

Table 6.11 – Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for CT Participants contains the number of verified outcomes for the major WHI outcomes categories. Since about 3% of the self-reports still need to be adjudicated, the numbers in these tables give a lower bound on the number of outcomes that currently have occurred.

Currently, for the CT we observe approximately 105% of the invasive breast cancer, 75% of the colorectal cancer and 40% of the hip fracture, and 65% of the CHD cases of what was assumed for

the power calculations. Note that DVT and PE, which are only adjudicated for HRT participants, are not included in this table.

Table 6.12 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants contains counts of the number of self-reports for some of the WHI outcomes that are not adjudicated. As for many of the confirmed outcomes, the participants over-report (see *Tables 6.3* and *6.4)*. The numbers in these tables should be seen as upper bounds to the number of outcomes that have currently occurred. Not surprisingly, for many of the outcomes, the rates differ considerably by minority status and by age at baseline.

Similar tables for the HRT, DM, CaD, and the OS components are in the chapters about these components. Currently, the rate of fractures in the OS and CT is very similar. The rate of cardiovascular events is slightly higher and the rate of cancers is slightly lower in the CT than in the OS.

Table 6.13 – Locally Verified Other Cancers and *Table 6.14 – Locally Verified Other Fractures* split out the other cancers and other fractures for the locally verified outcomes by event type and by study. Since for OS participants other fractures are only locally verified at the three bone mineral density clinics, we provide the number of self-reported fractures for these participants. In the CT, approximately 80% of self-reported fractures are confirmed, though the location of the fracture is misreported in approximately 25-30% of cases.

6.6 Vital Status

Table 6.15 – Cause of Death (Annualized Percentages) presents the cause of death for CT and OS participants. To reduce the time that it takes before cause of death information is available on WHI participants who have passed away, clinics are encouraged to report a "temporary" cause of death for those participants for whom some, but not all, documentation related to the death has been collected. The goal is that a temporary cause is entered in the database as soon as possible, preferably within eight weeks. The cause based on the complete documentation should be entered as soon as all documents are collected. Cases for which reported unsuccessful requests for documentation have been made over a one-year period can be closed out with incomplete documentation.

As of the August 31, 2004 database, there were 3,141 deaths in the CT and 4,969 in the OS.

Table 6.16 – Lost-to-Follow-up and Vital Status by Clinic: CT Participants displays information about the follow-up and vital status by clinic. Since 1999, clinics are regularly provided with a list of participants for whom there is no *Form 33* within the last 18 months and who are not known to be deceased. Clinics are asked to make every effort to try to locate these participants and to encourage further study participation. Some participants had information in the database that indicated that she never wanted to be contacted again by WHI. If this were the case, clinics were to verify whether this participation status was correct. If indeed a participant has expressed this opinion, she is not to be contacted again. For these participants, we will still be able to obtain limited vital status information from National Death Index (NDI) searches.

About 4.6% of the CT participants are deceased; we do not know the vital status of about 1.4% of the CT participants, and 2.7% of the participants request no further follow-up. In addition, we lack

recent outcomes information on an additional 14 participants. The study design assumed that 3% per year of the participants would be lost-to-follow-up or death. As the average follow-up of participants is now 7.5 years, we note that the follow-up is much better than what was assumed in the design.

There is considerable clinic-to-clinic variation in the vital status data. The percentage of participants who are lost-to-follow-up ranges from 0.1 to 8.2% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.2 to 8.6%.

Table 6.17 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.16* but about the OS. For OS, the participants are considered lost-to-follow-up if we have not received a *Form 33* within the last 24 months. Approximately 3.7% of the OS participants are either lost-to-follow-up or have stopped follow-up.

Table 6.1
Timeliness and Completeness of Local Adjudications – CT Participants[1]

Data as of: August 31, 2004

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
		≤ 90		≤ 180		Closed		Open	
Date of Form 33 encounter	N	N	%	N	%	N	%	N	%
<= June 30 1996	3995	269	7%	779	19%	3992	100%	3	<1%
1996 July-December	1388	307	22%	714	51%	1388	100%	0	0%
1997 January-June	2188	764	35%	1327	61%	2188	100%	0	0%
1997 July-December	2556	982	38%	1520	59%	2555	100%	1	<1%
1998 January-June	3579	1661	46%	2771	77%	3578	100%	1	<1%
1998 July-December	4163	2355	57%	3325	80%	4162	100%	1	<1%
1999 January-June	4607	2823	61%	3795	82%	4605	100%	2	<1%
1999 July-December	4484	2867	64%	3689	82%	4483	100%	1	<1%
2000 January-June	4716	3096	66%	3948	84%	4711	100%	5	<1%
2000 July-December	4411	2977	67%	3801	86%	4407	100%	4	<1%
2001 January- June	5213	3639	70%	4531	87%	5206	100%	7	<1%
2001 July-December	4767	3225	68%	4278	90%	4763	100%	4	<1%
2002 January-June	5282	3951	75%	4756	90%	5266	100%	16	<1%
2002 July-December	5277	3976	75%	4831	92%	5239	99%	38	1%
2003 January-June	5426	4028	74%	4916	91%	5368	99%	58	1%
2003 July	937	667	71%	832	89%	928	99%	9	1%
2003 August	916	667	73%	823	90%	900	98%	16	2%
2003 September	851	616	72%	763	90%	825	97%	26	3%
2003 October	1007	735	73%	917	91%	964	96%	43	4%
2003 November	755	538	71%	693	92%	718	95%	37	5%
2003 December	820	595	73%	745	91%	777	95%	43	5%
2004 January	970	769	79%	900	93%	918	95%	52	5%
2004 February	838	611	73%	759	91%	773	92%	65	8%
2004 March	1389	1108	80%	1279	92%	1280	92%	109	8%
2004 April	958	748	78%	852	89%	852	89%	106	11%
2004 May	860	691	80%	744	87%	744	87%	116	13%
2004 June	911	706	77%	706	77%	706	77%	205	23%
2004 July	818	463	57%	463	57%	463	57%	355	43%
2004 August	682	120	18%	120	18%	120	18%	562	82%
Total	74764	45954	61%	59577	80%	72879	97%	1885	3%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Table 6.2
Timeliness and Completeness of Local Adjudications – OS Participants[1]

Data as of: August 31, 2004

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
		≤ 90		≤ 180		Closed		Open	
Date of Form 33 encounter	N	N	%	N	%	N	%	N	%
<= June 30 1996	238	81	34%	124	52%	238	100%	0	0%
1996 July-December	1313	305	23%	698	53%	1312	100%	1	<1%
1997 January-June	2157	845	39%	1401	65%	2157	100%	0	0%
1997 July-December	2299	710	31%	1355	59%	2299	100%	0	0%
1998 January-June	2836	1268	45%	2036	72%	2835	100%	1	<1%
1998 July-December	3808	2002	53%	2898	76%	3807	100%	1	<1%
1999 January-June	4754	2839	60%	3920	82%	4752	100%	2	<1%
1999 July-December	4226	2519	60%	3405	81%	4224	100%	2	<1%
2000 January-June	5931	3774	64%	4884	82%	5927	100%	4	<1%
2000 July-December	4317	2819	65%	3616	84%	4309	100%	8	<1%
2001 January- June	5380	3560	66%	4580	85%	5376	100%	4	<1%
2001 July-December	4713	3118	66%	4120	87%	4703	100%	10	<1%
2002 January - June	5767	4100	71%	5125	89%	5748	100%	19	<1%
2002 July-December	4926	3501	71%	4319	88%	4882	99%	44	1%
2003 January-June	5807	4171	72%	5197	89%	5737	99%	70	1%
2003 July	1125	787	70%	986	88%	1103	98%	22	2%
2003 August	975	682	70%	840	86%	940	96%	35	4%
2003 September	960	698	73%	850	89%	922	96%	38	4%
2003 October	949	627	66%	835	88%	888	94%	61	6%
2003 November	612	433	71%	552	90%	586	96%	26	4%
2003 December	709	526	74%	637	90%	660	93%	49	7%
2004 January	889	670	75%	810	91%	834	94%	55	6%
2004 February	913	701	77%	826	90%	841	92%	72	8%
2004 March	957	719	75%	859	90%	859	90%	98	10%
2004 April	845	669	79%	778	92%	778	92%	67	8%
2004 May	792	599	76%	650	82%	650	82%	142	18%
2004 June	980	722	74%	722	74%	722	74%	258	26%
2004 July	1105	540	49%	540	49%	540	49%	565	51%
2004 August	963	150	16%	150	16%	150	16%	813	84%
Total	71246	44135	62%	57713	81%	68779	97%	2467	3%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Figure 6.1 Clinical Trial Timeliness per Period of Self-Report

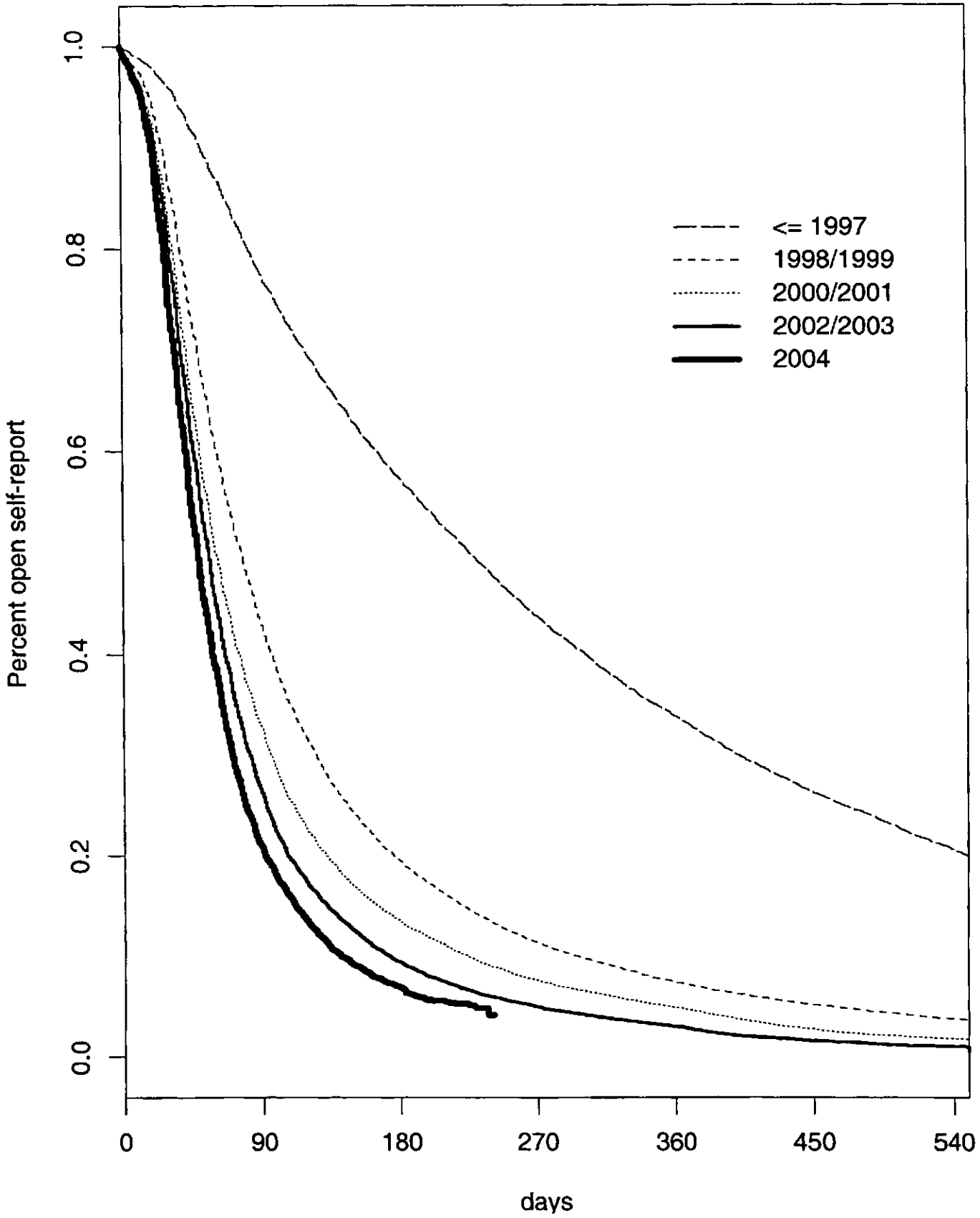


Figure 6.2 Observational Study Timeliness per Period of Self-Report

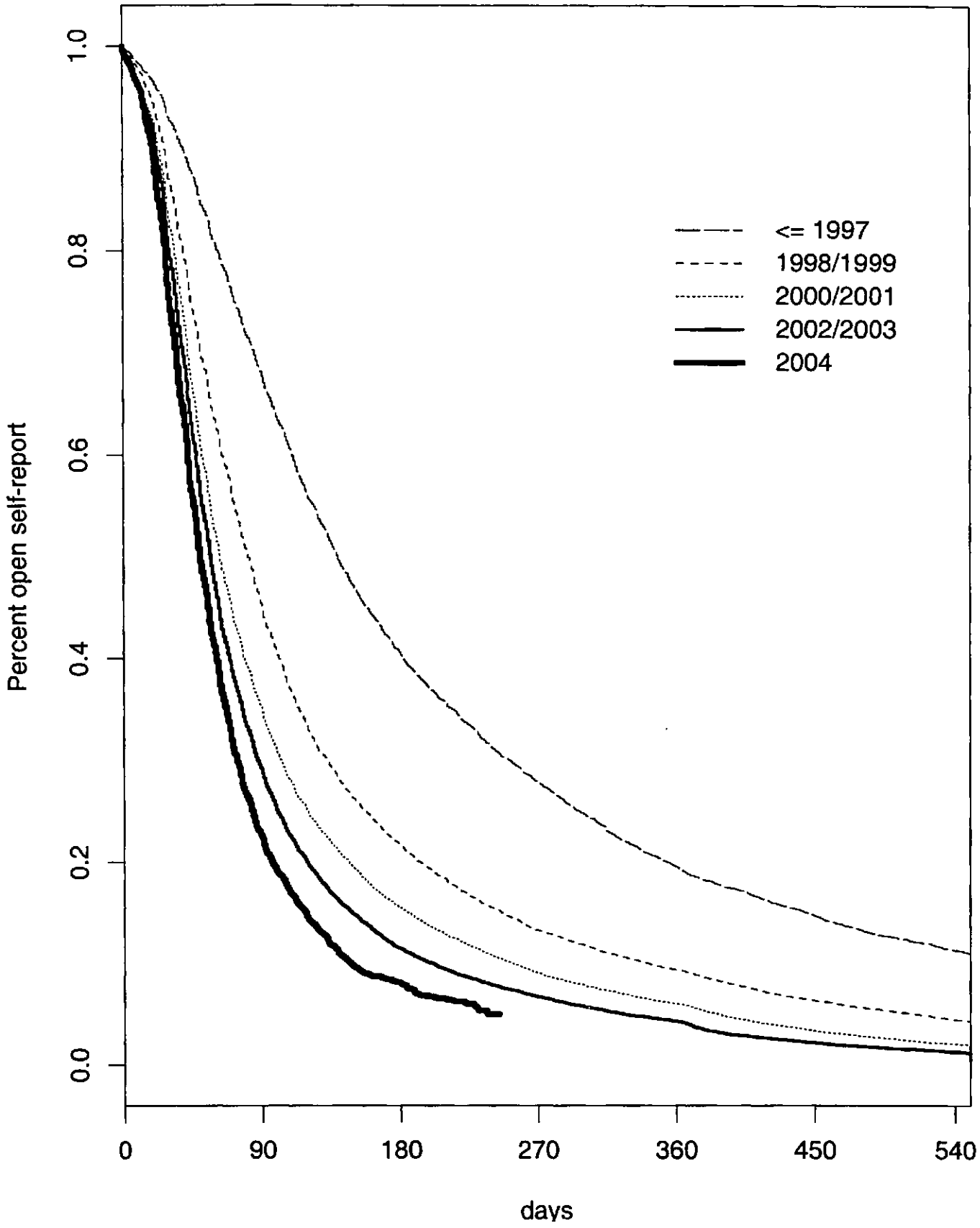


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: August 31, 2004

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	(%)[1]	N	(%)[1]	N	(%)[1]	N	(%)[1]
Cardiovascular											
Clinical MI	1311	1262	96%	899	(71%)	197	(16%)	151	(12%)	15	(1%)
Angina[2]	2483	2384	96%	1137	(48%)	107	(4%)	1100	(46%)	40	(2%)
Congestive heart failure	924	882	95%	653	(74%)	54	(6%)	165	(19%)	10	(1%)
CABG/PTCA	2936	2832	96%	2241	(79%)	238	(8%)	323	(11%)	30	(1%)
Carotid artery disease[3]	393	380	97%	324	(85%)	28	(7%)	24	(6%)	4	(1%)
Stroke/TIA[4]	2220	2122	96%	1623	(76%)	96	(5%)	369	(17%)	34	(2%)
PVD	278	268	96%	157	(59%)	33	(12%)	73	(27%)	5	(2%)
DVT[5]	423	409	97%	280	(68%)	54	(13%)	67	(16%)	8	(2%)
Pulmonary embolism[5]	214	209	98%	180	(86%)	11	(5%)	17	(8%)	1	(<1%)
Cancers											
Breast cancer	2639	2545	96%	2464	(97%)	1	(<1%)	67	(3%)	13	(1%)
Ovarian cancer	252	242	96%	176	(73%)	47	(19%)	14	(6%)	5	(2%)
Endometrial cancer	319	307	96%	241	(79%)	40	(13%)	23	(7%)	3	(1%)
Colorectal cancer	721	698	97%	603	(86%)	47	(7%)	46	(7%)	2	(<1%)
Other cancer[6]	3024	2901	96%	2197	(76%)	152	(5%)	500	(17%)	52	(2%)
Fractures											
Hip fracture	724	693	96%	562	(81%)	55	(8%)	67	(10%)	9	(1%)
Vertebral fracture	1082	1045	97%	592	(57%)	45	(4%)	376	(36%)	32	(3%)
Other fracture	8389	8178	97%	6735	(82%)	93	(1%)	1149	(14%)	201	(2%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 295 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 485 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] HRT participants only.
[6] Excludes non-melanoma skin cancer.

Table 6.4
Agreement of the Local Adjudications with Self-Reports — OS Participants

Data as of: August 31, 2004

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	(%)[1]	N	(%)[1]	N	(%)[1]	N	(%)[1]
Cardiovascular											
Clinical MI	1297	1232	95%	828	(67%)	207	(17%)	169	(14%)	28	(2%)
Angina[2]	2913	2780	95%	1237	(44%)	178	(6%)	1299	(47%)	66	(2%)
Congestive heart failure	1130	1080	96%	813	(75%)	63	(6%)	183	(17%)	21	(2%)
CABG/PTCA	3298	3133	95%	2439	(78%)	285	(9%)	356	(11%)	53	(2%)
Carotid artery disease[3]	459	440	96%	367	(83%)	34	(8%)	33	(8%)	6	(1%)
Stroke/TIA[4]	2707	2571	95%	1893	(74%)	117	(5%)	487	(19%)	74	(3%)
PVD	383	368	96%	222	(60%)	43	(12%)	96	(26%)	7	(2%)
Cancers											
Breast cancer	3810	3643	96%	3355	(92%)	19	(1%)	215	(6%)	54	(1%)
Ovarian cancer	349	330	95%	234	(71%)	55	(17%)	39	(12%)	2	(1%)
Endometrial cancer	419	405	97%	309	(76%)	61	(15%)	27	(7%)	8	(2%)
Colorectal	841	801	95%	669	(84%)	50	(6%)	69	(9%)	13	(2%)
Other cancer[5]	4108	3879	94%	2712	(70%)	267	(7%)	795	(20%)	105	(3%)
Fractures											
Hip fracture	976	922	94%	732	(79%)	10	(1%)	157	(17%)	23	(2%)
Vertebral fracture	139	136	98%	87	(64%)	6	(4%)	38	(28%)	5	(4%)
Other fracture	898	883	98%	660	(75%)	19	(2%)	168	(19%)	36	(4%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 299 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, 9 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 594 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] Excludes non-melanoma skin cancer.

Table 6.5
Agreement of Central Adjudications with Local Adjudications — CT Participants

Data as of: August 31, 2004

	Locally confirmed N	Called forward for central adjudication N	% [1]	Centrally adjudicated N	% [2]	In agreement N	% [3]
Cardiovascular							
Clinical MI	1474	1050	71%	1019	97%	915	90%
Angina [4]	2210	1639	74%	1599	98%	1238	77%
Congestive heart failure	1492	1041	70%	992	95%	783	79%
CABG/PTCA	2415	1727	72%	1678	97%	1633	97%
DVT [5]	369	369	100%	363	98%	350	96%
Pulmonary embolism [5]	244	244	100%	236	97%	230	97%
Stroke [6]	1340	633	47%	587	93%	532	91%
Cancers							
Breast cancer	2496	2496	100%	2449	98%	2443	>99%
Invasive	1969	1969	100%	1924	98%	1884	98%
Non-invasive	527	527	100%	525	>99%	455	87%
Ovarian cancer	215	215	100%	202	94%	160	79%
Endometrial cancer	306	306	100%	295	96%	284	96%
Colorectal cancer	665	665	100%	638	96%	615	96%
Fractures							
Hip fracture	677	677	100%	632	93%	595	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 6.6
Agreement of Central Adjudications with Local Adjudications — OS Participants

Data as of: August 31, 2004

	Locally confirmed N	Called forward for central adjudication N	%[1]	Centrally adjudicated N	%[2]	In agreement N	%[3]
Cardiovascular							
Clinical MI	1592	751	47%	731	97%	600	82%
Angina[4]	2534	1420	56%	1404	99%	1106	79%
Congestive heart failure	1935	868	45%	835	96%	669	80%
CABG/PTCA	2693	1344	50%	1321	98%	1265	96%
Cancers							
Breast cancer	3459	3459	100%	3356	97%	3295	98%
Invasive	2827	2827	100%	2743	97%	2627	96%
Non-Invasive	632	632	100%	613	97%	499	81%
Ovarian cancer	288	288	100%	274	95%	229	84%
Endometrial cancer	439	439	100%	423	96%	398	94%
Colorectal cancer	749	749	100%	725	97%	688	95%
Fractures							
Hip fracture	912	912	100%	835	92%	798	96%

[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 6.7
Source of Outcomes Identified by Central Adjudications – CT Participants

Data as of: August 31, 2004

	Centrally confirmed	Reason for central investigation						Denied self-reports reviewed by CCC
		Locally confirmed same outcome		Locally confirmed other outcome		Self-report but no outcome found		
	N	N	%	N	%	N	%	N
Cardiovascular								
Clinical MI	1039	895	86%	136	13%	8	1%	121
Angina	1555	1222	79%	312	20%	21	1%	N/A
Congestive heart failure	905	762	84%	136	15%	7	1%	N/A
CABG/PTCA	1680	1614	96%	61	4%	5	<1%	N/A
DVT	363	347	96%	8	2%	8	2%	90
Pulmonary embolism	241	230	95%	5	2%	6	2%	18
Stroke	581	524	90%	39	7%	18	3%	329
Cancers								
Breast cancer	2459	2448	100%	3	<1%	8	<1%	94
Ovarian cancer	171	160	94%	8	5%	3	2%	28
Endometrial cancer	312	283	91%	28	9%	1	<1%	30
Colorectal cancer	627	614	98%	5	1%	8	1%	75
Fractures								
Hip fracture	615	595	97%	11	2%	9	1%	87

Table 6.8
Source of Outcomes Identified by Central Adjudications – OS Participants

Data as of: August 31, 2004

	Centrally confirmed N	Reason for central investigation						Denied self-reports reviewed by CCC N
		Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	
Cardiovascular								
Clinical MI	735	587	80%	141	19%	7	1%	81
Angina	1376	1112	81%	251	18%	13	1%	N/A
Congestive heart failure	755	659	87%	91	12%	5	1%	N/A
CABG/PTCA	1307	1246	95%	53	4%	8	1%	N/A
Cancers								
Breast cancer	3326	3299	99%	4	<1%	23	1%	183
Ovarian cancer	242	229	95%	10	4%	3	1%	51
Endometrial cancer	455	397	87%	52	11%	6	1%	41
Colorectal cancer	699	688	98%	4	1%	7	1%	107
Fractures								
Hip fracture	809	798	99%	2	<1%	9	1%	117

Table 6.9
Agreement of Locally and Centrally Adjudicated Cause of Death for All CT Participants

Data as of: August 31, 2004

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	2816	2618	93%	2298	(88%)	163	(6%)	157	(6%)
Cardiovascular									
Atherosclerotic cardiac[3]	437	402	92%	370	(92%)	17	(4%)	15	(4%)
Cerebrovascular	206	190	92%	178	(94%)	5	(3%)	7	(4%)
Pulmonary embolism	20	19	95%	17	(89%)	0	(0%)	2	(11%)
Other cardiovascular	160	142	89%	83	(58%)	40	(28%)	19	(13%)
Unknown cardiovascular	35	33	94%	5	(15%)	21	(64%)	7	(21%)
Total cardiovascular deaths	858	786	92%	653	(83%)	83	(11%)	50	(6%)
Cancer									
Breast cancer	70	66	94%	65	(98%)	1	(2%)	0	(0%)
Ovarian cancer	102	96	94%	86	(90%)	9	(9%)	1	(1%)
Endometrial cancer	14	14	100%	13	(93%)	1	(7%)	0	(0%)
Colorectal cancer	130	125	96%	123	(98%)	1	(1%)	1	(1%)
Other cancer	940	890	95%	857	(96%)	26	(3%)	7	(1%)
Unknown cancer site	55	52	95%	38	(73%)	13	(25%)	1	(2%)
Total cancer deaths	1311	1243	95%	1182	(95%)	51	(4%)	10	(1%)
Accident/injury									
Homicide	6	6	100%	5	(83%)	1	(17%)	0	(0%)
Accident	69	65	94%	60	(92%)	4	(6%)	1	(2%)
Suicide	11	11	100%	11	(100%)	0	(0%)	0	(0%)
Other injury	7	7	100%	1	(14%)	4	(57%)	2	(29%)
Total accidental deaths	93	89	96%	77	(87%)	9	(10%)	3	(3%)
Other									
Other known cause	470	422	90%	348	(82%)	8	(2%)	66	(16%)
Unknown cause	84	78	93%	38	(49%)	12	(15%)	28	(36%)
Total deaths - other causes	554	500	90%	386	(77%)	20	(4%)	94	(19%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.10
Agreement of Locally and Centrally Adjudicated Cause of Death for All OS Participants

Data as of: August 31, 2004

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	4393	2226	51%	1793	(81%)	187	(8%)	246	(11%)
Cardiovascular									
Atherosclerotic cardiac[3]	592	305	52%	242	(79%)	22	(7%)	41	(13%)
Cerebrovascular	346	147	42%	126	(86%)	5	(3%)	16	(11%)
Pulmonary embolism	35	14	40%	10	(71%)	0	(0%)	4	(29%)
Other cardiovascular	264	148	56%	64	(43%)	59	(40%)	25	(17%)
Unknown cardiovascular	57	28	49%	1	(4%)	19	(68%)	8	(29%)
Total cardiovascular deaths	1294	642	50%	443	(69%)	105	(16%)	94	(15%)
Cancer									
Breast cancer	298	146	49%	137	(94%)	5	(3%)	4	(3%)
Ovarian cancer	147	72	49%	66	(92%)	4	(6%)	2	(3%)
Endometrial cancer	40	19	48%	13	(68%)	6	(32%)	0	(0%)
Colorectal cancer	172	91	53%	84	(92%)	3	(3%)	4	(4%)
Other cancer	1287	695	54%	644	(93%)	23	(3%)	28	(4%)
Unknown cancer site	102	64	63%	45	(70%)	17	(27%)	2	(3%)
Total cancer deaths	2046	1087	53%	989	(91%)	58	(5%)	40	(4%)
Accident/injury									
Homicide	9	6	67%	5	(83%)	1	(17%)	0	(0%)
Accident	93	54	58%	46	(85%)	2	(4%)	6	(11%)
Suicide	21	17	81%	14	(82%)	1	(6%)	2	(12%)
Other injury	10	4	40%	2	(50%)	1	(25%)	1	(25%)
Total accidental deaths	133	81	61%	67	(83%)	5	(6%)	9	(11%)
Other									
Other known cause	762	324	43%	253	(78%)	6	(2%)	65	(20%)
Unknown cause	158	92	58%	41	(45%)	13	(14%)	38	(41%)
Total deaths - other causes	920	416	45%	294	(71%)	19	(5%)	103	(25%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.11
Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: August 31, 2004

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14662		31394		12888	
Mean follow-up (months)	89.5		96.1		92.3		87.8		85.6	
Cardiovascular										
CHD[1]	1916	(0.38%)	106	(0.14%)	214	(0.19%)	871	(0.38%)	725	(0.79%)
CHD death[2]	506	(0.10%)	25	(0.03%)	38	(0.03%)	213	(0.09%)	230	(0.25%)
Total MI[3]	1567	(0.31%)	85	(0.12%)	183	(0.16%)	719	(0.31%)	580	(0.63%)
Clinical MI	1489	(0.29%)	79	(0.11%)	176	(0.16%)	682	(0.30%)	552	(0.60%)
Evolving Q-wave MI[4]	82	(0.02%)	7	(0.01%)	7	(0.01%)	40	(0.02%)	28	(0.03%)
Possible evolving Q-wave MI[4]	371	(0.07%)	37	(0.05%)	52	(0.05%)	162	(0.07%)	120	(0.13%)
Angina	2210	(0.44%)	114	(0.16%)	301	(0.27%)	1102	(0.48%)	693	(0.75%)
CABG/PTCA	2415	(0.48%)	115	(0.16%)	303	(0.27%)	1217	(0.53%)	780	(0.85%)
Carotid artery disease	408	(0.08%)	11	(0.01%)	45	(0.04%)	210	(0.09%)	142	(0.15%)
Congestive heart failure	1492	(0.29%)	69	(0.09%)	151	(0.13%)	636	(0.28%)	636	(0.69%)
Stroke	1392	(0.27%)	52	(0.07%)	137	(0.12%)	626	(0.27%)	577	(0.63%)
PVD	363	(0.07%)	16	(0.02%)	42	(0.04%)	173	(0.08%)	132	(0.14%)
CHD[1]/Possible evolving Q-wave MI	2266	(0.45%)	142	(0.19%)	265	(0.24%)	1024	(0.45%)	835	(0.91%)
Coronary disease[5]	5301	(1.04%)	294	(0.40%)	663	(0.59%)	2519	(1.10%)	1825	(1.98%)
Total cardiovascular disease	6910	(1.36%)	353	(0.48%)	838	(0.74%)	3284	(1.43%)	2435	(2.65%)
Cancer										
Breast cancer	2512	(0.49%)	278	(0.38%)	532	(0.47%)	1197	(0.52%)	505	(0.55%)
Invasive breast cancer	2017	(0.40%)	207	(0.28%)	437	(0.39%)	960	(0.42%)	413	(0.45%)
Non-invasive breast cancer	514	(0.10%)	74	(0.10%)	98	(0.09%)	245	(0.11%)	97	(0.11%)
Ovary cancer	213	(0.04%)	20	(0.03%)	44	(0.04%)	101	(0.04%)	48	(0.05%)
Endometrial cancer[6]	324	(0.06%)	32	(0.04%)	72	(0.06%)	159	(0.07%)	61	(0.07%)
Colorectal cancer	661	(0.13%)	38	(0.05%)	91	(0.08%)	335	(0.15%)	197	(0.21%)
Other cancer[7]	2617	(0.52%)	206	(0.28%)	424	(0.38%)	1280	(0.56%)	707	(0.77%)
Total cancer	6081	(1.20%)	555	(0.75%)	1122	(1.00%)	2944	(1.28%)	1460	(1.59%)
Fractures										
Hip fracture	660	(0.13%)	13	(0.02%)	40	(0.04%)	230	(0.10%)	377	(0.41%)
Vertebral fracture	718	(0.14%)	25	(0.03%)	76	(0.07%)	300	(0.13%)	317	(0.34%)
Other fracture[7]	7027	(1.38%)	828	(1.13%)	1303	(1.16%)	3288	(1.43%)	1608	(1.75%)
Total fracture	8033	(1.58%)	861	(1.17%)	1398	(1.24%)	3672	(1.60%)	2102	(2.29%)
Deaths										
Cardiovascular deaths	914	(0.18%)	37	(0.05%)	63	(0.06%)	375	(0.16%)	439	(0.48%)
Cancer deaths	1377	(0.27%)	82	(0.11%)	194	(0.17%)	658	(0.29%)	443	(0.48%)
Other known cause	565	(0.11%)	30	(0.04%)	60	(0.05%)	240	(0.10%)	235	(0.26%)
Unknown cause	166	(0.03%)	6	(0.01%)	19	(0.02%)	68	(0.03%)	73	(0.08%)
Not yet adjudicated	119	(0.02%)	5	(0.01%)	9	(0.01%)	60	(0.03%)	45	(0.05%)
Total death	3141	(0.62%)	160	(0.22%)	345	(0.31%)	1401	(0.61%)	1235	(1.34%)

[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 6.11 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: August 31, 2004

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)	86.6	86.1	88.1	85.1	90.0	85.3
Cardiovascular						
CHD[1]	8 (0.38%)	23 (0.21%)	197 (0.38%)	42 (0.21%)	1617 (0.39%)	29 (0.43%)
CHD death[2]	2 (0.09%)	8 (0.07%)	84 (0.16%)	9 (0.04%)	393 (0.09%)	10 (0.15%)
Total MI[3]	7 (0.33%)	20 (0.18%)	141 (0.28%)	35 (0.17%)	1341 (0.32%)	23 (0.34%)
Clinical MI	7 (0.33%)	19 (0.17%)	136 (0.27%)	33 (0.16%)	1273 (0.31%)	21 (0.31%)
Evolving Q-wave MI[4]	0 (0.00%)	2 (0.02%)	5 (0.01%)	2 (0.01%)	71 (0.02%)	2 (0.03%)
Possible evolving Q-wave MI[4]	3 (0.14%)	9 (0.08%)	39 (0.08%)	13 (0.06%)	303 (0.07%)	4 (0.06%)
Angina	8 (0.38%)	28 (0.26%)	267 (0.52%)	70 (0.34%)	1809 (0.43%)	28 (0.42%)
CABG/PTCA	9 (0.43%)	21 (0.19%)	221 (0.43%)	61 (0.30%)	2078 (0.50%)	25 (0.37%)
Carotid artery disease	3 (0.14%)	2 (0.02%)	26 (0.05%)	3 (0.01%)	369 (0.09%)	5 (0.07%)
Congestive heart failure	4 (0.19%)	12 (0.11%)	214 (0.42%)	41 (0.20%)	1201 (0.29%)	20 (0.30%)
Stroke	7 (0.33%)	30 (0.28%)	183 (0.36%)	36 (0.18%)	1116 (0.27%)	20 (0.30%)
PVD	4 (0.19%)	3 (0.03%)	53 (0.10%)	4 (0.02%)	296 (0.07%)	3 (0.04%)
CHD[1]/Possible evolving Q-wave MI	11 (0.52%)	31 (0.28%)	234 (0.46%)	54 (0.26%)	1903 (0.46%)	33 (0.49%)
Coronary disease[5]	19 (0.90%)	62 (0.57%)	626 (1.22%)	148 (0.73%)	4376 (1.05%)	70 (1.05%)
Total cardiovascular disease	29 (1.38%)	92 (0.84%)	817 (1.59%)	185 (0.91%)	5697 (1.37%)	90 (1.35%)
Cancer						
Breast cancer	6 (0.28%)	59 (0.54%)	203 (0.40%)	64 (0.31%)	2153 (0.52%)	27 (0.40%)
Invasive breast cancer	6 (0.28%)	45 (0.41%)	155 (0.30%)	53 (0.26%)	1735 (0.42%)	23 (0.34%)
Non-invasive breast cancer	0 (0.00%)	14 (0.13%)	49 (0.10%)	11 (0.05%)	436 (0.10%)	4 (0.06%)
Ovary cancer	1 (0.05%)	4 (0.04%)	14 (0.03%)	5 (0.02%)	185 (0.04%)	4 (0.06%)
Endometrial cancer[6]	1 (0.05%)	3 (0.03%)	19 (0.04%)	9 (0.04%)	287 (0.07%)	5 (0.07%)
Colorectal cancer	5 (0.24%)	12 (0.11%)	66 (0.13%)	22 (0.11%)	545 (0.13%)	11 (0.16%)
Other cancer[7]	9 (0.43%)	41 (0.38%)	193 (0.38%)	66 (0.32%)	2279 (0.55%)	29 (0.43%)
Total cancer	22 (1.04%)	115 (1.06%)	475 (0.93%)	157 (0.77%)	5243 (1.26%)	69 (1.03%)
Fractures						
Hip fracture	1 (0.05%)	5 (0.05%)	18 (0.04%)	9 (0.04%)	622 (0.15%)	5 (0.07%)
Vertebral fracture	2 (0.09%)	14 (0.13%)	11 (0.02%)	11 (0.05%)	669 (0.16%)	11 (0.16%)
Other fracture[7]	25 (1.19%)	105 (0.96%)	387 (0.76%)	188 (0.92%)	6236 (1.50%)	86 (1.29%)
Total fracture	27 (1.28%)	122 (1.12%)	411 (0.80%)	201 (0.99%)	7175 (1.72%)	97 (1.45%)
Deaths						
Cardiovascular deaths	6 (0.28%)	17 (0.16%)	140 (0.27%)	14 (0.07%)	726 (0.17%)	11 (0.16%)
Cancer deaths	8 (0.38%)	21 (0.19%)	121 (0.24%)	39 (0.19%)	1170 (0.28%)	18 (0.27%)
Other known cause	7 (0.33%)	6 (0.06%)	62 (0.12%)	10 (0.05%)	473 (0.11%)	7 (0.10%)
Unknown cause	1 (0.05%)	2 (0.02%)	21 (0.04%)	7 (0.03%)	133 (0.03%)	2 (0.03%)
Not yet adjudicated	0 (0.00%)	2 (0.02%)	17 (0.03%)	3 (0.01%)	93 (0.02%)	4 (0.06%)
Total death	22 (1.04%)	48 (0.44%)	361 (0.70%)	73 (0.36%)	2595 (0.62%)	42 (0.63%)

[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 6.12
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: August 31, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14662	31394	12888
Mean follow-up (months)	89.5	96.1	92.3	87.8	85.6
Hospitalizations					
Ever	32872 (6.47%)	3261 (4.43%)	5884 (5.22%)	15700 (6.84%)	8027 (8.73%)
Two or more	17563 (3.46%)	1444 (1.96%)	2786 (2.47%)	8415 (3.66%)	4918 (5.35%)
Other					
DVT[1]	731 (0.15%)	43 (0.06%)	103 (0.09%)	341 (0.15%)	244 (0.27%)
Pulmonary embolism	464 (0.09%)	30 (0.04%)	66 (0.06%)	236 (0.10%)	132 (0.14%)
Diabetes (treated)	4833 (1.00%)	667 (0.93%)	996 (0.92%)	2258 (1.03%)	912 (1.05%)
Gallbladder disease[2]	4926 (1.16%)	704 (1.08%)	1121 (1.16%)	2308 (1.22%)	793 (1.07%)
Hysterectomy	1958 (0.66%)	253 (0.60%)	423 (0.60%)	951 (0.72%)	331 (0.64%)
Glaucoma	6969 (1.43%)	669 (0.92%)	1342 (1.22%)	3366 (1.53%)	1592 (1.87%)
Osteoporosis	13822 (2.89%)	1341 (1.86%)	2453 (2.25%)	6727 (3.12%)	3301 (4.01%)
Osteoarthritis[3]	12247 (3.91%)	1727 (3.14%)	2731 (3.53%)	5611 (4.17%)	2178 (4.70%)
Rheumatoid arthritis	3750 (0.77%)	501 (0.70%)	816 (0.75%)	1712 (0.78%)	721 (0.83%)
Intestinal polyps	9820 (2.08%)	1159 (1.63%)	2049 (1.91%)	4914 (2.32%)	1698 (2.09%)
Lupus	671 (0.13%)	101 (0.14%)	150 (0.13%)	311 (0.14%)	109 (0.12%)
Kidney stones[3]	1692 (0.40%)	217 (0.37%)	347 (0.37%)	807 (0.42%)	321 (0.41%)
Cataracts[3]	20160 (5.29%)	1308 (2.18%)	3376 (3.65%)	10968 (6.28%)	4508 (8.33%)
Pills for hypertension	16809 (4.70%)	2078 (3.50%)	3536 (4.11%)	7856 (5.03%)	3339 (5.97%)

Outcomes	Race/Ethnicity: Am 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)	86.6	86.1	88.1	85.1	90.0	85.3
Hospitalizations						
Ever	140 (6.65%)	515 (4.72%)	3392 (6.62%)	1115 (5.47%)	27288 (6.55%)	422 (6.33%)
Two or more	87 (4.13%)	225 (2.06%)	1872 (3.65%)	530 (2.60%)	14625 (3.51%)	224 (3.36%)
Other						
DVT[1]	3 (0.15%)	2 (0.02%)	69 (0.14%)	11 (0.05%)	638 (0.16%)	8 (0.12%)
Pulmonary embolism	4 (0.19%)	2 (0.02%)	44 (0.09%)	3 (0.01%)	406 (0.10%)	5 (0.08%)
Diabetes (treated)	24 (1.26%)	132 (1.30%)	848 (1.87%)	327 (1.72%)	3430 (0.85%)	72 (1.15%)
Gallbladder disease[2]	20 (1.29%)	78 (0.79%)	394 (0.86%)	228 (1.47%)	4136 (1.19%)	70 (1.23%)
Hysterectomy	5 (0.53%)	35 (0.50%)	121 (0.54%)	69 (0.61%)	1714 (0.69%)	14 (0.36%)
Glaucoma	35 (1.76%)	136 (1.30%)	927 (1.95%)	302 (1.53%)	5477 (1.36%)	92 (1.47%)
Osteoporosis	60 (3.00%)	358 (3.46%)	817 (1.66%)	587 (3.09%)	11806 (3.01%)	194 (3.12%)
Osteoarthritis[3]	61 (0.11%)	287 (0.37%)	1213 (0.90%)	614 (1.33%)	9881 (5.34%)	191 (4.56%)
Rheumatoid arthritis	28 (1.48%)	72 (0.69%)	637 (1.34%)	334 (1.72%)	2611 (0.65%)	68 (1.07%)
Intestinal polyps	50 (2.59%)	202 (2.02%)	1030 (2.16%)	345 (1.77%)	8065 (2.09%)	128 (2.09%)
Lupus	5 (0.24%)	9 (0.08%)	85 (0.17%)	32 (0.16%)	532 (0.13%)	8 (0.12%)
Kidney stones[3]	13 (0.02%)	41 (0.04%)	170 (0.09%)	86 (0.11%)	1360 (0.54%)	22 (0.39%)
Cataracts[3]	85 (0.14%)	400 (0.43%)	1858 (1.06%)	756 (1.40%)	16787 (7.41%)	274 (5.41%)
Pills for hypertension	71 (5.20%)	355 (4.79%)	1642 (6.42%)	782 (5.13%)	13750 (4.53%)	209 (4.74%)

[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 6.13
Locally Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: August 31, 2004

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	89.5		83.2	
Ppts with other cancer	2617	(0.52%)	3464	(0.53%)
Accessory sinus	1	(<0.01%)	1	(<0.01%)
Adrenal gland	1	(<0.01%)	5	(<0.01%)
Anus	9	(<0.01%)	16	(<0.01%)
Appendix	5	(<0.01%)	8	(<0.01%)
Biliary tract, parts of (other/unspecified)	33	(0.01%)	31	(<0.01%)
Bladder	150	(0.03%)	197	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	7	(<0.01%)
Bones/joints/articular cartilage (other)	4	(<0.01%)	2	(<0.01%)
Brain	68	(0.01%)	78	(0.01%)
Cervix	48	(0.01%)	39	(0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	3	(<0.01%)
Connective/subcutaneous/soft tissues	23	(<0.01%)	38	(0.01%)
Endocrine glands, related structures	6	(<0.01%)	7	(<0.01%)
Esophagus	28	(0.01%)	32	(<0.01%)
Eye and adnexa	15	(<0.01%)	12	(<0.01%)
Genital organs	29	(0.01%)	18	(<0.01%)
Kidney	122	(0.02%)	152	(0.02%)
Larynx	14	(<0.01%)	11	(<0.01%)
Leukemia	116	(0.02%)	162	(0.02%)
Liver	26	(0.01%)	31	(<0.01%)
Lung	521	(0.10%)	649	(0.10%)
Lymph nodes	12	(<0.01%)	9	(<0.01%)
Lymphoma,Hodgkins	14	(<0.01%)	14	(<0.01%)
Lymphoma,Non-Hodgkins	227	(0.04%)	329	(0.05%)
Melanoma of the skin	365	(0.07%)	456	(0.07%)
Multiple myeloma	97	(0.02%)	80	(0.01%)
Oral (mouth)	19	(<0.01%)	13	(<0.01%)
Palate	5	(<0.01%)	6	(<0.01%)
Pancreas	129	(0.03%)	152	(0.02%)
Parotid gland (Stensen's duct)	9	(<0.01%)	16	(<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	10	(<0.01%)	13	(<0.01%)
Salivary glands, major (other/unspecified)	3	(<0.01%)	10	(<0.01%)
Stomach	39	(0.01%)	45	(0.01%)
Thyroid	76	(0.01%)	86	(0.01%)
Tongue, part of (other/unspecified)	18	(<0.01%)	20	(<0.01%)
Urinary organs (other/unspecified)	12	(<0.01%)	21	(<0.01%)
Uterus, not otherwise specified	37	(0.01%)	68	(0.01%)
Other/unknown site of cancer	216	(0.04%)	258	(0.04%)
Other/unknown cancers reported on death form	182	(0.04%)	430	(0.07%)

Table 6.14
Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants

Data as of: August 31, 2004

	CT		OS[1]	
Locally Verified				
Number of participants	68132		6365	
Mean follow-up time (months)	89.5		90.6	
Ppts with other fractures[2]	7027	(1.38%)	639	(1.33%)
Ankle	1240	(0.24%)	116	(0.24%)
Carpal bone(s) in wrist	169	(0.03%)	10	(0.02%)
Clavicle or collar bone	126	(0.02%)	13	(0.03%)
Elbow, not otherwise specified	26	(0.01%)	1	(<0.01%)
Humerus, shaft/unspecified	77	(0.02%)	6	(0.01%)
Humerus, upper end	776	(0.15%)	59	(0.12%)
Humerus, lower end	91	(0.02%)	10	(0.02%)
Metacarpal bone(s)	242	(0.05%)	23	(0.05%)
Patella	322	(0.06%)	28	(0.06%)
Pelvis	301	(0.06%)	45	(0.09%)
Radius or ulna	2014	(0.40%)	191	(0.40%)
Sacrum and coccyx	91	(0.02%)	11	(0.02%)
Scapula	34	(0.01%)	6	(0.01%)
Shaft of femur	104	(0.02%)	9	(0.02%)
Tarsal/metatarsal bones	1168	(0.23%)	121	(0.25%)
Tibia and fibula	589	(0.12%)	32	(0.07%)
Tibial plateau	159	(0.03%)	10	(0.02%)
Upper radius/ulna	351	(0.07%)	33	(0.07%)
Unknown other fracture	5	(<0.01%)	0	(0.00%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			83.2	
Elbow			616	(0.09%)
Foot			2103	(0.32%)
Hand			402	(0.06%)
Knee			718	(0.11%)
Lower Arm			3035	(0.47%)
Lower Leg			2399	(0.37%)
Pelvis			600	(0.09%)
Tailbone			173	(0.03%)
Upper Arm			1275	(0.20%)
Upper Leg			361	(0.06%)
Vertebra			1440	(0.22%)
Other Fracture			2379	(0.37%)

[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 6.15
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: August 31, 2004

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	89.5		83.2	
Total death	3141	(0.62%)	4969	(0.76%)
Adjudicated death	3022	(0.60%)	4753	(0.73%)
Centrally adjudicated death	2614	(0.51%)	0	(0.00%)
Locally adjudicated death (final)	198	(0.04%)	4377	(0.67%)
Temporary adjudicated death	204	(0.04%)	360	(0.06%)
Identified by NDI search	6	(<0.01%)	16	(<0.01%)
Cardiovascular				
Atherosclerotic cardiac	506	(0.10%)	614	(0.09%)
CHD deaths locally adjudicated before 10/99	0	(0.00%)	82	(0.01%)
Definite CHD deaths	245	(0.05%)	253	(0.04%)
Possible CHD deaths	261	(0.05%)	279	(0.04%)
Cerebrovascular	224	(0.04%)	363	(0.06%)
Pulmonary embolism	31	(0.01%)	36	(0.01%)
Other cardiovascular	138	(0.03%)	275	(0.04%)
Unknown cardiovascular	15	(<0.01%)	65	(0.01%)
Total cardiovascular deaths	914	(0.18%)	1353	(0.21%)
Cancer				
Breast cancer	77	(0.02%)	306	(0.05%)
Ovarian cancer	96	(0.02%)	151	(0.02%)
Endometrial cancer	16	(<0.01%)	42	(0.01%)
Colorectal cancer	133	(0.03%)	179	(0.03%)
Other cancer	983	(0.19%)	1338	(0.21%)
Unknown cancer site	72	(0.01%)	105	(0.02%)
Total cancer deaths	1377	(0.27%)	2121	(0.33%)
Accident/injury				
Homicide	6	(<0.01%)	9	(<0.01%)
Accident	76	(0.01%)	96	(0.01%)
Suicide	13	(<0.01%)	21	(<0.01%)
Other injury	4	(<0.01%)	10	(<0.01%)
Total accidental deaths	99	(0.02%)	136	(0.02%)
Other				
Other known cause	466	(0.09%)	809	(0.12%)
Unknown cause	166	(0.03%)	334	(0.05%)
Total deaths – other causes	632	(0.12%)	1143	(0.18%)

Table 6.16
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: August 31, 2004

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	87	5.1	1576	91.5	14	0.8	1	0.1	26	1.5	18	1.0	1722
Birmingham	111	6.1	1657	90.4	14	0.8	0	0.0	31	1.7	19	1.0	1832
Bowman	78	5.1	1331	86.8	22	1.4	0	0.0	58	3.8	45	2.9	1534
Brigham	90	3.9	2157	93.8	27	1.2	0	0.0	4	0.2	22	1.0	2300
Buffalo	84	5.3	1481	92.7	4	0.3	1	0.1	25	1.6	2	0.1	1597
Chapel Hill	66	4.3	1433	93.2	0	0.0	0	0.0	34	2.2	5	0.3	1538
Chicago	86	5.3	1443	88.8	18	1.1	0	0.0	53	3.3	25	1.5	1625
Chi-Rush	61	4.6	1152	87.1	34	2.6	0	0.0	40	3.0	36	2.7	1323
Cincinnati	45	3.2	1286	92.5	5	0.4	0	0.0	52	3.7	2	0.1	1390
Columbus	69	4.5	1397	90.1	36	2.3	1	0.1	36	2.3	11	0.7	1550
Detroit	40	2.9	1188	86.2	21	1.5	0	0.0	119	8.6	10	0.7	1378
GWU-DC	61	4.0	1414	93.4	12	0.8	2	0.1	17	1.1	8	0.5	1514
Gainesville	92	4.4	1906	91.5	9	0.4	0	0.0	63	3.0	14	0.7	2084
Honolulu	59	4.2	1240	88.2	17	1.2	2	0.1	67	4.8	21	1.5	1406
Houston	41	3.2	1129	88.7	17	1.3	0	0.0	72	5.7	14	1.1	1273
Iowa City	113	4.6	2257	92.7	2	0.1	0	0.0	39	1.6	23	0.9	2434
Irvine	53	3.3	1468	90.5	7	0.4	1	0.1	58	3.6	35	2.2	1622
L.A.	71	4.2	1510	90.0	21	1.3	0	0.0	52	3.1	23	1.4	1677
La Jolla	124	5.7	1807	83.5	71	3.3	0	0.0	61	2.8	101	4.7	2164
Madison	43	2.8	1476	94.7	7	0.4	0	0.0	30	1.9	2	0.1	1558
Medlantic	78	5.2	1322	88.8	16	1.1	0	0.0	45	3.0	28	1.9	1489
Memphis	102	5.9	1538	88.5	1	0.1	0	0.0	91	5.2	6	0.3	1738
Miami	51	3.4	1240	83.5	15	1.0	0	0.0	57	3.8	122	8.2	1485
Milwaukee	64	3.9	1504	91.3	17	1.0	0	0.0	53	3.2	9	0.5	1647
Minneapolis	92	4.6	1826	91.9	39	2.0	0	0.0	28	1.4	3	0.2	1988
NY-City	86	4.6	1701	90.4	35	1.9	4	0.2	38	2.0	18	1.0	1882
Nevada	95	6.4	1352	91.6	1	0.1	0	0.0	21	1.4	7	0.5	1476
Newark	97	4.0	2157	88.3	81	3.3	0	0.0	87	3.6	20	0.8	2442
Oakland	68	4.4	1456	93.5	6	0.4	0	0.0	19	1.2	9	0.6	1558
Pawtucket	120	4.5	2423	91.6	11	0.4	0	0.0	63	2.4	29	1.1	2646
Pittsburgh	89	5.4	1526	92.1	6	0.4	0	0.0	36	2.2	0	0.0	1657
Portland	80	4.9	1473	89.8	20	1.2	0	0.0	39	2.4	28	1.7	1640
San Antonio	39	2.8	1242	89.4	2	0.1	0	0.0	88	6.3	18	1.3	1389
Seattle	99	5.5	1604	88.7	35	1.9	0	0.0	35	1.9	36	2.0	1809
Stanford	76	4.3	1614	92.3	5	0.3	0	0.0	39	2.2	14	0.8	1748
Stonybrook	62	4.6	1241	91.7	20	1.5	0	0.0	26	1.9	5	0.4	1354
Torrance	43	4.3	860	86.0	27	2.7	0	0.0	45	4.5	25	2.5	1000
Tucson	137	6.5	1801	85.8	10	0.5	0	0.0	63	3.0	88	4.2	2099
U.C. Davis	120	6.2	1720	88.9	16	0.8	2	0.1	41	2.1	36	1.9	1935
Worcester	69	4.2	1531	94.0	9	0.6	0	0.0	10	0.6	10	0.6	1629
Total	3141	4.6	61439	90.2	730	1.1	14	<0.1	1861	2.7	947	1.4	68132

[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 6.17
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: August 31, 2004

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	128	5.2	2268	92.1	33	1.3	0	0.0	15	0.6	19	0.8	2463
Birmingham	156	6.2	2133	84.3	138	5.5	1	<0.1	66	2.6	35	1.4	2529
Bowman	103	4.6	1900	85.3	136	6.1	0	0.0	32	1.4	56	2.5	2227
Brigham	94	3.2	2753	93.4	55	1.9	2	0.1	21	0.7	21	0.7	2946
Buffalo	173	7.7	2016	89.7	28	1.2	1	<0.1	23	1.0	7	0.3	2248
Chapel Hill	86	4.1	1961	94.1	10	0.5	0	0.0	23	1.1	3	0.1	2083
Chicago	103	5.5	1680	88.9	28	1.5	2	0.1	31	1.6	45	2.4	1889
Chi-Rush	116	5.7	1685	82.2	103	5.0	4	0.2	44	2.1	97	4.7	2049
Cincinnati	104	4.6	1964	87.3	69	3.1	12	0.5	57	2.5	43	1.9	2249
Columbus	102	4.6	2040	91.9	44	2.0	3	0.1	18	0.8	12	0.5	2219
Detroit	90	4.3	1822	86.3	73	3.5	0	0.0	99	4.7	28	1.3	2112
GWU-DC	107	4.8	2097	93.3	27	1.2	1	<0.1	10	0.4	5	0.2	2247
Gainesville	148	5.3	2514	90.0	25	0.9	1	<0.1	83	3.0	21	0.8	2792
Honolulu	90	4.3	1792	84.8	56	2.7	9	0.4	122	5.8	44	2.1	2113
Houston	142	6.7	1860	87.3	18	0.8	2	0.1	81	3.8	27	1.3	2130
Iowa City	135	4.3	2888	92.6	11	0.4	0	0.0	62	2.0	24	0.8	3120
Irvine	109	4.9	2001	89.7	10	0.4	1	<0.1	57	2.6	52	2.3	2230
L.A.	104	4.7	1995	90.9	35	1.6	0	0.0	37	1.7	24	1.1	2195
La Jolla	229	6.6	2934	84.7	109	3.1	0	0.0	46	1.3	145	4.2	3463
Madison	103	5.2	1836	92.7	18	0.9	0	0.0	22	1.1	2	0.1	1981
Medlantic	113	5.2	1994	90.9	16	0.7	0	0.0	37	1.7	33	1.5	2193
Memphis	149	5.9	2177	86.5	67	2.7	0	0.0	104	4.1	19	0.8	2516
Miami	78	5.7	1028	74.8	72	5.2	1	0.1	49	3.6	146	10.6	1374
Milwaukee	94	4.2	2018	89.8	39	1.7	1	<0.1	42	1.9	52	2.3	2246
Minneapolis	106	3.9	2464	90.4	59	2.2	3	0.1	41	1.5	54	2.0	2727
NY-City	168	5.8	2455	84.6	121	4.2	32	1.1	29	1.0	98	3.4	2903
Nevada	192	8.8	1942	89.3	15	0.7	0	0.0	21	1.0	4	0.2	2174
Newark	134	4.0	2943	87.3	160	4.7	1	<0.1	84	2.5	51	1.5	3373
Oakland	125	6.1	1844	89.8	45	2.2	0	0.0	24	1.2	15	0.7	2053
Pawtucket	166	4.6	3147	87.7	105	2.9	88	2.5	47	1.3	35	1.0	3588
Pittsburgh	123	6.4	1551	80.9	122	6.4	0	0.0	64	3.3	57	3.0	1917
Portland	106	4.7	2027	90.8	35	1.6	0	0.0	38	1.7	26	1.2	2232
San Antonio	88	4.5	1679	86.5	49	2.5	2	0.1	101	5.2	23	1.2	1942
Seattle	123	7.4	1409	84.7	43	2.6	11	0.7	23	1.4	54	3.2	1663
Stanford	145	5.4	2420	90.7	40	1.5	3	0.1	54	2.0	7	0.3	2669
Stonybrook	89	4.4	1878	92.6	32	1.6	0	0.0	15	0.7	14	0.7	2028
Torrance	77	5.1	1289	85.8	51	3.4	1	0.1	36	2.4	49	3.3	1503
Tucson	213	7.7	2342	84.2	42	1.5	0	0.0	36	1.3	149	5.4	2782
U.C. Davis	142	6.3	2028	89.4	29	1.3	1	<0.1	41	1.8	28	1.2	2269
Worcester	116	5.2	2065	92.2	38	1.7	1	<0.1	11	0.5	8	0.4	2239
Total	4969	5.3	82839	88.4	2206	2.4	184	0.2	1846	2.0	1632	1.7	93676

[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.

7. Other Analyses

7.1 Overview

During the screening process, all participants were administered a *Form 2 – Eligibility Screen*, which asked a basic question about their racial/ethnic background. The question asked them to choose which racial or ethnic group they most identified with: American Indian or Alaskan Native; Asian or Pacific Islander; Black or African-American; Hispanic/Latino; White; or Other (specify). The Special Populations Advisory Committee, in reviewing the race/ethnicity data, felt that this question did not provide a thorough description of race for several reasons: it did not allow for participants of mixed heritage to select more than one race/ethnicity; it did not separate out Hispanic as an ethnicity independent of race; and the text provided for the "Other" category was not key entered by most clinics and therefore not available for analyses.

In order to provide a more complete description of race/ethnicity and to provide more detailed information for subgroup analyses, *Form 41 – Addendum to Personal Information* was administered to all CT and OS participants as part of their annual contact between 2003 and 2004. This form was modeled after the race/ethnicity questions used by the US Census Bureau during the 2000 national census. The US Census format separates race/ethnicity into two major questions: one that asks if the person is Spanish, Hispanic, or Latino, and a second question that allows the respondent to select one or more races from a list of more than a dozen options. *Figure 7.1 – Form 41 - Addendum to Personal Information* shows the precise wording of the form that was administered to WHI participants.

7.2 Results

As of August 31, 2004, 97.1% of CT (N=61,050) and 85.5% of OS (N=72,502) participants who were not deceased or lost to follow-up had completed *Form 41*. Response may increase for OS participants, as the form is still in the process of being collected in the annual mailed packet. These race/ethnicity breakdowns may be helpful for investigators looking for information on specific subgroups, but the small numbers in the Asian, Pacific Islander, and Hispanic categories may preclude statistical analyses other than those that are descriptive.

Table 7.1 – Form 41 Race Breakdown by Hispanic Origin Among Women who Completed Form 41 divides the race responses by Hispanic affiliation and whether one or more races were chosen. Though participants could mark more than one race, the vast majority only chose one. One point of interest is that 11% of the women who indicated Hispanic ethnicity on *Form 41* chose "some other race" (only). It is possible that these women consider their race to be Hispanic and do not feel a racial affiliation with any other category.

Table 7.2 – Comparison of Form 2 and Completed Form 41 Responses by Hispanic Origin highlights the agreement between *Form 41* and the original responses provided during screening on *Form 2*. Responses to *Form 41* and *Form 2* were fairly consistent, with the exception of participants who originally indicated that they were American Indian/Alaskan Native on *Form 2*. In this population, approximately 28% of these women went on to indicate that they were White (only) on *Form 41*, and an additional 9% went on to indicate a category other than White or American Indian/Alaskan Native. Reasons for this discrepancy are being considered. Among those who initially chose "Other" on *Form 2*, approximately 25% chose some other race or multiple races on *Form 41*and over half indicated that they were White (only). Among those who left the race question on *Form 2* blank, over 75% indicated they were White (only) on *Form 41*.

Figure 7.1
Form 41 – Addendum to Personal Information Ver. 1.1

These questions ask about your racial/ethnic background. This information will help us describe the groups of women who are participating in the WHI. Please answer both questions. Mark the appropriate box with an "x" (☒) or write the information in the space provided.

1. Are you Spanish/Hispanic/Latino? Mark the "**No**" box if **not** Spanish/Hispanic/Latino.

☐$_0$ **No**, not Spanish/Hispanic/Latino
☐$_1$ Yes, Puerto Rican
☐$_2$ Yes, Mexican, Mexican American, or Chicano
☐$_3$ Yes, Cuban
☐$_4$ Yes, other Spanish/Hispanic/Latina
(Please specify what group: _____)

2. What is your race? **Mark one or more races** to indicate what you consider yourself to be.

☐$_1$ White
☐$_2$ Black, African-American, or Negro
☐$_3$ American Indian or Alaska Native
(Please specify enrolled or principal tribe: _____)
☐$_4$ Asian Indian
☐$_5$ Chinese
☐$_6$ Filipino
☐$_7$ Japanese
☐$_8$ Korean
☐$_9$ Vietnamese
☐$_{10}$ Other Asian (Please specify race: _____)
☐$_{11}$ Native Hawaiian
☐$_{12}$ Guamanian or Chamorro
☐$_{13}$ Samoan
☐$_{14}$ Other Pacific Islander (Please specify race: _____)
☐$_{15}$ Some other race (Please specify race: _____)

Table 7.1
Form 41 Race Breakdown by Hispanic Origin Among Women who Completed Form 41[1]

Data as of: August 31, 2004

	Spanish/Hispanic/Latino			
	No		Yes	
Participants who marked only one race				
White	112162	(87.9 %)	4115	(79.8 %)
Black, African-American, or Negro	10045	(7.9 %)	143	(2.8 %)
American Indian or Alaska Native	273	(0.2 %)	51	(1.0 %)
Asian[2]	3120	(2.4 %)	56	(1.1 %)
Asian Indian	71	(2.3 %)	3	(5.4 %)
Chinese	716	(23.0 %)	15	(26.8 %)
Filipino	286	(9.2 %)	22	(39.3 %)
Japanese	1898	(60.8 %)	9	(16.1 %)
Korean	87	(2.8 %)	2	(3.6 %)
Vietnamese	9	(0.3 %)	0	(0.0 %)
Other Asian	53	(1.7 %)	5	(8.9 %)
Native Hawaiian and Other Pacific Islander[2]	119	(0.1 %)	18	(0.4 %)
Native Hawaiian	89	(74.8 %)	7	(38.9 %)
Guamanian or Chamorro	8	(6.7 %)	2	(11.1 %)
Samoan	2	(1.7 %)	0	(0.0 %)
Other Pacific Islander	20	(16.8 %)	9	(50.0 %)
Some other race	308	(0.2 %)	575	(11.2 %)
Participants who marked multiple races				
Two races including Some other race	328	(0.3 %)	83	(1.6%)
Two races excluding Some other race, or three or more races	1284	(1.0 %)	116	(2.3%)

[1] Completion indicates response to both questions. Excludes 834 (0.6%) participants who left "Are you Spanish/Hispanic/Latino?" blank and 756 (0.6%) participants who left "What is your race?" blank.

[2] Percentages within 'Asian' and 'Native Hawaiian and Other Pacific Islander' subgroups sum to 100% and are not included in total percentage.

Table 7.2
Comparison of Form 2 and Completed Form 41 Responses by Hispanic Origin[1]

Data as of: August 31, 2004

	Form 2 Race													
	White		Black/African American		American Indian/ Alaskan Native		Asian/Pacific Islander		Hispanic/ Latino		Other		Missing	
Form 41 Race	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Not Spanish, Hispanic, or Latino														
White	110718	99.08	164	1.58	133	28.73	31	0.94	202	84.87	695	55.69	219	77.11
Black, African-American, or Negro	36	0.03	9840	94.88	36	7.78	2	0.06	18	7.56	83	6.65	30	10.56
American Indian or Alaska Native	47	0.04	26	0.25	185	39.96	0	0.00	2	0.84	12	0.96	1	0.35
Asian	7	0.01	1	0.01	2	0.43	2990	91.02	1	0.42	108	8.65	11	3.87
Native Hawaiian and Other Pacific Islander	4	0.00	1	0.01	0	0.00	72	2.19	0	0.00	41	3.29	1	0.35
Some other race	143	0.13	57	0.55	4	0.86	7	0.21	10	4.20	75	6.01	12	4.23
Two races including Some other race	245	0.22	24	0.23	1	0.22	12	0.37	4	1.68	38	3.04	4	1.41
Two races excluding Some other race, or three or more races	550	0.49	258	2.49	102	22.03	171	5.21	1	0.42	196	15.71	6	2.11
Spanish, Hispanic, or Latino														
White	538	91.34	5	5.21	6	23.08	1	1.69	3416	82.27	123	60.89	26	78.79
Black, African-American, or Negro	0	0.00	80	83.33	1	3.85	0	0.00	53	1.28	7	3.47	2	6.06
American Indian and Alaska Native	2	0.34	0	0.00	14	53.85	0	0.00	27	0.65	7	3.47	1	3.03
Asian	1	0.17	0	0.00	0	0.00	35	59.32	12	0.29	8	3.96	0	0.00
Native Hawaiian and Other Pacific Islander	0	0.00	0	0.00	0	0.00	4	6.78	9	0.22	4	1.98	1	3.03
Some other race	19	3.23	3	3.13	1	3.85	2	3.39	526	12.67	23	11.39	1	0.32
Two races including Some other race	13	2.21	0	0.00	0	0.00	1	1.69	55	1.32	12	5.94	2	0.63
Two races excluding Some other race, or three or more races	16	2.72	8	8.33	4	15.38	16	27.12	54	1.30	18	8.91	0	0.00

[1] Completion indicates response to both questions on Form 41. Excludes 834 (0.6%) participants who left "Are you Spanish/Hispanic/Latino?" blank and 756 (0.6%) participants who left "What is your race?" blank.
[2] Percentages sum to 100% within Hispanic origin group.

8. Laboratory Studies

8.1 Overview

Blood samples are collected on all CT participants at baseline and year 1 and on a 6% subsample of participants at years 3, 6, and 9. Blood samples are collected on all OS participants at baseline and Year 3. All blood samples are obtained in the fasting state (at least 12 hours), maintained at 4°C for up to one hour until plasma or serum is separated from cells. In addition, urine samples are collected on both CT and OS participants at the three Bone Density Clinical Centers at baseline, year 1 and year 9 for CT, and baseline and year 3 for OS participants. Barcoded plasma, serum, RBCs, buffy coat, and urine aliquots are frozen at -70°C and sent on dry ice to the central repository (McKesson Biological Services, Rockville, MD) where storage at -70°C is maintained.

8.2 Central Laboratories

DNA Extraction

Through the end of 2003 DNA extraction for WHI was done by BioServe Biotechnologies, Laurel, MD. In March 2004 the Laboratory Working Group selected the Specimen Processing Laboratory (SPL) at FHCRC to perform further DNA extractions. For each buffy coat, SPL prepares up to four daughter aliquots containing 1 µg DNA each and divides the remaining DNA into parent aliquots containing up to 150 ug DNA each, depending on the quantity of DNA extracted. Through August 2004, 5400 DNA extractions have been completed.

Hormones

In mid-2003 the Laboratory Working Group recommended that the CCC identify a hormone laboratory with an estradiol assay that uses 0.5 ml or less sample. An RFP was issued in August 2003 and the Laboratory Working Group selected Frank Stanczyk, Director, Reproductive Endocrine Research Laboratory, USC Keck School of Medicine, Women's & Children's Hospital, Los Angeles, California, to perform future hormone assays for WHI.

8.3 Core Studies

Core Analytes

The analyses of the twenty core analytes are done by Medical Research Laboratories, Highland Heights, Kentucky (MRL). MRL has completed the analyses of the core analytes for baseline, year 1, and year 3 samples in the CT 6% subsample. Analysis of year 6 bloods began in September 2002, with about 300 samples analyzed every two months, and is expected to be completed by the end of 2004. Analysis of year 9 bloods is scheduled to start in early 2005 and to be completed by August 2005. See *Table 8.1* for a list of the assays included in the core analytes. See *Sections 2* and *3* in this report for presentation of the laboratory results for HT and DM.

MRL completed the analysis of the 1% OS Measurement Precision Study (OS-MPS). See *Section 5.3* in the February 1, 1999, to August 25, 1999, Semi-Annual Progress Report for the results.

Hormones
Esoterix (Calabasas Hills, CA; formerly Endocrine Sciences) completed hormone analyses on baseline and year 1 samples for the 300 participants included in the approved paper "Correlates of endogenous sex hormone concentrations in WHI." (See *Table 8.1* for a list of the analytes.) Analyses of the data are near completion.

CVD Biomarker Case-Control Study of CHD, Stroke, and VTE in the HT Clinical Trial
This study includes all locally adjudicated cases of CHD, stroke, and VTE occurring by February 2001. The University of Leiden was contracted to perform an initial set of polymorphisms related to clotting, MRL to perform the lipid and some inflammation assays analyses, and the University of Vermont to perform the thrombosis assays and additional inflammation assays. Results from these assays have been received.

In 2003, glucose, insulin, and additional hormone receptor polymorphisms were added (Wake Forest University) to the analytes to be done, and results from these additional polymorphisms have been received. In February 2005, the Steering Committee also approved several additional assays, including 10 lipoprotein subfractions, LDL particle size and concentration, MMP-7, MMP-8, a panel of 10 cytokines, APC-ETP, free and total TFPI, and progesterone polymorphisms. The CCC issued RFPs for laboratories to perform these assays in early 2004 and proposals were due in September.

Table 8.1 – Summary of WHI Blood Studies by CT/OS and Disease Type lists all the assays for this study and *Table 8.2* shows the number completed and expected assays for the Estrogen-plus-Progestin and the E-Alone cases and controls in the CVD Biomarker Study. PIs can arrange to see the data on the WHI website.

Biological Markers and the Effect of HT on Risk of Fractures in the WHI CT
In late 2003, the CCA-WG also developed a proposal for a study on whether the effect of HT on risk of fracture depends on levels of sex hormones, bone turnover, or genetic markers of sex hormone metabolism and action of hormone therapy on the risk of fractures. The Steering Committee approved the proposal in October 2003, and final sample size calculations and recommendations are being made, with plans to finalize the proposal in by the end of the year.

Biological Markers and the Effect of HT and ET on Risk of Breast Cancer in the WHI CT
In early 2004 the CCA-WG developed a proposal for a study of sex hormones and genetic variants in breast cancer and the proposal was approved by the Steering Committee in October 2003. The group identified a panel of sex hormones, insulin and IGF analytes, lipids, micronutrients, and estrogen/progestin metabolism-related genes to be included in the study. The proposal is currently undergoing final review by the CCA-WG.

Genome-wide Scan of Single Nucleotide Polymorphisms (SNPs) in Relation to Coronary Heart Disease, Stroke, and Breast Cancer
Following the fall 2003 SC meeting the CCA-WG developed a proposal for a study of E+P and E-Alone effects in relation to genome-wide SNPs for CHD, breast cancer, and stroke. The proposal was revised to strengthen the design by incorporating important replication using different OS cases and controls, reducing the dependence on pooled DNA, increasing the number of cases and controls, and reducing the amount of DNA requested from 25 to 1 ug. The revised proposal was resubmitted for review in the fall 2004 blood competition as well as for consideration for internal (CCA-WG) funding. Concept approved has been obtained for the use

of CCA-WG, following review by genomic experts under NHLBI auspices. It is expected that an RFP for the laboratory work will be able to be released in the near future.

Proteomic Patterns in Relation to Colorectal Cancer in the Hormone Therapy Trials and Observational Study

The CCA-WG has also followed up on the fall 2003 SC discussion of proteomic analyses in the HT trials. Since the colorectal cancer data in relation to E+P and E-Alone are in need of biological elucidation a concept was drafted toward identifying peptide peaks that may distinguish colorectal cancer cases and controls, and that may distinguish E+P and E-Alone users from non-users. Following discussion with potential collaborators at the National Cancer Institute, the concept arose that colorectal cases and control plasma specimens from the OS would first be analyzed to identify peaks using Q-star technology, with specimens from the HT trial to be considered at a later stage for validation purposes. In March 2004, the Design and Analysis Committee also recommended that reproducibility testing be done with other samples, such as those participants who were screened but not enrolled in WHI. Information on proteomic technologies continues to evolve and to be assessed by the CCA-WG, with an initiative for SC consideration expected in upcoming months.

8.4 Ancillary Studies

WHI has made available 1.8 ml baseline and 1.8 ml Year 3 serum, citrate plasma, and EDTA plasma samples for use by OS ancillary studies. In late 2003 CT DNA samples were also made available for ancillary studies. Eleven ancillary studies submitted proposals for the spring 2004 OS blood competition, with one requesting CaD DNA samples, and 19 ancillary studies submitted proposals for the fall 2004. As of August 31, 2004, WHI has 27 approved ancillary studies using WHI blood specimens, with 16 funded, 3 submitted for funding, and 8 not yet submitted. In the past 6 months, two ancillary studies were removed from the approval list and from the list of committed blood sample because they did not obtain funding within 30 months of WHI approval. Another approved ancillary study was removed at the request of the ancillary study investigator.

Table 8.1 – Summary of WHI Blood Studies by CT/OS and Disease Type lists the approved ancillary studies by disease type as well as the corresponding blood and DNA assays and *Table 8.3 – OS Blood Committed to Ancillary Studies (AS)* gives a summary of the volume of OS blood samples committed to OS ancillary studies by disease type as of August 31, 2004. To date, no more baseline serum is available for current CHD and hip fracture cases, and very limited baseline citrate and EDTA plasma is available for stoke cases. *Table 10.2 – Ancillary Studies* lists additional key information about ancillary studies, including sample size and funding dates.

Table 8.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analytes
CT Studies				
-	**CT**	Core analytes (6% at baseline, Y1, Y3, Y6, Y9)	-	**Blood:** α- and β-carotene; γ-tocopherol; β-cryptoxanthine; FVII Ag; FVIIc; fibrinogen; glucose; insulin; lipids (cholesterol; HDL; HDL-2; HDL-3; LDL; Lp(a); triglyceride); lutein+zeaxanthin; lycopene; retinol
-	**OS**	OS Measurement Precision Study (OS-MPS) (800 at baseline and 3 months)	-	Same as core analytes
-	**DM**	DM Hormone (300 at baseline and Y1)	-	**Blood:** albumin; androstenedione; bioavailable estradiol; DHEA; DHES; DHT; estradiol; estrone; estrone-sulfate; progesterone; prolactin; SHBG; testosterone
-	**CaD**	Vitamin D (460 at Y3)	-	**Blood:** 25-hydroxy vitamin D_3
CHD; Stroke; VTE	**Hf**	CVD Biomarkers (400 CHD, 270 stroke, 222 VTE baseline and Y1)	-	**Blood:** APC resistance; ATIII; 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. *Added in 2004:* adiponectin; APC-ETP; IL-beta; IL-2; IL-4; IL-8; IL-10; IL-12; IL-18; lipid subfractions by NMR; LDL particle size; and LDL particle concentration by NMR; macrophage inhibitory cytokine-1; MMP-7; MMP-8; MMP-9; TMP-1; TFPI activity; TFPI free; TFPI total; TNF-alpha **DNA:** ERα-PvuII4; ERα-1989/G; ER β-1730A/G; ER β-CArepeats; FXII val34leu; FV-HR2; FV-Leiden; GPIβα-Kob;a; GPIβα-VNTR; GPIIIα-P1A1-A2; Integrin α2-807C/T; MTHFR; PT19911; PT20210; PAI-1; MTHFR; *Added in* 2004: ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; ESR2 A1730G; GP1ba M145T; GPIIIa P1-P2; ITGA2 807
OS Ancillary Studies				
Cardiovascular				
CHD	**83**	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	**Blood:** cholesterol; CRP; D-dimer; HDL; homocysteine; sICAM-1; IL-6; LDL; Lp(a); tPA; triglyceride **DNA:** Factor V Leiden; MTHFR; PAI-1
CHD	**110**	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	**Blood:** DHES; estradiol; estrone sulfate; FVII Ag; FVIIc; fibrinogen; estrone sulfate; SHBG; testosterone; cholesterol; HDL; HDL-2; HDL-3; LDL; Lp(a); triglyceride
CHD	**137**	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	**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

Table 8.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analytes
CHD	**164**[2]	The IGF System and Coronary Heart Disease[2]	Robert Kaplan	**Blood:** IGF-I total; IGFBP-3
CHD	**165**	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	**Blood:** free T4; TPO-Ab; TSH
CHD	**189**[2]	Biochemical and Anthropometric Heterogeneity among Morbid Obese Women in the Women's Health Initiative Observational Study	Lew Kuller	**Blood:** adiponectin; ghrelin; glucose; insulin; leptin; NMR lipoproteins
Stroke	**126**	Hormones and Biomarkers Predicting Stroke in Women	Sylvia Wassertheil-Smoller	**Blood:** cholesterol; CRP; D-dimer; E-selectin; F1+2; FVII activity; fibrinogen; glucose; HDL; homocysteine; IL-6; insulin; Lp(a); MMP-9; neopterin; NMR lipoprotein particle size; PAI-1 Ag; tPA; TNF-alpha; triglyceride; VCAM-1; vWF
Stroke	**165**	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	**Blood:** free T4; TPO-Ab; TSH
Stroke	**169**[2]	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women[2]	Robert Kaplan	**Blood:** cholesterol; CRP; elastase; glucose; HDL; insulin; LDL; MMP-2; MMP-9; triglyceride; **DNA:** apoE genotype (ε2; ε3; ε4);
Hypertension	**133**	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso	**Blood:** CRP; sICAM-1; IL-1β; MMP-9; IL-6; TNF-α **DNA:** ACE; α-adducin genes; AGT; ATIR
Fracture				
Hip fracture	**90**[3]	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	**Blood:** cystatin-C; estradiol; homocysteine; IGF-1; SHBG; testosterone; TSH **DNA:** androgen receptor (AR); ApoE4; aromatase (CYP19); Coll A1 Sp 1; ESR1; ESR2; LDL receptor-related protein 5 (LRP5); TGF-beta-1(Leu10pro); SHBG
Hip fracture	**181**[2;3]	Estradiol, cytokines and bone turnover: Effects on hip fracture[2]	Jane Cauley	**Blood:** CTx; IL-6sR; OPG; PINP; RANKL; TNF-alpha-SR-1; TNF-alpha-SR-2
Cancer				
Breast Cancer	**129**[4]	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	**Blood:** total estradiol; glucose; IGF-1; IGF free; IGFBP-3; insulin

Table 8.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analytes
Breast Cancer	**134**	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	**Blood:** 2-OH estrone; 16a-OH estrone
Breast Cancer	**152[4]**	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: IGF-1; IGF BP-3; insulin; insulin receptor substrate 1
Breast Cancer	**167[2]**	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer[2]	Steve Cummings	**Blood**: estradiol total; SHBG; total testosterone
Breast Cancer	**188[2]**	Inflammation and the Risk of Hormonally-Linked Cancer	Francesmary Modugno	**Blood:** EGF; EGFR; eot; FGF; GCSF; GMCSF; IFNs; IL-1 cluster; IL-2; IL-4; IL-5; IL-6; IL-8; IL-10; IL-12p40; IL-13; IL-15; IL-17; sIL-6r I; sIL-2r; MCP; MIPs; TNFa; VEGF; TNF-α ; TNF-α soluble receptors I and II **DNA:** IGF-1 (CA)n 192/192; IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL-1RNVNTR*2; IL-10-1082/-819/-592 (GCC/GCC);Il-8-251-A-T; TGFβ1 29 (CC); TGFβR1*6A; TNFα-308 (AA)
Colorectal Cancer	**108.1**	Gene-environment effects and colorectal cancer	Henry Lin	**DNA:** PTGS2/Cox-2 val511ala
Colorectal Cancer	**129[4]**	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal; Breast; and Endometrial Cancer	Howard Strickler	**Blood:** total estradiol; glucose; IGF-1; IGFBP-3; insulin
Colorectal Cancer	**152[4]**	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: IGF-1; IGF BP-3; insulin; insulin receptor substrate 1
Colorectal Cancer	**192[2]**	Estrogen & progesterone-related genes and colorectal cancer risk	Shumin Zhang	**DNA:** ESR1 (PVII; Xbal); 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
Endometrial Cancer	**129[4]**	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	**Blood:** estradiol; glucose; IGF-1; IGFBP-3; insulin
Endometrial Cancer	**152[4]**	Growth Factor Genes and Female Breas,; Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: genes for IGF-1; IGF BP-3; insulin; insulin receptor substrate 1

Table 8.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analytes
Endometrial Cancer	**188**[2]	Inflammation and the Risk of Hormonally-Linked Cancer	Francesmary Modugno	**Blood:** EGF; EGFR; eot; FGF; GCSF; GMCSF; 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 **DNA:** IL-1B-31 (TT); IL-1B-511 (TT); IL-1RNVNTR*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); TNFα-308 (AA); TGFβ1 29 (CC); TGFβR1*6A;
Lung Cancer	**182b**	Genetic and Epigenetic Markers of Lund Cancer Risk in Post-Menopausal Women	Nicolas Schlecht	**DNA:** Dnmt1; Dnmt3b; MGMT; MS; MTHFR; MTRR; p16; p53; RASSF1A; RARbeta
Ovarian Cancer	**97**	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	**Blood:** CA-125; M-CSF; OVX1
Ovarian Cancer	**121**	Hyperinsulinemia and Ovarian Cancer	Francesmary Modugno	**Blood:** glucose; IGF-I; IGFBP-I; IGFBP-3; insulin
Ovarian Cancer	**188**[2]	Inflammation and the Risk of Hormonally-Linked Cancer	Francesmary Modugno	**Blood:** IL-1 cluster; IL-2; IL-4; IL-5; IL-6; IL-8; IL-10; IL-12p40; IL-13; IL-15; IL-17; TNFa; IFNs; FGF; GCSF; GMCSF; EGF; VEGF; MCP; MIPs; eot; sIL-6r I; sIL-2r; EGFR; and TNFa soluble receptors I and II **DNA:** TNFα-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL-1RNVNTR*2;TGFβ1 29 (CC); TGFβR1*6A;IL-10-1082/-819/-592 (GCC/GCC);Il-8-251-A-T;IGF-1 (CA)n 192/192
Pancreatic Cancer	**146**	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	**Blood:** B12; folate; GST; homocysteine; IGF-I; IGF-II; IGFBP-1; IGFBP-3; insulin; pyridozal-5-phosphate **DNA:** CYP1A1; GSTM1; NAT1; NAT2; MTHFR-667; MTHFR-1287
Other				
Diabetes Mellitus; Type II	**132**	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	**Blood:** CRP; E-selectin;;glucose; ICAM-1; IL-6; insulin; TNF-α; VCAM-1 **DNA:** AP2; CAPN10; E-selectin ser128arg; NOS3; PPAR-g2Pro12AIa; TNF alpha G308A; UCP2
Diabetes	**180**[2]	Macrovascular Complications of Diabetes in Postmenopausal Women[2]	Rongling Li	**DNA:** ACE; ADRB2; AGT; AGTR1; GNB3; NOS3; PPARG; retinol; TNF; UCP3
Eye disease	**105**	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	**Blood:** α- and β-carotene; all trans-β-carotene; 9-cis-β-carotene;13-cis-β-carotene; α- and β-cryptoxanthine; α-; δ-; and γ-tocopherol; 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

Table 8.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analytes
Frailty/ Disability	**179[2]**	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women[2]	Andrea LaCroix	**Blood:** CRP; D-dimer; FVII Ag; FVIIc; FVIII; FXI α1-antitrypsin; fibrinogen; IL-6; PAP complex; **DNA**: ACE gene insertion (I) polymorphism; two promotor polymorphisms (-174G/C and -572G/C) of IL-6 gene
Sarcopenia	**191**	Cytokines, Hormones, and Sarcopenia in Older Women	Zhao Chen	**Blood**: CRP; growth hormone; IGF-1; IGFBP-1; IGFBP-3; IL-1a; IL-1b; IL-1ra; IL-6; IL-6sR; IL-10; insulin; leptin; TNF-a; TNF-b; TNF RII.

[1] Some ancillary studies include more than one disease.

[2] Pending funding.

[3] Ancillary studies 90 and 181 share cases and controls.

[4] Ancillary studies 129 and 152 share cases and controls.

Table 8.2
Number of Assays Completed in CVD Biomarker Study:
Estrogen-plus-Progesterone Cases and Controls
Cases as of February 2001

	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
Assays[1]	Baseline (N=229)	Year 1 (N=160)	Baseline (N=229)	Year 1 (N=171)	Baseline (N=145)	Year 1 (N=105)	Baseline (N=145)	Year 1 (N=112)	Baseline (N=152)	Year 1 (N=88)	Baseline (N=152)	Year 1 (N=101)	Baseline (N=513)	Year 1 (N=359)
Inflamation														
Adiponectin[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
CRP	222	148	216	151	140	97	142	110	149	85	149	91	494	341
E-selectin	218	150	222	153	141	99	144	108	-	-	147	90	500	341
IL-1 beta[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
IL-2[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
IL-4[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
IL6	220	148	224	154	140	96	143	109	-	-	146	90	500	342
IL-8[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
IL-10[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
IL-12[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
IL-18[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
Macrophage inhibitory cytokine-1	*	-	*	-	-	-	-	-	-	-	-	-	-	-
MMP-9[3]	229	154	228	156	145	103	145	111	-	-	152	92	512	349
MMP-7[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
MMP-8[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
TFPI activity[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI, free[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI, total[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TMP-1[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
TNF-alpha[3]	*	-	*	-	-	-	-	-	-	-	-	-	-	-
Thrombosis														
Antithrombin III	-	-	222	149	-	-	140	104	149	85	148	86	497	335
D-dimer	226	153	227	155	142	101	145	110	150	86	152	90	511	344
Factor VIII	226	153	228	155	142	101	144	110	151	86	152	91	511	345
Factor IX Conc	-	-	226	-	-	-	144	-	150	-	151	-	508	-
Fibrinogen	226	153	228	155	142	101	144	110	151	86	152	91	511	345
Fragment 1+2	209	141	208	149	132	93	140	106	142	82	141	90	477	334
PAI-1	211	143	210	150	132	94	142	109	143	83	143	91	483	339
PAP	211	143	209	150	132	94	142	108	143	83	143	91	482	338
Protein C	-	-	160	-	-	-	109	-	105	-	112	-	371	-
Protein S Total	-	-	160	-	-	-	108	-	105	-	112	-	370	-
Protein S Free	-	-	160	-	-	-	108	-	104	-	110	-	368	-
Prothrombin Ag	-	-	219	150	-	-	142	106	147	84	148	88	496	340
TAFI	223	151	220	151	140	99	142	110	149	85	150	91	499	341
vWF	226	153	228	155	141	101	144	109	150	86	151	89	510	342
APC-ETP[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Table 8.2
Number of Assays Completed in CVD Biomarker Study:
Estrogen-plus-Progesterone Cases and Controls (continued)
Cases as of February 2001

Assays[1]	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
	Baseline (N=229)	Year 1 (N=160)	Baseline (N=229)	Year 1 (N=171)	Baseline (N=145)	Year 1 (N=105)	Baseline (N=145)	Year 1 (N=112)	Baseline (N=152)	Year 1 (N=88)	Baseline (N=152)	Year 1 (N=101)	Baseline (N-512)	Year 1 (N=359)
Lipids														
HDL Conc	218	144	219	148	141	100	141	102	142	77	144	88	492	329
HDL-2	215	142	218	148	140	99	140	102	141	77	144	87	490	328
HDL-3	215	142	218	148	140	99	140	102	141	77	144	87	490	328
LDL Conc	209	138	216	146	137	98	139	99	140	75	140	87	484	323
LDL Particle Size[5]	221	144	219	150	139	98	139	107	-	-	145	87	490	334
Lp(a)	207	133	211	143	137	98	136	101	-	-	131	84	466	320
Total cholesterol	220	144	220	148	141	101	141	102	142	77	144	88	493	329
Triglyceride	220	144	220	148	141	101	141	102	142	77	144	88	493	329
Lipoprotein subfractions (10)[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
LDL particle conc[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
Other Analytes														
Homocysteine	228	153	228	155	143	101	145	109	152	86	151	92	511	345
Glucose[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Insulin[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Polymorphisms														
MTHF	227		229		144		143		146		149		508	
PAI-1	227		229		144		143		146		149		508	
Prothrombin 20210	227		229		144		143		146		149		508	
Prothrombin 19911	227		229		144		143		146		149		508	
Factor XIII val34leu	227		229		144		143		146		149		508	
ERB-1710AG	217		217		138		136		144		146		486	
EX1-10	210		210		131		128		136		136		461	
F5LE	227		229		144		143		146		149		508	
GPIM	217		217		137		136		143		147		487	
HR1	227		229		144		143		146		149		508	
ITGA1807CT	216		217		137		136		143		147		487	
IVS1-154	212		212		137		133		142		143		476	
IVS1-401	211		203		128		122		135		139		452	
IVS1-1415	200		202		124		127		132		138		455	
IVS1-1505	213		214		136		136		140		144		481	

[1] Some assays done only on CHD/stroke cases and others done only on VTE cases.

[2] Controls may be matched to more than one case, and cases may be controls for other diseases in table.

[3] Assays added in 2004, to be completed after labs selected.

[4] Assays added in summer of 2003, to be completed in 2004.

[5] Includes 12 sizes: LDL1-7, LHDL, VLDL, MidA, MidB, and MidC

Table 8.2
Number of Assays Completed in CVD Biomarker Study:
Estrogen-Alone Cases and Controls
Cases as of February 2001

	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
Assays[1]	Baseline (N=173)	Year 1 (N=118)	Baseline (N=173)	Year 1 (N=127)	Baseline (N=127)	Year 1 (N=89)	Baseline (N=127)	Year 1 (N=91)	Baseline (N=71)	Year 1 (N=50)	Baseline (N=71)	Year 1 (N=52)	Baseline (N=365)	Year 1 (N=254)
Inflamation														
CRP	168	112	167	121	127	80	126	84	68	47	67	49	354	249
E-selectin	165	113	170	120	123	81	126	83	-	-	69	49	359	247
IL6	171	114	169	122	124	82	125	84	-	-	66	48	354	249
MMP-9	173	116	173	123	126	84	127	86	-	-	71	49	365	253
TFPI, Free[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI, total[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI activity[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Thrombosis														
Antithrombin III	-	-	170	121	-	-	117	80	68	46	69	49	351	247
D-dimer	172	115	172	123	126	83	126	86	70	47	71	49	364	253
TGFB[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Factor VIII	173	115	173	123	127	83	126	86	71	47	71	49	364	253
Factor IX Conc	-	-	172	-	-	-	125	-	71	-	70	-	361	-
Fibrinogen	173	115	173	123	127	83	126	86	71	47	71	49	364	253
Fragment 1+2	158	107	156	118	122	76	119	81	62	45	62	45	331	239
PAI-1	158	107	157	119	121	76	120	81	64	45	62	45	333	240
PAP	158	107	157	119	121	76	120	81	64	45	62	45	333	240
Protein C	-	-	115	-	-	-	91	-	46	-	46	-	247	-
Protein S Total	-	-	115	-	-	-	90	-	46	-	46	-	246	-
Protein S Free	-	-	113	-	-	-	90	-	46	-	46	-	244	-
Prothrombin Ag	-	-	169	120	-	-	123	84	65	46	67	49	353	249
TAFI	165	111	168	121	123	81	125	85	67	47	68	49	355	250
vWF	172	115	171	123	126	83	126	86	70	47	71	49	363	253
APC-ETP[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Table 8.2
Number of Assays Completed in CVD Biomarker Study:
Estrogen-Alone Cases and Controls (continued)
Cases as of February 2001

	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
Assays[1]	Baseline (N=173)	Year 1 (N=118)	Baseline (N=173)	Year 1 (N=127)	Baseline (N=127)	Year 1 (N=89)	Baseline (N=127)	Year 1 (N=91)	Baseline (N=71)	Year 1 (N=50)	Baseline (N=71)	Year 1 (N=52)	Baseline (N=365)	Year 1 (N=254)
Lipids														
HDL Conc	165	109	169	118	121	79	119	79	60	39	62	43	345	236
HDL-2	164	108	167	114	121	78	119	79	59	39	62	43	343	232
HDL-3	165	108	167	115	121	78	119	79	59	39	62	43	343	233
LDL Conc	156	104	164	112	117	74	117	76	58	36	61	43	337	227
LDL Particle Size[5]	165	109	166	116	121	79	124	83	-	-	62	46	346	240
Lp(a)	157	103	162	112	118	74	116	76	-	-	57	41	330	225
Total cholesterol	167	109	169	118	122	79	120	79	61	39	62	43	346	236
Triglyceride	167	109	169	118	122	79	120	79	61	39	62	43	346	236
Other Analytes														
Homocysteine	173	115	173	124	126	83	127	85	71	47	71	49	365	253
Glucose[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Insulin[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Polymorphisms														
Factor V Leiden	172		172		122		126		70		67		359	
Factor V-HR2	172		172		122		126		70		67		359	
MTHF	172		172		122		126		70		67		359	
PAI-1	172		172		122		126		70		67		359	
Prothrombin 20210	172		172		122		126		70		67		359	
Prothrombin 19911	172		172		122		126		70		67		359	
Factor XIII val34leu	172		172		128		126		70		67		359	
ERB_1710AG	163		165		119		123		65		66		348	
EX1_10	154		153		113		120		64		63		330	
F5LE	172		172		122		126		70		67		359	
GPIM	162		165		119		124		66		66		349	
HR1	172		172		122		126		70		67		359	
ITGA1807CT	162		164		119		124		66		66		348	
IVS1_154	161		161		117		123		65		63		341	
IVS1_401	148		151		109		113		62		62		320	
IVS1_1415	153		148		109		115		61		61		318	
IVS1_1505	162		160		117		122		63		63		339	

[1] Some assays done only on CHD/stroke cases and others done only on VTE cases.

[2] Controls may be matched to more than one case, and cases may be controls for other diseases in table.

[3] Assays added in 2004, to be completed after labs selected.

[4] Assays added in summer of 2003, to be completed in 2004.

[5] Includes 12 sizes: LDL1-7, LHDL, VLDL, MidA, MidB, and MidC

Table 8.3
OS Blood Committed to Ancillary Studies (AS)

Disease[1]	Cases reported as of 8-04	AS #	Cases committed	Volume Committed (Baseline/Year 3) Serum (ml)	Citrate Plasma (ml)	EDTA Plasma (ml)	DNA (μg)
Cardiovascular							
CHD	2,012	83	650		1.0	0.5	3
		110	385	1.8[2]			
		137	1,060				3
		164[3]	350			0.3	
		165	800	0.25-0.55			
		189[3]	150	0.32		0.1	
Stroke	1,677	126	1,100		1.5	1.5	
		165	750	0.25-0.55			
		169[3]	188	1.25	0.15		1
Hypertension	19,875	133	800			0.8	2
Fracture							
Hip Fracture	888	90	400[4]	1.7			3
		181[3]	400[4]	0.75[5]			
Cancer							
Breast Cancer	3,627	129	900[6]	0.25			
		134	200	0.3			
		152	900[6]				3
		167[3]	400			1.0	
		188[3]	500	0.125			1
Colorectal Cancer	774	108	50				1
		129	500[6]	0.25			
		152	500[6]				3
		192[3]	800				1
Endometrial Cancer	488	129	300[6]	0.25			
		152	300[6]				3
		188[3]	500	0.125			1
Lung Cancer	649	182[3]	550				1
Ovarian Cancer	309	97	264 baseline, 132 Yr 3	1.0 baseline`, 1.0 Yr 3			
		121	200	0.5			
		188[3]	350	0.125			1
Pancreatic Cancer	152	146	106			0.6	3
Other							
Diabetes	4,569	132	1,800			0.75	3
		180[3]	3,164				3
Eye Disease	See note 7	105	1,700	0.6			
Frailty/Disability	See note 7	179[3]	1,200		0.7	0.25	1
Sarcopenia	See note 7	191[3]	400			0.3	

[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

9. Clinical Center Performance Monitoring

9.1 Performance Monitoring

A four step plan is used to identify clinic-specific performance issues in a timely fashion, to reinforce good performance, and to provide assistance or institute corrective action if performance is inadequate. CCC staff train, monitor, and communicate with CC staff on an ongoing basis.

9.2 PMC Committee Activity

The Performance Monitoring Committee (PMC) provides a facilitating and monitoring role for CCs. In July 1998, the PMC separated its monitoring activities into two separate groups, with one group addressing outcomes and one group addressing adherence/retention and other issues. Membership of the Adherence and Retention PMC (A&R PMC) includes: Sally Shumaker, CFC PI, chair; Shari Ludlum and Linda Pottern, Project Office; Betty Caan, Oakland Clinical Center PI; Gerardo Heiss, Chapel Hill Clinical Center PI; Michelle Naughton and Steve Rapp, CFC; and Barb Cochrane, Julie Hunt, Andrea LaCroix, Bernedine Lund, and Lesley Tinker, CCC. Membership of the Outcomes PMC (O-PMC) includes Anne McTiernan, CCC, chair; David Curb, Honolulu Clinical Center PI; Marian Limacher, Gainesville Clinical Center PI; Ronald Prineas, CFC; Shari Ludlum and Jacques Rossouw, Project Office; and Charles Kooperberg, Bernedine Lund, and Lori Proulx-Burns, CCC.

Since March 1, 2004, the A&R PMC continued its streamlined quarterly review of CCs to better focus of study priorities before closeout: 1) study wide A&R priorities (i.e., stop follow-up, lost-to-follow-up, absolutely no follow-up, undeliverable addresses, CaD pill collections and final E-Alone collections after the stopping of E-Alone intervention March 1, 2004, and collection rates for *Form 33 – Medical History Update*, *Form 60 – FFQ*, *Form 17 – CaD Management and Safety*, and *Form 85 – Mammogram*); 2) targeted review and offer of A&R PMC assistance for lower performing CCs; and 3) a cursory review for higher performing CCs.

During the same time, the O-PMC held three committee conference calls. A summary of each CC included: 1) recent and cumulative data on collection of required outcomes forms, outcomes packet assembly, and local adjudication; 2) a graph showing the timeliness of outcomes processing over time; 3) CC responsiveness to CCC queries for more information on cancer and CVD cases; and 4) a summary of number of staff and local adjudicators. In the letters to CCs, specific goals were listed for CCs. The Outcomes Collection and Processing Backlog report was updated to show the current timeliness of local adjudication, including the number of current open adjudications and number currently open for more than 30 days. See *Table 9.1 – Outcomes Collection and Processing Backlog.*

During this time, the O-PMC continued its routine review of CCs. The committee held three conference calls, focusing its review on the CCs with lowest performance. The committee also held targeted conference calls with three CCs to discuss issues with outcomes processing in more detail and to provide direction and interim goals for improving performance. CCC outcomes staff conducted 2-5 day outcomes visits to six CCs. To assist in reducing backlog in local adjudication, the CCC performed local adjudication for two CCs, adjudication over 330

cases during a two months. CCC staff also continued intensive interactions with two CCs. Weekly calls with OC staff at one CC began in March and increased to daily calls in August to assist the CC with daily and weekly priorities and organization of outcomes tasks. In April 2004 the PO directed the CCC to assume outcomes collection and ascertainment for the second CC, collecting outcomes data from participants not attending CC visits and outcomes ascertainment on all participants for one CC. In late July the CCC received the CC IRB's approval for making contact with the participants and began the outcomes collection. In the next 6 months, additional targeted calls and possible visits calls with one-two other CCs are being scheduled.

The PMC report showing data as of August 31, 2004 is in *Tables 9.2 - 9.6*. E-Alone adherence summary data was deleted from the report with the stopping of the E-Alone intervention March 1, 2004. The CCs also receive these tables monthly.

Table 9.1

Outcomes Collection and Processing Backlog[1] Data as of 8/31/04

Clinic	Form 33 Missing[2] CT 12/1/03-5/31/04 #	CT %	OS 11/1/02-10/31/03 #	OS %	Form 33D Missing[3] Cumulative #	Cumulative %	Outcomes Processing: Cases[4] Cum #	Ave # / month in last 12 months	# Not assigned	Backlog: > 2 Months ave workload # Cases	# Months	# Cases to add/month to catch-up by Nov 30, 2004	Catch-up Workload: # Cases per month	# Cases per Day	% Increase in ave workload	Death[5] Cum #	% Unresolved	Local Adjudication[6] Cases assigned in last 12 months # Open	# Open > 30 days
Atlanta	69	4.2	50	2.1	17	0.4	4,956	63	124	0	0	0	63	3	0	215	17.2	2	1
Birmingham	87	5.0	211	6.8	7	0.1	6,925	83	195	29	0.3	10	93	5	12	266	12.0	31	14
Bowman	89	8.2	162	11.0	7	0.2	3,539	42	88	4	0.1	1	43	2	2	142	9.2	18	4
Winston Salem	33	8.7	34	5.1	1	0.1	1,216	18	18	0	0	0	18	1	0	39	2.6	9	1
Brigham	68	3.1	140	4.9	24	0.4	6,669	96	184	0	0	0	96	5	0	184	12.0	36	0
Buffalo	38	2.5	75	3.5	14	0.3	5,527	73	147	1	0	0	73	4	0	257	25.3	2	2
Chapel Hill	40	2.7	25	1.2	1	0.0	4,137	63	52	0	0	0	63	3	0	152	2.6	0	0
Chicago	61	8.0	43	4.7	32	1.6	2,296	28	79	23	0.8	8	36	2	29	92	20.7	1	1
Evanston	45	5.7	82	9.2	24	1.1	2,578	31	83	21	0.7	7	38	2	23	97	9.3	1	0
Chi-Rush	129	10.2	212	10.9	55	1.8	3,972	33	134	68	2.1	23	56	3	70	177	11.3	5	5
Cincinnati	60	4.4	176	8.2	29	0.8	4,546	54	21	0	0	0	54	3	0	149	1.3	0	0
Columbus	113	7.6	44	2.1	15	0.4	4,923	75	101	0	0	0	75	4	0	171	12.3	33	13
Detroit	175	13.0	193	9.5	8	0.3	3,675	52	167	63	1.2	21	73	4	40	130	19.2	7	0
Gainesville	35	3.2	47	3.5	14	0.5	3,276	45	88	0	0	0	45	2	0	133	7.5	1	1
Jacksonville	55	6.0	71	5.4	8	0.3	2,822	36	53	0	0	0	36	2	0	107	13.1	1	0
GWU	61	4.2	37	1.7	35	1.0	4,349	62	138	14	0.2	5	67	3	8	168	17.3	8	7
Honolulu	137	10.1	229	11.2	27	1.2	2,661	38	96	20	0.5	7	45	2	18	149	26.2	12	0
Houston	159	12.9	116	5.7	14	0.6	2,615	37	185	111	3.0	37	74	4	100	183	23.0	94	39
Iowa City	50	5.1	48	3.4	24	0.9	3,467	51	96	0	0	0	51	3	0	95	17.9	0	0
Bettendorf	13	1.8	22	1.9	5	0.2	3,096	40	35	0	0	0	40	2	0	106	6.6	4	2
Des Moines	5	0.8	4	1.0	2	0.2	1,533	18	48	12	0.7	4	22	1	22	47	2.1	1	1
Irvine	109	6.9	124	5.8	29	0.9	3,380	43	115	29	0.7	10	53	3	23	162	24.7	14	9
La	110	6.8	73	3.5	17	0.5	4,330	60	109	0	0	0	60	3	0	175	13.1	14	6
La Jolla	275	13.3	351	10.7	478	9.9	5,197	52	633	529	10.2	176	228	11	338	353	24.1	29	20
Madison	76	5.0	28	1.5	41	1.2	3,935	53	142	36	0.7	12	65	3	23	146	19.2	35	8
Mediantic	92	6.5	85	4.0	15	0.5	3,984	51	112	10	0.2	3	54	3	6	191	8.9	10	4
Memphis	84	6.3	102	5.6	56	1.7	4,504	58	89	0	0	0	58	3	0	183	10.4	13	7
MemSat	9	3.0	44	7.5	1	0.1	1,105	16	8	0	0	0	16	1	0	68	1.5	1	1
Miami	205	14.3	340	25.2	13	0.6	2,460	34	77	9	0.3	3	37	2	9	132	25.0	81	6
Milwaukee	108	6.7	129	6.0	44	1.2	4,351	59	76	0	0	0	59	3	0	159	6.3	1	0
Minneapolis	100	5.3	148	5.6	65	1.4	6,021	78	119	0	0	0	78	4	0	198	16.7	21	15
Nevada	31	2.2	28	1.4	8	0.2	4,661	64	170	42	0.7	14	78	4	22	287	17.4	8	0
Newark	150	8.9	273	11.1	22	0.5	4,779	64	191	63	1.0	21	85	4	33	164	28.0	73	15
New Brunswick	80	11.9	40	5.0	44	3.2	1,583	23	69	23	1.0	8	31	2	35	67	35.8	24	21
NYC	147	8.1	291	10.5	26	0.6	5,139	70	248	108	1.5	36	106	5	51	254	22.0	32	27
Oakland	37	2.5	60	3.1	30	1.1	3,339	46	130	38	0.8	13	59	3	28	193	14.5	43	16
Pawtucket	85	5.2	189	8.8	30	0.7	5,100	62	84	0	0	0	62	3	0	190	15.3	14	9
Fall River	18	2.0	39	3.0	10	0.4	2,683	39	64	0	0	0	39	2	0	98	33.3	11	10
Pittsburgh	50	3.2	222	12.2	5	0.1	7,374	81	169	7	0.1	2	83	4	2	212	6.6	2	2
Portland	107	6.8	82	3.8	13	0.4	4,194	60	97	0	0	0	60	3	0	186	20.4	1	0
San Antonio	120	8.9	157	8.4	12	0.5	2,714	35	51	0	0	0	35	2	0	127	23.6	36	16
Seattle	129	7.5	171	10.9	15	0.4	4,556	59	94	0	0	0	59	3	0	222	13.1	14	8
Stanford	80	4.8	87	3.4	7	0.2	4,496	67	99	0	0	0	67	3	0	221	11.8	0	0
Stony Brook	68	5.2	39	2.0	23	0.7	4,508	70	136	0	0	0	70	4	0	151	9.9	15	6
Torrance	134	13.9	125	8.7	45	2.4	2,230	28	59	3	0.1	1	29	1	4	120	27.5	25	2
Tucson	94	8.1	86	5.8	2	0.1	4,566	52	75	0	0	0	52	3	0	203	7.9	3	0
Phoenix	84	10.3	108	9.6	20	1.0	2,579	31	38	0	0	0	31	2	0	147	15.6	18	1
UC Davis	107	5.9	83	3.9	26	0.6	5,407	70	82	0	0	0	70	4	0	262	17.9	54	23
Worcestr	43	2.7	26	1.2	3	0.1	4,748	66	160	28	0.4	9	75	4	14	185	9.2	39	18
CC Ave	106	6.1	139	6.2	37	0.9	4,817	63	141	32	0.5	11	74	4	17.0	203	15.7	22	9

1 - From CC databases, numbers may not match quarterly CCC reports; 2 - From Task Completeness - Outcomes 33 missing; 3 - From *WHIP2030-Timeliness of Outcomes Processing*; 4 - From *WHIP1263 - Timeliness of Case Packet Assembly* for cum date and last 12 mo data; 5 - From *WHIP1225 -Unresolved Deaths* (unresolved defined as any open death < one year old, or closed but missing proxy *Form 33/33D*. Excludes NDI deaths); 6 - From *WHIP 1264 - Timeliness of Local Outcome Adjudications* for Cases Assigned in last 12 months

Table 9.2
Performance Monitoring Committee Report
Data as of 8/31/04
DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Jul 03 - Aug 04[3]		Dec 03 - May 03		Cum Aug 04	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	12.3	1	9.0	1	90.8	2	10.1	2
Oakland	11.3	1	11.2	1	98.4	1	6.4	1
Madison	10.6	1	9.2	1	92.2	2	5.5	1
Iowa City	10.4	1	7.2	2	94.4	1	7.0	1
Stanford	10.3	1	8.2	1	92.1	2	8.1	2
Columbus	10.3	1	7.2	2	89.0	2	8.4	2
Minneapolis	10.2	1	9.4	1	95.4	1	8.7	2
Milwaukee	10.2	1	8.3	1	85.9	3	6.8	1
Pittsburgh	10.1	1	8.0	1	92.6	2	7.2	1
GWU-DC	10.0	1	8.7	1	95.6	1	7.7	1
Seattle	10.0	2	7.7	2	87.2	3	11.1	3
Irvine	9.5	2	8.0	2	91.2	2	8.5	2
Chicago	9.4	2	8.1	1	87.8	3	11.1	3
Portland	9.2	2	7.4	2	88.4	3	10.7	3
Chapel Hill	8.9	2	8.1	1	94.6	1	6.8	1
Worcester	8.9	2	7.1	3	93.7	1	6.6	1
Torrance	8.9	2	7.7	2	75.5	4	14.2	4
Gainesville	8.8	2	7.4	2	93.2	1	7.8	1
UC Davis	8.7	2	7.1	2	87.0	3	12.1	3
Brigham	8.4	2	7.5	2	93.3	1	8.4	2
LA	8.4	3	6.8	3	84.4	4	11.1	3
Tucson	8.4	3	7.2	2	93.0	2	13.7	4
Pawtucket	8.3	3	6.4	3	91.8	2	10.0	2
Buffalo	8.3	3	6.0	3	94.9	1	9.6	2
Memphis	8.1	3	5.7	4	86.6	3	13.3	4
Stony Brook	8.1	3	6.4	3	92.3	2	9.6	2
Chi-Rush	7.9	3	5.0	4	84.7	3	14.6	4
Bowman	7.9	3	5.6	4	83.9	4	13.2	3
Newark	7.9	3	6.1	3	80.8	4	11.8	3
Atlanta	7.9	3	5.9	3	83.7	4	8.0	1
Houston	7.8	4	4.3	4	87.9	3	12.1	3
Cincinnati	7.4	4	4.3	4	96.0	1	9.2	2
NYC	7.3	4	7.0	3	88.6	2	11.0	3
Honolulu	7.3	4	5.4	4	84.9	3	18.5	4
LaJolla	7.2	4	5.8	3	81.9	4	16.4	4
Detroit	6.9	4	5.7	4	80.1	4	15.2	4
Birmingham	6.6	4	6.0	3	84.0	4	12.5	3
San Antonio	5.7	4	3.7	4	83.5	4	14.5	4
MedStar	5.4	4	4.8	4	88.6	3	13.6	4
Miami	4.8	4	5.6	4	78.3	4	22.6	4
CC Average	**8.6**		**6.9**		**88.8**		**10.8**	
Ave F/U 7.5 yr	Design Assumption 11.4				Goal ≥ 90%		Design Assumption 20.5	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)
[2] Based on FFQs collected after randomization through AV9.
[3] Based on FFQs collected in the last 12 months
[4] From *WHIP 1445-Task Completeness*; complete if encounter date on *Form 60* is -6/+12 months from visit target date, using 6 month period ending 3 months before the data as of date; excludes deaths
[5] From *WHIP0751- DM Intervention & F/U Status*, includes stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 9.3
Performance Monitoring Committee Report
Data as of 8/31/04
HT

	Task Completeness Dec 03 – May 04			
	Form 10[1]		Form 85[2]	
	%	Quartile	%	Quartile
Oakland	100.0	1	91.0	1
Gainesville	100.0	1	91.5	1
San Antonio	100.0	1	83.7	3
Nevada	99.4	1	86.6	2
Chapel Hill	99.4	1	90.2	1
Chi-Rush	99.3	1	85.5	3
Stanford	99.3	1	79.2	4
Worcester	99.1	1	93.4	1
Cincinnati	98.6	1	88.8	2
Stony Brook	98.5	1	89.8	1
Pittsburgh	98.3	2	89.1	2
NYC	98.1	2	80.4	3
Minneapolis	98.1	2	90.1	1
Buffalo	97.9	2	91.0	1
Atlanta	97.9	2	89.6	2
Pawtucket	97.8	2	92.4	1
Portland	97.6	2	86.2	3
Birmingham	97.6	2	86.6	2
GWU-DC	97.4	2	78.4	4
Brigham	97.3	2	88.8	2
UC Davis	96.9	3	85.9	3
Miami	96.9	3	73.7	4
Bowman	96.5	3	87.1	2
Iowa City	96.4	3	92.2	1
Tucson	96.3	3	79.8	4
Torrance	96.3	3	74.0	4
Chicago	96.3	3	89.2	2
Milwaukee	95.5	3	87.1	2
Madison	95.3	3	92.1	1
Memphis	95.1	3	81.4	3
Seattle	95.1	3	68.1	4
MedStar	94.7	4	82.6	3
LaJolla	93.3	4	66.1	4
Columbus	92.6	4	84.9	3
Irvine	92.4	4	75.3	4
Newark	91.7	4	83.2	3
Honolulu	87.6	4	88.9	2
LA	87.4	4	84.4	3
Detroit	86.0	4	71.1	4
Houston	83.0	4	68.7	4
CC Average	**96.3**		**84.8**	
Ave F/U 7.3 yr	Goal ≥ 90%		Goal ≥ 90%	

[1] From *WHIP1445 – Task Completeness*, complete if encounter date on *Form 10 – HRT Management and Safety* is -3/+3 months from target date.

[2] From *WHIP1445 – Task Completeness*, complete if mammogram date on *Form 85 – Mammogram* date is -12/+6 months from AV target date.

Table 9.4
Performance Monitoring Committee Report
Data as of 8/31/04
CaD

	Adherence Summary ≥ 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Sep 03 - Aug 04		Dec 03 - May 03		Cum Aug 04	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.6	1	77.5	1	99.1	1	14.5	1
Stanford	70.4	1	69.9	1	98.8	2	25.8	1
Iowa City	68.5	1	62.5	1	99.2	1	21.4	1
Minneapolis	67.0	1	66.7	1	96.6	3	22.6	1
Nevada	66.8	1	68.6	1	99.7	1	25.4	1
Chapel Hill	65.0	1	66.3	1	99.4	1	16.5	1
Columbus	63.3	1	60.8	2	95.0	4	26.8	2
Portland	61.8	1	61.5	2	96.2	3	28.8	2
Gainesville	61.6	1	60.3	2	99.2	1	31.0	2
Brigham	60.8	1	59.3	2	98.6	2	28.1	2
Pittsburgh	60.6	2	60.4	2	98.4	2	32.5	3
Milwaukee	60.5	2	61.7	2	95.9	4	24.3	1
Chi-Rush	60.3	2	57.7	2	95.7	4	32.7	3
Cincinnati	59.7	2	63.3	1	99.2	1	30.7	2
Pawtucket	59.7	2	62.5	1	99.3	1	25.2	1
Birmingham	58.4	2	62.3	1	97.9	3	27.7	2
Worcester	58.3	2	61.9	2	98.6	2	19.3	1
Madison	56.3	2	54.7	3	96.2	4	27.8	2
Honolulu	56.3	2	56.7	3	96.7	3	36.8	4
Buffalo	55.8	2	62.1	1	99.5	1	22.6	1
Torrance	55.6	3	58.3	2	91.9	4	32.9	3
GWU-DC	55.3	3	53.7	3	97.3	3	29.8	2
UC Davis	55.1	3	59.0	2	97.5	3	31.0	2
LA	54.8	3	54.6	3	96.2	4	29.1	2
Seattle	54.2	3	57.4	3	93.9	4	32.6	3
Bowman	53.3	3	56.5	3	99.0	1	31.7	3
Tucson	52.8	3	55.5	3	97.6	3	36.9	4
Atlanta	52.8	3	54.5	3	98.3	2	31.1	3
Stony Brook	52.5	3	51.1	3	97.6	3	35.6	4
Chicago	51.4	3	52.9	3	98.7	2	34.2	4
San Antonio	51.0	4	50.5	4	99.0	1	33.9	4
NYC	48.6	4	51.0	4	97.5	3	34.1	4
LaJolla	48.4	4	43.6	4	98.3	2	33.6	3
Irvine	48.3	4	47.8	4	98.5	2	32.5	3
Newark	47.5	4	46.6	4	93.3	4	31.6	3
Memphis	46.3	4	49.9	4	98.0	2	41.5	4
Detroit	43.8	4	43.0	4	90.2	4	37.3	4
Houston	43.1	4	40.8	4	87.2	4	38.5	4
MedStar	42.7	4	48.6	4	98.1	2	29.1	2
Miami	32.5	4	41.2	4	97.9	3	48.2	4
CC Average	**56.5**		**57.1**		**97.3**		**29.7**	
Ave F/U 6.5 yr	-		-		Goal ≥ 90%		Design Assump. 30.5	

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*,complete if encounter date on *Form 17 - CaD Management and Safety* is -3/+3 months from target date ending 3 months before the data as for date; excludes deaths.

[4] From *WHIP CCC753-CaD Intervention & F/U Status*; includes stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 9.5
Performance Monitoring Committee Report
Data as of 8/31/04
OS

	% Stopped[1]	
	Cum Feb 04	
	%	Quartile
Brigham	4.6	1
Chapel Hill	5.4	1
GWU-DC	5.4	1
Stony Brook	5.8	1
Worcester	6.0	1
Columbus	6.0	1
Madison	6.4	1
Atlanta	6.6	1
Pawtucket	6.9	1
Iowa City	7.1	1
Minneapolis	7.4	2
LA	7.5	2
Portland	7.6	2
Stanford	7.7	2
Oakland	8.0	2
Newark	8.0	2
MedStar	8.3	2
Milwaukee	8.4	2
Bowman	8.6	2
Gainesville	9.0	2
Buffalo	9.0	2
Cincinnati	9.1	3
UC Davis	9.3	3
Chicago	9.5	3
Irvine	9.8	3
Nevada	10.0	3
Birmingham	10.2	3
Detroit	10.3	3
NYC	10.3	3
Memphis	10.8	3
San Antonio	11.0	4
Torrance	11.0	4
Houston	11.8	4
Honolulu	12.1	4
LaJolla	12.1	4
Seattle	12.2	4
Chi-Rush	12.8	4
Pittsburgh	13.2	4
Tucson	14.3	4
Miami	19.9	4
CC Average	**9.1**	
Ave F/U 6.9 yr	-	

[1] From WHIP CCC752 OS Intervention & F/U Status; includes stopped F/U, lost-to-F/U, and deaths

Table 9.6
Performance Monitoring Committee Report
Data as of 8/31/04
OC

	Task Completeness						Outcomes Processing Sep 03 - Aug 04							
	CT Form 33[1] Dec 03 - May 04		OS Form 33[2] May 03 - Oct 03		Form 33D[3] Sep 03 - Aug 04		Cases Assembled ≤ 12 weeks[4]		Cases Adjudicated ≤ 14 days[5]		Cases Open > 16 weeks[6]		Cases Closed ≤ 16 weeks[7]	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	97.8	1	98.4	1	98.6	1	91.1	2	89.3	3	24.8	3	85.6	2
Oakland	97.5	1	97.0	1	94.1	4	86.9	3	53.1	4	12.9	1	64.1	4
Buffalo	97.5	1	96.8	2	98.3	2	89.4	2	98.1	1	29.2	3	82.7	2
Chapel Hill	97.3	1	98.5	1	97.3	2	99.4	1	92.8	2	2.1	1	99.7	1
Worcester	97.3	1	98.9	1	99.1	1	90.5	2	80.4	3	21.5	2	83.3	2
Iowa City	97.1	1	97.7	1	97.4	2	91.3	2	95.5	2	19.4	2	80.4	3
Brigham	96.9	1	96.3	2	96.8	3	90.7	2	76.4	4	17.4	2	80.0	3
Pittsburgh	96.8	1	82.1	4	99.4	1	90.0	2	99.8	1	13.5	1	84.2	2
Pawtucket	95.9	1	93.1	3	96.1	3	93.8	1	86.6	3	21.6	3	83.8	2
GWU-DC	95.8	1	98.0	1	95.3	3	85.4	4	99.7	1	10.5	1	77.2	3
Atlanta	95.8	2	98.1	1	98.5	1	94.3	1	79.1	3	31.1	4	84.3	2
Cincinnati	95.6	2	92.5	3	94.0	4	99.2	1	99.6	1	3.6	1	98.9	1
Gainesville	95.5	2	95.7	2	98.3	1	91.8	2	98.9	1	13.8	1	89.0	1
Stanford	95.2	2	96.2	2	99.8	1	94.7	1	74.3	4	6.5	1	88.0	1
Birmingham	95.0	2	90.1	3	99.1	1	92.2	2	94.7	2	21.5	2	75.8	3
Madison	95.0	2	98.1	1	92.3	4	92.5	1	63.0	4	15.7	2	86.7	1
Stony Brook	94.8	2	98.1	1	97.2	2	86.3	3	86.4	3	14.8	1	79.2	3
Minneapolis	94.7	2	94.7	2	95.4	3	95.7	1	96.9	2	20.3	2	87.9	1
Memphis	94.3	2	94.7	3	91.8	4	86.4	3	96.8	2	23.5	3	73.0	3
UC Davis	94.1	2	96.1	2	97.0	3	85.8	4	100.0	1	26.8	3	79.4	3
MedStar	93.5	3	95.5	2	98.2	2	88.7	3	92.7	2	35.4	4	85.4	2
Milwaukee	93.3	3	94.8	2	95.0	4	96.6	1	92.1	2	5.6	1	90.7	1
Portland	93.2	3	97.0	2	95.9	3	84.9	4	87.8	3	19.8	2	69.2	4
LA	93.2	3	96.2	2	97.1	2	84.0	4	86.7	3	19.8	2	65.2	4
Chicago	93.1	3	92.7	3	94.8	4	86.5	3	98.3	1	19.4	2	77.2	3
Irvine	93.1	3	92.5	3	98.7	1	87.9	3	97.4	1	39.3	4	85.6	2
Seattle	92.5	3	88.0	4	96.4	3	93.3	1	86.6	3	23.9	3	89.1	1
Columbus	92.3	3	97.5	1	99.1	1	91.2	2	66.7	4	27.0	3	83.6	2
NYC	91.9	3	89.1	4	97.8	2	86.5	3	89.5	2	37.4	4	69.9	4
Bowman	91.7	3	87.6	4	98.6	1	88.9	3	69.8	4	14.0	1	75.8	3
San Antonio	91.1	4	92.2	3	96.3	3	95.4	1	76.0	4	17.8	2	87.0	1
Tucson	91.0	4	92.9	3	97.5	2	89.1	3	97.7	1	23.0	3	86.0	1
Newark	90.2	4	89.7	4	93.4	4	88.8	3	46.1	4	30.6	4	72.4	4
Honolulu	89.9	4	88.6	4	96.4	3	83.2	4	97.6	1	34.0	4	79.9	3
Chi-Rush	89.8	4	86.4	4	90.3	4	91.9	2	93.5	2	30.4	4	85.3	2
Houston	87.1	4	93.8	3	97.0	3	56.7	4	59.7	4	48.6	4	25.1	4
Detroit	87.0	4	89.2	4	98.3	2	79.6	4	93.1	2	40.0	4	71.9	4
LaJolla	86.7	4	88.7	4	48.4	4	45.6	4	77.6	3	79.5	4	31.2	4
Torrance	86.1	4	91.1	3	82.8	4	80.7	4	77.9	3	20.9	2	72.9	4
Miami	85.7	4	72.4	4	97.1	2	80.4	4	50.3	4	23.5	3	70.6	4
CC Ave	**93.5**		**93.5**		**94.8**		**89.4**		**86.4**		**28.1**		**80.0**	
Goals	≥ 94.3%		≥ 95.0%		≥ 95.4%		≥ 80%		≥ 80%		< 20%		≥ 80%	

[1] From *WHIP 1445-Task Completeness;* complete if encounter date is -3/+3 months from target date
[2] From *WHIP 1445-Task Completeness*; complete if encounter date is -2/+10 months from AV1,4+ target date, -2/+9 from AV2, and -3/+15 for AV3
[3] From *WHIP 2030-Timeliness of Outcomes Processing*; includes both CT and OS
[4] From *WHIP 1263-Timeliness of Outcomes Packet Assembly;* percent of assembled cases that were assembled (assigned) within 12 weeks
[5] From *WHIP 1264-Timeliness of Local Adjudications;* percent of adjudicated cases that were adjudicated within 14 days
[6] From *WHIP 2030-Timeliness of Outcomes Processing*; percent of open cases that were open more than 16 weeks
[7] From *WHIP 2030-Timeliness of Outcomes Processing*; percent of closed cases that were closed within 16 weeks

10. Other Study Activities

A number of WHI-related scientific endeavors have been initiated by study investigators. Publications in scholarly journals are approved through the Presentations and Publications Advisory Committee and the Project Office. Ancillary studies are approved by the Design and Analysis Advisory Committee and the Project Office. Those initiatives that could potentially threaten the integrity of the Clinical Trial results before the completion of the study are to be referred to the DSMB for review. A full statement of the relevant policies may be found in the *WHI Manuals, Vol. 1 – Study Protocol and Policies, Section 3 – Study Policies.*

Table 10.1 – Publications presents current and proposed publications that have been approved by the Publications and Presentations Committee.

Table 10.2 - Ancillary Studies lists all approved ancillary studies (except for those that have been dropped) along with some key features of the studies and their current funding status

Table 10.1
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 4(5):519-29, 1995
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, pp. 510-542, 1996.
5	Women Health Initiative: Why Now? What is it? What's New?	Gen	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	11	American Psychologist. 52(2):101-116, 1997 Feb.
6	Low-fat Diet Practices of Older Women: "Prevalence and Implication for Dietary Assessment"	Gen	**Patterson**, Kristal, Coates, Ritenbaugh, Van Horn, Caggiula, Snetselaar, Tylavsky	11	Journal of the American Dietetic Association. 96(7):670-9, 1996 Jul.
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. 50(2):50-5, 1995 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	Controlled Clinical Trials 19:61-109, 1998
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	Controlled Clinical Trials. 17(6):509-25, 1996 Dec.
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 3(2):71-76, 1996
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 9(8):881-889, 2000
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 13:1-9, 2003.
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. 9(9):843-53 , 2000 Sep-Oct
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. 1(5):225-34, 2001 Dec

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	OS	**Wassertheil-Smoller**, Anderson, 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. 55, 711-717 (1999)
25	Hormone Replacement Therapy and the QT Interval	CT	**Kadish**, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz	11	Annals of Noninvasive Electrocardiology, 2004Oct;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	In press, Controlled Clinical 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 168:236-40, 1998
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	Gen	**Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins	11	Annals of Epidemiology 1999:9:178-197
37	Depression as Mediated by Social Support, Life Events, and Sexual Activity in Postmenopausal Non-Hispanic White and Latina Women	Gen	**Larisch**, Talavera, Langer, Velasquez, Elder	11	in press
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
43	Sleep Complaints of Postmenopausal Women	CT	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	11	Clinical Journal of Women's Health 1:244-252, 2001
51	The Relationship of Social Support and Social Burden to Breast Cancer Screening in the Women's Health Initiative	Gen	**Messina**, Lane, Glanz, Smith, Taylor, Frishman, Powell	11	in press, Health Psychology (2004) Vol23, No 6, page numbers tba
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	Gen	**Levine**, Shumaker, Naughton, Kaplan, Kripke, Bowen	11	Psychological Assesment, 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

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	Controlled Clinical Trials 19:604-621. 1998
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	Gen	**Pastore**, Carter, Hulka, Wells	11	In press, Maturitas
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, Vol. 347, No. 10. 2002
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 Lypocene 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	Annals of Epidemiology 2001;11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status	Gen	**Liu**	11	Menopausal Medicine, Vol.6(2), p.1-4, 1998
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	Gen	**Jeffcoat**, Lewis, Reddy, Wang, Redford	11	Periodontol 2000, 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
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	Gen	**Howard**, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetselaar	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**, Berman, Snetselaar, Granek, Boe, Huber, Milas, Spivak, Chlebowski	11	Controlled Clinical 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, 1999;5:155-159

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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, No. 1, December 2000, 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, Snetselaar, Frishman, Stefanick	11	Am J Med 2002;113;384-92
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	In press, AJEpi
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
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, 22 (5), 513-522. 2003
98	Antioxidant Use in the Women's Health Initiative Participants	Gen	**Shikany**, Patterson, Agurs-Collins, Anderson, Wang	11	Preventive Medicine, Vol. 36, Issue 3; Mar 2003, 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	Anti Hypertensive Drug Treatment and Cardiovascular Outcomes in Older Women: The WHI OS	OS	**Wassertheil-Smoller**, Psaty, Greenland, Margolis, Oberman, Kotchen, Mouton, Hilkert, Black, Anderson, Trevisan, Aragaki	11	in press, JAMA
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	CT	**Rossouw**, Hurd	11	Journal of Women's Health 8:3-5, 1999.

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	Controlled Clinical 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, Altimari	11	Controlled Clinical 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
115	Prevalence and 3-year Incidence of Abuse in Older Women	OS	**Mouton**, Rodabough, Rovi, Hunt, Brzyski	11	Am J of Public Health, April 2004, Vol. 94, No.4
120	Obesity, Body Size, and Risk of Postmenopausal Breast Cancer: The Women's Health Initiative	OS	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	11	Cancer Causes Control 2002;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, McNeeley, 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
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, Pederson, Soule, Vosburg	11	J Am Diet Assoc. 2004;104:76-85.

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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.
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
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	Racial/Ethnic Differences in Breast Cancer Incidence Rates	OS	**Chlebowski**, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan, Anderson, Chen, Aragaki, McTiernan	11	in press, JNCI
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	OS	**Margolis**, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	11	In press, Archives of Internal Medicine. Jan?
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 Assesment, 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 Results from the Women's Health Initiative	Gen	**Chen**, Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson	11	Menopause. 11(3):264-274, 2004.

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	11	American Journal of Obstetrics and Gynecology . 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	11	in press, Am J Preventative Medicine
189	Dietary Adherence in the WHI Dietary Modification Trial	CT	**The Writing Group for the WHI Investigators**	11	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	11	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	11	Diversity in Health Care Research: Strategies for Multisite, Multidisciplinary and Multi-ethnic Projects. J. W. Hawkins, L. A. Haggerty (eds.): pp.181-207 Springer. 2003
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	11	in press, approx - Volume 17, Issue 1/2 (spring/summer, 2005) Journal of Women & Aging.
203	Estrogen Plus Progestin Influence on Breast Cancer and Mammography in Healthy Postmenopausal Women	CT	**Chlebowski**, Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich, McTiernan	11	JAMA. 2003;289:3243-3253
204	Effect of Estrogen Plus Progestin 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	Are Postmenopausal Survivors of Breast Cancer at an Increased Risk for Osteoporosis?	Gen	**Chen**, Barad, Ritenbaugh, Gass, Lopez, LeBoff, Bassford, Maricic	11	in press, Archives of Internal Medicine
208	The Effects of Estrogen Plus Progestin 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.

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
210	Estrogen Plus Progestin 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	NEJM 2003; 349:523-34
211	Effects of Estrogen plus Progestin 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	NEJM, May 2003;348:1839-1854
212	Effect of Estrogen Plus Progestin 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 Progestin	CT	**Anderson**, Judd, Kaunitz, Barad, Beresford, Liu, Pettinger, McNeeley, Lopez	11	JAMA. 2003;290:1739-1748.
222	Venous Thromboembolism in the Estrogen plus Progestin Trial of the Women's Health Initiative	CT	**Cushman**, Prentice, Kuller, Sidney, Stafford, Psaty, Rodabough, Rosendaal	11	JAMA, Vol 292, No 13; 1573 – 1580.
224	Estimation of Dependence Between Paired Correlated Failure Times in the Presence of Covariate Measurement Error	OS	**Gorfine**, Hsu, Prentice	11	Journal of Royal Stat Society B. 65: Issue 3, 633-661, August 2003
225	Estrogen Plus Progestin 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 Progestin 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
232	Women's Health Initiative: Statistical Aspects and Early Results	Gen	**Prentice**, Anderson	11	in press, Encyclopedia of Clinical Trials
233	Estrogen Plus Progestin 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
235	Hormone Replacement Therapy and Risk of Cardiovascular Disease	CT	**Kuller**	11	Arterioscler Thromb Vasc Biol. 2003;23: 11-16

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
240	Risks and benefits of estrogen plus progestin 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	Journal of the American Medical Association 2002;288(3):321-333.
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
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
271	Factors associated with treatment initiation after screening and diagnosis of osteoporosis	CT	**Brennan**, Wactawski-Wende, Crespi, Dmochowski	11	In Press, AJEpi
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 (WHIMS)	CT	**Espeland**, Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp	11	in press, Am J Epidemiology
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
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	In press, Journal of Clinical Oncology (11/11)
317	Pelvic Organ Prolapse in Older Women: Prevalence and Risk Factors	CT	**Nygaard**, Bradley, Brandt	11	In press, Obstetrics & Gynecology (fall 2004)
323	Correlation between pelvic organ prolapse, pelvic floor disorder, urinary incontinence, defecation disorder, voiding dysfunction	OS	**Nygaard**	11	submitted, Journal of Women's Health
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

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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
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.
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	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	Gen	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	10	submitted, J Bone and Mineral Research
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	10	resubmitted - Circulation
188	Electrocardiographic Repolarization Phenotypes and Mortality Risk in Postmenopausal Women	CT	**Rautaharju**, LaCroix, Kooperberg, Larson	10	submitted, Am J of Cardiology
229	Symptoms and Side Effects Associated with Combined Estrogen plus Progestin in the Women's Health Initiative	CT	**Barnabei**, Cochrane, O'Sullivan, Schenken, Chen, Johnson, Laube, McGovern, Nygaard, Wells, Williams, Young	10	in review, Obstetrics and Gynecology
243	Combined Hormone Therapy and Coronary Heart Disease in the Women's Health Initiative Clinical Trial and Observational Study	CT	**Prentice**, Wactawski-Wende, Stefanick, Limacher, Langer, Kuller, Howard, Curb, Barad, Anderson, Kotchen	10	Submitted, Am J Epi
249	Combined Hormone Therapy Effects on Urinary Incontinence in the WHI	CT	**Hendrix**, Handa, Aragaki, Barnabei, Cochrane, Iglesia, McNeeley, Naughton, Nygaard, Wallace	10	submitted, JAMA
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	10	submitted to Quality of Life Research

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
272	HT, medications, and the development of gallstone disease in women in the WHI CT.	CT	**Wallace**, Cirillio, Greenland, LaCroix, Limacher, Rodabough	10	submitted, JAMA
282	Improving Dietary Self-Monitoring and Adherence with Hand-Held Computers: A Pilot Study	CT	**Glanz**, Murphy, Moylan, Evensen, Curb	10	in review, AmericanJournal of Health Promotion
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	10	Submitted to JNCI.
294	Weighted Estimators for Proportional Hazards Regression with Missing Covariates	OS	**Qi**, Wang, Prentice	10	submitted to JASA
302	Frailty: Emergence and Consequences in WHI Participants	Gen	**Woods**, LaCroix, Brunner, Cochrane, Masaki, Murray, Newman	10	
378	Expression and ambivalence over expression of negative emotion: Cross-sectional associations with psychosocial factors and health related quality of life	Gen	**Michael**, Bowen, Brzyski, Cochrane, O'Connor, Perrin, Ritenbaugh, Wisdom	10	submitted, Journal of Psychosomatic Research
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	
41	Cross sectional correlates of Fasting Hyperinsulinemia Among a Multi Ethnic Sample of Postmenopausal Women	Gen	**Pradhan**, Manson, Rodrigues, Johnson, Wagenknecht, Allen, LaCroix	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	
78	Lack of a Relationship between antioxidants and BMD: Results from the WHI	Gen	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	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	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	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**, Heimburger, 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**, Lauerman, Chirumbole, Kuller	9	
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	**Whampler**, 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	
218	Psychological Effects of Physical and Verbal Abuse among Postmenopausal Women	OS	**Mouton**, Rodabough, Cochrane, Brzyski, Rovi, Talamantes, Burge, Katerndahl	9	
220	The Women's Health Initiative: A Glimpse Behind the Scenes	CT	**Furniss**	9	
326	The Association between osteoporosis and oral bone loss in postmenopausal women	CT	**Wactawski-Wende**, Hovey, Hausmann, Trevisan, Grossi, Genco	9	
345	Postmenopausal CEE therapy reduces coronary heart disease risk	CT	**Hsia**, Langer, Caralis, Crawford, Heckbert, Hendrix, Johnson, Kostis, Kuller, Manson, Pettinger	9	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
348	Effects of CEE on Health Related QOL and Psychosocial Factors in the WHI	CT	**Brunner**, Ockene, Aragaki, Assaf, Brzyski, Gass, Granek, LaCroix, Mason, Matthews, Wallace, Woods	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	
154	Does Acidogenic Diet Contribute to the Incidence of Hip Fracture?	OS	**Barzel**, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	8	
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	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	
248	Progression of Coronary Calcification in Postmenopausal Women	OS	**Hsia**, Klouj, Prasad, Burt, Adams-Campbell, Howard	8	
298	Effect of Aspirin Supplementation on rates of Colorectal Cancer	OS	**Allison**, Langer, Garland, Criqui, Wu	8	
312	Accuracy of food portion estimation among postmenopausal women	CT	**Coy**, Frank, Lee, Meyskens	8	
20	Demographic, menstrual, and reproductive correlates of endogenous sex hormone concentrations in the WHI	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	
57	Regional Differences in Stroke Morbidity at Baseline in the WHI	Gen	**Johnson**, Hall, Oberman, Sheps, Hulka, Hays, Baum, Schenken, Burke, Limacher, Anderson, Jeppson	7	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	OS	**Paskett**, Sherman, Andersen, Hays, McDonald, Naughton	7	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	
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	
190	Predictors of LVH	CT	**Oberman**, Ko, Lasser, LaCroix, Wylie	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	
201	Normal Electrocardiographic Patterns in Older Adult Women. Depolarization and Repolarization Phenotypes	Gen	**Rautaharju**, Prineas, Hsia, Kadish, Lund	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	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
279	Symptom Experiences after stopping E+P in the WHI	CT	**Ockene**, Cochrane, Barad, Larson, Barnabei, Brzyski, Gass, Gold, Hays, Lane, Manson, Rosal, Wylie-Rosette	7	
280	Diet, physical activity, energy balance and endogenous sex hormone concentrations in the WHI	CT	**McTiernan**, Wu, Chlebowski, Modugno, Mossavar-Rahmani, Perri, Stanczyk, Van Horn	7	
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	7	
331	Pelvic Floor Symptoms in Older, Community-Dwelling Women	CT	**Bradley**, Kennedy, Nygaard	7	
347	Effect of CEE & E+P on Stroke in the WHI	CT	**Hendrix**, Wassertheil-Smoller, Aragaki, Bray, Criqui, Howard, Johnson, Kooperberg, Mouton, Rapp, Trevisan	7	
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	7	
148	Outcomes of Pap Smears on Postmenopausal Women		**Yasmeen**, Romano, Hubbell, La Valluer, Johnson, Lane, McIntosh, Hendrix	6	
334	Sexual Function and the effect of discontinuation of E+P Therapy among participants in WHI	CT	**Gass**, Cochrane	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 Post-menopausal Women	Gen	**Ockene**, Rosal, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson, Sato	5	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	OS	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	5	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	
174	HMG Co-A Reductase Inhibitor (Statin) Use and the Risk of Breast Cancer in the Women's Health Initiative Observational Study	OS	**Cauley**, LaCroix, Chlebowski, Margolis, McTiernan, Vitolins, Furberg, Bauer	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	
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	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	
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	5	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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, Tylavsky, Wactawski-Wende, Pettinger	5	
289	Occurrence of Second Malignancy following Nonmelanoma Skin Cancer: A Prospective OS from the WHI.	OS	**Rosenberg**, Greenland, Khandekar, McTiernan, Rodabough	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**	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	5	
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	**Mehta**, 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	
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	5	
311	Relationship of Supplement Use to Age Related Maculopathy	OS	**Gruber**, Mares-Perlman, Wallace, Moeller, Oxton, Chappel	5	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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 estrogen plus progestin on cardiovascular disease	CT	**Rossouw**, Barad, Barnabei, Ko, Manson, Margolis, Prentice, Stefanick, Wu	5	
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	5	
344	Are older women presenting with non-specific chest pain at increased cardiovascular risk?	Gen	**Robinson**, Wallace, Cochrane, Ko, Limacher, Ockene, Wassertheil-Smoller	5	
346	Estrogen + Progestin & CEE influence on Breast Cancer Diagnosis	CT		5	
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	5	
354	Effect of CEE on Bone Mass and Risk for Fractures	CT	**Jackson**, Wactawski-Wende, Bassford, Beresford, Ko, LaCroix, Lewis, Pettinger, Robbins, Satterfield, Watts	5	
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	5	
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	
124	Relationships Between Nutritional Intake and Measures of Cognition	WHIMS	**Espeland**, Bowen, Haan, Brunner, Snetselaar, Dunn	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	
209	Estrogen Metabolism, Body Mass Index, Hormone Replacement Therapy and Post-menopausal Breast Cancer Risk	OS	**Modugno**, Cochrane, Chlebowski, Kuller, Stefanick, Rohan, Lasser, Kip	4 9	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	
256	Inflammation and ARM in the WHISE Study	CT	**Klein**, Klein, Knudtson, Seddon, Wallace, Hyman	4	
259	Alcohol, Caffeine and ARM in the WHISE Study	CT	**Klein**, Seddon, Klein, Johnson, Tomany, 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 Modifcation: A Theoretical Framework	CT	**Rosal**, Ockene, Fletcher	4	
270	The Effect of Calcium plus Vitamin D on Risk for Fractures and Colorectal Cancer: Principal Results of the Women's Health Initiative Calcium plus Vitamin D Trial	CT	**The Writing Group for the WHI Investigators**	4	
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	4	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
281	Prevalence of ST Segment Depression on Holtor 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	
324	Extreme Obesity in a large sample of US Women: a growing threat	OS	**McTigue**, Kuller, Burke, Kotchen, Lewis, Stefanick, Van Horn	4	
325	Association of Alcohol Intake with Cognition during the WHISCA E+P CT	CT	**Espeland**	4	
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	4	
337	Joint Analyses of CT and OS data on E+P use and cancers of the breast, colorectum, ovary, and endometrium	Gen	**Prentice**, Anderson, Chlebowski, Hendrix, Hubbell, Kooperberg, Kuller, Lane, Langer, Manson, McTiernan, O'Sullivan, Stefanick	4	
339	Validity of self-reported diabetes mellitus in the WHI	Gen	**Margolis**, Bonds, Brzyski, Howard, Phillips, Robinson, Safford, Tinker	4	
340	Postmenopausal HT and Hip Geometry	CT	**Chen**	4	
342	Other combinations of height and weight are better predictors of BMD then BMI	OS	**Robbins**	4	
359	Fractures and osteoporosis in diabetics	OS	**Bonds**, Johnson, Margolis, Robbins, Rodrigues, Strotmeyer	4	
360	Obesity and risk of Dementia in Postmenopausal Women	WHIMS	**Kerwin**, Kotchen	4	
361	Estrogen Therapy with and without progestin and the risk of hip and knee joint replacement in postmenopausal women	CT	**Wallace**	4	
363	Air Pollution and Cardiovascular Disease Incidence in the Women's Health Initiative Observational Study	CT	**Kaufman**	4	
366	Association of vasomotor symptoms with cardiovascular outcomes	CT	**Barad**	4	

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WOMEN'S
HEALTH
INITIATIVE

WHI Clinical Coordinating Center

MEMORANDUM

Date: December 9, 2004

To: Recipients of the August 31, 2004 Semi-Annual Progress Report

From: Mary Pettinger
Statistics Unit Manager

Subject: Correction to Report

We have noticed an error in the graphs of percent energy from saturated fat in Figure 3.2 of the most recent Semi-Annual Progress Report. Enclosed is the entire Figure 3.2 with the corrected graphs. I apologize for any confusion this error may have caused.

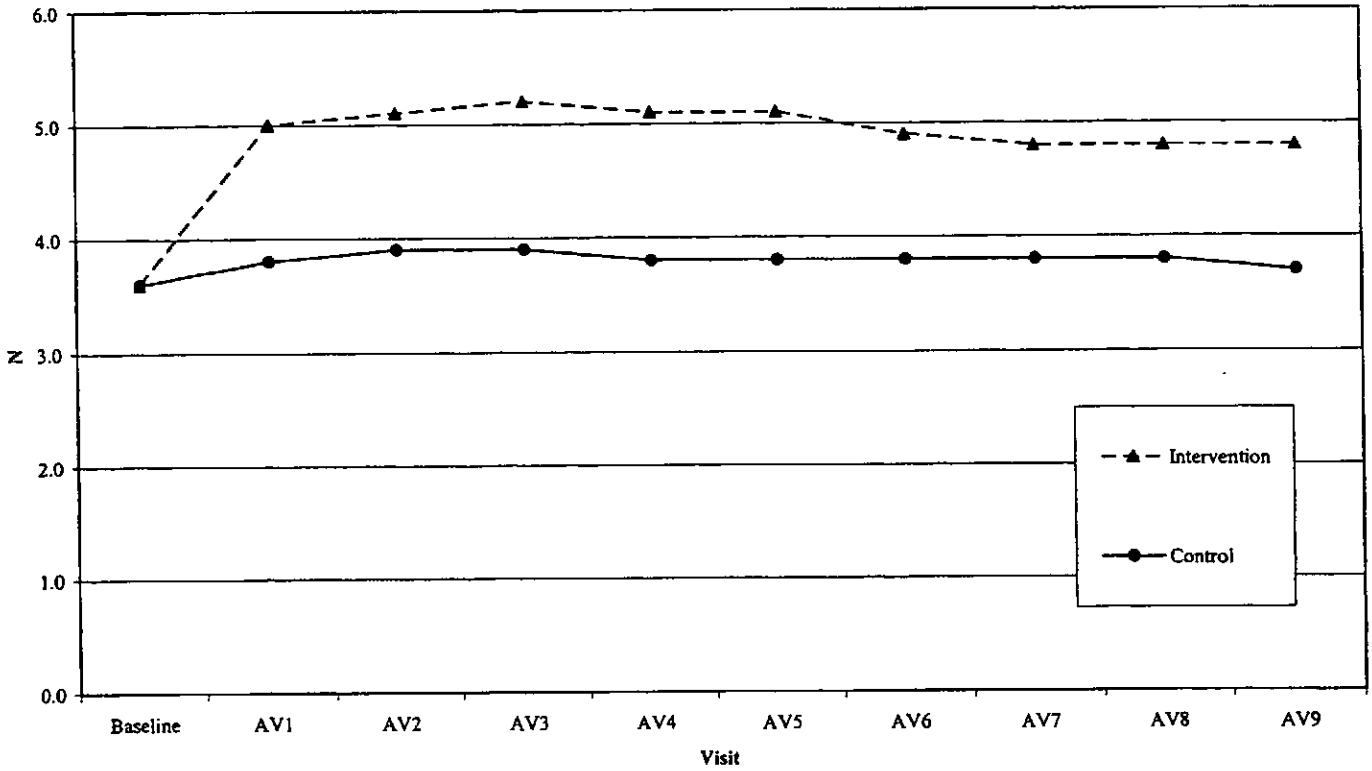
H:\

1100 Fairview Ave. N. M3-A410, PO Box 19024, Seattle, Washington 98109-1024
Phone: 206-667-6883 Fax 206-667-4142

Figure 3.1 (continued)
Nutrient Intake

Data as of: August 31, 2004

Fruit & Vegetable Servings per Day



Grain Servings per Day

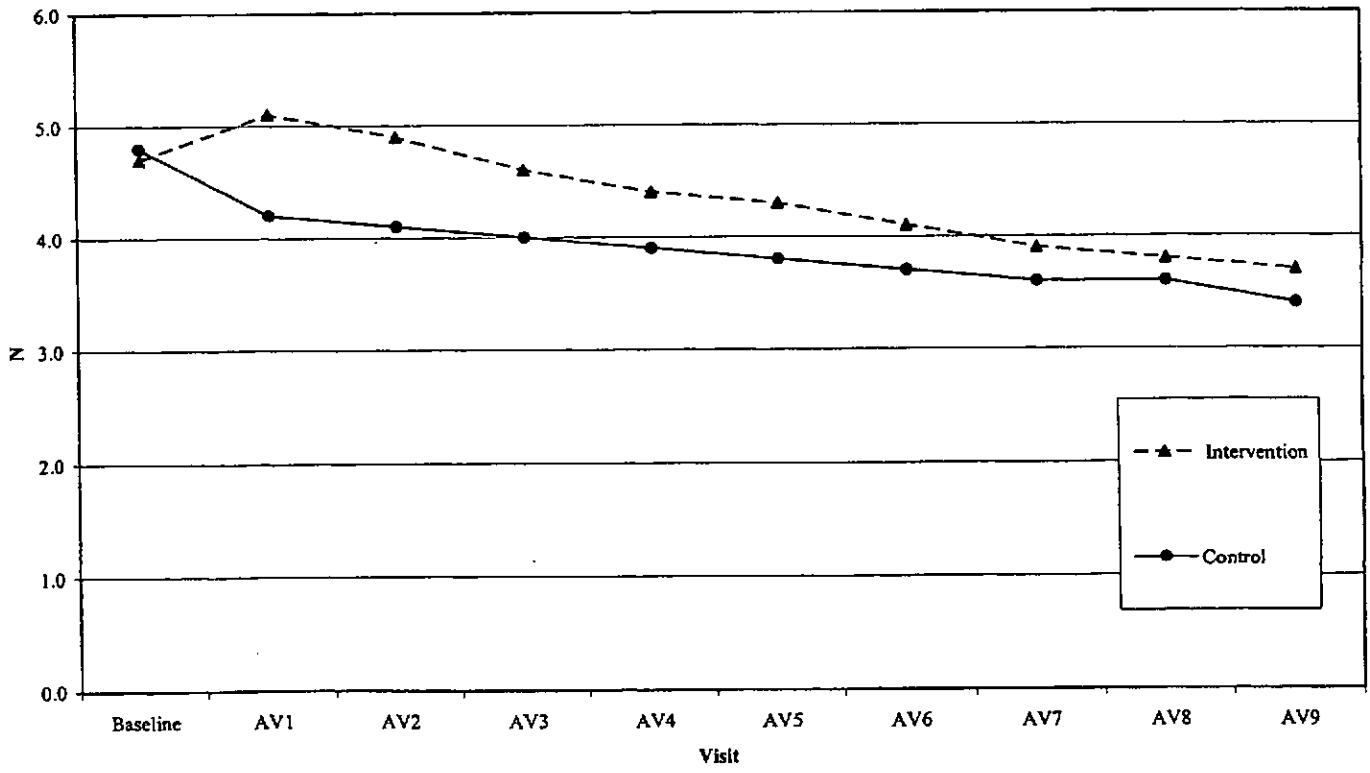
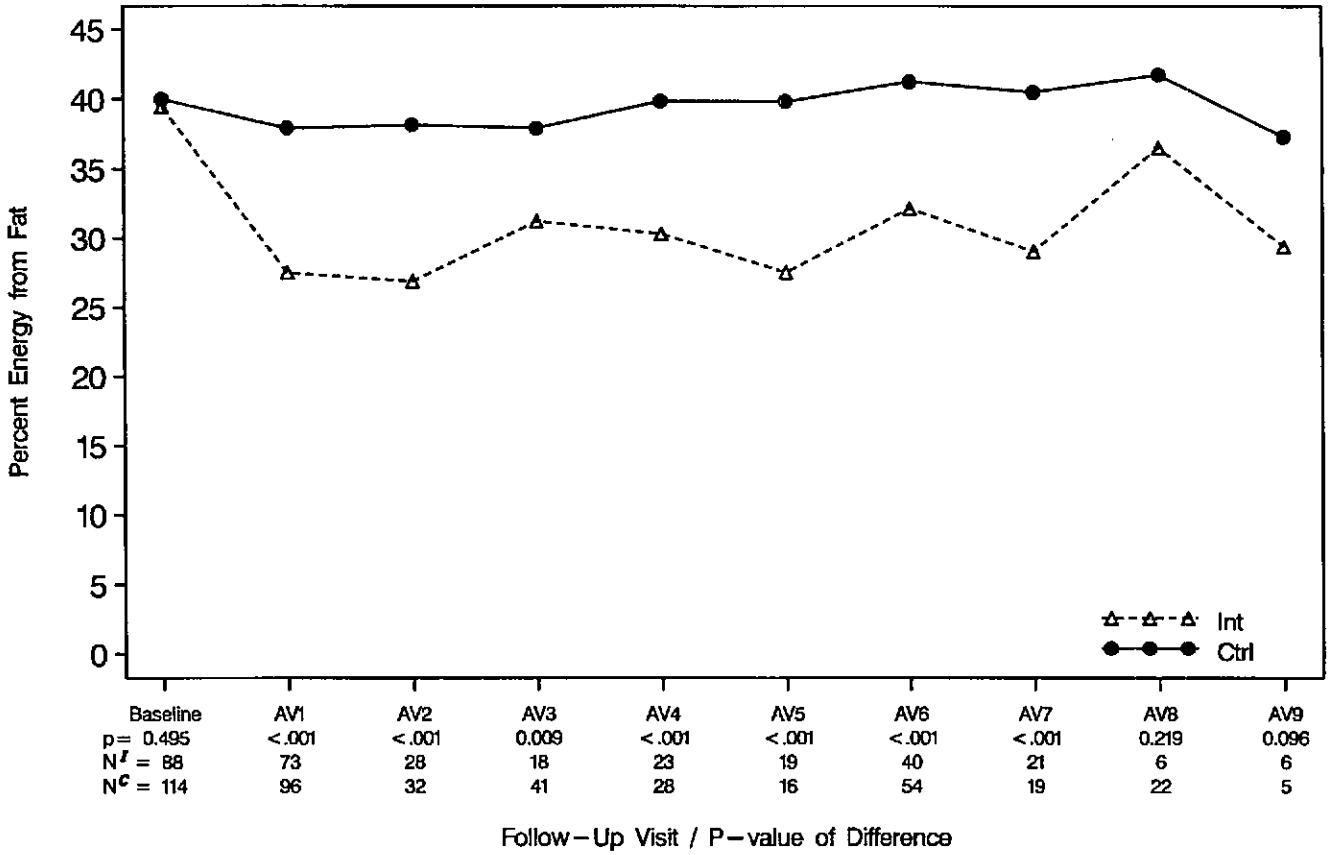


Figure 3.2
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: August 31, 2004



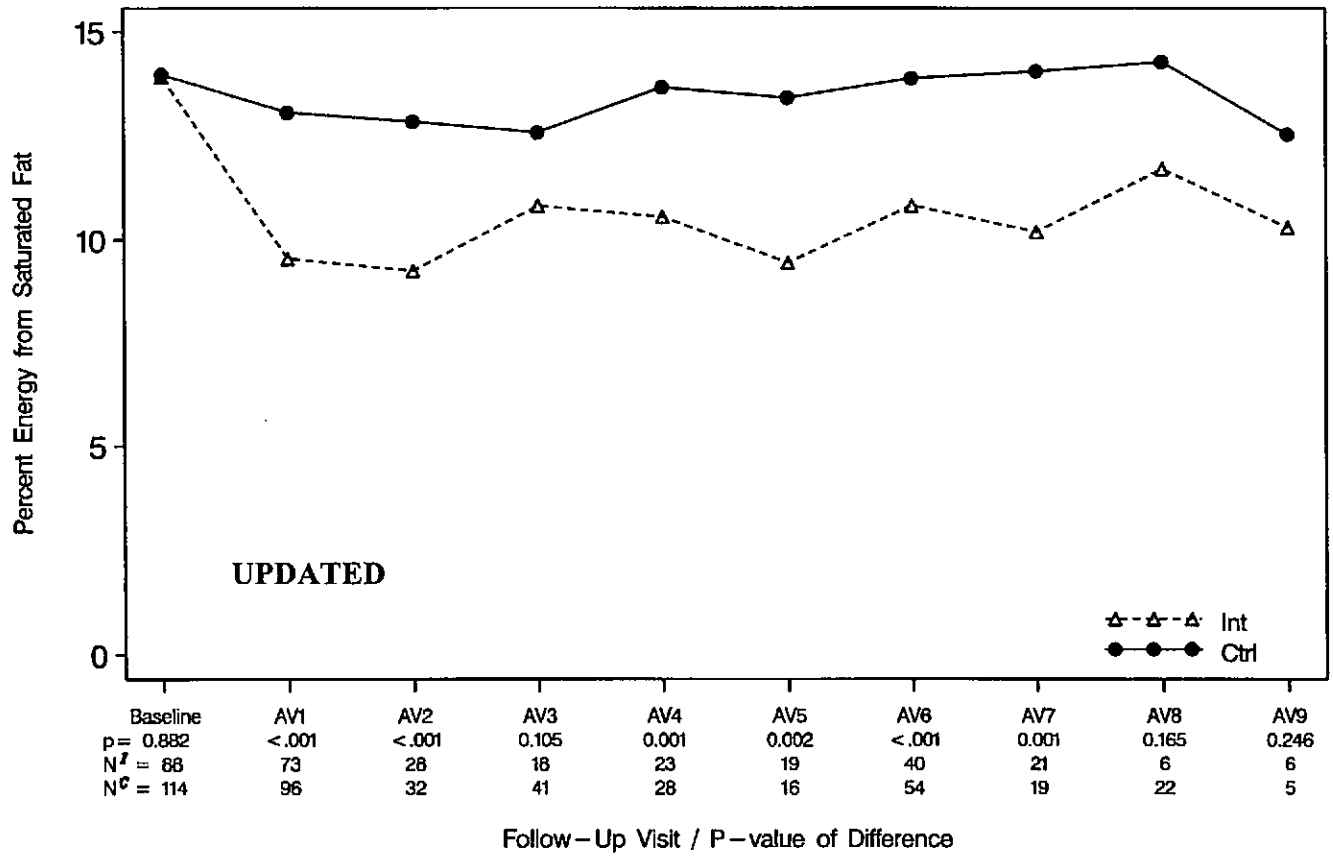
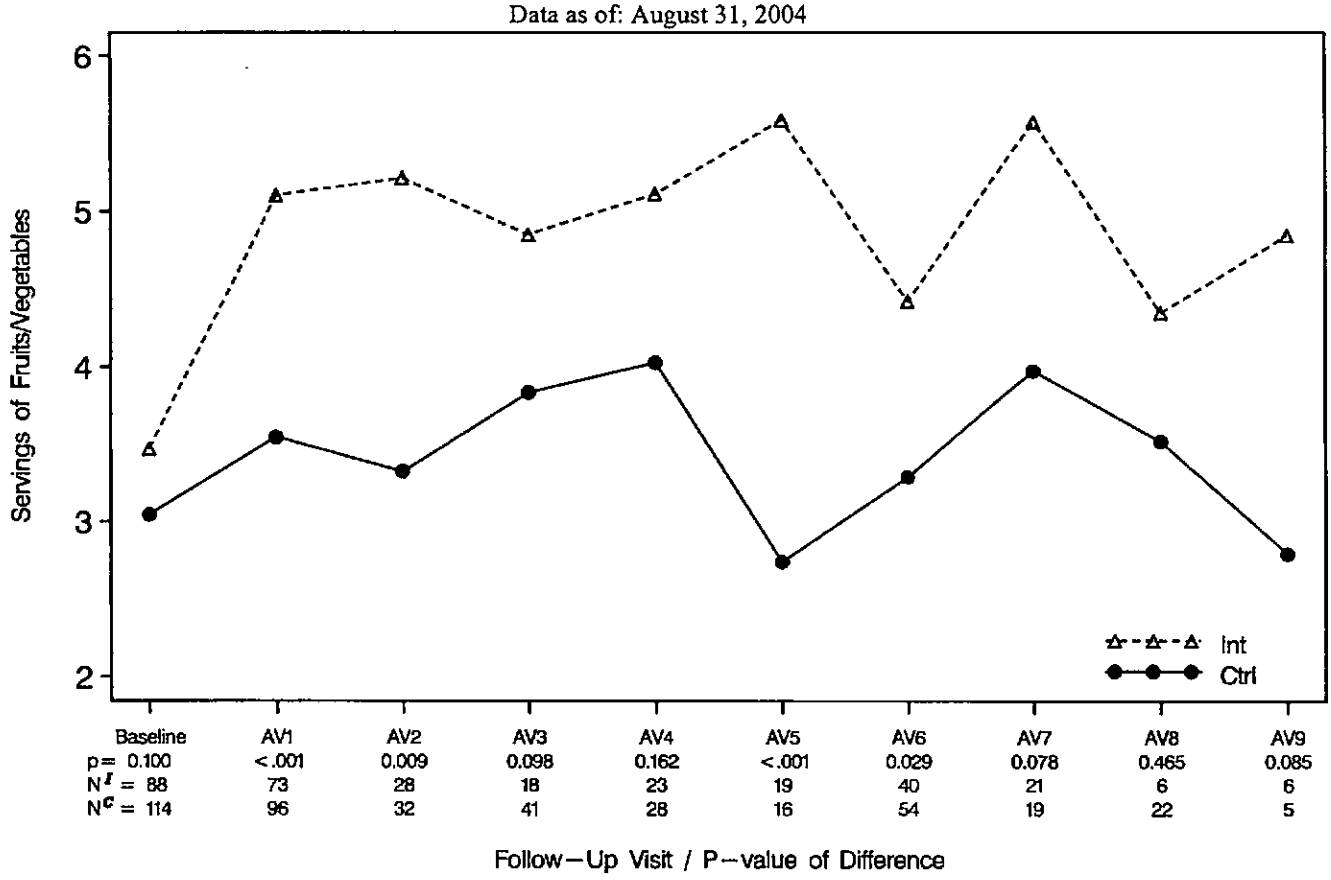
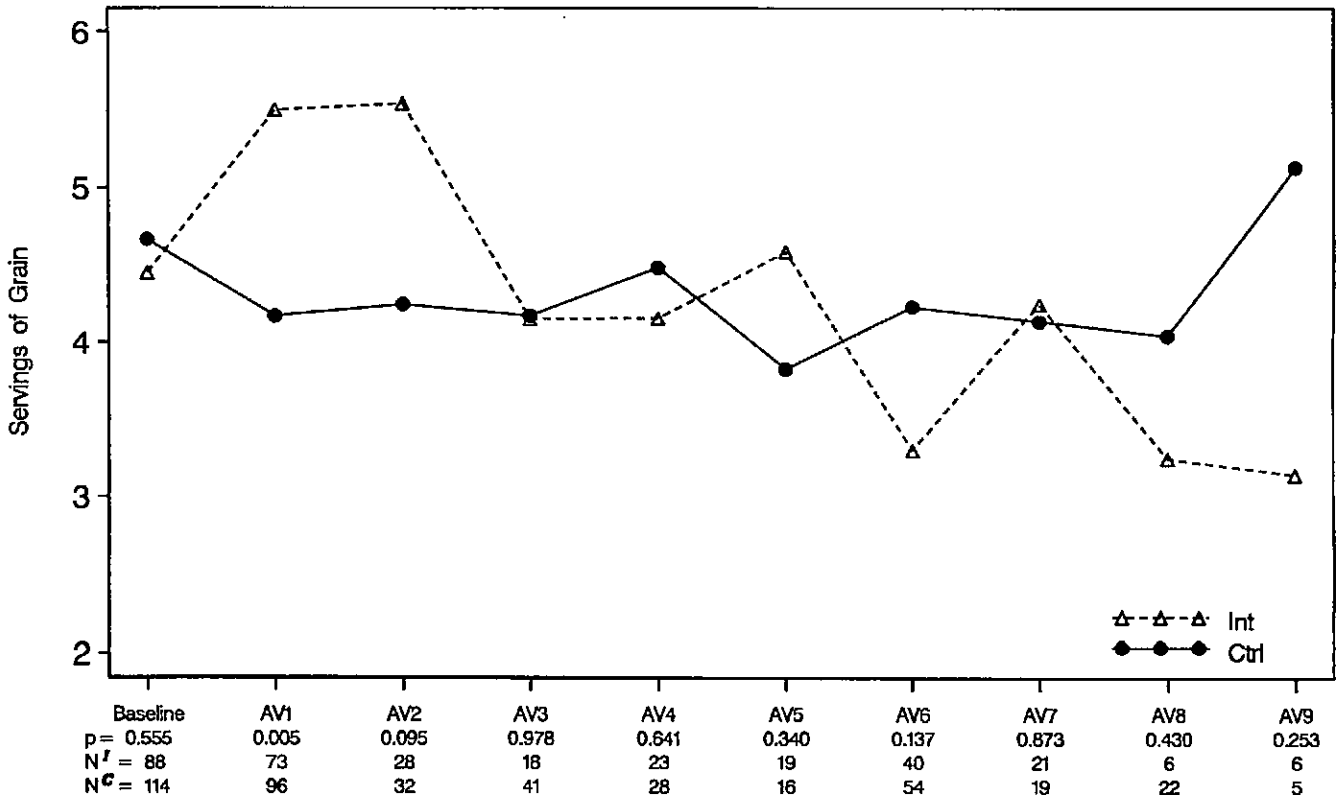


Figure 3.2 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women
Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.100	<.001	0.009	0.098	0.162	<.001	0.029	0.078	0.465	0.085
N^I =	88	73	28	18	23	19	40	21	6	6
N^C =	114	96	32	41	28	16	54	19	22	5

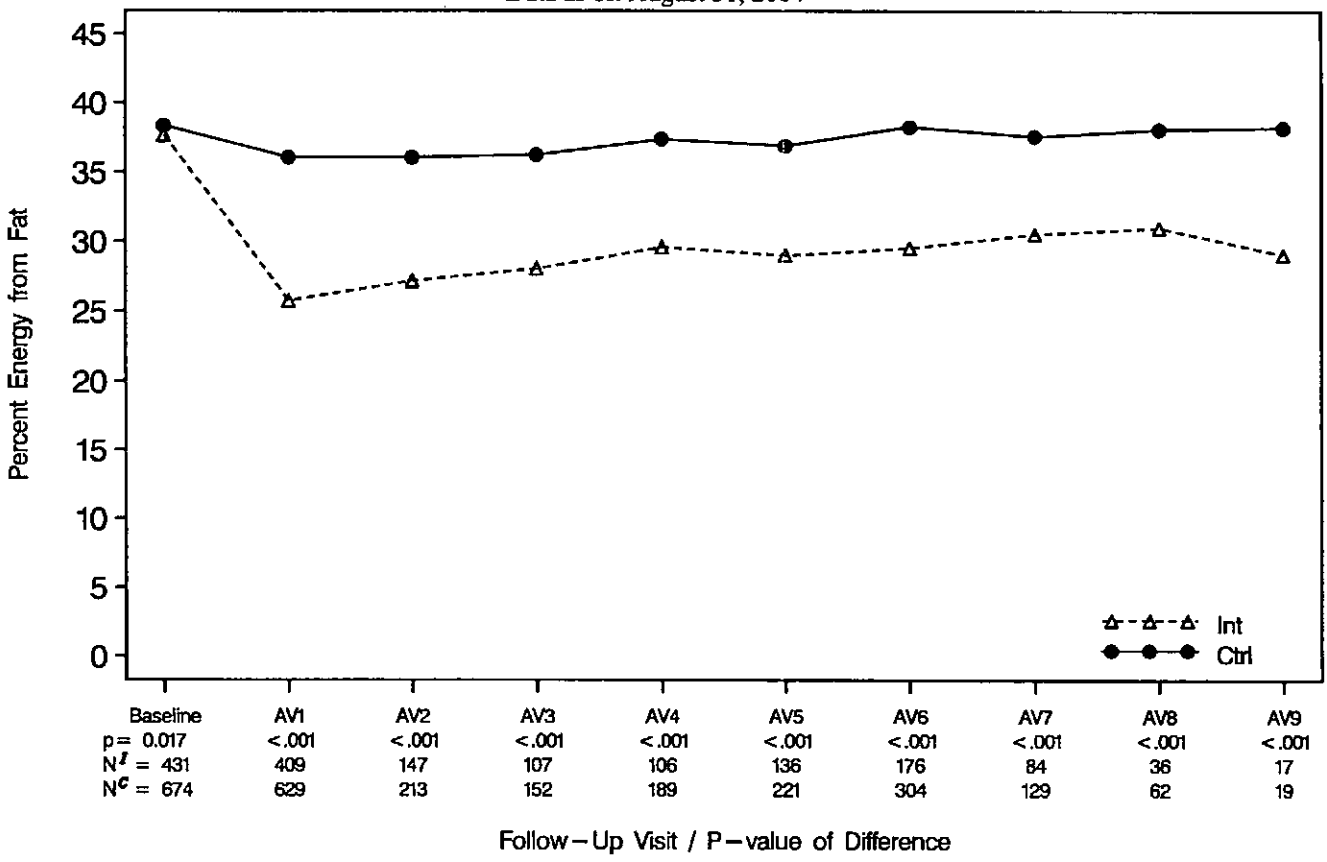
Follow–Up Visit / P–value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.555	0.005	0.095	0.978	0.641	0.340	0.137	0.873	0.430	0.253
N^I =	88	73	28	18	23	19	40	21	6	6
N^C =	114	96	32	41	28	16	54	19	22	5

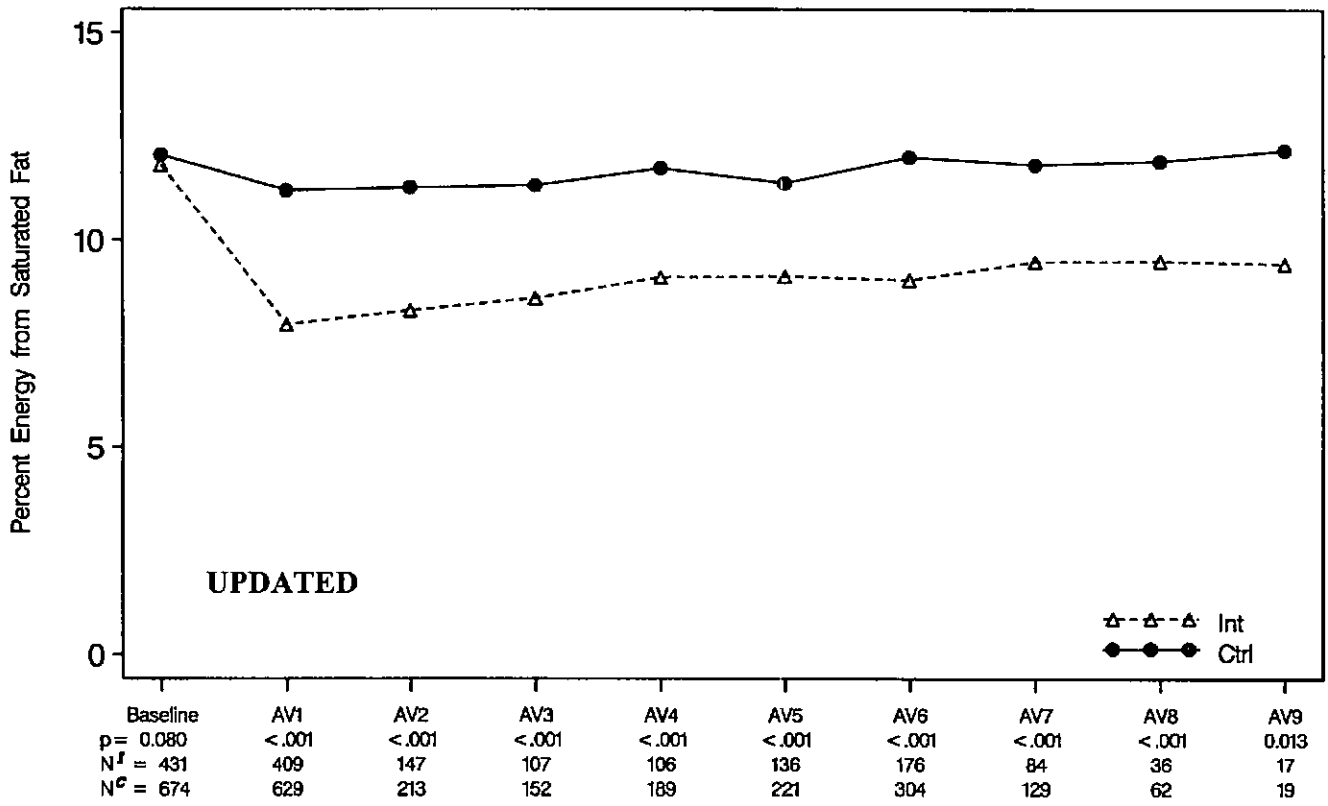
Follow–Up Visit / P–value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women
Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.017	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	431	409	147	107	106	136	176	84	36	17
N^C =	674	629	213	152	189	221	304	129	62	19

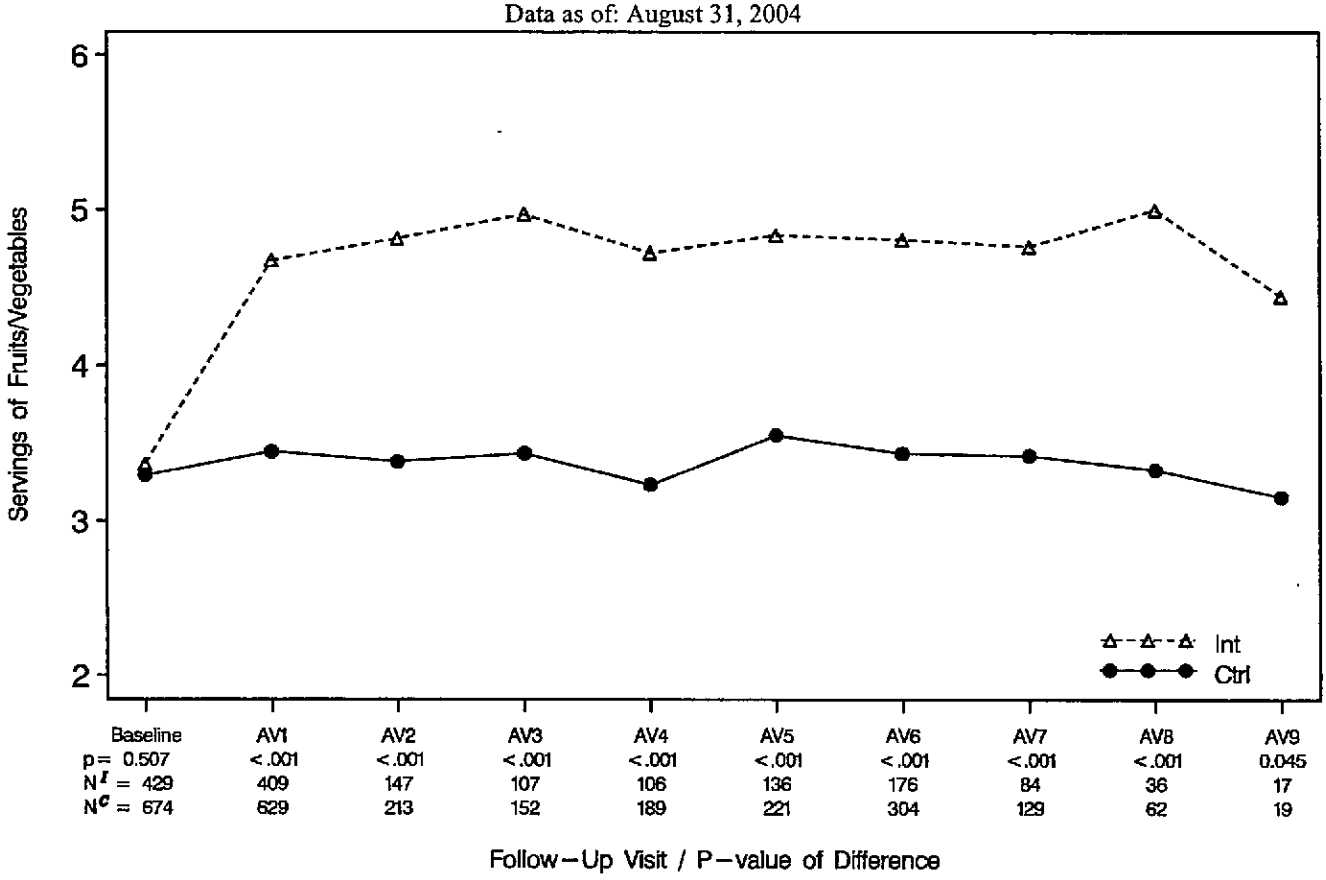
Follow−Up Visit / P−value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.080	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.013
N^I =	431	409	147	107	106	136	176	84	36	17
N^C =	674	629	213	152	189	221	304	129	62	19

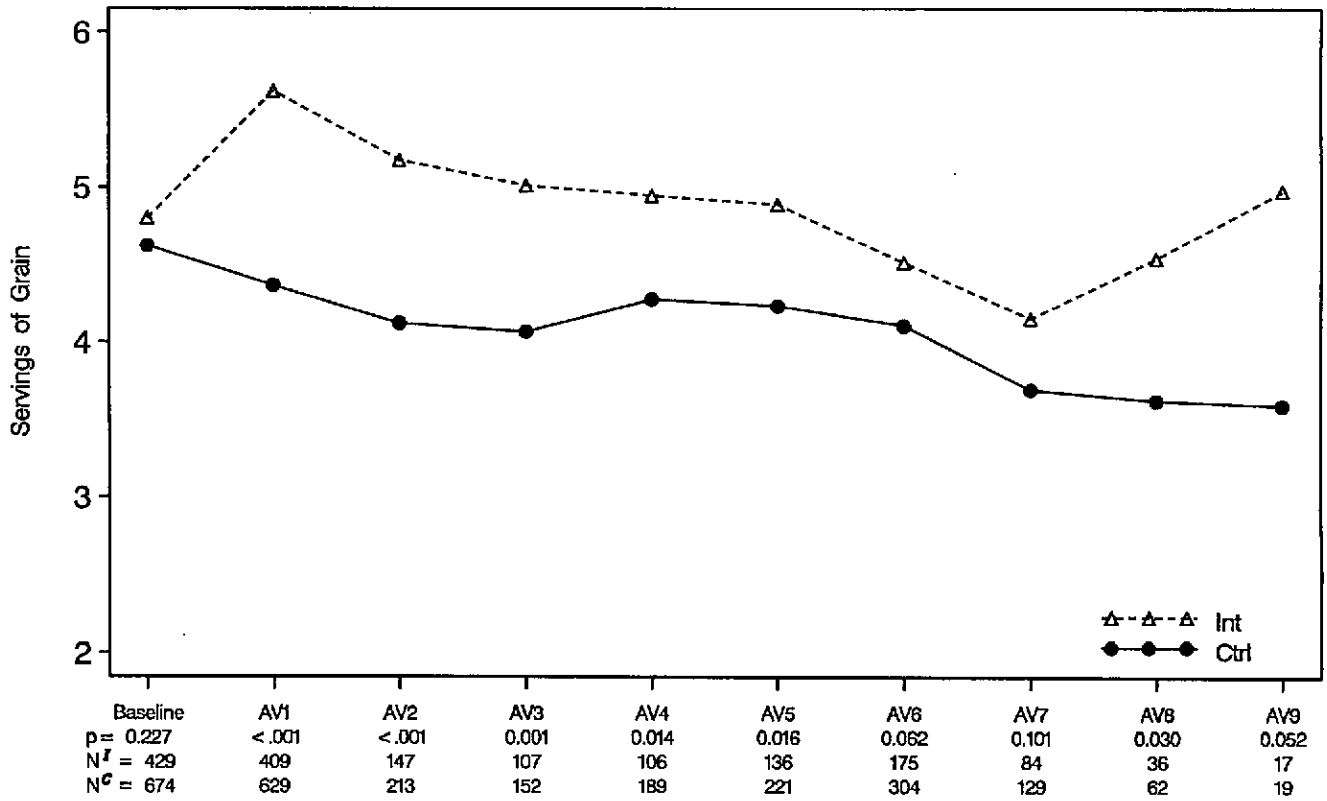
Follow−Up Visit / P−value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women
Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.507	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.045
N^I =	429	409	147	107	106	136	176	84	36	17
N^C =	674	629	213	152	189	221	304	129	62	19

Follow–Up Visit / P–value of Difference

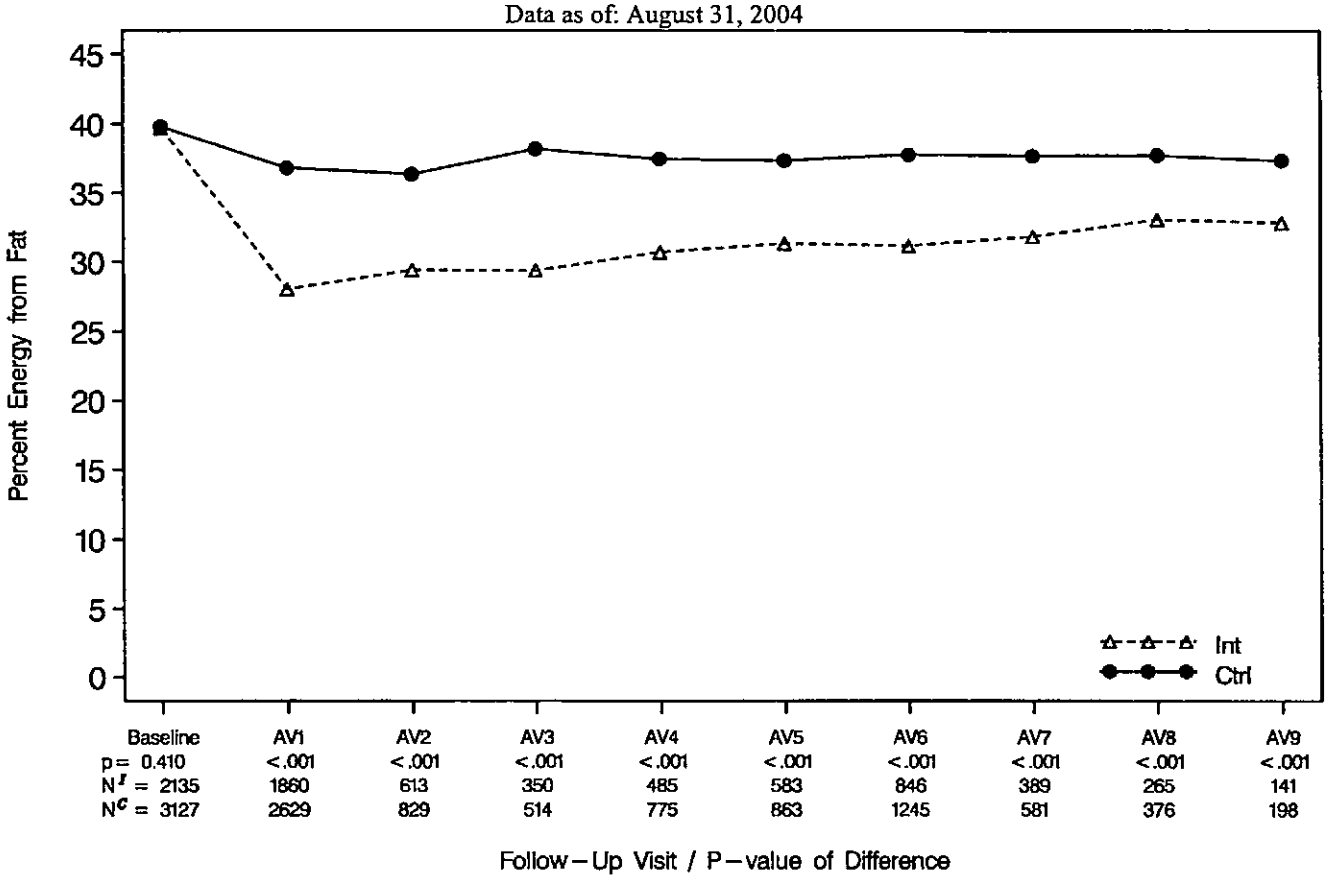


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.227	<.001	<.001	0.001	0.014	0.016	0.062	0.101	0.030	0.052
N^I =	429	409	147	107	106	136	175	84	36	17
N^C =	674	629	213	152	189	221	304	129	62	19

Follow–Up Visit / P–value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in Black Women

Data as of: August 31, 2004



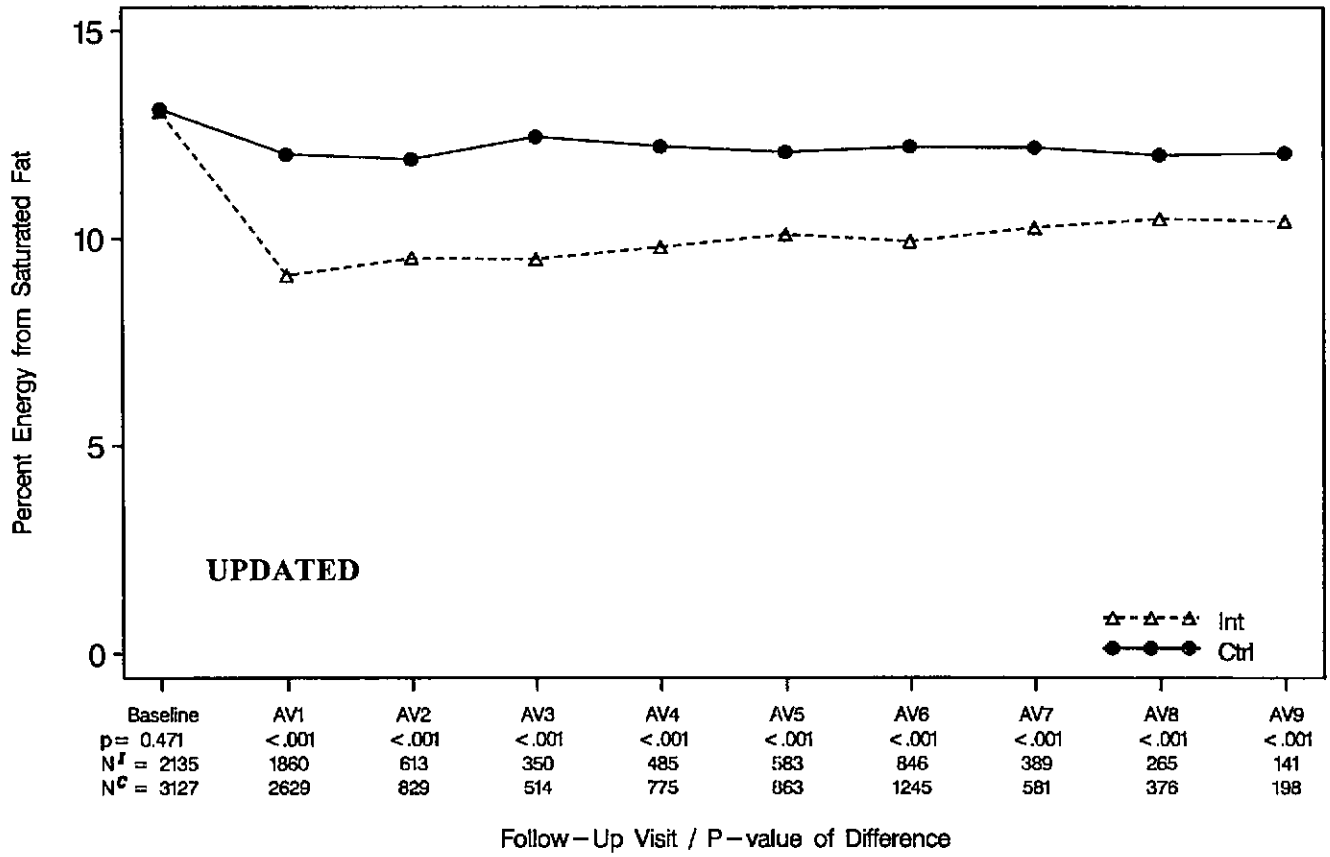
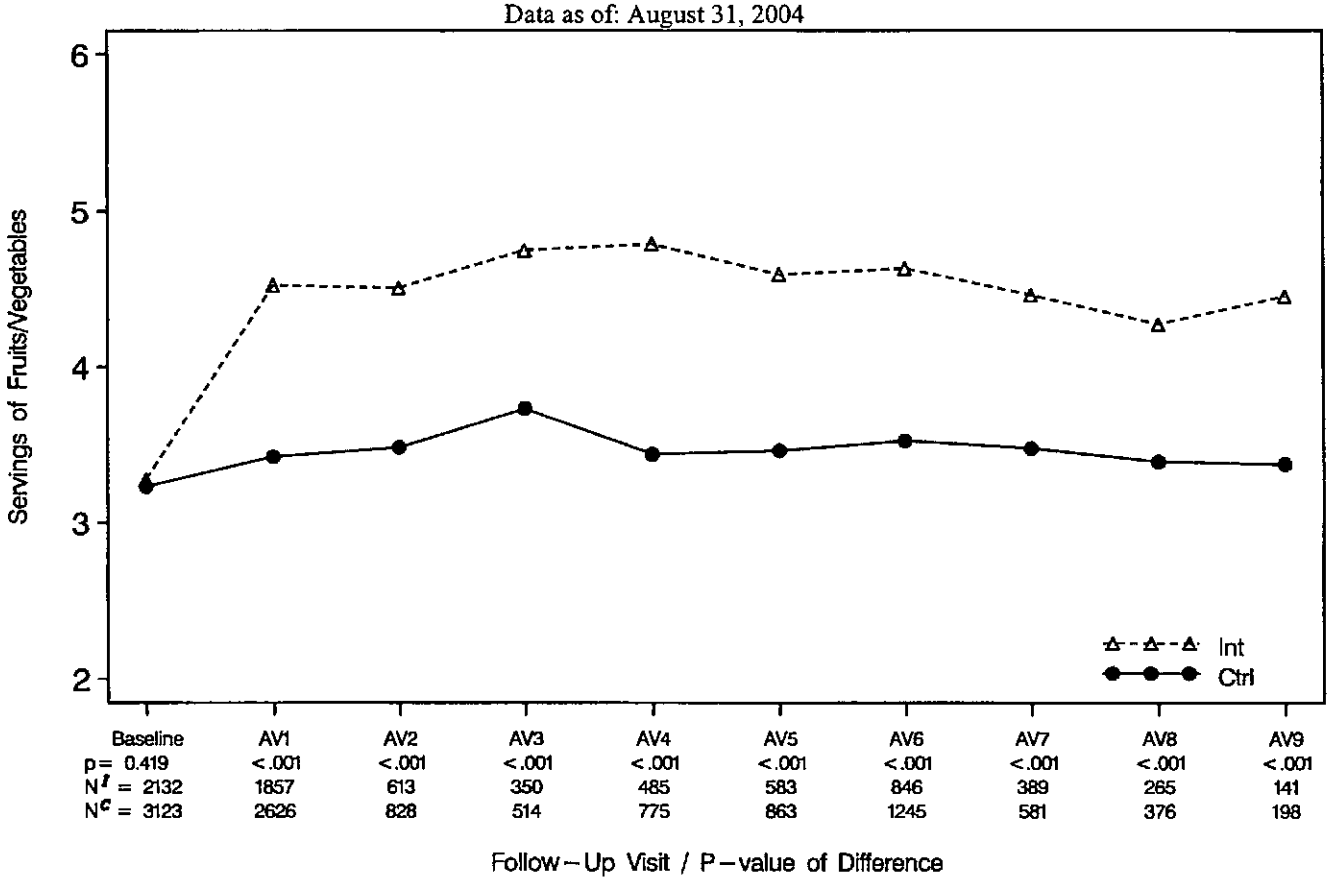


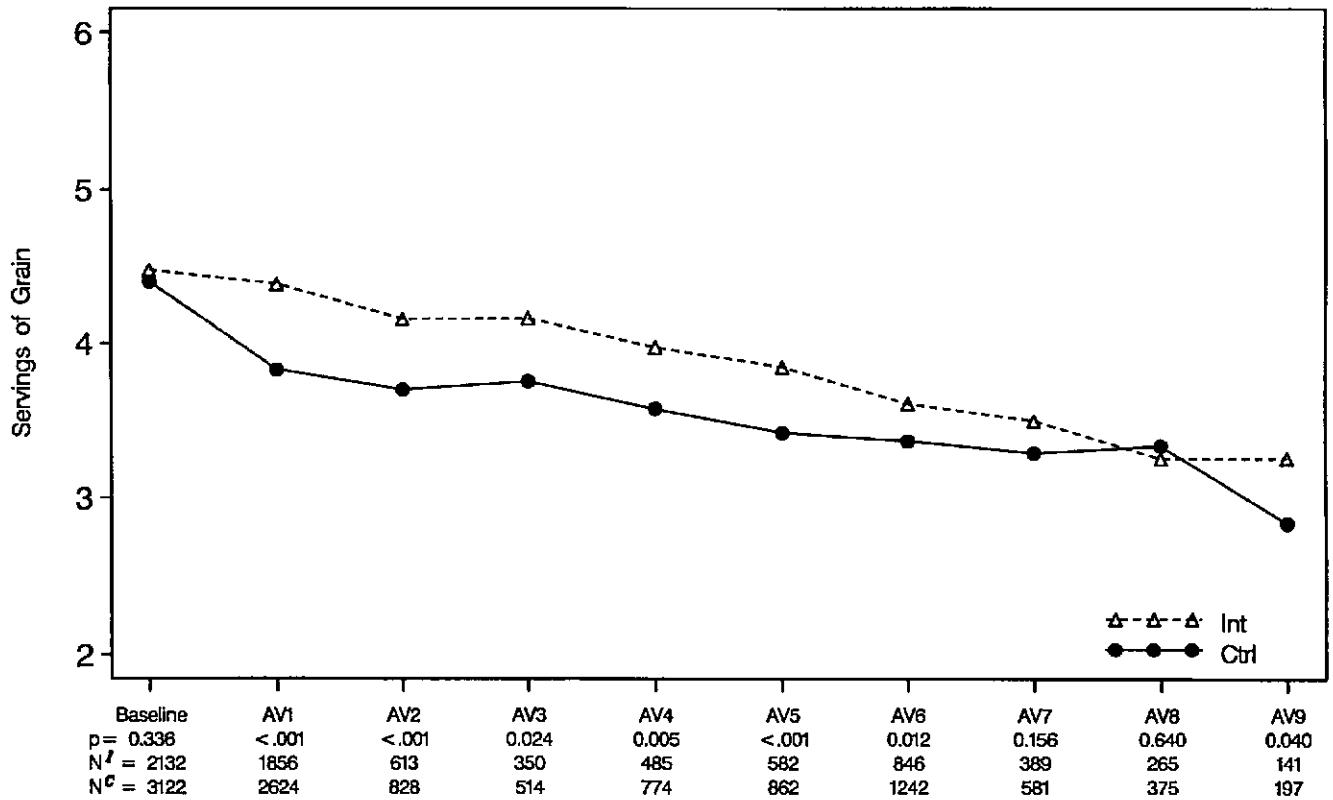
Figure 3.2 (continued)
Nutrient Intake Monitoring in Black Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.419	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	2132	1857	613	350	485	583	846	389	265	141
N^C =	3123	2626	828	514	775	863	1245	581	376	198

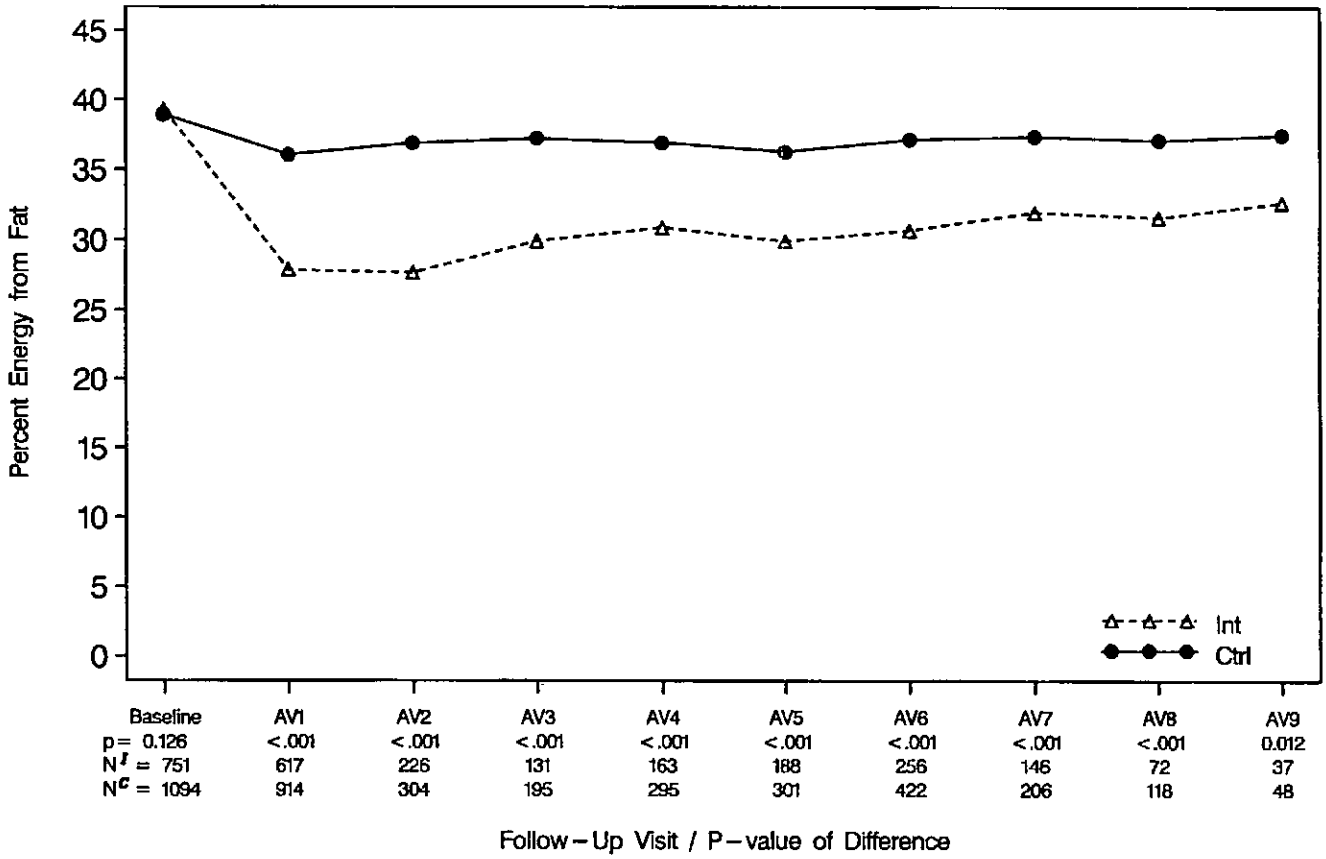
Follow−Up Visit / P−value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.336	<.001	<.001	0.024	0.005	<.001	0.012	0.156	0.640	0.040
N^I =	2132	1856	613	350	485	582	846	389	265	141
N^C =	3122	2624	828	514	774	862	1242	581	375	197

Follow−Up Visit / P−value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women
Data as of: August 31, 2004



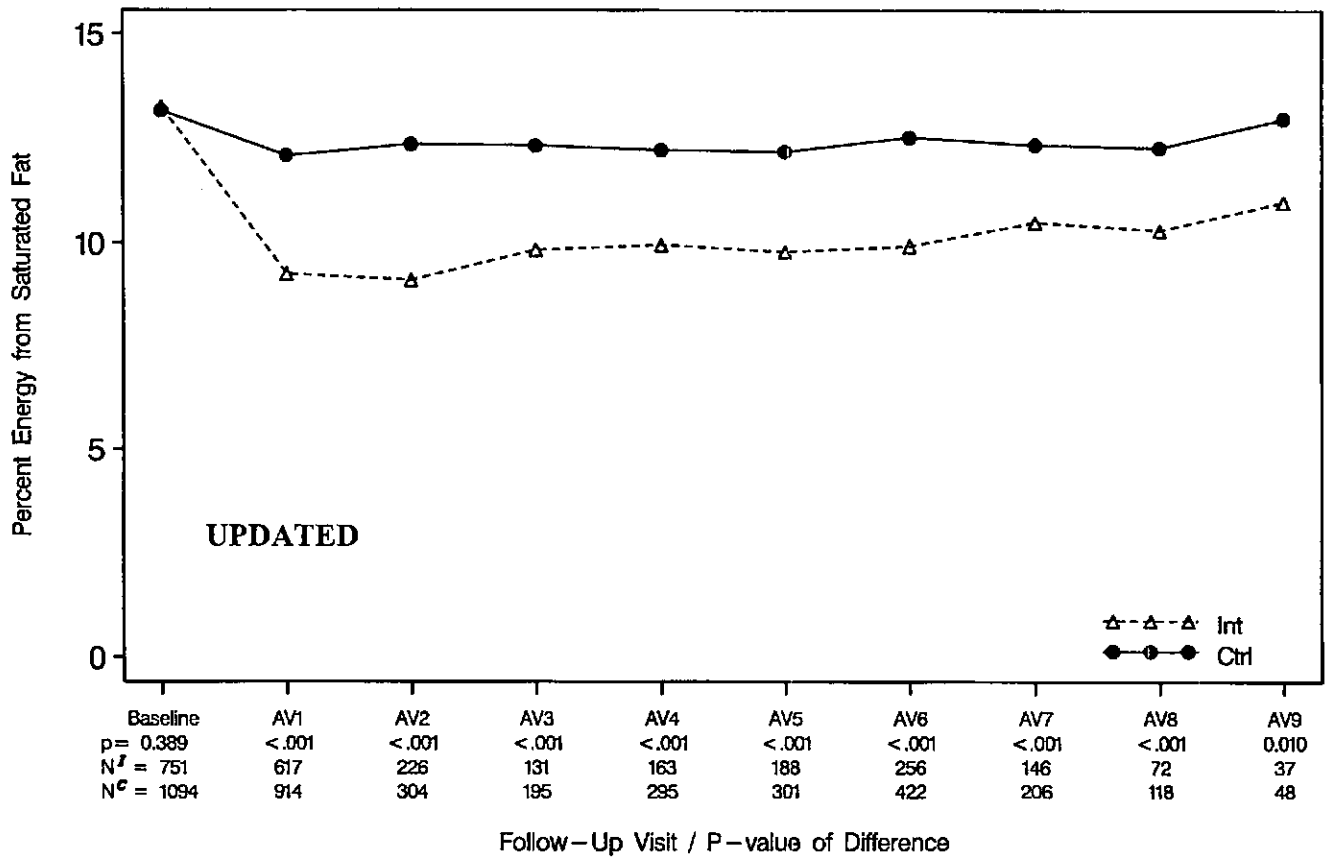
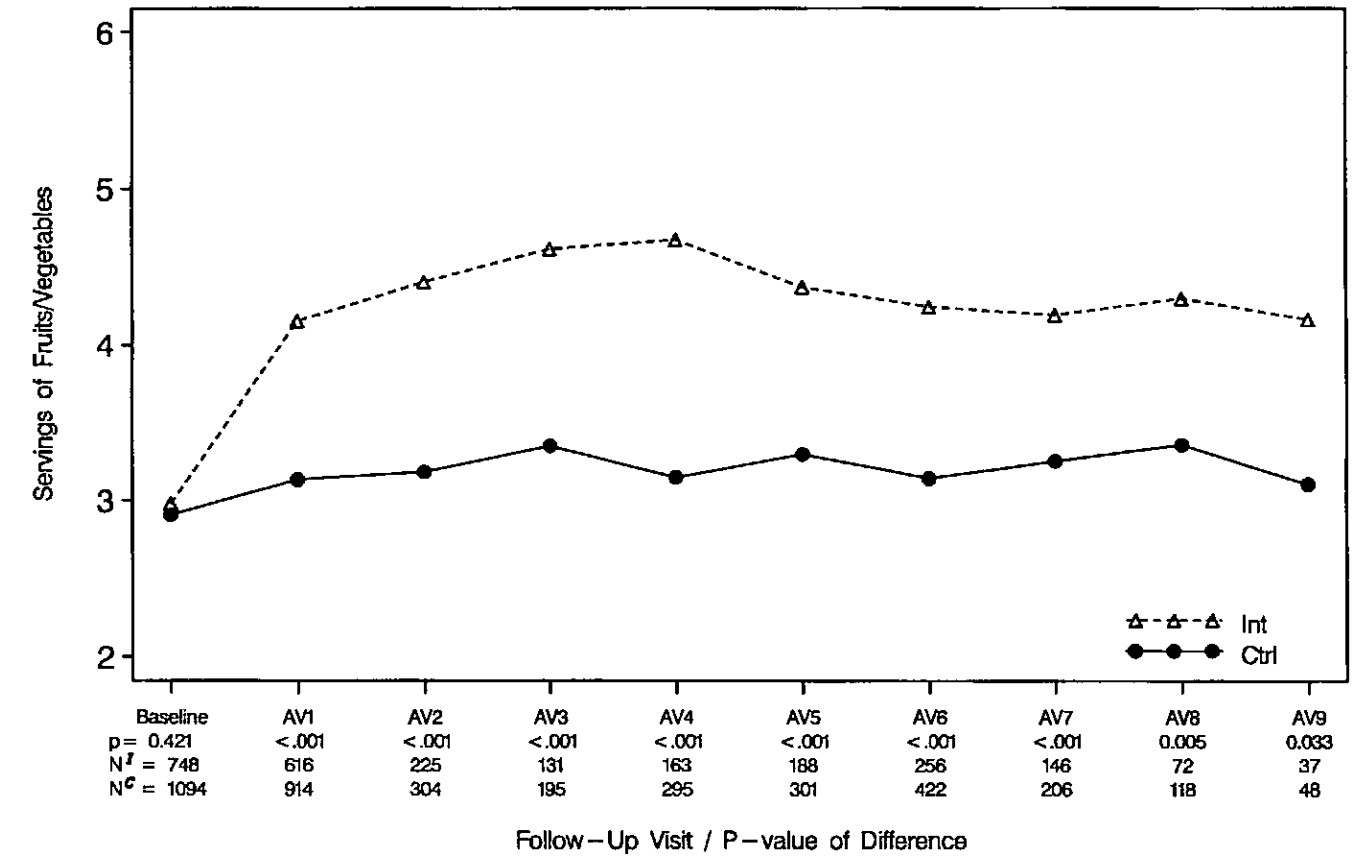


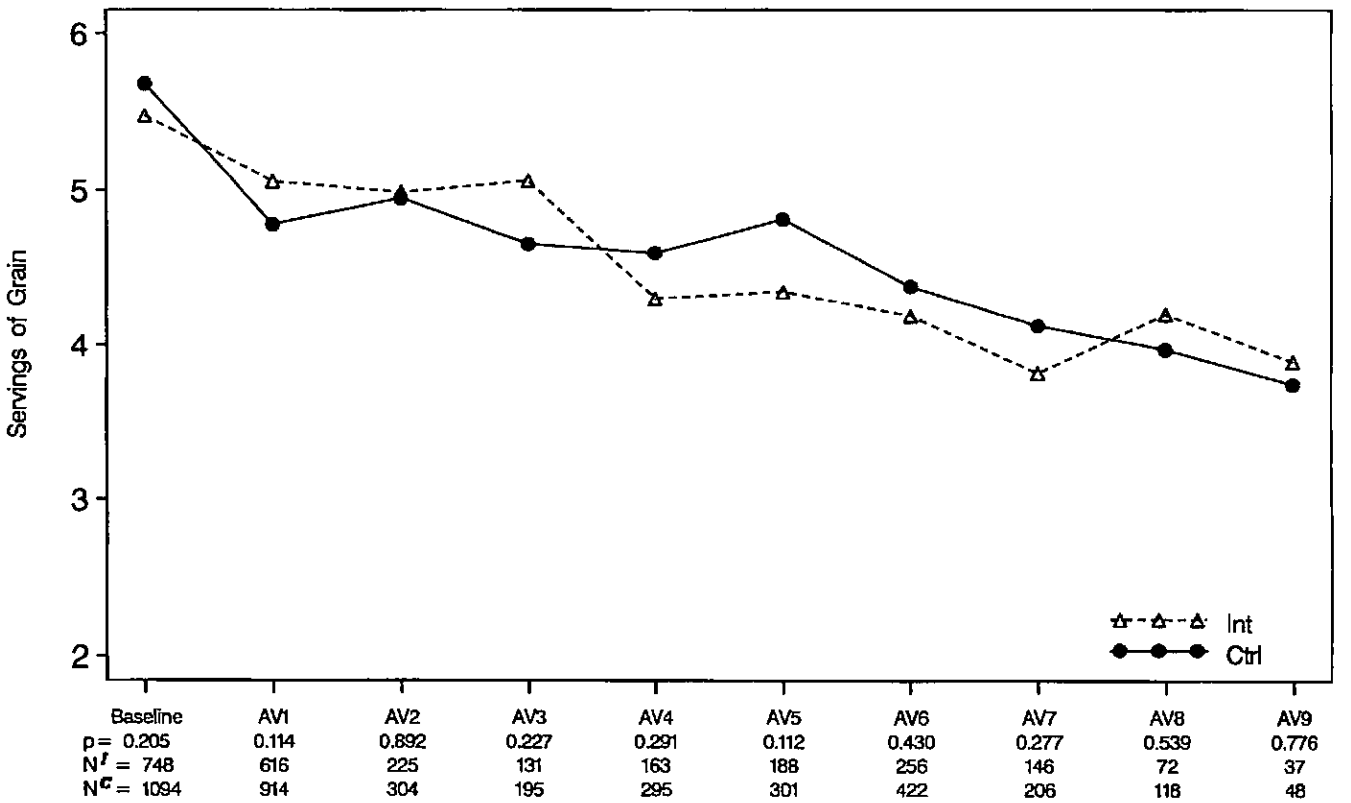
Figure 3.2 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.421	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.005	0.033
N^I =	748	616	225	131	163	188	256	146	72	37
N^C =	1094	914	304	195	295	301	422	206	118	48

Follow−Up Visit / P−value of Difference

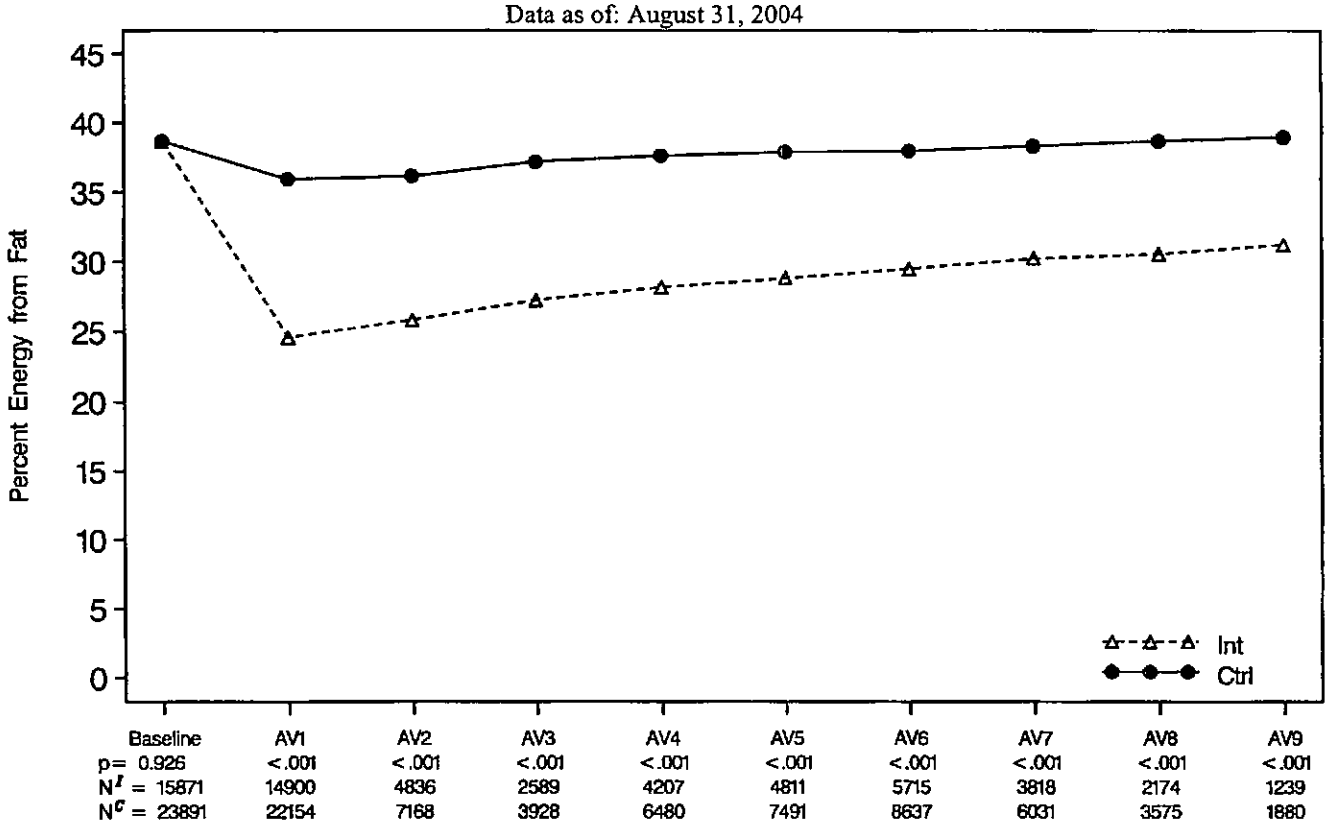


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.205	0.114	0.892	0.227	0.291	0.112	0.430	0.277	0.539	0.776
N^I =	748	616	225	131	163	188	256	146	72	37
N^C =	1094	914	304	195	295	301	422	206	118	48

Follow−Up Visit / P−value of Difference

Figure 3.2 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2004



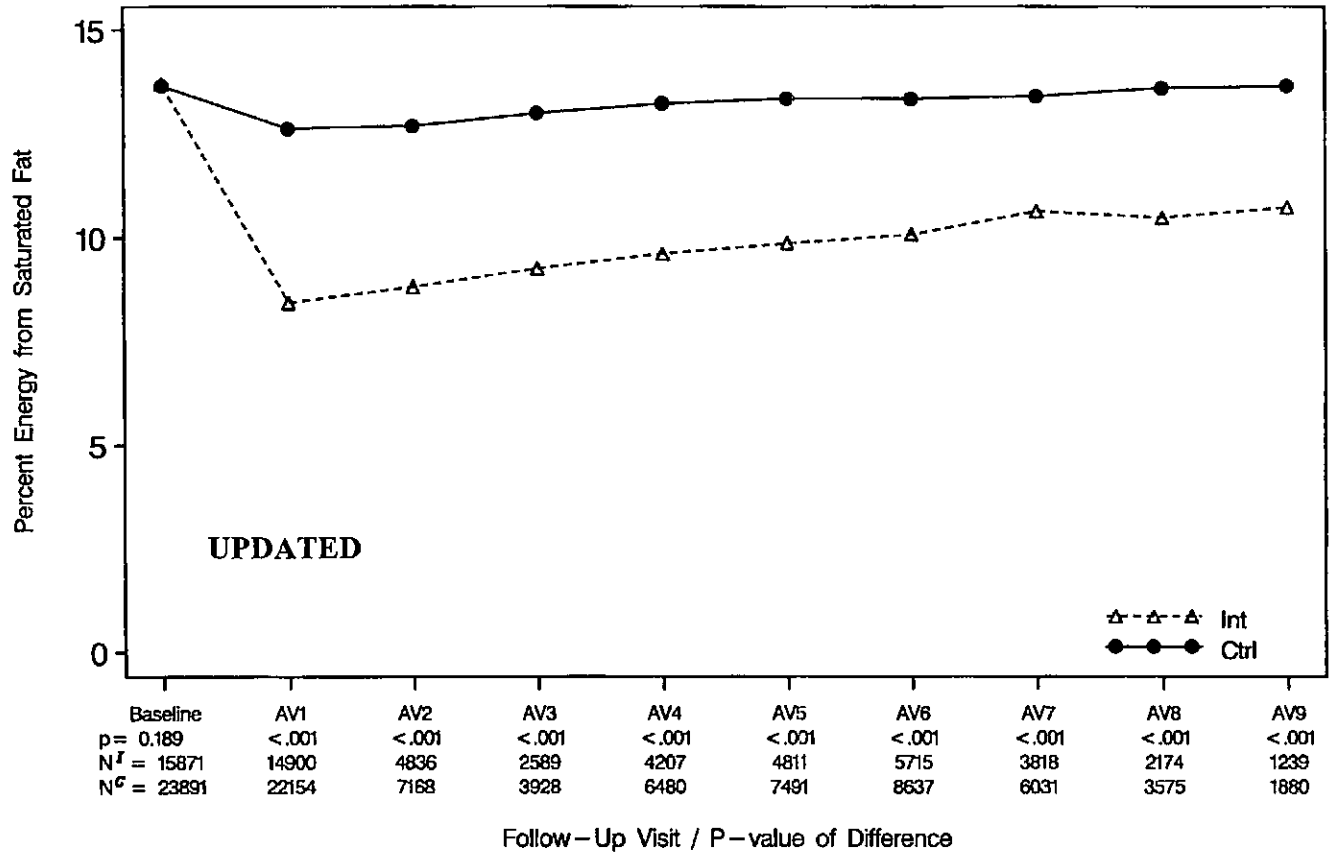
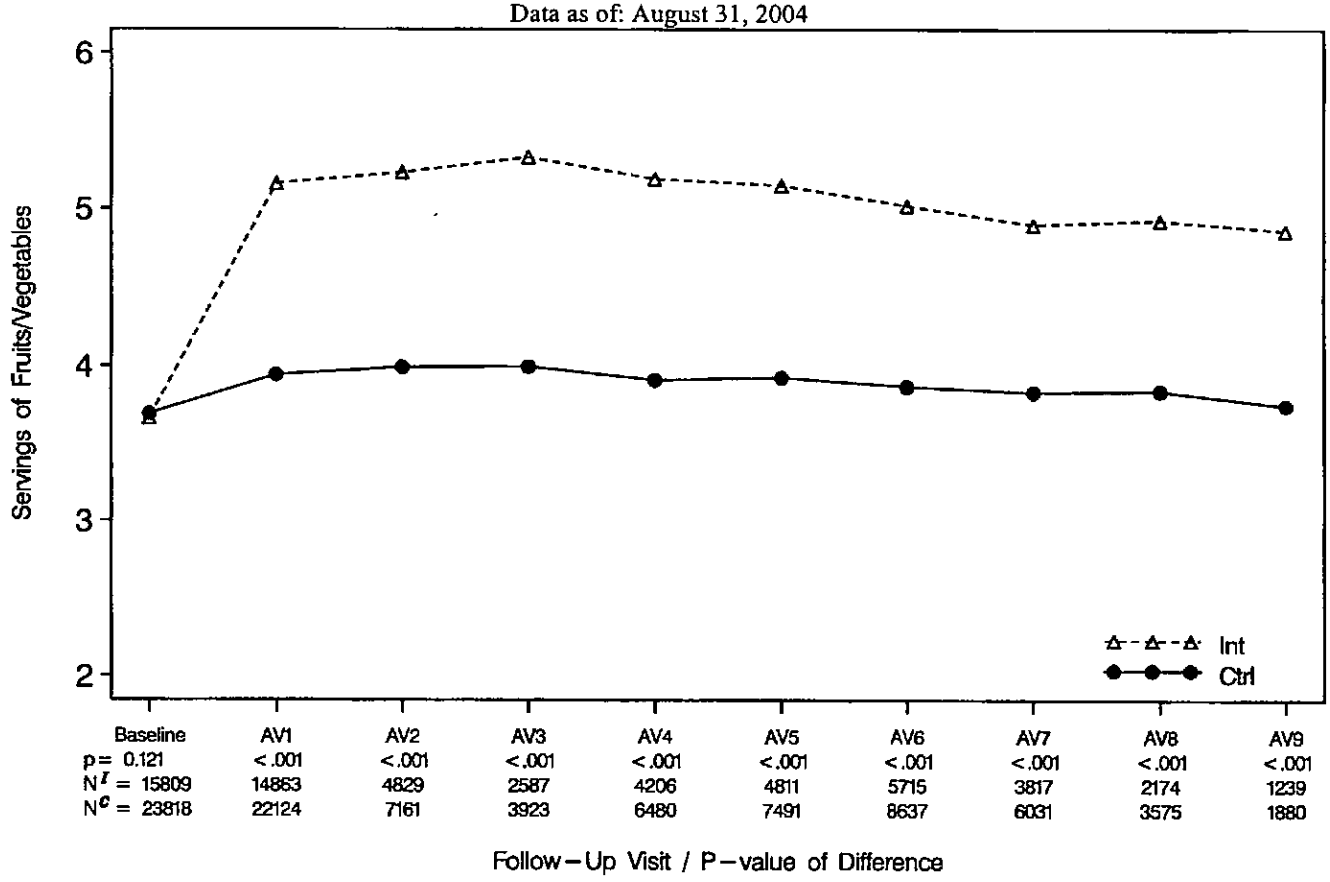


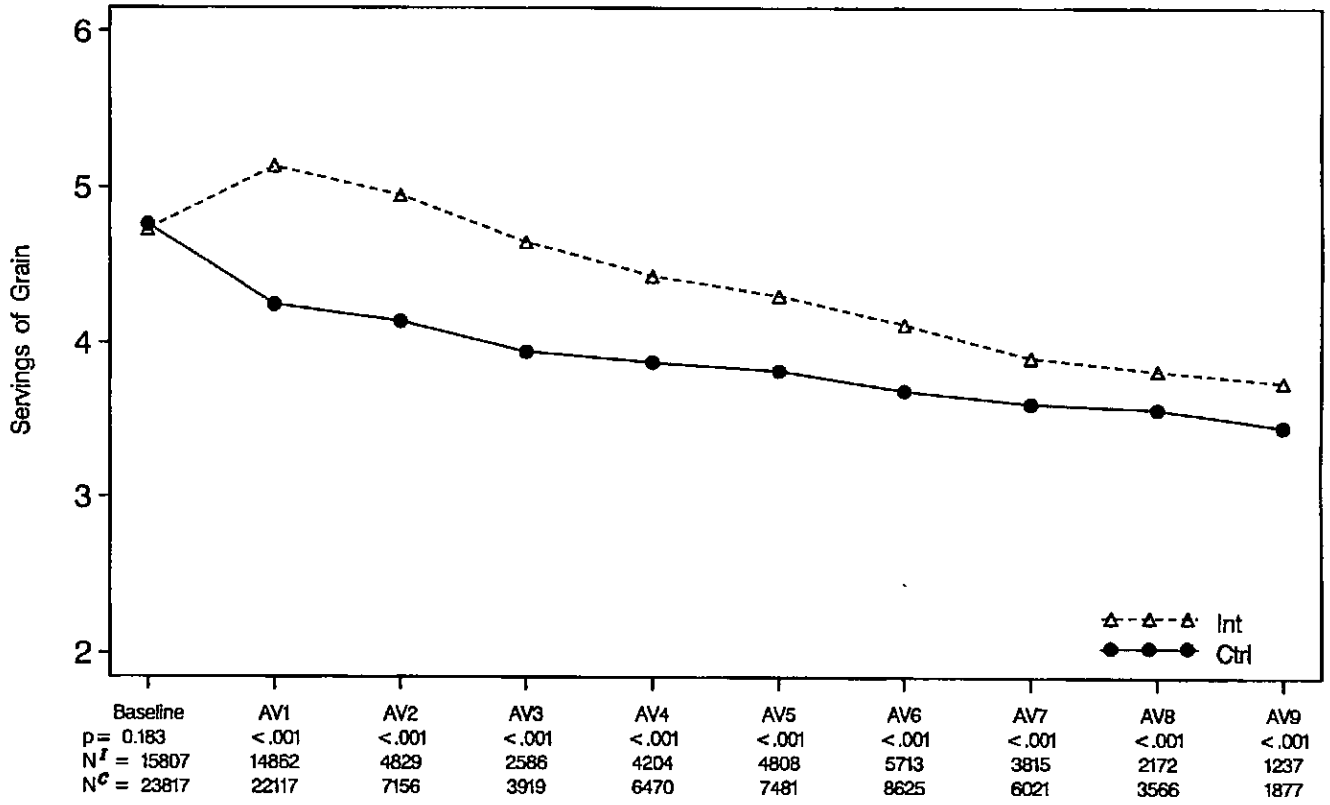
Figure 3.2 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.121	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	15809	14863	4829	2587	4206	4811	5715	3817	2174	1239
N^C =	23818	22124	7161	3923	6480	7491	8637	6031	3575	1880

Follow−Up Visit / P−value of Difference

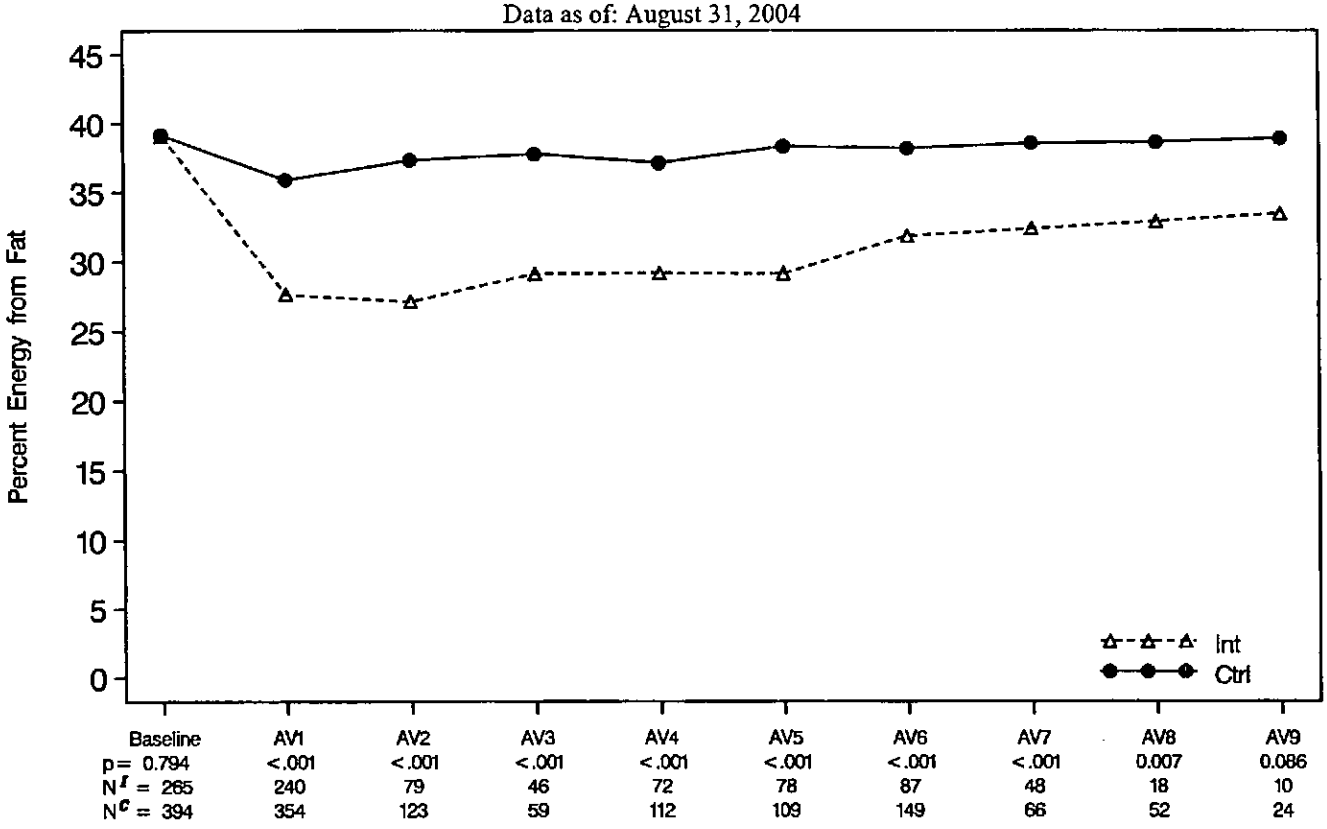


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.183	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
N^I =	15807	14862	4829	2586	4204	4808	5713	3815	2172	1237
N^C =	23817	22117	7156	3919	6470	7481	8625	6021	3566	1877

Follow−Up Visit / P−value of Difference

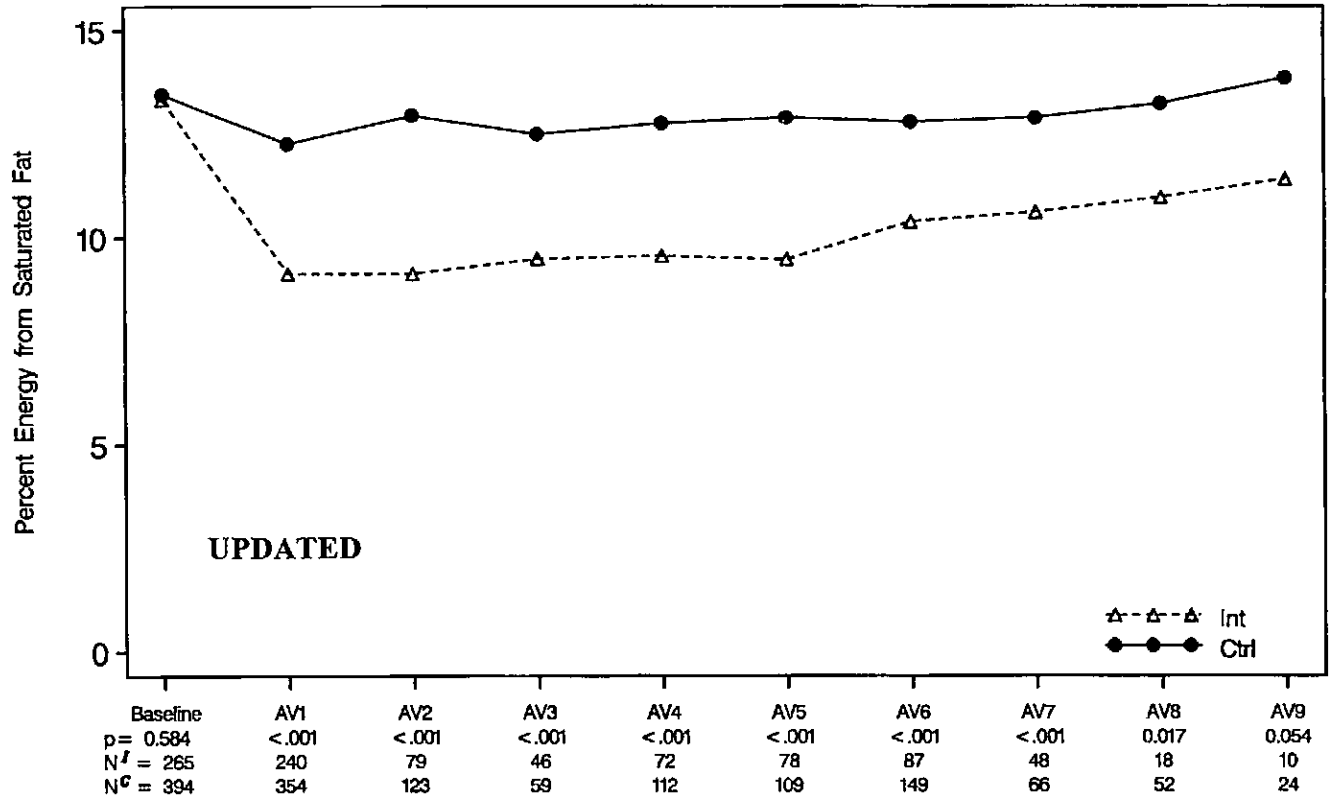
Figure 3.2 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.794	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.007	0.086
N^I =	265	240	79	46	72	78	87	48	18	10
N^C =	394	354	123	59	112	109	149	66	52	24

Follow-Up Visit / P-value of Difference

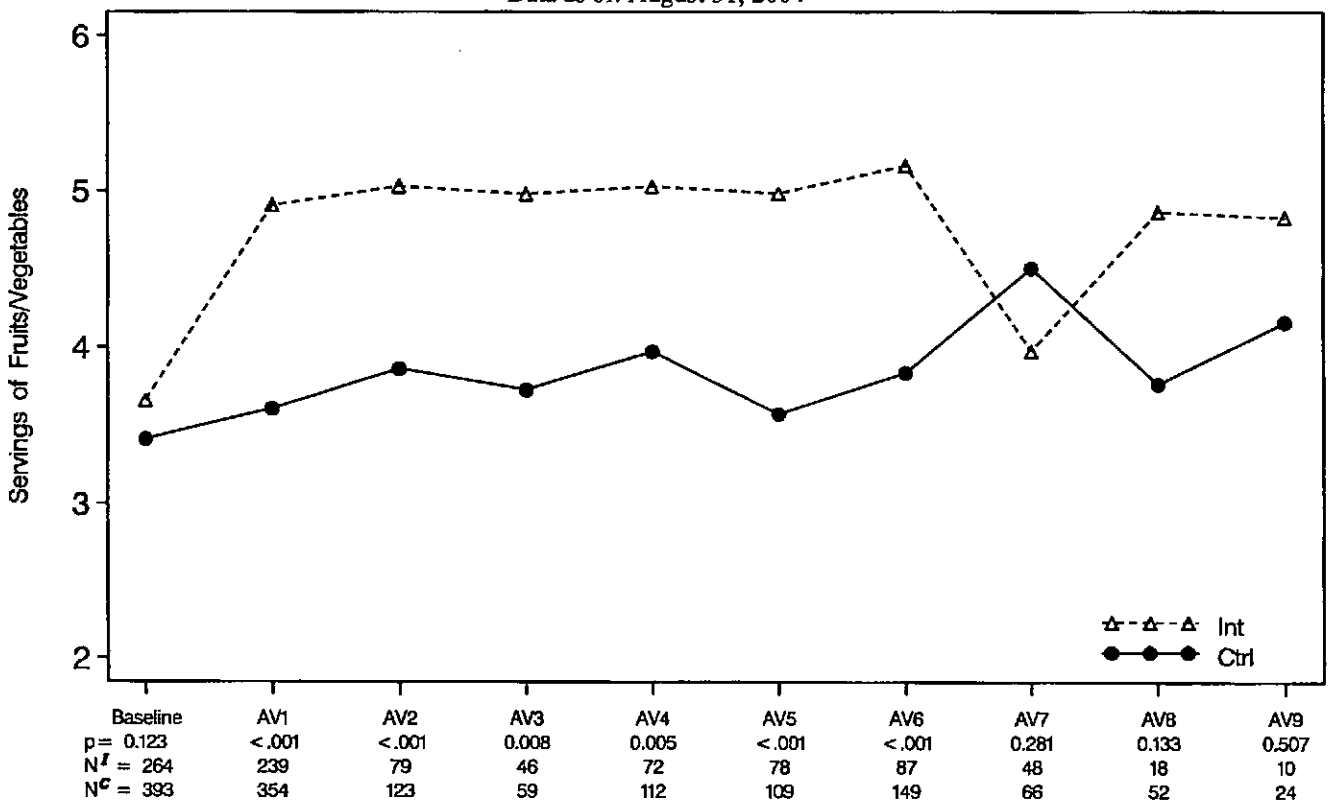


	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.584	<.001	<.001	<.001	<.001	<.001	<.001	<.001	0.017	0.054
N^I =	265	240	79	46	72	78	87	48	18	10
N^C =	394	354	123	59	112	109	149	66	52	24

Follow-Up Visit / P-value of Difference

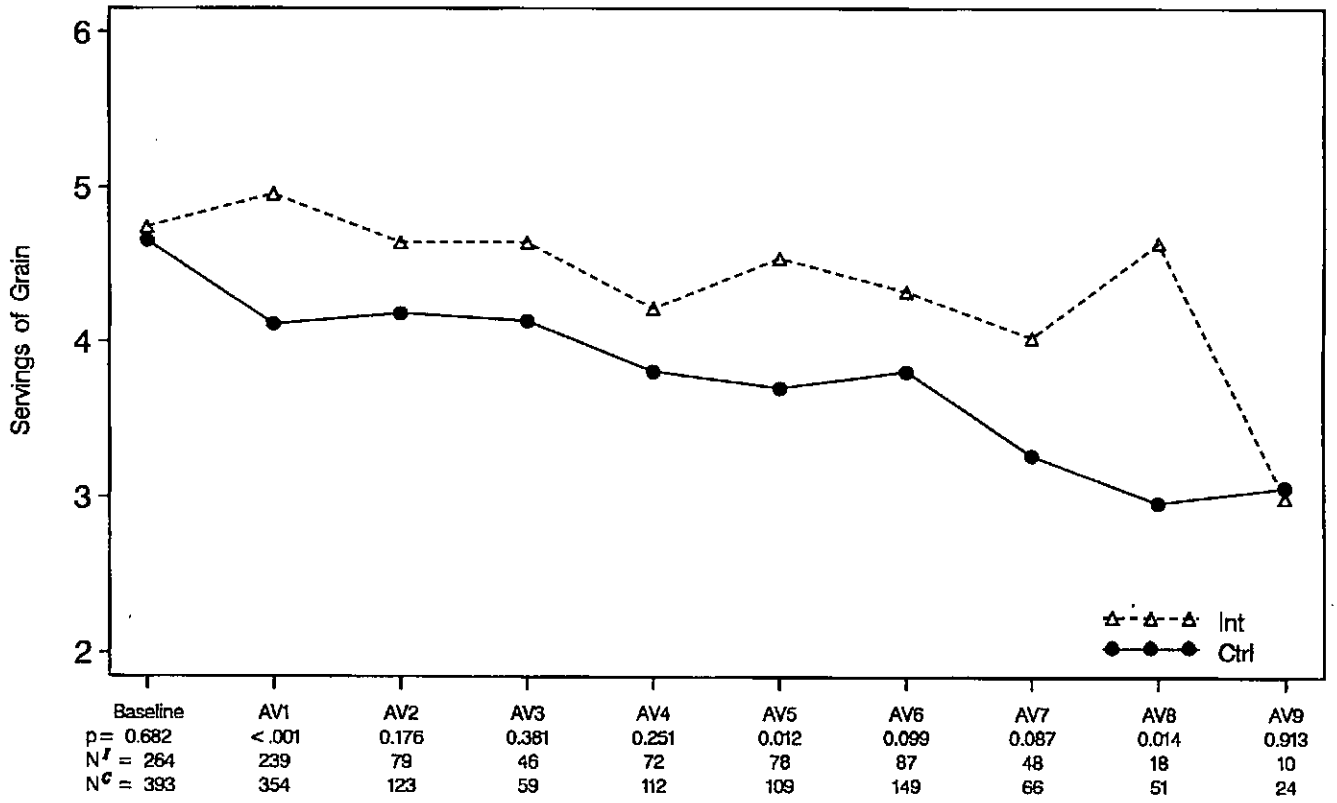
Figure 3.2 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity Women

Data as of: August 31, 2004



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.123	<.001	<.001	0.008	0.005	<.001	<.001	0.281	0.133	0.507
N^I =	264	239	79	46	72	78	87	48	18	10
N^C =	393	354	123	59	112	109	149	66	52	24

Follow–Up Visit / P–value of Difference



	Baseline	AV1	AV2	AV3	AV4	AV5	AV6	AV7	AV8	AV9
p=	0.682	<.001	0.176	0.381	0.251	0.012	0.099	0.087	0.014	0.913
N^I =	264	239	79	46	72	78	87	48	18	10
N^C =	393	354	123	59	112	109	149	66	51	24

Follow–Up Visit / P–value of Difference

Table 3.3
Control - Intervention Difference in % Energy from Fat in WHI DM Participants
Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year[1]

Data as of: August 31, 2004

	Model Including Attendance				Model Including Completion				Model Including Fat Scores			
	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2 for Inclusi
Demographics			15.5%				15.5%				15.5%	
Age												
60-69	6645				6645				6645			
50-54 vs. 60-69	2003	0.48			2003	0.58			2003	0.44		
55-59 vs. 60-69	3149	-0.17			3149	-0.20			3149	-0.21		
70-79 vs. 60-69	2154	-1.37 **			2154	-1.20 **			2154	-1.26 **		
Ethnicity												
White	11513				11513				11513			
American Indian vs. White	53	3.31			53	3.81			53	3.80		
Asian/Pacific Islander vs. White	310	0.18			310	0.26			310	0.28		
Black vs. White	1431	-1.44 **			1431	-1.50 **			1431	-1.00		
Hispanic vs. White	469	-2.07 *			469	-2.13 *			469	-1.99 *		
Unknown vs. White	175	-2.50			175	-2.35			175	-2.23		
Education												
Post H.S.	10972				10972				10972			
0-8 Years vs. Post H.S.	126	0.08			126	0.63			126	0.74		
Some H.S. or Diploma vs. Post H.S.	2853	-0.87 *			2853	-0.76 *			2853	-0.78 *		
Family Income												
>75K	2499				2499				2499			
<20K vs. >75K	2366	-1.15 *			2366	-1.10 *			2366	-1.15 *		
20-35K vs. >75K	3304	-0.74			3304	-0.53			3304	-0.53		
35-50K vs. >75K	2919	-0.99 *			2919	-0.86			2919	-0.86		
50-75K vs. >75K	2863	-0.32			2863	-0.29			2863	-0.28		
HRT Randomized												
No	11696				11696				11696			
Yes vs. No	2255	0.73			2255	0.80 *			2255	0.84 *		
Visit			15.9%	(0.4%)			15.9%	(0.4%)			15.9%	(0.4%
Visit Year												
AV-6	3155				3155				3155			
AV-7 vs. AV-6	3826	-0.83 **			3826	-0.85 **			3826	-0.81 **		
AV-8 vs. AV-6	3389	-0.83 *			3389	-0.94 **			3389	-0.74 *		
AV-9 vs. AV-6	3532	2.95 **			3532	4.57 **			3532	3.24 **		
Clinic Effect			20.6%	(4.7%)			20.6%	(4.7%)			20.6%	(4.7%
Intervention Participation												
# Sessions Attended in Previous 12 Months			23.9%	(3.3%)								
None	11392											
1 vs. None	496	4.19 **										
2 vs. None	649	5.80 **										
3 vs. None	748	6.52 **										
4+ vs. None	666	7.75 **										
# Sessions Completed in Previous 12 Months							24.1%	(3.5%)				
None					10743							
1 vs. None					282	3.39 **						
2 vs. None					324	4.38 **						
3 vs. None					587	6.19 **						
4+ vs. None					2015	8.27 **						
# Fat Scores Provided in Previous 12 Months											25.2%	(4.6%)
None									11585			
1 vs. None									409	4.08 **		
2 vs. None									398	5.93 **		
3 vs. None									463	6.75 **		
4+ vs. None									1096	8.81 **		

[1] Model adjusted for clinic effects.

* P-value <0.05 from a two-sided test.

** P-value <0.01 from a two-sided test.

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	4	
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**	4	
373	Unopposed Estrogen and the Risk of Peripheral Arterial Disease	CT	**Hsia**, Criqui, Heckbert, Herrington, Manson, Masaki, McDermott, Robinson	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	WHIMS	**Haan**	3	
161	Reproductive History and Cognitive Function in WHIMS	WHIMS	**Haan**, Frishman, Stefanick	3	
176	Validating and Improving the Gail and Colleagues Model Of Breast Cancer Risk in the WHI	Gen		3	
205	Risk Factors for Sarcopenia among a Multiethnic Cohort of Postmenopausal Women	Gen	**Chen**	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	
239	Risks and Benefits of A Low-Fat Dietary Pattern in Healthy Postmenopausal Women: Principal results from the Women's Health Initiative Randomized Controlled Trial	CT	**Patterson**, The Writing Group for the WHI Investigators	3	
245	Factors Associated with Self-Reported Severity of Constipation in the Women's Health Initiative	Gen	**Morse**, Ockene, Nygaard, Crawford	3	

Table 10.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	
318	The Association of Depressive Symptoms with BMD and Fracture: A Prospective Study form the WHI OS	OS	**Scholes**	3	
328	Leukocyte count as a predictor of Cancer in Postmenopausal women	OS	**Margolis**, Lopez, McTiernan, Thomson	3	
341	Race, socioeconomic status, and morbidity burden in the WHI Baseline Data	Gen	**Gold**, Aickin, Hubbell, Mason, Michael, Rodrigues, Safford, Whitlock	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 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
216	Decision-making about cancer screening among older women	Catherine Messina	Dorothy Lane	none	HRT	1916	no	2005-2010	pending
198	Women's Thoughts and Feelings About Participating In a Clinical Trial	Kathleen Furniss	Norm Lasser	none	HRT	50	no	6/04-12/04	funded
197	Validity of self-reported diabetes mellitus in the Women's Health Initiative	Karen Margolis	Karen Margolis	4 needed	DM, HRT, OS	600/300	no	3/05-2/07	pending
192	Estrogen & progesterone-related genes and colorectal cancer risk	Shumin Zhang	JoAnn Manson	none	OS	800/1600	yes	7/05-6/09	pending
191	Cytokines, Hormones and Sarcopenia in Older Women	Zhao Chen	Tamsen Bassford	none	OS	400/1000	yes	7/05-6/09	pending
189	Biochemical and Anthropometric Heterogeneity among Morbid Obese Women in the Women's Health Initiative Observational Study	Lew Kuller	Lew Kuller	none	OS	150/1300	yes	6/04-9/04	pending
188	Inflammation and the Risk of Hormonally-Linked Cancer	Frances-mary Modugno	Lew Kuller	none	OS	1350/750	yes	7/05-6/10	pending
185	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly Stopping Hormone Replacement Study Pills	Cheryl Ritenbaugh	Cheryl Ritenbaugh	none	HRT	155	no	3/04-9/04	funded
184	Measures for Changes in Skeletal Muscle Mass	Zhao Chen	Tamsen Bassford	none	BMD	120	no	12/04-12/07	pending
183	Effects of Hormone Therapy (Estrogen Alone or Estrogen Plus Progestin) on Subclinical Neurological Pathology – the MRI Study	Mark Espeland	Sally Shumaker	14	HRT	1450	no	7/04-6/06	funded

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
182	Genetic and Epigenetic Markers of Lung Cancer Risk in Post-menopausal women	Nicolas Schlecht	Sylvia Smoller	none	OS	550/1100	yes	5/05-4/10	pending
181	Estradiol, Cytokines and Bone Turnover: Effects on Hip Fracture	Jane Cauley	Lew Kuller	none	OS	400/400	yes	2004-2008	pending
180	Macrovascular Complications of Diabetes in Postmenopausal Women	Rongling Li	Karen Johnson	none	OS	3164	yes	12/04-11/08	pending
179	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women	Andrea LaCroix	Andrea LaCroix	none	OS	1200/600	yes	01/05-12/07	pending
178	Mammographic Density and Invasive Breast Cancer	Etta Pisano	Gerardo Heiss	all	HRT	317/951	no	2003-2005	funded
177	Relative Risk Differences Between FFQs and Food Records	Amy Subar	Ruth Patterson	all	DM	600/1200	no	9/03-9/04	funded
175	Physical Function Determinants in Minority Women	J. Skye Nicholas	Tamsen Bassford	none	OS	100	no	08/03-08/06	funded
171	Analysis of Heart Rate Variability from Ultra-short Records: The WHI Study	Yvonne L. Michael	Cheryl Ritenbaugh	none	DM and HRT	76	no	1/03-6/03	funded
169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Robert Kaplan	S. Wassertheil-Smoller	none	OS	188/752	yes	12/04-11/06	pending
167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Steve Cummings	Steve Cummings	none	OS	400/600	yes	6/04-12/05	pending
165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	Gerardo Heiss	none	OS	1550/3200	yes	2003-2005	funded
164	The IGF System and Coronary Heart Disease	Robert Kaplan	S. Wassertheil-Smoller	none	OS	350/350	yes	1/1/04-12/31/07	pending
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Jennifer Hays	Jennifer Hays	none	CT & OS	405	no	1/03-12/04	pending

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
162	Interactive Telephone Strategy to Maintain Diet Change	Shirley Beresford		none	CT	310	no	7/1/03-6/30/08	tabled
161	Bone Mass Response to Termination of Estrogen + Progestin	Jane Cauley	Lew Kuller	none	CT	350	no	7/10/02-10/01/02	funded
160	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly stopping Hormone Replacement Study Pills	Barbara Valanis	Cheryl Ritenbaugh	none	CT	250	no	7/02-8/17/02	funded
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Charles Mouton	Robert Schenken	none	OS	217/217	no		Approval expired
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Tom Rohan	S. Wassertheil-Smoller	none	OS	3500/3500	yes	4/03-3/06	dropped
153	Longitudinal Changes in Hip Geometry and Lower Limb Skeletal Muscle among Aging Women	Zhao Chen	Tamsen Bassford	none	All BMD women	all BMD women	no	07/03-06/08	funded
152	Polymorphisms of INS/IGF Signal Pathways & Female Cancer	Gloria Ho	S. Wassertheil-Smoller	none	OS	1700/900	yes	07/03-06/07	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	Joel Kaufman	Garnet Anderson	none	OS	all OS women	no	5/02-4/05	funded
149	Molecular Epidemiology and Prevention of Breast Cancer	Jennifer Hu	Electra Paskett	none	OS	800/800	yes	dropped	dropped
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Preisler	Henry Black	none	OS	59/177	yes		Approval expired

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson	none	OS	106/318	yes	03/03-02/04	funded
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	none	OS	80	no	04/01-06/01	funded
140	Environmental Epidemiology of Arrhythmogenesis in WHI	Eric Whitsel	Gerardo Heiss	none	CT	all CT women	no	04/03-03/08	funded
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Greg Burke	none	OS	416	no	8/01-8/02	funded
137	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	Jennifer Hays	none	OS	1060/2120	yes	10/03-09/07	funded
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	none	HRT	400	no	7/01-6/06	funded
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	Lew Kuller	none	OS	200/200	yes	6/1/02-5/31/04	funded
133	Biochemical and Genetic Markers of Hypertension in Women	Howard Sesso	JoAnn Manson	none	OS	800/800	yes	12/03-11/07	funded
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	JoAnn Manson	none	OS	1800/2700	yes	7/02-6/07	funded
130	A Randomized Controlled Trial of Fat Reduction, Calcium/Vitamin D Supplementation, Hormone Replacement Therapy, and risk of Proliferative Forms of Benign Breast Disease	Thomas Rohan	S. Wassertheil-Smoller	all	DM, HRT	3000	no	7/01-06/06	funded

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	S. Wassertheil-Smoller	none	OS	1700/900	yes	1/15/02-12/31/05	funded
128	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study	Tom Weber	S. Wassertheil-Smoller	none	OS	1500/1500	yes	07/03-06/07	dropped
127	CHD Risk Perception Study	Janice Barnhart	S. Wassertheil-Smoller	none	OS	350	no	4/1/2002-3/31/2006	funded
126	Hormones and Biomarkers Predicting Stroke in Women	Sylvia Smoller	S. Wassertheil-Smoller	none	OS Umbrella Study	1100/1100	yes	07/03-06/06	funded
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Joylin Namie	Robert Langer	none	DM	90-150	no	6/00-12/00	funded
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Francesmary Modugno	Lew Kuller	none	OS	225/200	yes	9/1/02-08/01/04	funded
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Christine L. Coy	Allan Hubbell	none	DM	191	no	12/1999-4/2000	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley K. Nichols	Rebecca Jackson	none	OS	400	no	2/01-1/04	funded
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford	none	OS	1000	no	8/1/99 - 7/31/02	funded

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	JoAnn Manson	none	OS	385/385	yes	8/1/00 - 7/31/03	funded
108.1	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski	none	OS	50/150	yes	01/03-12/03	funded
105	Carotenoids in Age-Related Eye Disease Study (CAREDS)	Julie Mares-Perlman	Catherine Allen	Iowa City Portland	OS	1700	yes	5/1/00 - 4/30/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	none	OS	150	no	7/1/99 - 6/30/02	funded
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker	Sally Shumaker	WHIMS sites	HRT	1800	no	4/1/99 - 3/31/05	funded
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Mona Fouad	Albert Oberman	none	OS	120	no	10/98 - 9/98	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	58	OS	775	no	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski	none	ALL	40	no	12/1/98 - 3/31/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	none	OS	1000	no	04/02-03/06	funded
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	Garnet Anderson	none	OS	264/528 baseline, 132/264 Yr 3	yes	9/30/01 - 9/29/04	funded
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez	David Curb	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer		OS	725	no	3/11/98 - 6/30/99	funded

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard	Barbara V. Howard	none	CT		no	N/A	tabled
90	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	Steve Cummings	none	OS	400/400	yes	4/03-3/06	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	M.J. Polk	Robert Schenken	none	HRT	50	no	N/A	funded
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Julie E. Dunn	Linda Van Horn	none	DM+OS	260	no	11/98 - 12/03	funded
83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	JoAnn Manson	none	OS	650/650	yes	9/1/99 - 8/30/03	funded
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	none	OS	200	no	7/1/97 - 6/30/01	funded
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad	Al Oberman	none	CT	40	no	7/1/97 - 9/30/97	funded
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Rowan Chlebowski	Rowan Chlebowski Harbor UCLA	none	DM	28	no	9/1/97 - 8/13/98	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ockene	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	none	DM	50	no	7/1/97 - 9/30/97	funded

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	22,67,29	OS	228	no	5/1/97 - 4/30/98	funded
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	none	OS	800	no	9/1/97 - 8/30/02	funded
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status:WHI	David Sheps	Gerardo Heiss	10	OS	3200	no	9/1/97 - 8/31/00	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	51	OS	782	no	1/1/97 - 12/31/05	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease in Postmenopausal Women	Margita Zakarija	Mary Jo O'Sullivan	51	OS	1040	no	ongoing	funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	all	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines	Gerardo Heiss	not specified	OS	800	no	10/1/96 - 6/30/99	funded
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	John Robbins	30	HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	John Robbins	none	HRT	110	no	on-going	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	none	DM Partners		no	12/1/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	none	OS	120	no	9/1/96 - 8/31/98	funded
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Gregory Burke	none	DM	260	no	9/1/96 - 8/31/98	funded

Table 10.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	none	DM	200	no	10/1/96 - 9/30/97	funded
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	Sylvia Smoller	none	All	1607	no	2/1/96 - 6/30/96	funded
47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	none	DM	150	no	5/1/96 - 4/30/97	funded
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Sally Shumaker	Sally Shumaker	all except #18	HRT	4800	no	5/1/96 - 4/30/05	funded
36	Hormone Replacement Therapy and Changes in Mammographic Density	Gerardo Heiss	Gerardo Heiss		HRT	NA	no	1/98 - 12/02	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	none	HRT	330	no	12/1/96 - 12/31/02	funded
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	none	OS	300	no	N/A	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	none	OS	2700	no	2/96 - 1/98	funded
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	none	OS	1000	no	10/25/94 - 10/24/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	none	OS	1300	no	9/16/96 - 09/15/01	funded

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Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	none	OS	600	no	8/1/95 - 7/31/99	funded
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and osteoporosis	Marjorie Jeffcoat	Beth Lewis	none	OS	650	no	6/1/95 - 5/31/04	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	none	DM	160	no	4/1/95 - 9/30/96	funded