Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
March 1, 2003 to August 31, 2003

Prepared by
WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Ross Prentice, Principal Investigator

Funded by National Institutes of Health Contract No. N01-WH-2-2110

December 4, 2003

WHI Semi-Annual Progress Report

Contents Page

Executive Summary

This report, summarizing data accumulated through August 31, 2003, 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, intermediate and clinical outcomes, and study performance issues.

The Hormone Replacement Therapy (HRT) component randomized 27,347 women into two trials, one of unopposed estrogen (ERT) for the 10,739 women who previously had a hysterectomy and a parallel one 16,608 of estrogen plus progestin (PERT) in women with a uterus. Intervention in the PERT trial was stopped in July of 2002, on the recommendation of the DSMB. The average follow-up in both trials is now over 6 years. Drop-out and "drop-in" rates in the ERT trial are somewhat higher than design assumptions but reflect no abrupt changes with the PERT trial stoppage. Vital status is known within the last 18 months for all but 4.2% of women; 4.2% of HRT participants are deceased. The current event rates for CHD, breast cancer, colorectal cancer, and hip fractures are 75%, 90%, 70%, and 40% of projected rates. Event rates are provided by age group, race/ethnicity, and hysterectomy strata.

The Dietary Modification (DM) component randomized 48,835 women. 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 7.7% at AV-8. For the first time, there was an improvement in the C-I at recent visits, which may reflect recent intervention initiatives. For fruit and vegetable intake, the mean difference between the arms of the trial remains consistently in excess of 1 more serving per day. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-third serving at AV-8. Currently, 3.8% of the DM participants are lost-to-follow-up or have stopped follow-up and 3.4% of participants are deceased. The average follow-up time for DM women is over 6.5 years. The current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 115%, 70%, and 65%, respectively, of design assumptions. Event rate comparisons by randomization assignment are presented 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 and is now 53%-64%, though still lower than desirable. 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; as only 2.2% of participants are lost-to-follow-up or have stopped follow-up, and 3.0% of the participants are known to be deceased. With approximately 5 years of average follow-up, the current rates of hip fractures, invasive breast cancer, and colorectal cancer are approximately 40%, 120%, and 75%, respectively, of what was assumed in the study design. Comparisons of event rates by age and race/ethnicity are presented for all monitored outcomes.

A modification has been introduced in outcomes reporting to bring this reporting more closely into alignment with what will be final results. For this report, the primary analyses of outcomes designated for a specific trial component to be routinely centrally adjudicated use this central data, if

available; otherwise local adjudication data are used. (Analyses from previous reports used only locally adjudicated data.) Agreement rates between approaches are provided in the section on outcomes processing. Information on the timeliness and quality of outcomes ascertainment is provided.

A section on laboratory studies provides an update on the status of analyte determinations in the CVD Biomarker studies, as well as an update on specimen commitments to date on the OS. Some aspects of clinical center performance are described. Finally, approved manuscript proposals and ancillary study activities are documented.

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, 2003. Topics include intervention adherence, follow-up, intermediate and clinical event rates, clinical center performance, 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 been in publishing the final disease-specific results of the randomized trial of combined estrogen plus progestin (PERT)[1] and in developing and implementing case-control studies of biomarkers in selected endpoints of this trial. At the time of this writing, 6 outcome-specific papers have been published on PERT findings:

- Hays J, Ockene J, Brunner R, Kotchen J, Manson J, Patterson R, Aragaki A, Shumaker S, Bryski R, LaCroix A, Granick I, Valanis B. Effects of estrogen plus progestin on health related quality of life. NEJM 2003;384:1839-1854.

- Smoller, Hendrix, Limacher, Heiss, Kooperberg, Baird, et al. Effect of Estrogen Plus Progestin on Stroke in Postmenopausal Women: The Women's Health Initiative. JAMA 2003;289:2673-2684.

- Chlebowski R, Hendrix S, Langer R, Stefanick M, Gass M, Lane D, Rodabough R, Gilligan MA, Cyr M, Thomson C, Kandekar J, Petrovitch H, McTiernan A. Influence of Estrogen Plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women: The Women's Health Initiative Randomized Trial. JAMA 2003;289:3243-3253.

- Manson J, Hsia J, Johnson K, Rossouw JE, Assaf A, Lasser N, Trevisan J, Black H, Heckbert S, Detrano R, Strickland O, Wong N, Crouse R, Stein E, Cushman M. Estrogen plus progestin and risk of coronary heart disease: Final results of the Women's Health Initiative. NEJM 2003;349:523-534.

- Cauley J, Robbins J, Chen Z, Cummings S, Jackson R, LaCroix A, LeBoff M, Lewis C, McGowan J, Neuner J, Pettinger M, Stefanick M, Wactawski-Wende J, Watts N. The effects of estrogen plus progestin on risk of fracture and bone mineral density: The Women's Health Initiative Clinical Trial. JAMA 2003;290:1729-1738.

- Anderson GL, Judd HL, Kaunitz A, Barad D, Beresford S, Pettinger M, Liu J, McNealey SG, Lopez AM. Effects of estrogen plus progestin on gynecologic cancers and associated diagnostic procedures: The Women's Health Initiative Randomized Trial. JAMA 2003;290:1739-1748.

[1] Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women, JAMA 2002: 288: 321-333.

In addition to these articles, manuscripts have been submitted for publication on final trial outcomes for colorectal cancer and diabetes. Manuscripts are in preparation for venous thromboembolisms, gynecologic symptoms, and urinary incontinence. The WHI has also supported the efforts of ancillary studies to develop and publish manuscripts related to the effects on dementia and eye disease. Support in terms of additional analyses and datasets has been given to the FDA and to Wyeth. WHI investigators presented key study findings at a recent meeting of the Metabolic and Endocrinologic Drugs Advisory Committee of the Food and Drug Administration.

An intriguing analysis is underway for an article describing the joint analysis of observational study and clinical trial data that attempts to identify the types of adjustments that must be made to bring these two study designs into alignment and if successful, to apply these results to other study preparations used by women in the observational study. This effort, led by Ross Prentice, has focused on coronary heart disease findings, but also has examined stroke and venous disease.

Analyses of biomarkers for CVD are nearing completion, with most of the priority analytes measures from both baseline and year 1 blood specimens. Results of selected baseline analytes were published in the papers by Manson et al. on CHD and Smoller et al. on stroke. Though some of the biomarkers examined correlated with event rates, none were successful in identifying subgroups of women at particularly high or low risk. Some analysis of change in biomarkers, examining more mechanistic hypotheses have been presented at previous Steering Committee meetings, but have yet to yield papers for publication.

A process is in place to identify biomarkers for other disease processes. The Case-Control Analyte Working Group, lead by Rebecca Jackson, has fostered several disease specific subgroups to propose analytes for subsequent measurement in appropriate case-control study designs for all clinical trial components. The CVD and Osteoporosis subgroups have submitted their proposals and the CVD proposal has already been approved. The breast cancer and colorectal cancer subgroups have not yet provided a formal proposal but each are encouraged to complete their task over the next few months.

During the spring of 2003, the WHI investigators submitted a proposal to NHLBI requesting support to continue follow-up (without intervention) of all WHI participants through 2010. In the last few months, the WHI was informed of the NHLBI decision to fund 2 years of additional follow-up of the HT program participants (beyond 2005) but no further follow-up of other WHI participants. The NHLBI will fund the continuation of the Clinical Coordinating Center through 2010 to support access to data and specimens for appropriate ancillary studies. Funding to continue a reduced version of the WHI organization will be included in the CCC budget request. In addition, in 2006 the NHLBI will issue a Broad Agency Announcement (BAA) so that any qualified investigator can compete for support and access to the WHI resource. The WHI investigators are considering their response to this recent development.

Additional special efforts of the last few months included:

- Further development of close-out planning (Close-out Working Group, Rebecca Jackson, chair)

- Preparation for the 2003 implementation of a centralized Personalized Evaluation of Fat Intake (PEFI) intervention in the DM.

- Intensive performance monitoring and targeted support of Clinical Center with regard to outcomes data processing to reduce backlogs and to assure rapid completion of the final trial database upon close-out.

All reports summarize Clinical Center (CC) data provided to the CCC by August 31, 2003. 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*. With sadness we note that Dr. Catherine (Kit) Allen, Principal Investigator of the Madison Wisconsin Clinical Center died on September 8, 2003.

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	Cheryl Ritenbaugh, PhD	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
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

Table 1.1 (continued)
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
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	Catherine Allen, PhD	Madison, WI
Wake Forest University	Gregory Burke, MD MS	Winston-Salem/Greensboro, NC
Wayne State University	Susan Hendrix, DO	Detroit, MI

2. HRT Component

The intervention activities of the estrogen plus progestin trial (PERT) were stopped in July 2002, following the recommendation of the DSMB. PERT trial participants were informed with a centralized mailing beginning July 8, with personal contacts by clinic staff over the next few weeks. A procedure was put in place to collect final outcomes for the intervention period, to unblind the women, explain the study results, and provide information on the transition to a follow-up phase without intervention. These participants are no longer being dispensed study medications but most of the remaining elements of the WHI protocol are continuing. At the same time, participants in the estrogen only arm (ERT) were informed of the PERT study findings and the continuing need for their participation was reinforced.

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* documents the age and racial/ethnic distribution for each trial.

2.2 Adherence

Adherence to study medications is determined at clinic visits by weighing returned bottles, if available, or by self-report in the small proportion of women with missed pill collection. *Table 2.2 – HRT Adherence Summary for Participants Without a Uterus* gives descriptive data on all women who are considered due for each contact for participants with hysterectomy (ERT vs. placebo) trial. Almost all participants were randomized more than five years ago, 77% more than six years ago and 1965 (18%) have been in the study more than eight years. In each of follow-up years five through eight, an estimated 6% of participants have stopped study pills. The adherence summaries for AV-5 through AV-8 are 54%, 50%, 46%, and 45%, only very slightly lower (0%-1%) than the last report. *Figure 2.1 – HRT Adherence Summary* presents the secular trends in adherence rates for each visit type for the entire ERT trial cohort. A change in the methodology for calculating adherence (described previously) has not been applied retrospectively to the results prior to the February 2002 report. The increase between the previous two cycles is likely to be an artifact of this change. These trends suggest that the adherence summary has been relatively stable over the last 6 months.

Drop-out and drop-in rates for the ERT trial are presented in *Table 2.3 – HRT Drop-Out and Drop-In Rates by Follow-up Time* along with associated design assumptions for combined stopping pills and death or loss to follow-up. Results for each interval as well as the overall cumulative loss to intervention are provided. In AV-5 through AV-8 the difference between the observed and projected cumulative stopping intervention rates appear to be somewhat divergent. Overall, about 55% of women in the ERT trial have stopped their study pills at some point but 49% were active at their last contact.

A small proportion (1.5% per year) of the HRT participants were expected to stop study hormone pills and begin taking hormones outside of the trial. The observed "drop-in" rates continue to be larger than expected. Reported reasons for stopping pills are listed in *Table 2.4*. Tabulations of reasons for stopping by age and race/ethnicity are presented in *Table 2.5*.

2.3 Symptoms

Women may report symptoms potentially related to HRT at routine follow-up contacts or through non-routine contacts with the CC. The primary symptoms being monitored are vaginal bleeding and breast changes. Reports of bleeding and breast changes by contact type and hysterectomy strata are shown in *Tables 2.6* and *2.7*, respectively. Reports of bleeding in women on PERT reached a high of nearly 30% at 6 months (SAV-1), declining to approximately 7% after AV-5 with later reductions likely associated with the end of intervention. Reports of breast changes peaked at 6 weeks after randomization and declined to less than 2% in both strata, with a possible further drop in the PERT arm after the intervention ended.

2.4 Intermediate Outcomes

Bone mineral density (BMD) measures are collected in three clinical centers (Pittsburgh, Birmingham, and Tucson) at baseline and at follow-up years 1, 3, 6, and 9. These data, shown in *Table 2.8 – Bone Mineral Density Analysis: HRT Participants* suggest small but significant increases in BMD between baseline and AV-1, with larger differences observed over greater follow-up time (AV-3 and AV-6) for whole body and spine. For hip, the largest increase occurs at AV-3. *Table 2.9 – 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.

2.5 Vital Status

Table 2.10 – 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. We note a difference in the rate of lost to follow-up between the women without a uterus (2.0%) and the women with a uterus (0.8%), presumably a result of the closure of the intervention of the PERT component. Currently, 4.2% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 4.2% 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 6.4 years, suggesting that approximately 17.7% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

2.6 Outcomes

Table 2.11 –Verified Outcomes (Annualized Percentages) contains counts of the number of verified, major WHI outcomes for HRT participants by age and race/ethnicity. For the first time in the current report we are reporting centrally adjudicated outcomes for those outcomes that are centrally adjudicated for all participants in a component. 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. Locally verified outcomes for events for which central adjudication has not yet been completed are included in the counts. See *Section 6 - Outcomes* for detailed procedures. The use of centrally adjudicated outcomes has resulted in a decrease of cases of ovarian cancer for some components. This is explained in detail in *Section 6*.

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 40% 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 class 1 and 2; *Fatal/ disabling stroke* contains strokes with Glasgow scale class 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 2.12 – 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 most cancers 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 2.13 – Frequency of Various Subcategories of Stroke Diagnosis presents the distribution of stroke diagnostic categories for HRT participants by hysterectomy status. The distribution of the subtype of stroke appears to be similar for the women with and without a uterus.

Table 2.14 – Frequency of Disability Levels Following Stroke compares the Glasgow scale for strokes between hysterectomy strata. From this table it appears that the largest number of strokes fall in Glasgow classes 1 and 2, the less disabling strokes, but a substantial number of participants die within one month of a stroke.

Table 2.15 – 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 6.3 – 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.

2.7 Issues

The WHI investigators have published six articles on the final results of the combined hormone trial since the initial publication. Several other more exploratory analyses are planned for some of the more frequent outcomes. Some of these analyses were presented to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee meeting on October 7, 2003. Together these efforts demonstrate the commitment of the WHI investigators to make these results widely available to the public and the medical and health policy communities. Continuing efforts to follow these women and obtain high quality data on the post-intervention effects are proceeding as planned.

The commitment of the WHI Investigators to the ERT trial remains equally high. It is the express intention of the WHI community to provide strong and compelling data on the risks and benefits of estrogen alone for women with a hysterectomy. The data presented here suggest that, though the adherence is lower than desired and projected, there have not been any significant changes in adherence in this trial since the companion trial was stopped. Study investigators consistently reinforce the importance of the continuation of the ERT trial until the comparative risks and benefits become clear.

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

Data as of: August 31, 2003

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3,421	125%	13%	10
55-59	5,410	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	2,025	135%	12%	10
55-59	3,494	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
HRT Adherence Summary for Participants Without a Uterus

Data as of: August 31, 2003

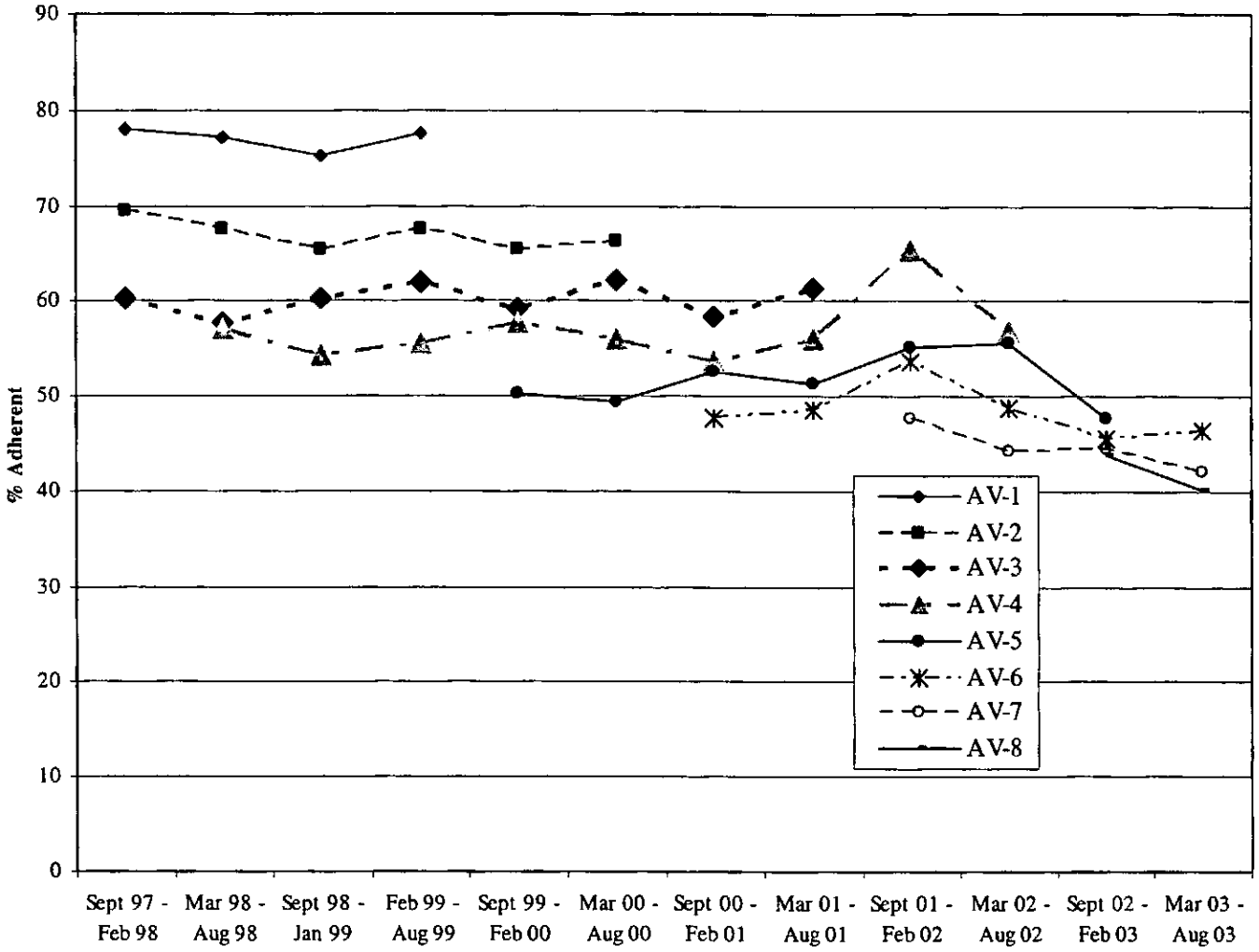
Contact	Due N	Conducted[1] N	%	Conducted in Window N	%	Stopped HRT during interval N	%	Missed Pill Collection N	%	Total with Collections N	%	Medication Rate[2,3] <50% N	%	Medication Rate[2,3] 50%-80% N	%	Medication Rate[2,3] 80% + N	%	Adherence Summary[4] %
Annual Visit – 1	10739	10352	96	8538	80	884	8	81	1	10619	99	816	8	1275	12	8528	80	80
Annual Visit – 2	10739	10061	94	7944	75	1045	10	196	2	9614	98	994	10	1185	12	7435	76	70
Annual Visit – 3	10739	10045	94	7445	70	854	8	209	2	8550	98	875	10	1044	12	6631	76	63
Annual Visit – 4	10739	9838	92	6777	65	708	7	174	2	7736	98	667	8	953	12	6116	77	58
Annual Visit – 5	10705	9708	91	6345	61	669	6	151	2	7047	98	586	8	897	12	5564	77	54
Annual Visit – 6	8243	7413	90	4501	57	490	6	129	3	4992	97	395	8	628	12	3969	78	50
Annual Visit – 7	4516	3947	87	2318	53	246	6	73	3	2550	97	213	8	326	12	2011	77	46
Annual Visit – 8	1965	1700	87	932	50	110	6	28	3	1044	97	92	9	117	11	835	78	45
Annual Visit – 9	545	454	83	245	48	41	8	8	3	277	97	32	11	38	13	207	73	40

[1] Based on Form 33 collection.
[2] Medication rate calculated as number of pills taken divided by 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 number of women consuming ≥ 80% of pills / # due for visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Figure 2.1
HRT Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills[1]

Data as of August 31, 2003

Participants Without Uterus



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

Table 2.3
HRT Drop-Out and Drop-In Rates (%) by Follow-Up Time (ERT Trial)

Data as of: August 31, 2003

	Design		Without Uterus	
	Int	Cum	Int[1]	Cum[2]
Drop-Outs[3]				
AV-1	8.8	8.8	8.3	8.3
AV-2	5.9	14.2	9.8	18.0
AV-3	5.9	19.2	8.1	25.9
AV-4	5.9	24.0	6.7	32.5
AV-5	5.9	28.5	6.4	38.8
AV-6	5.9	32.7	6.2	44.6
AV-7	5.9	36.7	5.7	49.8
AV-8	5.9	40.4	5.8	54.9
Drop-Ins[4]				
AV-1	1.5	1.5	2.9	2.9
AV-3	2.9	4.4	4.2	7.0
AV-6	4.4	8.7	1.1	8.0

[1] The first event of stopping or death or lost to follow-up in the interval.
[2] Estimated cumulative rate of stopping or death or lost to follow-up. Cumulative rates calculated as Kaplan-Meier estimates
[3] Drop-out rates derived from Form 7 by date..
[4] Cumulative Drop-in rates derived from medication inventory collected at AV-1, AV-3, AV-6, AV-9.
Interval estimates back-calculated from cumulative rates.

Table 2.4
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of August 31, 2003

Reasons[2]	(N = 5478)	
Personal/family		
Demands of work	92	1.7%
Family illness, emergency or other family demands[3]	226	4.1%
Financial problems	12	0.2%
Lack of cooperation/support from family/friends[4]	61	1.1%
Living in nursing home	19	0.3%
Issues of interest in study[5]	135	2.5%
Travel		
Too far to CC	195	3.6%
Moved out of area or refuses to be followed to another CC	44	0.8%
Other travel issues[6]	106	1.9%
Visits & Procedures		
Doesn't like visits, calls	61	1.1%
Mammogram Issues[7]	35	0.6%
Doesn't like gynecologic procedures	14	0.3%
Doesn't like required forms or safety procedures[8]	93	1.7%
Problems with other procedures[9]	13	0.2%
Worried about health effects of medical tests/procedures	26	0.5%
Wants test results[10]	1	<0.1%
Problems with CC[11]	32	0.6%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[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 mammograms (DM, HRT)" and "Cost of mammograms (DM, HRT)."
[8] Combines "Doesn't like filling out forms (other than those required for safety) ," and "Doesn't like required safety forms and/or procedures (HRT, CaD)."
[9] Combines "Doesn't like having blood drawn," "Doesn't like ECG (DM, HRT)," and "Doesn't like other procedures (other than those required for safety)."
[10] Combines "Wants results of blood analyses," and "Wants results of bone mineral density measurement (BD sites only)."
[11] Combines "Problem with the CC," "Problem with CC staff person (other than DM Group Nutritionist)," and "Staff change/turnover."

Table 2.4 (continued)
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of August 31, 2003

Reasons[2]	(N = 5478)	
Symptoms		
Vaginal Bleeding	5	0.1%
Breast Symptoms[3]	213	3.9%
Vaginal Changes	15	0.3%
Hot flashes/night sweats	33	0.6%
Other[4]	1069	19.5%
Health Conditions		
Breast Cancer	110	2.0%
Complex or atypical hyperplasia	0	0.0%
Endometrial cancer	2	<0.1%
Venous thromboembolism[5]	77	1.4%
High triglycerides (> 1000 mg/dL)	2	<0.1%
Malignant melanoma	17	0.3%
Gallbladder disease	21	0.4%
Heart Attack	87	1.6%
Stroke	127	2.3%
Meningioma	6	0.1%
Depression	13	0.2%
Cholesterol (high or concern about levels)	12	0.2%
Osteoporosis	38	0.7%
Cognitive/memory changes	55	1.0%
Other[6]	618	11.3%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[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", "Bloating/Gas", "Constipation", "Other gastrointestinal problems", "Headaches", "Weight loss/gain", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[5] Combines "Deep vein thrombosis", and "Pulmonary embolism".
[6] Combines "Removed from intervention due to WHI symptom management", "Removed from intervention due to adverse health event", "Communication problem", "Hypercalcemia", "Kidney failure/dialysis", "Renal calculi", "Arthritis", "Diabetes", "Loss of vision and/or hearing", and "Other health conditions not listed above".

Table 2.4 (continued)
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of August 31, 2003

Reasons[2]	(N = 5478)	
Intervention		
Doesn't like randomized nature of intervention	99	1.8%
Expected some benefit from intervention	43	0.8%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	4	0.1%
Takes too many pills	53	1.0%
Other pill issues[3]	162	3.0%
CaD Issues[4]	39	0.7%
DM Issues[5]	5	0.1%
Taking active HRT[6]	215	3.9%
Will not be on any HRT[7]	671	12.2%
Taking SERMs or other hormone medications[8]	47	0.9%
Other Health Issues		
Worried about cost if adverse effects occur	16	0.3%
Expected more health care	14	0.3%
Advised not to participate by health care provider[9]	652	11.9%
Study conflicts with other health issues[10]	608	11.1%
Other		
Other reasons not listed above	1133	20.7%
Refuses to give a reason	85	1.6%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman
[3] Combines "Doesn't like taking pills (HRT, CaD)", "Doesn't like taste of pills (HRT, CaD)", and "Unable to swallow pills (HRT, CaD)".
[4] Combines "Wants to take her own calcium (CaD)", "Feels diet is already sufficient in calcium/Vitamin D (CaD)", "Taking more than the maximum allowable IU of Vit D (CaD)", and "Taking Calcitriol (CaD)".
[5] Combines "Doesn't like DM requirements", "Problem with DM Group Nutritionist or group members (DM)", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes (DM)", "Doesn't like self-monitoring (DM)", "Doesn't like budgeting fat grams (DM)", "Has concerns regarding long-term risks/benefits of low fat diet (DM)", "Unhappy that not losing weight (DM)", "Not in control of meal preparation (DM)", "Too difficult to meet or maintain dietary goals (DM)", "Doesn't like eating low fat diet (DM)", "Doesn't like eating 5 vegetables/fruits per day (DM)", "Doesn't like eating 6 grains per day (DM)", "Feels fat gram goal is unrealistic (DM)", and "Eating pattern conflicts with personal health beliefs (DM)".
[6] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[7] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen) (HRT)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider (HRT)", and "Taking testosterone medications (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 2.5

Reasons for Stopping HRT[1] by Age at Screening and Race/Ethnicity: HRT Participants Without Uterus

Data as of August 31, 2003

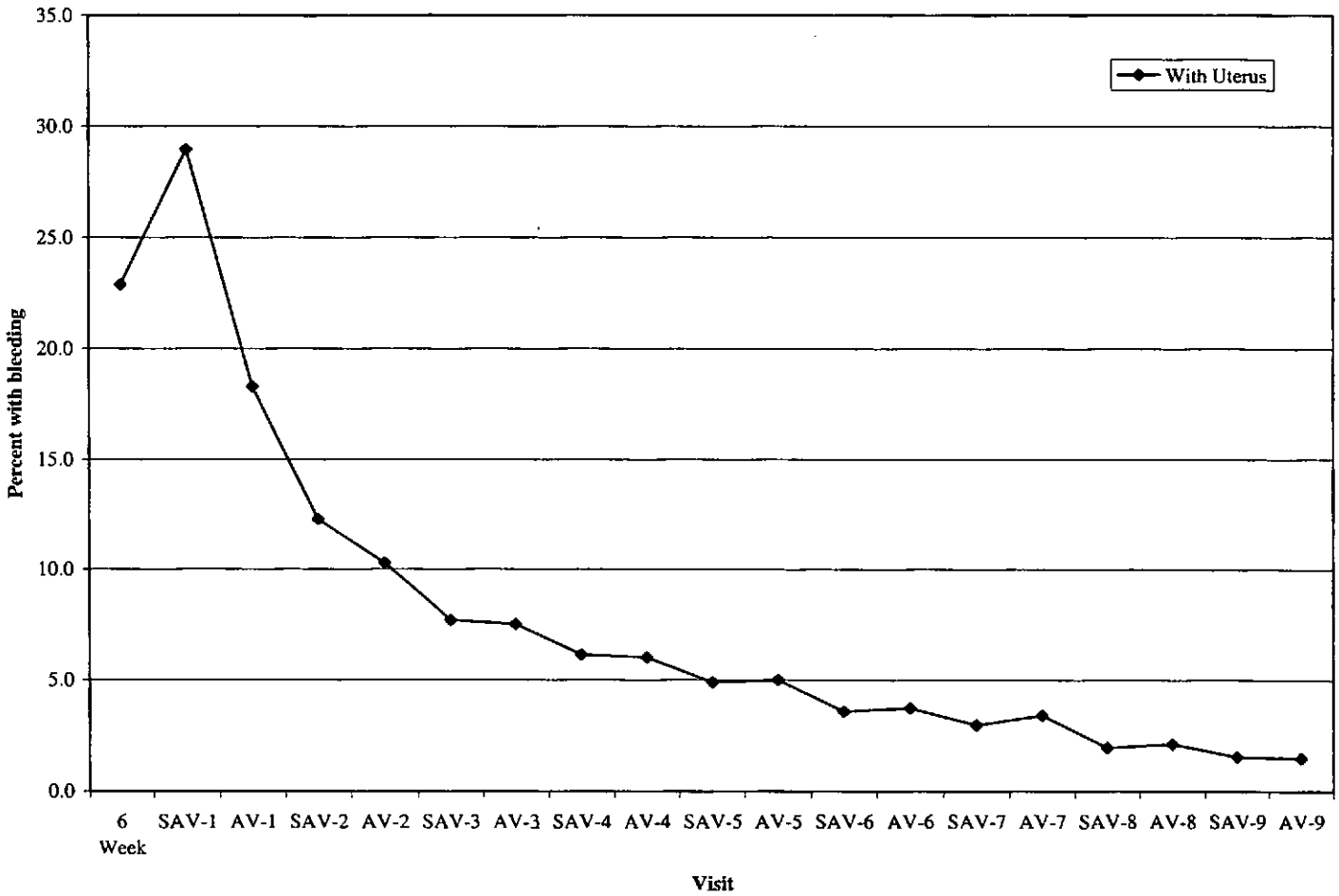
	All (N = 10,739)		Age at Screening: 50 – 54 (N = 1,396)		55 – 59 (N = 1,916)		60 – 69 (N = 4,852)		70 –79 (N = 2,575)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	5478	51.0%	700	50.1%	927	48.4%	2394	49.3%	1457	56.6%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	226	4.1%	29	4.1%	45	4.9%	104	4.3%	48	3.3%
Vaginal bleeding	5	0.1%	1	0.1%	2	0.2%	1	<0.1%	1	0.1%
Breast symptoms[6]	213	3.9%	15	2.1%	30	3.2%	86	3.6%	82	5.6%
Taking active HRT[7]	215	3.9%	34	4.9%	48	5.2%	89	3.7%	44	3.0%
Will not be on any HRT[8]	671	12.2%	56	8.0%	108	11.7%	315	13.2%	192	13.2%
Advised not to participate by health care provider[9]	652	11.9%	86	12.3%	105	11.3%	279	11.7%	182	12.5%
Study conflicts with other health issues[10]	608	11.1%	83	11.9%	98	10.6%	273	11.4%	154	10.6%

	Race/Ethnicity: American Indian/ Alaskan Native (N = 75)		Asian/Pacific Islander (N = 164)		Black/African American (N = 1,616)		Hispanic/Latino (N = 651)		White (N = 8,084)		Unknown (N = 149)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	39	52.0%	79	48.2%	851	52.7%	375	57.6%	4062	50.2%	72	48.3%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	1	2.6%	2	2.5%	48	5.6%	26	6.9%	146	3.6%	3	4.2%
Vaginal bleeding	0	0.0%	0	0.0%	2	0.2%	1	0.3%	2	<0.1%	0	0.0%
Breast symptoms[6]	4	10.3%	2	2.5%	30	3.5%	15	4.0%	160	3.9%	2	2.8%
Taking active HRT[7]	1	2.6%	1	1.3%	22	2.6%	15	4.0%	173	4.3%	3	4.2%
Will not be on any HRT[8]	4	10.3%	12	15.2%	99	11.6%	35	9.3%	511	12.6%	10	13.9%
Advised not to participate by health care provider[9]	5	12.8%	10	12.7%	72	8.5%	39	10.4%	516	12.7%	10	13.9%
Study conflicts with other health issues[10]	5	12.8%	11	13.9%	69	8.1%	30	8.0%	485	11.9%	8	11.1%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Percentages are of HRT participants without uterus in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same age or race/ethnicity category who stopped HRT.
[5] 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".
[6] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[7] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 2.6
Reports of Bleeding

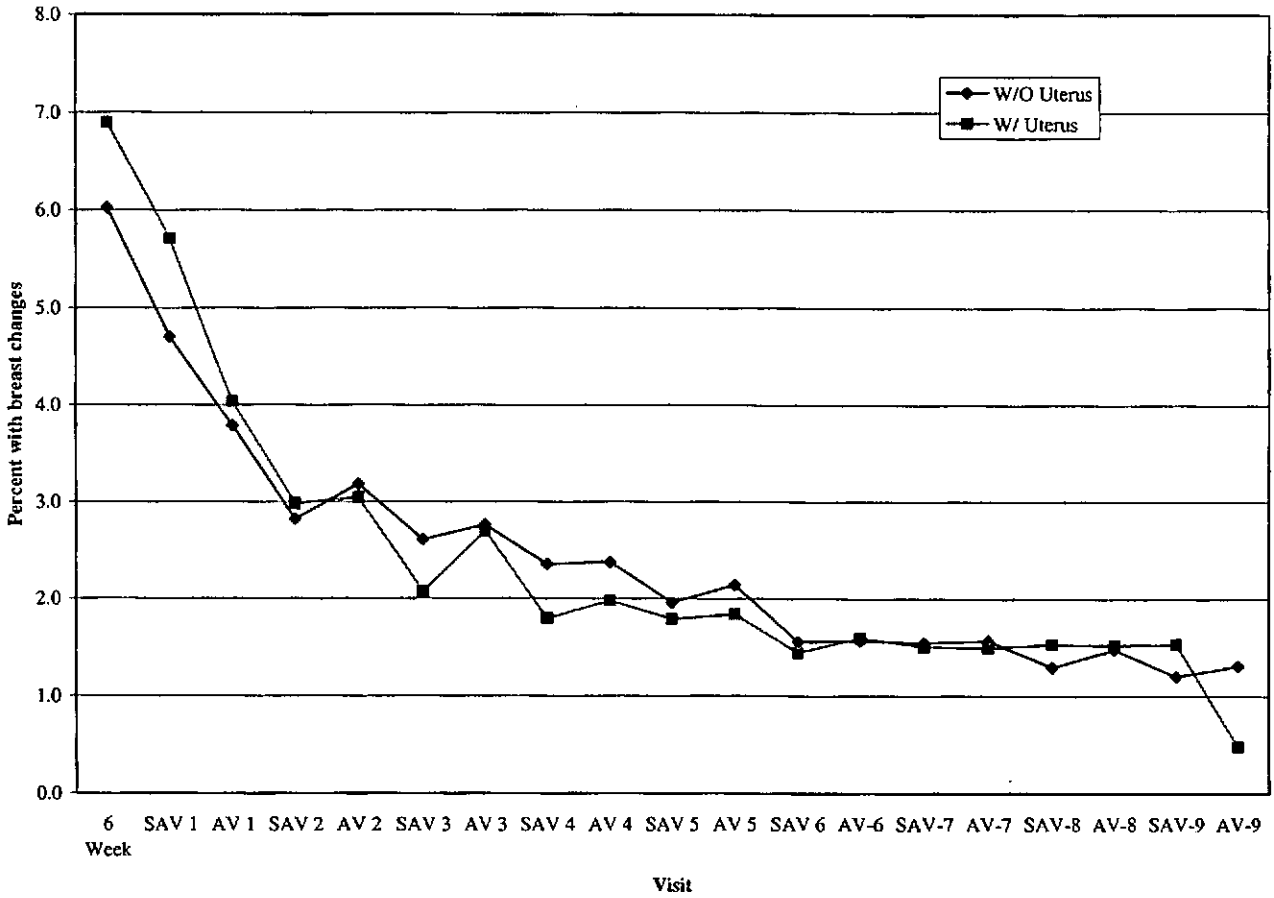
Data as of: August 31, 2003



Contact	With Uterus	
Semi-Annual Visit 3 – Number with Bleeding	1196	(7.7%)
Annual Visit 3 – Number with Bleeding	1186	(7.5%)
Semi-Annual Visit 4 – Number with Bleeding	950	(6.1%)
Annual Visit 4 – Number with Bleeding	937	(6.0%)
Semi-Annual Visit 5 – Number with Bleeding	753	(4.9%)
Annual Visit 5 – Number with Bleeding	765	(5.0%)
Semi-Annual Visit 6 – Number with Bleeding	491	(3.6%)
Annual Visit 6 – Number with Bleeding	434	(3.7%)
Semi-Annual Visit 7 – Number with Bleeding	258	(3.0%)
Annual Visit 7 – Number with Bleeding	208	(3.4%)
Semi-Annual Visit 9 – Number with Bleeding	81	(2.0%)
Annual Visit 8 – Number with Bleeding	54	(2.1%)
Semi-Annual Visit 9 – Number with Bleeding	23	(1.5%)
Annual Visit 9 – Number with Bleeding	10	(1.5%)

Table 2.7
Reports of Breast Changes

Data as of: August 31, 2003



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	220	(2.6%)	276	(2.1%)
Annual Visit 3 – Number with Breast Changes	229	(2.8%)	356	(2.7%)
Semi-Annual Visit 4 – Number with Breast Changes	183	(2.4%)	223	(1.8%)
Annual Visit 4 – Number with Breast Changes	179	(2.4%)	243	(2.0%)
Semi-Annual Visit 5 – Number with Breast Changes	141	(2.0%)	208	(1.8%)
Annual Visit 5 – Number with Breast Changes	150	(2.1%)	208	(1.8%)
Semi-Annual Visit 6 – Number with Breast Changes	95	(1.6%)	143	(1.4%)
Annual Visit 6 – Number with Breast Changes	80	(1.6%)	130	(1.6%)
Semi-Annual Visit 7 – Number with Breast Changes	59	(1.5%)	91	(1.5%)
Annual Visit 7 – Number with Breast Changes	41	(1.6%)	63	(1.5%)
Semi-Annual Visit 8 – Number with Breast Changes	23	(1.3%)	42	(1.5%)
Annual Visit 8 – Number with Breast Changes	16	(1.5%)	26	(1.5%)
Semi-Annual Visit 9 – Number with Breast Changes	8	(1.2%)	15	(1.5%)
Annual Visit 9 – Number with Breast Changes	4	(1.3%)	2	(0.5%)

Table 2.8
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: August 31, 2003

	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	776	1.03	0.12	857	1.02	0.10
AV6	648	1.04	0.12	699	1.02	0.11
AV9	76	1.02	0.13	105	1.02	0.11
AV1 % Change from baseline BMD[2]	841	0.44	2.81	925	0.26	2.35
AV3 % Change from baseline BMD[2]	774	2.16	4.41	852	1.99	3.81
AV6 % Change from baseline BMD[2]	646	2.41	5.57	697	2.50	5.42
AV9 % Change from baseline BMD[2]	76	2.19	6.46	104	2.95	7.03
Spine Scan						
Baseline	908	0.97	0.16	992	0.95	0.16
AV1	819	0.99	0.16	894	0.97	0.16
AV3	760	1.00	0.17	833	0.99	0.17
AV6	621	1.01	0.17	680	0.99	0.17
AV9	71	0.97	0.17	100	0.98	0.17
AV1 % Change from baseline BMD[2]	816	1.90	4.57	892	2.08	4.34
AV3 % Change from baseline BMD[2]	757	3.51	6.18	829	4.10	6.04
AV6 % Change from baseline BMD[2]	618	4.49	7.67	679	4.85	7.51
AV9 % Change from baseline BMD[2]	71	2.94	8.46	100	5.25	8.15
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	776	0.88	0.15	860	0.86	0.14
AV6	649	0.87	0.14	710	0.84	0.13
AV9	75	0.84	0.16	105	0.82	0.12
AV1 % Change from baseline BMD[2]	838	0.72	3.31	925	0.63	3.17
AV3 % Change from baseline BMD[2]	770	2.20	4.85	854	2.15	4.76
AV6 % Change from baseline BMD[2]	644	0.16	5.89	701	0.61	5.75
AV9 % Change from baseline BMD[2]	75	-1.53	7.07	103	-1.50	6.40

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

Table 2.9
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of: August 31, 2003

	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	151	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	128	1.08	0.11	67	1.08	0.12	44	1.09	0.11	36	1.10	0.14	469	1.02	0.12	581	1.01	0.11
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]	151	2.04	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]	128	0.59	4.02	67	0.41	4.07	44	5.08	5.69	35	6.58	6.79	467	2.65	5.78	580	2.49	5.38
Spine Scan																		
Baseline	171	1.04	0.15	98	1.08	0.19	65	0.96	0.13	60	0.92	0.14	660	0.95	0.16	812	0.93	0.15
AV1	150	1.05	0.16	85	1.09	0.19	44	0.97	0.11	48	0.95	0.16	614	0.97	0.16	744	0.96	0.16
AV3	148	1.07	0.17	86	1.11	0.20	51	0.95	0.13	43	0.95	0.14	553	0.99	0.17	687	0.97	0.16
AV6	114	1.08	0.17	65	1.08	0.19	44	0.98	0.13	34	0.96	0.15	456	0.99	0.17	566	0.98	0.17
AV1 % Change from baseline BMD[2]	150	1.92	4.39	85	1.74	4.81	44	-0.70	4.46	48	1.81	6.89	611	2.11	4.56	742	2.14	4.09
AV3 % Change from baseline BMD[2]	148	3.43	6.14	86	2.92	6.37	51	-0.35	5.62	43	3.15	6.89	550	3.92	6.10	683	4.31	5.93
AV6 % Change from baseline BMD[2]	114	3.19	6.85	65	2.10	7.04	44	1.83	6.75	34	3.59	8.57	453	5.14	7.89	565	5.19	7.44
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	151	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	129	0.94	0.13	68	0.94	0.14	43	0.90	0.13	36	0.87	0.12	470	0.84	0.13	591	0.83	0.12
AV1 % Change from baseline BMD[2]	153	1.14	2.96	86	1.12	3.45	43	0.31	3.62	49	1.04	3.42	631	0.65	3.37	773	0.55	3.13
AV3 % Change from baseline BMD[2]	151	1.85	3.88	87	1.37	3.96	50	2.72	5.29	44	4.46	5.92	561	2.25	5.04	706	2.06	4.75
AV6 % Change from baseline BMD[2]	129	-1.64	5.34	67	-2.52	5.07	43	2.52	5.87	35	4.11	6.50	465	0.49	5.91	584	0.74	5.65

[1] Measured in (g/cm2).
[2] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 2.10
Lost-to-Follow-up and Vital Status: HRT Participants by Hysterectomy Status

Data as of: August 31, 2003

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	506	4.7	639	3.8	1145	4.2
Alive: Current Participation[1]	9525	88.7	15155	91.3	24680	90.2
Alive: Recent Participation[2]	166	1.5	222	1.3	388	1.4
Alive: Past/Unknown Participation[3]	9	0.1	1	0.0	10	0.0
Stopped Follow-Up[4]	321	3.0	459	2.8	780	2.9
Lost to Follow-Up[5]	212	2.0	132	0.8	344	1.3

[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 2.11
Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of: August 31, 2003

Outcomes	Total		Age 50-54		Age 55-59		Age 60-69		Age 70-79	
Number randomized	27347		3421		5410		12364		6152	
Mean follow-up (months)	76.8		82.2		79.1		75.9		73.7	
Cardiovascular										
CHD[1]	724	(0.41%)	36	(0.15%)	72	(0.20%)	332	(0.42%)	284	(0.75%)
CHD death[2]	188	(0.11%)	7	(0.03%)	17	(0.05%)	73	(0.09%)	91	(0.24%)
Total MI[3]	592	(0.34%)	31	(0.13%)	59	(0.17%)	276	(0.35%)	226	(0.60%)
Clinical MI	563	(0.32%)	30	(0.13%)	57	(0.16%)	262	(0.33%)	214	(0.57%)
Evolving Q-wave MI[4]	29	(0.02%)	1	(<0.01%)	2	(0.01%)	14	(0.02%)	12	(0.03%)
Possible evolving Q-wave MI[4]	123	(0.07%)	14	(0.06%)	15	(0.04%)	46	(0.06%)	48	(0.13%)
Angina	887	(0.51%)	35	(0.15%)	110	(0.31%)	423	(0.54%)	319	(0.84%)
CABG/PTCA	920	(0.53%)	37	(0.16%)	108	(0.30%)	447	(0.57%)	328	(0.87%)
Carotid artery disease	170	(0.10%)	4	(0.02%)	16	(0.04%)	94	(0.12%)	56	(0.15%)
Congestive heart failure	564	(0.32%)	29	(0.12%)	59	(0.17%)	231	(0.30%)	245	(0.65%)
Stroke	554	(0.32%)	23	(0.10%)	57	(0.16%)	241	(0.31%)	233	(0.62%)
Non-disabling stroke	298	(0.17%)	15	(0.06%)	31	(0.09%)	130	(0.17%)	122	(0.32%)
Fatal/disabling stroke	130	(0.07%)	4	(0.02%)	7	(0.02%)	51	(0.07%)	68	(0.18%)
Unknown status from stroke	126	(0.07%)	4	(0.02%)	19	(0.05%)	60	(0.08%)	43	(0.11%)
PVD	162	(0.09%)	7	(0.03%)	15	(0.04%)	79	(0.10%)	61	(0.16%)
DVT	307	(0.18%)	17	(0.07%)	44	(0.12%)	134	(0.17%)	112	(0.30%)
Pulmonary embolism	202	(0.12%)	10	(0.04%)	30	(0.08%)	98	(0.13%)	64	(0.17%)
CHD[1]/Possible evolving Q-wave MI	839	(0.48%)	50	(0.21%)	87	(0.24%)	375	(0.48%)	327	(0.87%)
Coronary disease[5]	2041	(1.17%)	105	(0.45%)	234	(0.66%)	945	(1.21%)	757	(2.00%)
DVT/PE	408	(0.23%)	19	(0.08%)	58	(0.16%)	194	(0.25%)	137	(0.36%)
Total cardiovascular disease	3031	(1.73%)	150	(0.64%)	348	(0.98%)	1418	(1.81%)	1115	(2.95%)
Cancer										
Breast cancer	742	(0.42%)	66	(0.28%)	136	(0.38%)	353	(0.45%)	187	(0.50%)
Invasive breast cancer	602	(0.34%)	51	(0.22%)	112	(0.31%)	281	(0.36%)	158	(0.42%)
Non-invasive breast cancer	144	(0.08%)	15	(0.06%)	25	(0.07%)	75	(0.10%)	29	(0.08%)
Ovarian cancer	60	(0.03%)	2	(0.01%)	12	(0.03%)	33	(0.04%)	13	(0.03%)
Endometrial cancer[6]	64	(0.06%)	1	(0.01%)	13	(0.06%)	35	(0.07%)	15	(0.07%)
Colorectal cancer	246	(0.14%)	15	(0.06%)	25	(0.07%)	123	(0.16%)	83	(0.22%)
Other cancer[7]	942	(0.54%)	69	(0.29%)	131	(0.37%)	436	(0.56%)	306	(0.81%)
Total cancer	1985	(1.13%)	150	(0.64%)	309	(0.87%)	944	(1.21%)	582	(1.54%)
Fractures										
Hip fracture	244	(0.14%)	3	(0.01%)	11	(0.03%)	72	(0.09%)	158	(0.42%)
Vertebral fracture	246	(0.14%)	7	(0.03%)	28	(0.08%)	99	(0.13%)	112	(0.30%)
Other fracture[7]	2597	(1.48%)	291	(1.24%)	416	(1.17%)	1220	(1.56%)	670	(1.77%)
Total fracture	2954	(1.69%)	299	(1.28%)	445	(1.25%)	1339	(1.71%)	871	(2.31%)
Deaths										
Cardiovascular deaths	342	(0.20%)	11	(0.05%)	29	(0.08%)	131	(0.17%)	171	(0.45%)
Cancer deaths	489	(0.28%)	23	(0.10%)	54	(0.15%)	237	(0.30%)	175	(0.46%)
Other known cause	190	(0.11%)	12	(0.05%)	27	(0.08%)	73	(0.09%)	78	(0.21%)
Unknown cause	65	(0.04%)	4	(0.02%)	5	(0.01%)	26	(0.03%)	30	(0.08%)
Not yet adjudicated	60	(0.03%)	5	(0.02%)	7	(0.02%)	19	(0.02%)	29	(0.08%)
Total death	1145	(0.65%)	55	(0.23%)	121	(0.34%)	486	(0.62%)	483	(1.28%)

[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 2.11 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Replacement Therapy

Data as of: August 31, 2003

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)	74.6	72.8	76.1	74.2	77.3	73.0
Cardiovascular						
CHD[1]	3 (0.37%)	8 (0.25%)	79 (0.45%)	18 (0.19%)	600 (0.42%)	16 (0.68%)
CHD death[2]	2 (0.25%)	3 (0.09%)	34 (0.20%)	2 (0.02%)	144 (0.10%)	3 (0.13%)
Total MI[3]	2 (0.25%)	7 (0.22%)	54 (0.31%)	16 (0.17%)	499 (0.35%)	14 (0.60%)
Clinical MI	2 (0.25%)	7 (0.22%)	53 (0.31%)	16 (0.17%)	472 (0.33%)	13 (0.55%)
Evolving Q-wave MI[4]	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	27 (0.02%)	1 (0.04%)
Possible evolving Q-wave MI[4]	0 (0.00%)	2 (0.06%)	13 (0.07%)	6 (0.06%)	101 (0.07%)	1 (0.04%)
Angina	5 (0.62%)	14 (0.44%)	96 (0.55%)	35 (0.37%)	729 (0.51%)	8 (0.34%)
CABG/PTCA	5 (0.62%)	9 (0.28%)	81 (0.47%)	34 (0.36%)	779 (0.55%)	12 (0.51%)
Carotid artery disease	1 (0.12%)	1 (0.03%)	7 (0.04%)	1 (0.01%)	160 (0.11%)	0 (0.00%)
Congestive heart failure	3 (0.37%)	7 (0.22%)	78 (0.45%)	16 (0.17%)	454 (0.32%)	6 (0.26%)
Stroke	5 (0.62%)	10 (0.31%)	78 (0.45%)	20 (0.21%)	431 (0.30%)	10 (0.43%)
Non-disabling stroke	1 (0.12%)	6 (0.19%)	33 (0.19%)	13 (0.14%)	239 (0.17%)	6 (0.26%)
Fatal/disabling stroke	1 (0.12%)	3 (0.09%)	20 (0.12%)	2 (0.02%)	102 (0.07%)	2 (0.09%)
Unknown status from stroke	3 (0.37%)	1 (0.03%)	25 (0.14%)	5 (0.05%)	90 (0.06%)	2 (0.09%)
PVD	2 (0.25%)	0 (0.00%)	15 (0.09%)	2 (0.02%)	143 (0.10%)	0 (0.00%)
DVT	1 (0.12%)	1 (0.03%)	27 (0.16%)	4 (0.04%)	273 (0.19%)	1 (0.04%)
Pulmonary embolism	3 (0.37%)	1 (0.03%)	19 (0.11%)	3 (0.03%)	174 (0.12%)	2 (0.09%)
CHD[1]/Possible evolving Q-wave MI	3 (0.37%)	10 (0.31%)	91 (0.52%)	24 (0.25%)	694 (0.49%)	17 (0.73%)
Coronary disease[5]	10 (1.24%)	26 (0.81%)	231 (1.33%)	71 (0.75%)	1676 (1.18%)	27 (1.15%)
DVT/PE	4 (0.49%)	1 (0.03%)	36 (0.21%)	6 (0.06%)	359 (0.25%)	2 (0.09%)
Total cardiovascular disease	17 (2.10%)	37 (1.16%)	335 (1.93%)	97 (1.02%)	2508 (1.77%)	37 (1.58%)
Cancer						
Breast cancer	3 (0.37%)	19 (0.59%)	62 (0.36%)	25 (0.26%)	628 (0.44%)	5 (0.21%)
Invasive breast cancer	3 (0.37%)	14 (0.44%)	52 (0.30%)	18 (0.19%)	510 (0.36%)	5 (0.21%)
Non-invasive breast cancer	0 (0.00%)	5 (0.16%)	10 (0.06%)	7 (0.07%)	122 (0.09%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	4 (0.02%)	0 (0.00%)	55 (0.04%)	1 (0.04%)
Endometrial cancer[6]	1 (0.30%)	0 (0.00%)	0 (0.00%)	2 (0.04%)	61 (0.07%)	0 (0.00%)
Colorectal cancer	1 (0.12%)	7 (0.22%)	24 (0.14%)	12 (0.13%)	198 (0.14%)	4 (0.17%)
Other cancer[7]	6 (0.74%)	14 (0.44%)	75 (0.43%)	27 (0.28%)	807 (0.57%)	13 (0.55%)
Total cancer	11 (1.36%)	40 (1.25%)	158 (0.91%)	63 (0.66%)	1691 (1.19%)	22 (0.94%)
Fractures						
Hip fracture	0 (0.00%)	3 (0.09%)	6 (0.03%)	4 (0.04%)	229 (0.16%)	2 (0.09%)
Vertebral fracture	2 (0.25%)	2 (0.06%)	2 (0.01%)	2 (0.02%)	236 (0.17%)	2 (0.09%)
Other fracture[7]	12 (1.48%)	33 (1.03%)	140 (0.81%)	84 (0.88%)	2303 (1.62%)	25 (1.07%)
Total fracture	13 (1.61%)	37 (1.16%)	147 (0.85%)	87 (0.92%)	2643 (1.86%)	27 (1.15%)
Deaths						
Cardiovascular deaths	3 (0.37%)	7 (0.22%)	59 (0.34%)	3 (0.03%)	266 (0.19%)	4 (0.17%)
Cancer deaths	3 (0.37%)	12 (0.38%)	43 (0.25%)	12 (0.13%)	413 (0.29%)	6 (0.26%)
Other known cause	3 (0.37%)	1 (0.03%)	24 (0.14%)	1 (0.01%)	161 (0.11%)	0 (0.00%)
Unknown cause	0 (0.00%)	0 (0.00%)	12 (0.07%)	5 (0.05%)	46 (0.03%)	2 (0.09%)
Not yet adjudicated	0 (0.00%)	1 (0.03%)	3 (0.02%)	3 (0.03%)	52 (0.04%)	1 (0.04%)
Total Death	9 (1.11%)	21 (0.66%)	141 (0.81%)	23 (0.24%)	938 (0.66%)	13 (0.55%)

[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 2.12
Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: August 31, 2003

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	76.4		77.1	
Cardiovascular				
CHD[1]	335	(0.49%)	389	(0.36%)
CHD death[2]	98	(0.14%)	90	(0.08%)
Total MI[3]	271	(0.40%)	321	(0.30%)
Clinical MI	258	(0.38%)	305	(0.29%)
Evolving Q-wave MI[4]	13	(0.02%)	16	(0.01%)
Possible evolving Q-wave MI[4]	46	(0.07%)	77	(0.07%)
Angina	476	(0.70%)	411	(0.39%)
CABG/PTCA	448	(0.66%)	472	(0.44%)
Carotid artery disease	88	(0.13%)	82	(0.08%)
Congestive heart failure	300	(0.44%)	264	(0.25%)
Stroke	250	(0.37%)	304	(0.28%)
Non-disabling stroke	133	(0.19%)	165	(0.15%)
Fatal/disabling stroke	52	(0.08%)	78	(0.07%)
Unknown status from stroke	65	(0.10%)	61	(0.06%)
PVD	79	(0.12%)	83	(0.08%)
DVT	111	(0.16%)	196	(0.18%)
Pulmonary embolism	69	(0.10%)	133	(0.12%)
CHD[1]/Possible evolving Q-wave MI	379	(0.55%)	460	(0.43%)
Coronary disease[5]	1001	(1.46%)	1040	(0.97%)
DVT/PE	149	(0.22%)	259	(0.24%)
Total cardiovascular disease	1425	(2.08%)	1606	(1.51%)
Cancer				
Breast cancer	250	(0.37%)	492	(0.46%)
Invasive breast cancer	205	(0.30%)	397	(0.37%)
Non-invasive breast cancer	46	(0.07%)	98	(0.09%)
Ovarian cancer	18	(0.03%)	42	(0.04%)
Endometrial cancer[6]	0	N/A	64	(0.06%)
Colorectal cancer	112	(0.16%)	134	(0.13%)
Other cancer[7]	362	(0.53%)	580	(0.54%)
Total cancer	723	(1.06%)	1262	(1.18%)
Fractures				
Hip fracture	86	(0.13%)	158	(0.15%)
Vertebral fracture	91	(0.13%)	155	(0.15%)
Other fracture[7]	1005	(1.47%)	1592	(1.49%)
Total fracture	1132	(1.66%)	1822	(1.71%)
Deaths				
Cardiovascular deaths	162	(0.24%)	180	(0.17%)
Cancer deaths	202	(0.30%)	287	(0.27%)
Other known cause	76	(0.11%)	114	(0.11%)
Unknown cause	34	(0.05%)	31	(0.03%)
Not yet adjudicated	32	(0.05%)	28	(0.03%)
Total death	506	(0.74%)	639	(0.60%)

[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 2.13
Frequency (%)[1] of Various Subcategories of Stroke Diagnosis: HRT Participants

Data as of: August 31, 2003

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Stroke Diagnosis				
Subarachoid hemorrhage	10	4.0%	10	3.3%
Intracerebral hemorrhage	25	10.0%	32	10.5%
Other intracranial hemorrhage	1	0.4%	2	0.7%
Occlusion of cerebral arteries with infarction	176	70.4%	218	71.7%
Acute cerebrovascular disease	2	0.8%	1	0.3%
Report of cerebrovascular death only	10	4.0%	11	3.6%
Missing/not centrally confirmed	26	10.4%	30	9.9%
Total	250	100%	304	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.14
Frequency (%)[1] of Disability Levels Following Stroke – Glasgow Scale: HRT Participants

Data as of: August 31, 2003

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Glasgow scale				
Good recovery	68	27.2%	82	27.0%
Moderately disabled	53	21.2%	84	27.6%
Severely disabled	50	20.0%	54	17.8%
Vegetative survival	1	0.4%	3	1.0%
Death or death within 1 month	27	10.8%	36	11.8%
Unable to categorize stroke	25	10.0%	17	5.6%
Not yet categorized	26	10.4%	28	9.2%
Total	250	100%	304	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.15
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, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3421	5410	12364	6152
Mean follow-up (months)	76.8	82.2	79.1	75.9	73.7
Hospitalizations					
Ever	12063 (6.89%)	1076 (4.59%)	1908 (5.35%)	5619 (7.18%)	3460 (9.16%)
Two or more	6231 (3.56%)	480 (2.05%)	878 (2.46%)	2878 (3.68%)	1995 (5.28%)
Other					
Diabetes (treated)	1833 (1.11%)	249 (1.11%)	360 (1.07%)	849 (1.15%)	375 (1.05%)
Gallbladder disease[1]	1768 (1.21%)	243 (1.20%)	363 (1.19%)	823 (1.27%)	339 (1.11%)
Hysterectomy	578 (0.54%)	48 (0.35%)	107 (0.46%)	292 (0.61%)	131 (0.60%)
Glaucoma	2550 (1.52%)	214 (0.93%)	425 (1.22%)	1215 (1.62%)	696 (1.99%)
Osteoporosis	5036 (3.03%)	376 (1.63%)	753 (2.17%)	2420 (3.26%)	1487 (4.36%)
Osteoarthritis[2]	4071 (3.76%)	510 (2.89%)	812 (3.28%)	1851 (3.96%)	898 (4.68%)
Rheumatoid arthritis	1374 (0.82%)	172 (0.76%)	297 (0.87%)	608 (0.81%)	297 (0.83%)
Intestinal polyps	3176 (1.95%)	325 (1.43%)	549 (1.61%)	1614 (2.22%)	688 (2.06%)
Lupus	238 (0.14%)	32 (0.14%)	48 (0.13%)	106 (0.14%)	52 (0.14%)
Kidney stones[2]	580 (0.40%)	70 (0.38%)	110 (0.38%)	262 (0.40%)	138 (0.44%)
Cataracts[2]	7155 (5.61%)	371 (1.98%)	1000 (3.46%)	3856 (6.62%)	1928 (8.89%)
Pills for hypertension	6184 (4.98%)	685 (3.63%)	1159 (4.21%)	2833 (5.22%)	1507 (6.37%)

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)	74.6	72.8	76.1	74.2	77.3	73.0
Hospitalizations						
Ever	65 (8.04%)	154 (4.82%)	1248 (7.19%)	530 (5.58%)	9905 (6.98%)	161 (6.87%)
Two or more	36 (4.45%)	70 (2.19%)	654 (3.77%)	227 (2.39%)	5169 (3.64%)	75 (3.20%)
Other						
Diabetes (treated)	11 (1.57%)	42 (1.44%)	303 (1.99%)	163 (1.86%)	1286 (0.95%)	28 (1.29%)
Gallbladder disease[1]	10 (1.63%)	26 (0.89%)	151 (0.97%)	100 (1.41%)	1456 (1.24%)	25 (1.29%)
Hysterectomy	2 (0.59%)	4 (0.18%)	34 (0.48%)	26 (0.48%)	506 (0.56%)	6 (0.42%)
Glaucoma	13 (1.71%)	49 (1.59%)	323 (2.02%)	149 (1.62%)	1979 (1.45%)	37 (1.70%)
Osteoporosis	24 (3.14%)	110 (3.58%)	253 (1.51%)	253 (2.86%)	4322 (3.22%)	74 (3.33%)
Osteoarthritis[2]	27 (4.94%)	87 (3.86%)	411 (3.91%)	293 (4.45%)	3183 (3.66%)	70 (4.64%)
Rheumatoid arthritis	9 (1.26%)	23 (0.75%)	224 (1.41%)	186 (2.06%)	908 (0.67%)	24 (1.08%)
Intestinal polyps	16 (2.15%)	47 (1.61%)	319 (1.97%)	157 (1.72%)	2608 (1.98%)	29 (1.34%)
Lupus	2 (0.25%)	4 (0.13%)	27 (0.16%)	16 (0.17%)	188 (0.13%)	1 (0.04%)
Kidney stones[2]	5 (0.80%)	19 (0.71%)	59 (0.41%)	42 (0.54%)	448 (0.38%)	7 (0.36%)
Cataracts[2]	36 (5.95%)	117 (4.96%)	655 (5.15%)	362 (4.81%)	5897 (5.74%)	88 (5.14%)
Pills for hypertension	38 (6.66%)	115 (5.14%)	578 (6.73%)	385 (5.40%)	4996 (4.79%)	72 (4.75%)

[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-specific DM recruitment data are presented in *Table 3.1 – Dietary Modification Component Age - Specific Recruitment.* The age fractions exceeded the design assumptions for ages 50-54, 55-59, 60-69. For the age category 70-79, recruitment was lower than designed.

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 7.7% at AV-8. For the first time, there was an improvement in the C-I to 8.4 at AV-9, which may reflect recent intervention initiatives (see *Section 3.6*). This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.3*). Because of sparse numbers, 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 constant over time: 11.5% missing at AV-1, 15.2% at AV-3, 11.5% at AV-5, and 12.5% at AV-8.

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. Compared to Control women, Intervention 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 vegetables 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 past year and controlling for visit year and clinic effect (*Table 3.4 – 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 only participant characteristic that was consistently associated with a lower C-I difference was being Black compared to White ($p<0.01$). 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 3.2 – Mean Body Weight for DM Participants Stratified by Treatment Arm.* Here 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-6, control women have gained weight over time and hence the difference between the arms of the trial is statistically

significant at every annual visit ($p<0.01$). From a trend perspective, these results are consistent with changes in energy intake estimated with the FFQ.

Tables 3.5 and *3.6 – Reasons for Stopping DM* give reasons for stopping DM Intervention activities categorized by general type and stratified by age and race/ethnicity. Overall, the major reasons for stopping given by participants were family responsibilities (10.8%), demands of work (9.1%), and issues of interest in the study (9.9%). Issues specifically related to the DM intervention were seldom mentioned. The age and race/ethnicity stratified analyses have sparse numbers and may be confounded by other factors, and therefore should be interpreted cautiously. These data suggest that older participants were less likely to indicate that they were stopping due the demands of work, but were also less likely to stop the DM intervention because it was "Too far to the CC." Compared to the other race/ethnicity groups, Hispanic/Latino women were most likely to indicate that they were stopping intervention because of family demands, but least likely to stop intervention because of lack of interest in the study. Black/African American women were most likely to stop DM because of demands of work and/or issues of interest in the study.

3.3 Bone Density Analyses

Tables 3.7 and *3.8 – 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 and hip scan. These increases were attenuated at AV-9. 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 and/or HRT, selection of health-conscious women, incomplete BMD data (e.g., 12.6% missing at AV-3), or measurement issues.

3.4 Vital Status

Table 3.9 – 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 3.8% of the DM participants are lost-to-follow-up or have stopped follow-up, and 3.4% 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 6.6 years, suggesting that approximately 18.2% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.5 Outcomes

Table 3.10 – 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. For the first time in the current report we are reporting centrally adjudicated outcomes 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. See *Section 6 – Outcomes* for detailed procedures. The use of centrally adjudicated outcomes has resulted in a decrease of cases of ovarian cancer for some components. This is explained in detail in *Section 6*. 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 3.11 - 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 6.3 – Outcomes Data Quality)*, the number in this table should be taken as an upper bound to the number of events that have occurred in DM participants.

3.6 Issues

As noted above, the C-I percent energy from fat difference is less than the design assumptions. The WHI investigators and staff have undertaken regular, annual initiatives to improve adherence.

In 2000, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of a series of three interviews using motivational enhancement counseling techniques. A preliminary evaluation of the IIP among intervention participants indicated that when examining change (increases) in fat intake from AV-1 to most recent data collection, participants who received IIP contact had an increase in fat intake that was 0.75 percentage points less (i.e., had less slippage) than intervention women who did not receive IIP ($p<0.05$).

In 2001, we conducted a Targeted Message Campaign. Participants received a mailing designed to help them rediscover their intrinsic motivation(s) for participating in WHI, which was followed by a supportive motivational enhancement call. Based on information collected on the call, a second targeted mailing allowed a woman to select an action consistent with her readiness to enhance her intervention adherence.

In 2002, a Dietary Modification Working Group developed a third initiative called the Personalized Evaluation of Fat Intake (PEFI). This intervention uses tailored, food-based, feedback to facilitate dietary goal re-setting for participants. The dietary assessment was performed using a questionnaire on usual fat-intake over the past 4 weeks. After scanning, computerized algorithms provide printed, individualized feedback on estimated grams of fat consumed (overall and by foods) and food-specific behavioral change suggestions. The dietary questionnaire was administered during summer sessions and the written feedback was provided and reinforced in fall sessions. Overall, 74.6% of WHI intervention participants completed this protocol and the top five sources of fat were peanuts and other nuts; popcorn made with oil; beef, pork, lamb; peanut butter; and cheese.

For 2003, we are conducting a centralized "self-help" PEFI protocol that is providing women the opportunity to participate in a second round of assessment and feedback. The CCC is mailing PEFI questionnaires to participants, scanning returned forms, printing the tailored feedback, and mailing

the printed feedback with interpretation guide to the participants. This initiative began in September, when we mailed the first 4,687 questionnaires. As of October 1, the CCC had scanned 2,251 questionnaires that had been returned by DM participants. Centralized PEFI will be completed by early spring of 2004.

Providing ongoing training and support of nutritionists remains a priority. At the Fall 2002 Steering Committee meeting, the WHI lead nutritionists conducted a workshop that provided a behavioral booster training aimed at re-energizing nutritionists by sharing information on effective adherence and retention strategies used by CCs, and identifying local options to support intervention participants' adherence to the low-fat dietary pattern. In 2003 and 2004, the CCC is leading a series of dietary behavioral-focused conference calls with CC nutritionists, which are co-lead by the CCC behaviorist and a CCC nutritionist. The intent of the calls is to support CC nutritionists in their motivational enhancement, group facilitation, or other behavioral approaches. During 2003, the focus is adherence and during 2004, it will be close-out of the dietary intervention. Note that a similar series of calls were conducted in 1999, 2000, and 2001; and were well attended and very positively rated by CC nutritionists.

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

Data as of: August 31, 2003

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6,961	149%	14%	10
55-59	11,040	118%	23%	20
60-69	22,710	108%	47%	45
70-79	8,124	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, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO 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]	5927	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]	5055	28.6	8.1	7880	37.6	7.1	9.0	0.1	<.01
FFQ Year 5[7]	5792	29.1	8.2	8967	37.8	7.3	8.7	0.1	<.01
FFQ Year 6[8]	5740	29.6	8.2	8834	37.8	7.1	8.2	0.1	<.01
FFQ Year 7[9]	2964	30.1	8.3	4528	37.9	7.3	7.8	0.2	<.01
FFQ Year 8[10]	1223	30.4	8.0	1993	38.1	7.3	7.7	0.3	<.01
FFQ Year 9[11]	457	30.3	8.3	705	38.7	7.8	8.4	0.5	<.01
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	805	21.7	7.3	1171	32.9	6.8	11.3	0.3	<.01
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	<.01
24 Hr Recall, Year 2	214	23.8	9.7	244	32.5	8.0	8.7	0.8	<.01
24 Hr Recall, Year 3	209	25.1	9.2	249	33.3	8.6	8.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	24.8	8.5	1183	33.0	7.6	8.3	0.4	<.01
24 Hr Recall, Year 4	214	25.8	9.3	240	33.2	8.6	7.4	0.8	<.01
24 Hr Recall, Year 5	127	26.2	9.5	187	34.2	8.4	7.9	1.0	<.01
24 Hr Recall, Year 6	84	26.3	10.0	106	35.0	8.0	8.7	1.3	<.01
24 Hr Recall, Year 6 Cohort	430	26.4	8.9	686	33.6	7.8	7.1	0.5	<.01
24 Hr Recall, Year 7	37	28.7	10.9	42	35.3	8.5	6.7	2.2	<.01
Total Energy (kcal)									
FFO Baseline	19541	1789.1	713.3	29294	1789.4	706.6	0.3	6.6	0.93
FFQ Year 1	18099	1473.9	534.4	26776	1584.3	641.6	110.4	5.8	<.01
FFQ Year 2	5927	1479.5	534.8	8669	1575.8	625.5	96.2	9.9	<.01
FFQ Year 3	3241	1476.1	538.0	4889	1571.6	644.3	95.4	13.7	<.01
FFQ Year 4	5055	1443.2	536.4	7880	1561.9	635.0	118.7	10.8	<.01
FFQ Year 5	5792	1449.9	538.6	8967	1552.4	637.5	102.4	10.1	<.01
FFQ Year 6	5740	1422.9	538.1	8834	1534.5	632.6	111.6	10.1	<.01
FFQ Year 7	2964	1424.6	541.8	4528	1544.6	634.9	120.0	14.2	<.01
FFQ Year 8	1223	1417.0	555.2	1993	1537.8	631.4	120.8	21.9	<.01
FFQ Year 9	457	1416.8	563.0	705	1521.7	572.5	104.9	34.2	<.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	214	1438.4	399.2	240	1534.0	457.9	95.6	40.5	0.04
24 Hr Recall, Year 5	127	1423.3	472.2	187	1578.2	530.9	154.9	58.4	0.01
24 Hr Recall, Year 6	84	1414.7	528.7	106	1652.4	531.9	237.7	77.5	<.01
24 Hr Recall, Year 6 Cohort	430	1407.9	393.4	686	1550.9	489.0	143.0	28.0	<.01
24 Hr Recall, Year 7	37	1239.8	347.2	42	1521.0	507.8	281.2	99.2	0.02

(continues)

[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] 1269 (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] 784 (14%) Intervention women had <=20% energy from fat at year 5.
[8] 631 (11%) Intervention women had <=20% energy from fat at year 6.
[9] 305 (10%) Intervention women had <=20% energy from fat at year 7.
[10] 114 (9%) Intervention women had <=20% energy from fat at year 8.
[11] 43 (9%) Intervention women had <=20% energy from fat at year 9

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: August 31, 2003

	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	5927	43.5	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	5055	46.2	23.9	7880	66.2	32.2	20.0	0.5	<.01
FFQ Year 5	5792	47.3	24.4	8967	66.2	32.8	18.9	0.5	<.01
FFQ Year 6	5740	47.1	23.8	8834	65.3	32.2	18.3	0.5	<.01
FFQ Year 7	2964	48.1	25.4	4528	66.1	32.7	18.0	0.7	<.01
FFQ Year 8	1223	48.3	25.2	1993	66.0	32.2	17.7	1.1	<.01
FFQ Year 9	457	48.6	28.4	705	66.2	30.5	17.6	1.8	<.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	214	41.7	20.3	240	58.4	25.7	16.7	2.2	<.01
24 Hr Recall, Year 5	127	42.2	23.0	187	61.5	28.7	19.3	3.0	<.01
24 Hr Recall, Year 6	84	42.6	28.5	106	65.7	29.8	23.0	4.3	<.01
24 Hr Recall, Year 6 Cohort	430	41.9	20.4	686	59.5	26.4	17.6	1.5	<.01
24 Hr Recall, Year 7	37	40.6	21.5	42	59.4	24.8	18.8	5.3	<.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	5927	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	5055	15.7	8.9	7880	23.1	12.2	7.4	0.2	<.01
FFQ Year 5	5792	16.1	9.1	8967	23.2	12.4	7.0	0.2	<.01
FFQ Year 6	5740	16.0	8.8	8834	22.8	12.2	6.8	0.2	<.01
FFQ Year 7	2964	16.5	9.5	4528	23.1	12.5	6.6	0.3	<.01
FFQ Year 8	1223	16.6	9.4	1993	23.3	12.6	6.7	0.4	<.01
FFQ Year 9	457	16.7	10.3	705	23.2	11.3	6.6	0.7	<.01
4DFR Baseline	892	20.6	8.9	1351	20.9	9.3	0.3	0.4	0.72
4DFR Year 1	805	10.6	5.2	1171	19.5	8.3	9.0	0.3	<.01
24 Hr Recall, Post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	<.01
24 Hr Recall, Year 1	221	11.7	6.2	268	20.1	10.1	8.4	0.8	<.01
24 Hr Recall, Year 2	214	12.3	8.2	244	19.5	9.9	7.2	0.9	<.01
24 Hr Recall, Year 3	209	13.4	7.7	249	20.3	10.8	6.9	0.9	<.01
24 Hr Recall, Year 3 Cohort	787	12.4	6.8	1183	19.7	9.3	7.3	0.4	<.01
24 Hr Recall, Year 4	214	13.5	7.7	240	19.6	10.1	6.1	0.9	<.01
24 Hr Recall, Year 5	127	13.4	7.4	187	20.8	10.6	7.4	1.1	<.01
24 Hr Recall, Year 6	84	13.3	9.2	106	21.3	10.8	8.1	1.5	<.01
24 Hr Recall, Year 6 Cohort	430	13.3	7.4	686	19.6	9.9	6.3	0.6	<.01
24 Hr Recall, Year 7	37	13.0	8.4	42	19.3	9.3	6.3	2.0	<.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

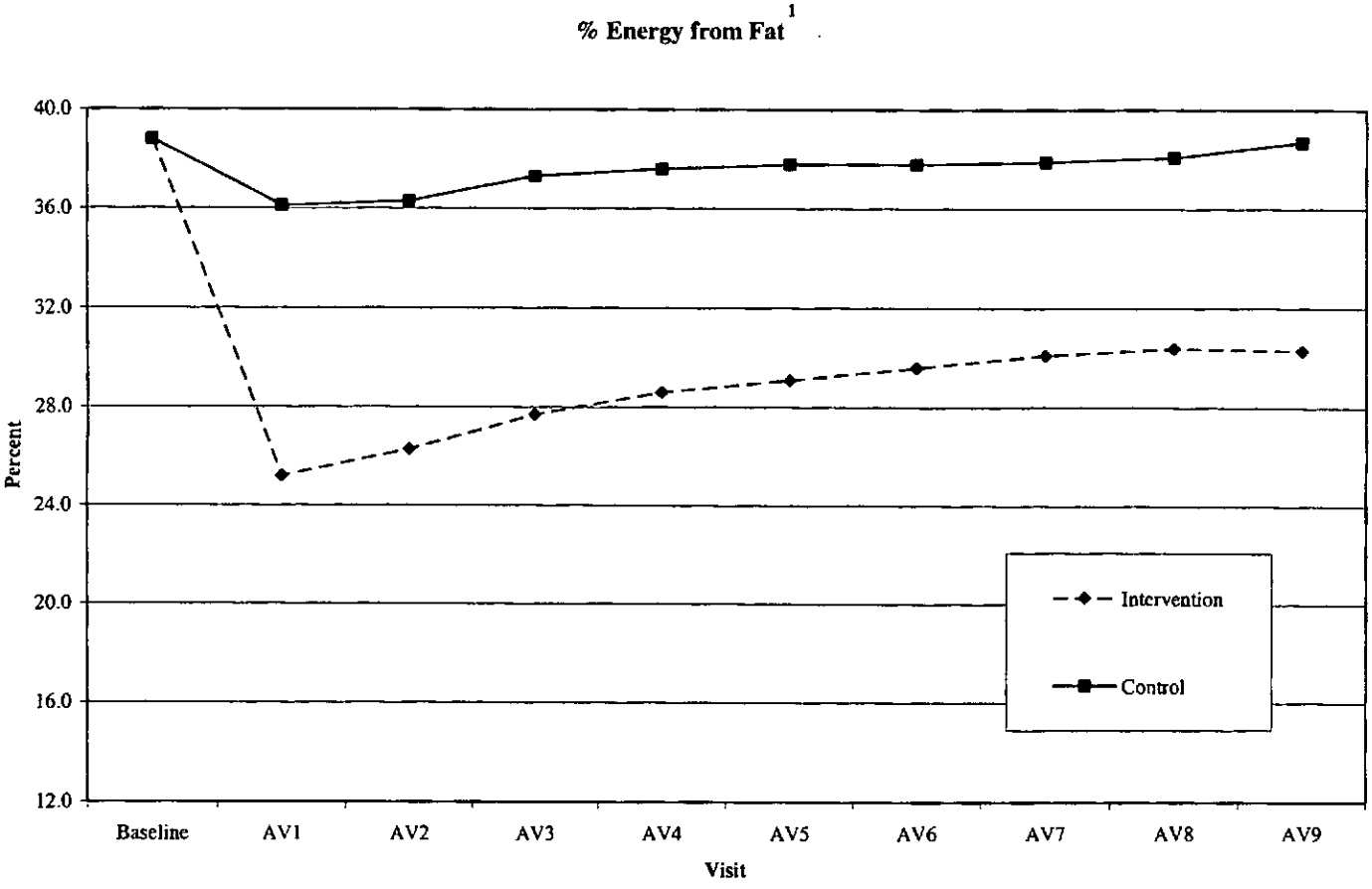
Data as of: August 31, 2003

	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	5927	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	5055	9.0	4.9	7880	12.8	6.7	3.8	0.1	<.01
FFQ Year 5	5792	9.1	5.0	8967	12.8	6.8	3.7	0.1	<.01
FFQ Year 6	5740	9.2	5.0	8834	12.6	6.6	3.4	0.1	<.01
FFQ Year 7	2964	9.2	5.2	4528	12.8	6.7	3.5	0.1	<.01
FFQ Year 8	1223	9.3	5.0	1993	12.6	6.4	3.3	0.2	<.01
FFQ Year 9	457	9.3	5.7	705	12.9	6.6	3.6	0.4	<.01
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.3	0.3	0.40
4DFR Year 1	805	7.4	3.4	1171	12.7	6.2	5.3	0.2	<.01
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.6	0.5	<.01
24 Hr Recall, Year 2	214	8.3	5.7	244	12.5	7.6	4.2	0.6	<.01
24 Hr Recall, Year 3	209	8.5	5.5	249	12.2	6.6	3.8	0.6	<.01
24 Hr Recall, Year 3 Cohort	787	8.7	4.6	1183	12.2	6.9	3.6	0.3	<.01
24 Hr Recall, Year 4	214	8.8	4.9	240	11.7	6.8	3.0	0.6	<.01
24 Hr Recall, Year 5	127	9.1	6.7	187	12.1	8.0	3.0	0.9	<.01
24 Hr Recall, Year 6	84	9.3	7.5	106	14.1	7.9	4.8	1.1	<.01
24 Hr Recall, Year 6 Cohort	430	8.9	4.7	686	12.3	6.3	3.4	0.4	<.01
24 Hr Recall, Year 7	37	8.3	4.7	42	12.9	5.8	4.6	1.2	<.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	5903	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	5045	5.1	2.4	7866	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	5769	5.1	2.5	8941	3.8	2.1	1.2	0.0	<.01
FFQ Year 6	5716	5.0	2.4	8809	3.8	2.0	1.2	0.0	<.01
FFQ Year 7	2945	4.9	2.4	4514	3.8	2.0	1.1	0.1	<.01
FFQ Year 8	1215	4.9	2.4	1983	3.7	2.0	1.1	0.1	<.01
FFQ Year 9	452	4.8	2.4	701	3.8	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	5902	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	5041	4.4	2.4	7854	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	5765	4.3	2.3	8930	3.8	2.1	0.5	0.0	<.01
FFQ Year 6	5713	4.2	2.4	8796	3.7	2.1	0.4	0.0	<.01
FFQ Year 7	2943	4.0	2.2	4510	3.7	2.1	0.3	0.1	<.01
FFQ Year 8	1215	3.9	2.2	1980	3.7	2.1	0.3	0.1	<.01
FFQ Year 9	451	3.9	2.2	698	3.6	1.9	0.3	0.1	0.07

[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, 2003



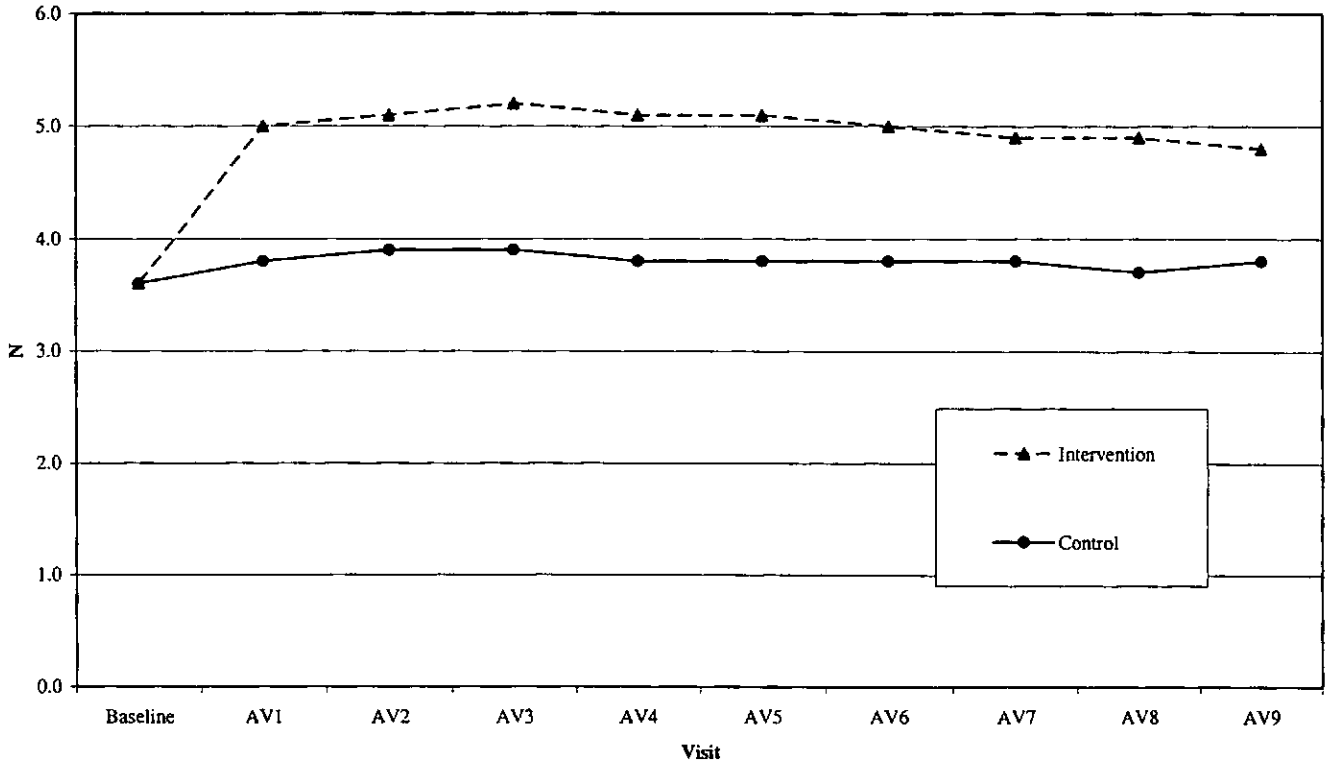
(continues)

[1] Baseline % energy from fat values are about 3% higher in both groups due to the use of FFQ % energy from fat as an exclusionary criterion during screening.

Figure 3.1 (continued)
Nutrient Intake

Data as of: August 31, 2003

Fruit & Vegetable Servings per Day



Grain Servings per Day

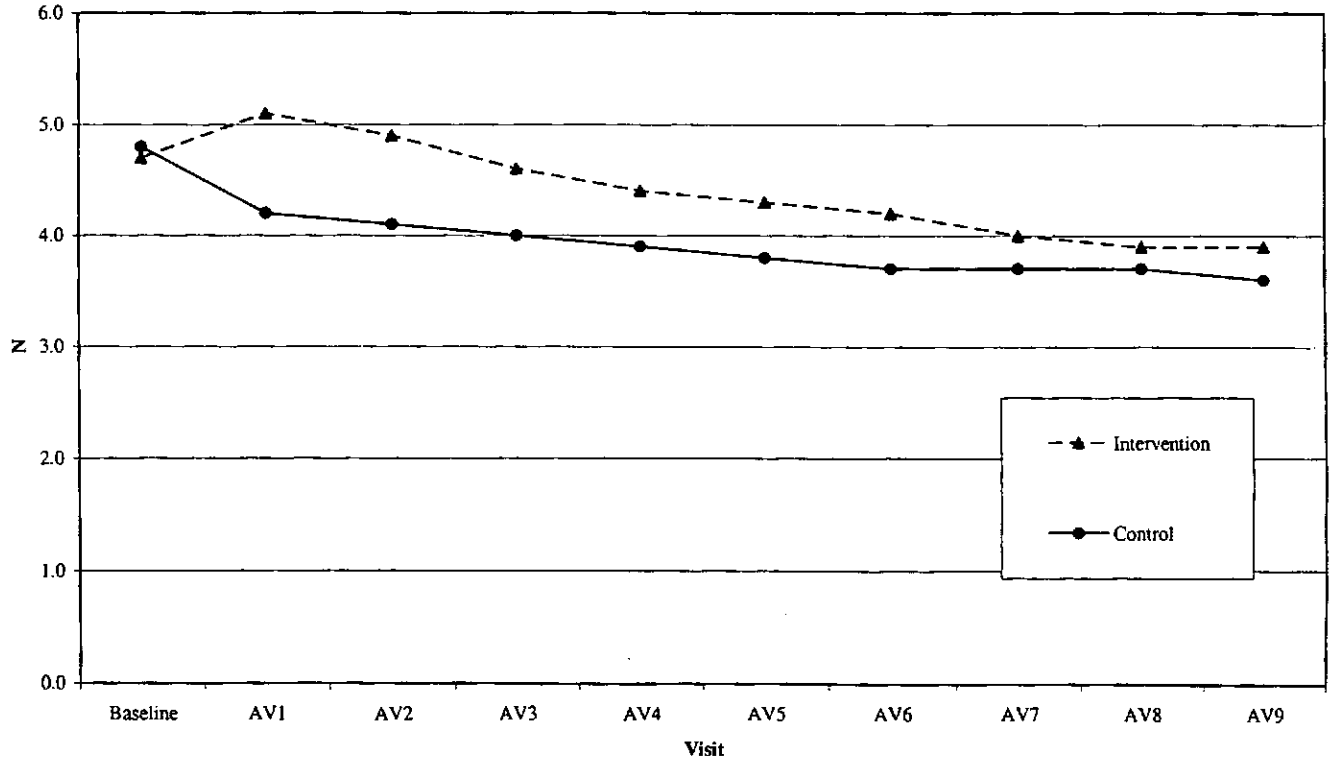


Table 3.3
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	88	39.5	5.7	114	40.0	5.2	0.5	0.8	0.49
FFQ Year 1[3]	73	27.5	8.9	96	38.0	8.0	10.5	1.3	<.01
FFQ Year 2[4]	28	26.9	8.8	32	38.2	6.8	11.3	2.0	<.01
FFQ Year 3[5]	18	31.3	8.9	41	38.0	7.0	6.7	2.1	<.01
FFQ Year 4[6]	23	30.3	9.3	28	39.9	7.6	9.6	2.4	<.01
FFQ Year 5[7]	19	27.6	7.6	16	39.9	7.8	12.3	2.6	<.01
FFQ Year 6[8]	31	32.0	7.0	37	41.5	7.4	9.5	1.8	<.01
FFQ Year 7[9]	18	29.1	8.6	15	40.2	8.8	11.1	3.0	<.01
FFQ Year 8[10]	5	36.5	9.4	11	38.8	8.5	2.3	4.7	0.65
FFQ Year 9[11]	1	32.6	N/A	2	39.8	2.1	7.2	N/A	N/A
4DFR Baseline	24	34.0	6.7	44	33.4	7.8	0.6	1.9	0.73
4DFR Year 1	18	20.5	6.2	32	34.6	7.4	14.2	2.1	<.01
Total Energy (kcal)									
FFQ Baseline	88	1717.5	795.9	114	1771.7	718.2	54.3	106.8	0.42
FFQ Year 1	73	1631.3	689.6	96	1545.5	753.4	85.8	112.8	0.52
FFQ Year 2	28	1508.4	565.8	32	1554.0	706.9	45.6	166.9	0.95
FFQ Year 3	18	1520.0	614.4	41	1589.0	704.1	69.0	191.9	0.83
FFQ Year 4	23	1441.3	478.9	28	1821.1	932.9	379.7	214.8	0.09
FFQ Year 5	19	1673.2	661.5	16	1366.0	724.8	307.2	234.5	0.10
FFQ Year 6	31	1061.4	465.9	37	1639.1	819.4	577.7	166.0	<.01
FFQ Year 7	18	1497.2	467.6	15	1747.2	1002.4	250.0	264.8	0.48
FFQ Year 8	5	1461.2	340.6	11	1406.2	476.2	55.0	238.3	0.63
FFQ Year 9	1	2320.2	N/A	2	1705.6	323.0	614.6	N/A	N/A
4DFR Baseline	24	1524.3	426.0	44	1672.0	606.8	147.7	139.7	0.47
4DFR Year 1	18	1283.9	418.7	32	1631.9	613.0	348.1	162.7	0.04
Total Fat (g)									
FFQ Baseline	88	76.5	40.3	114	79.3	35.6	2.8	5.4	0.34
FFQ Year 1	73	50.3	29.6	96	67.1	43.6	16.8	5.9	<.01
FFQ Year 2	28	45.8	29.0	32	68.5	40.0	22.7	9.1	<.01
FFQ Year 3	18	56.6	35.4	41	68.6	35.7	11.9	10.1	0.22
FFQ Year 4	23	48.9	21.7	28	81.3	44.5	32.4	10.2	<.01
FFQ Year 5	19	52.1	26.7	16	63.6	43.0	11.5	11.9	0.46
FFQ Year 6	31	37.5	18.0	37	76.3	44.5	38.7	8.5	<.01
FFQ Year 7	18	47.3	19.8	15	76.7	40.0	29.3	10.7	<.01
FFQ Year 8	5	58.0	13.4	11	62.8	30.7	4.8	14.5	0.95
FFQ Year 9	1	84.2	N/A	2	75.8	18.3	8.3	N/A	N/A
4DFR Baseline	24	57.4	17.5	44	63.8	30.8	6.4	6.8	0.83
4DFR Year 1	18	29.4	12.9	32	64.9	33.0	35.5	8.1	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[4] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[5] 1 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[6] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[7] 3 (16%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[8] 2 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.
[9] 3 (17%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 8.
[11] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	88	26.9	14.2	114	27.9	14.1	1.0	2.0	0.42
FFQ Year 1	73	17.4	11.0	96	23.7	18.0	6.2	2.4	<.01
FFQ Year 2	28	15.5	9.9	32	23.3	14.9	7.8	3.3	<.01
FFQ Year 3	18	19.8	13.9	41	22.9	11.9	3.0	3.5	0.27
FFQ Year 4	23	17.2	8.4	28	28.3	16.6	11.2	3.8	<.01
FFQ Year 5	19	18.3	11.6	16	22.0	17.0	3.7	4.8	0.50
FFQ Year 6	31	12.4	6.3	37	25.5	14.8	13.2	2.8	<.01
FFQ Year 7	18	16.4	7.3	15	26.2	15.9	9.8	4.2	0.01
FFQ Year 8	5	19.2	7.4	11	20.1	10.8	0.9	5.4	0.93
FFQ Year 9	1	33.7	N/A	2	25.3	6.4	8.4	N/A	N/A
4DFR Baseline	24	19.1	6.9	44	21.4	12.3	2.4	2.7	0.87
4DFR Year 1	18	9.0	4.2	32	21.0	10.9	12.0	2.7	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	88	15.2	9.5	114	15.3	7.6	0.1	1.2	0.48
FFQ Year 1	73	9.4	6.3	96	12.7	8.5	3.3	1.2	<.01
FFQ Year 2	28	8.9	6.6	32	14.0	8.8	5.1	2.0	<.01
FFQ Year 3	18	10.2	5.8	41	14.0	7.9	3.8	2.1	0.10
FFQ Year 4	23	9.3	4.7	28	15.6	8.9	6.3	2.1	<.01
FFQ Year 5	19	9.7	3.9	16	11.8	8.2	2.0	2.1	0.64
FFQ Year 6	31	7.6	4.3	37	15.4	10.8	7.9	2.1	<.01
FFQ Year 7	18	8.7	4.0	15	14.8	7.7	6.0	2.1	<.01
FFQ Year 9	5	11.6	2.2	11	14.2	7.2	2.6	3.4	0.60
FFQ Year 9	1	12.2	N/A	2	14.1	3.8	2.0	N/A	N/A
4DFR Baseline	24	11.5	4.6	44	12.2	6.2	0.7	1.5	0.92
4DFR Year 1	18	6.9	3.8	32	13.6	9.6	6.7	2.4	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	88	3.5	1.9	114	3.0	1.6	0.4	0.2	0.23
FFQ Year 1	73	5.1	2.9	96	3.5	2.1	1.6	0.4	<.01
FFQ Year 2	28	5.2	3.3	32	3.3	1.6	1.9	0.7	0.05
FFQ Year 3	18	4.9	2.0	41	3.8	2.3	1.0	0.6	0.03
FFQ Year 4	23	5.1	3.1	28	4.0	2.1	1.1	0.7	0.25
FFQ Year 5	19	5.6	2.4	16	2.7	1.4	2.8	0.7	<.01
FFQ Year 6	31	4.4	2.8	37	3.3	2.0	1.1	0.6	0.10
FFQ Year 7	18	5.8	3.4	15	4.0	2.5	1.8	1.1	0.11
FFQ Year 8	5	3.6	1.8	11	3.5	2.1	0.1	1.1	0.78
FFQ Year 9	1	2.8	N/A	2	3.3	2.2	0.5	N/A	N/A
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	88	4.5	2.5	114	4.7	2.7	0.2	0.4	0.49
FFQ Year 1	73	5.5	3.4	96	4.2	2.3	1.3	0.4	0.02
FFQ Year 2	28	5.5	3.0	32	4.2	2.9	1.3	0.8	0.15
FFQ Year 3	18	4.2	2.6	41	4.2	2.5	0.0	0.7	0.76
FFQ Year 4	23	4.2	2.2	28	4.5	2.8	0.3	0.7	0.72
FFQ Year 5	19	4.6	2.4	16	3.8	2.2	0.8	0.8	0.26
FFQ Year 6	31	2.9	2.0	37	4.2	2.9	1.3	0.6	0.07
FFQ Year 7	18	4.5	2.7	15	4.0	1.9	0.5	0.8	0.76
FFQ Year 8	5	3.6	1.6	11	2.8	1.5	0.8	0.8	0.37
FFQ Year 9	1	6.6	N/A	2	5.8	3.4	0.9	N/A	N/A

(continues)

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

Table 3.3 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO Baseline	431	37.7	4.4	674	38.4	4.7	0.7	0.3	0.02
FFQ Year 1[3]	409	25.8	7.3	629	36.1	6.6	10.3	0.4	<.01
FFQ Year 2[4]	147	27.2	7.4	213	36.1	6.9	8.9	0.8	<.01
FFQ Year 3[5]	107	28.1	7.5	152	36.3	6.4	8.2	0.9	<.01
FFQ Year 4[6]	106	29.6	8.3	189	37.4	6.6	7.8	0.9	<.01
FFQ Year 5[7]	136	29.0	8.2	221	36.9	7.1	7.9	0.8	<.01
FFQ Year 6[8]	120	29.1	8.0	222	37.9	6.4	8.7	0.8	<.01
FFQ Year 7[9]	41	29.1	9.0	81	36.9	7.6	7.9	1.6	<.01
FFQ Year 8[10]	8	32.9	5.6	20	37.4	6.4	4.6	2.6	0.08
FFQ Year 9[11]	3	27.0	9.2	5	32.9	6.1	6.0	5.3	0.39
4DFR Baseline	70	30.2	5.4	104	31.4	6.8	1.2	1.0	0.18
4DFR Year 1	68	21.5	7.6	88	31.6	5.8	10.1	1.1	<.01
Total Energy (kcal)									
FFO Baseline	431	1699.9	722.7	674	1674.9	711.3	25.0	44.1	0.50
FFQ Year 1	409	1501.7	587.0	629	1523.7	635.3	22.0	39.2	0.94
FFQ Year 2	147	1512.0	636.7	213	1500.3	777.2	11.7	77.6	0.24
FFQ Year 3	107	1496.2	630.5	152	1414.8	582.8	81.5	76.1	0.28
FFQ Year 4	106	1475.7	616.6	189	1507.8	612.0	32.1	74.5	0.97
FFQ Year 5	136	1513.9	636.6	221	1499.4	809.9	14.6	81.6	0.24
FFQ Year 6	120	1400.3	505.4	222	1545.0	752.2	144.6	76.6	0.14
FFQ Year 7	41	1415.6	585.8	81	1383.9	534.6	31.7	105.8	0.74
FFQ Year 8	8	1299.4	755.4	20	1339.9	530.9	40.5	250.9	0.76
FFQ Year 9	3	1552.4	259.8	5	956.2	279.8	596.2	199.6	0.04
4DFR Baseline	70	1683.3	400.1	104	1732.3	387.9	48.9	60.7	0.38
4DFR Year 1	68	1524.9	374.1	88	1619.6	397.2	94.7	62.5	0.12
Total Fat (g)									
FFO Baseline	431	71.9	34.1	674	72.2	34.8	0.4	2.1	0.99
FFQ Year 1	409	43.5	23.5	629	62.3	31.4	18.9	1.8	<.01
FFQ Year 2	147	46.1	24.6	213	61.1	35.6	15.0	3.4	<.01
FFQ Year 3	107	47.3	28.0	152	57.7	28.0	10.3	3.5	<.01
FFQ Year 4	106	49.5	28.8	189	63.3	29.6	13.8	3.6	<.01
FFQ Year 5	136	50.4	30.3	221	62.7	39.0	12.2	3.9	<.01
FFQ Year 6	120	45.1	21.2	222	65.4	34.6	20.3	3.5	<.01
FFQ Year 7	41	47.0	28.9	81	57.6	27.5	10.5	5.4	0.02
FFQ Year 8	8	48.1	31.7	20	57.1	28.4	8.9	12.3	0.41
FFQ Year 9	3	48.3	22.2	5	34.8	11.6	13.5	11.6	0.49
4DFR Baseline	70	57.1	19.1	104	61.8	23.4	4.7	3.4	0.24
4DFR Year 1	68	36.6	17.4	88	57.6	19.9	21.0	3.0	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 99 (24%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 1.
[4] 24 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 2.
[5] 18 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 12 (11%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 18 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 12 (10%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 7 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 8.
[11] 1 (33%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	431	22.8	12.0	674	22.9	12.0	0.1	0.7	0.94
FFQ Year 1	409	13.5	8.0	629	19.5	10.8	6.0	0.6	<.01
FFQ Year 2	147	14.3	8.5	213	19.2	11.9	5.0	1.1	<.01
FFQ Year 3	107	14.8	10.1	152	18.1	9.8	3.3	1.3	<.01
FFQ Year 4	106	15.4	10.1	189	19.9	9.6	4.5	1.2	<.01
FFQ Year 5	136	16.0	10.2	221	19.7	13.4	3.7	1.3	<.01
FFQ Year 6	120	13.9	7.6	222	20.7	12.0	6.8	1.2	<.01
FFQ Year 7	41	15.5	10.9	81	18.3	10.1	2.8	2.0	0.06
FFQ Year 8	8	15.1	9.3	20	18.3	10.0	3.2	4.1	0.42
FFQ Year 9	3	16.2	8.0	5	10.6	3.7	5.6	4.0	0.43
4DFR Baseline	70	17.2	7.1	104	18.8	8.4	1.7	1.2	0.26
4DFR Year 1	68	10.5	5.5	88	17.7	7.2	7.2	1.0	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	431	15.6	7.4	674	15.7	7.8	0.0	0.5	0.54
FFQ Year 1	409	9.1	5.0	629	13.6	7.2	4.5	0.4	<.01
FFQ Year 2	147	9.8	5.5	213	13.0	8.0	3.2	0.8	<.01
FFQ Year 3	107	10.1	5.7	152	12.1	6.1	2.0	0.7	<.01
FFQ Year 4	106	10.8	6.2	189	13.4	6.5	2.6	0.8	<.01
FFQ Year 5	136	10.6	7.4	221	13.5	8.1	2.8	0.9	<.01
FFQ Year 6	120	9.8	4.9	222	13.9	7.1	4.1	0.7	<.01
FFQ Year 7	41	9.6	5.9	81	12.0	6.1	2.4	1.2	0.02
FFQ Year 8	8	9.4	6.4	20	11.7	5.9	2.3	2.5	0.32
FFQ Year 9	3	10.1	4.7	5	7.8	2.8	2.3	2.6	0.56
4DFR Baseline	70	13.1	5.3	104	14.6	6.5	1.5	0.9	0.12
4DFR Year 1	68	8.8	4.4	88	12.9	5.9	4.1	0.9	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	429	3.4	1.7	674	3.3	1.9	0.1	0.1	0.26
FFQ Year 1	407	4.7	2.4	629	3.5	1.9	1.2	0.1	<.01
FFQ Year 2	146	4.8	2.7	213	3.4	1.9	1.4	0.2	<.01
FFQ Year 3	107	5.0	2.5	152	3.4	2.1	1.5	0.3	<.01
FFQ Year 4	105	4.7	2.4	189	3.2	1.9	1.5	0.3	<.01
FFQ Year 5	136	4.8	2.3	221	3.6	2.0	1.3	0.2	<.01
FFQ Year 6	119	4.7	2.4	222	3.5	2.0	1.3	0.2	<.01
FFQ Year 7	41	5.0	2.2	81	3.3	1.8	1.7	0.4	<.01
FFQ Year 8	8	4.3	2.7	20	2.9	1.2	1.4	0.7	0.43
FFQ Year 9	3	4.3	1.1	5	3.0	1.4	1.3	1.0	0.15
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	4.8	2.5	674	4.6	2.2	0.2	0.1	0.47
FFQ Year 1	407	5.6	2.6	629	4.4	2.1	1.3	0.1	<.01
FFQ Year 2	146	5.2	2.5	213	4.1	2.3	1.1	0.3	<.01
FFQ Year 3	107	5.0	2.4	152	4.1	2.1	0.9	0.3	<.01
FFQ Year 4	105	4.9	2.3	189	4.3	2.1	0.7	0.3	<.01
FFQ Year 5	136	4.9	2.2	221	4.2	2.8	0.7	0.3	<.01
FFQ Year 6	118	4.7	2.2	222	4.3	2.5	0.4	0.3	0.03
FFQ Year 7	41	4.3	2.2	81	3.7	1.7	0.6	0.4	0.23
FFQ Year 8	8	3.8	2.1	20	4.0	1.9	0.2	0.8	0.72
FFQ Year 9	3	5.9	1.8	5	3.1	1.5	2.8	1.2	0.06

(continues)

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

Table 3.3 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	2135	39.7	5.3	3127	39.9	5.2	0.1	0.1	0.41
FFQ Year 1[3]	1860	28.0	8.4	2629	36.9	7.4	8.8	0.2	<.01
FFQ Year 2[4]	613	29.4	8.0	829	36.4	7.3	7.0	0.4	<.01
FFQ Year 3[5]	350	29.4	7.9	514	38.2	7.2	8.8	0.5	<.01
FFQ Year 4[6]	485	30.7	8.3	775	37.5	7.4	6.8	0.4	<.01
FFQ Year 5[7]	579	31.3	8.6	856	37.4	7.4	6.1	0.4	<.01
FFQ Year 6[8]	670	31.1	8.1	992	37.5	7.6	6.4	0.4	<.01
FFQ Year 7[9]	240	31.7	7.7	369	37.4	6.9	5.6	0.6	<.01
FFQ Year 8[10]	117	32.3	8.2	156	37.1	7.3	4.8	0.9	<.01
FFQ Year 9[11]	22	31.3	9.1	43	36.3	9.8	5.1	2.5	0.04
4DFR Baseline	243	34.0	6.7	371	34.2	6.9	0.2	0.6	0.76
4DFR Year 1	219	23.5	7.9	307	34.2	7.0	10.8	0.7	<.01
Total Energy (kcal)									
FFO Baseline	2135	1744.4	826.9	3127	1739.4	834.9	5.0	23.3	0.72
FFQ Year 1	1860	1382.7	633.4	2629	1492.4	774.6	109.7	21.8	<.01
FFQ Year 2	613	1393.4	717.5	829	1449.0	724.7	55.6	38.4	0.36
FFQ Year 3	350	1386.7	631.4	514	1537.1	791.3	150.3	50.6	0.01
FFQ Year 4	485	1342.7	622.4	775	1436.1	743.8	93.4	40.5	0.09
FFQ Year 5	579	1349.4	637.0	856	1377.6	690.5	28.1	36.0	0.50
FFQ Year 6	670	1304.4	566.9	992	1386.3	737.0	81.9	33.7	0.24
FFQ Year 7	240	1309.6	593.3	369	1373.5	704.6	63.9	55.0	0.48
FFQ Year 8	117	1280.8	651.6	156	1378.4	797.9	97.6	90.4	0.61
FFQ Year 9	22	1165.1	357.1	43	1243.1	515.3	78.0	122.8	0.68
4DFR Baseline	243	1704.3	526.0	371	1651.0	478.3	53.4	41.1	0.32
4DFR Year 1	219	1345.6	341.6	307	1584.5	481.8	239.0	38.0	<.01
Total Fat (g)									
FFO Baseline	2135	77.7	40.7	3127	77.8	41.3	0.1	1.2	0.92
FFQ Year 1	1860	43.6	26.8	2629	62.3	37.2	18.7	1.0	<.01
FFQ Year 2	613	46.4	32.5	829	60.1	36.0	13.6	1.8	<.01
FFQ Year 3	350	46.1	27.0	514	66.3	38.6	20.2	2.4	<.01
FFQ Year 4	485	46.2	26.7	775	60.9	35.7	14.7	1.9	<.01
FFQ Year 5	579	47.4	27.6	856	58.5	34.6	11.1	1.7	<.01
FFQ Year 6	670	45.8	25.9	992	58.9	36.5	13.1	1.6	<.01
FFQ Year 7	240	46.3	25.6	369	58.3	35.0	12.0	2.6	<.01
FFQ Year 8	117	46.9	30.7	156	57.8	38.8	10.8	4.4	0.01
FFQ Year 9	22	41.3	18.8	43	50.9	28.1	9.6	6.6	0.17
4DFR Baseline	243	65.1	25.7	371	63.9	26.3	1.2	2.2	0.54
4DFR Year 1	219	34.9	14.7	307	61.5	25.7	26.6	1.9	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 323 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 80 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 46 (13%) Black/African American Intervention women had <=20% energy from fat at year 3.
[6] 54 (11%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 46 (8%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 59 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 18 (8%) Black/African American Intervention women had <=20% energy from fat at year 7.
[10] 6 (5%) Black/African American Intervention women had <=20% energy from fat at year 8.
[11] 3 (14%) Black/African American Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	2135	25.8	14.3	3127	25.9	14.7	0.1	0.4	0.91
FFQ Year 1	1860	14.3	9.2	2629	20.5	12.8	6.2	0.3	<.01
FFQ Year 2	613	15.3	11.8	829	19.8	12.3	4.5	0.6	<.01
FFQ Year 3	350	15.0	9.5	514	21.8	13.4	6.8	0.8	<.01
FFQ Year 4	485	14.9	9.3	775	20.0	12.4	5.2	0.7	<.01
FFQ Year 5	579	15.3	9.4	856	19.2	12.2	3.8	0.6	<.01
FFQ Year 6	670	14.7	8.7	992	19.2	12.7	4.5	0.6	<.01
FFQ Year 7	240	15.1	9.0	369	19.2	12.0	4.1	0.9	<.01
FFQ Year 8	117	15.1	10.5	156	19.1	14.4	4.0	1.6	0.02
FFQ Year 9	22	13.1	6.2	43	16.1	8.3	3.0	2.0	0.19
4DFR Baseline	243	20.3	9.3	371	20.2	9.1	0.1	0.8	0.96
4DFR Year 1	219	10.6	5.2	307	18.7	8.2	8.1	0.6	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	2135	16.0	8.9	3127	16.0	8.9	0.0	0.3	0.98
FFQ Year 1	1860	8.7	5.6	2629	12.7	8.0	4.0	0.2	<.01
FFQ Year 2	613	9.2	6.2	829	12.1	7.5	2.9	0.4	<.01
FFQ Year 3	350	9.3	5.6	514	13.4	8.0	4.1	0.5	<.01
FFQ Year 4	485	9.5	5.7	775	12.4	7.6	2.9	0.4	<.01
FFQ Year 5	579	9.6	5.7	856	12.1	7.7	2.5	0.4	<.01
FFQ Year 6	670	9.5	5.7	992	12.1	7.6	2.7	0.3	<.01
FFQ Year 7	240	9.5	5.5	369	11.9	7.6	2.4	0.6	<.01
FFQ Year 8	117	9.6	6.4	156	11.8	8.2	2.2	0.9	0.01
FFQ Year 9	22	8.3	4.1	43	10.8	6.7	2.6	1.6	0.09
4DFR Baseline	243	14.5	6.7	371	13.8	6.7	0.7	0.6	0.15
4DFR Year 1	219	7.6	3.2	307	13.7	6.9	6.1	0.5	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	2132	3.3	1.9	3123	3.2	1.9	0.0	0.1	0.73
FFQ Year 1	1854	4.5	2.6	2623	3.4	2.1	1.1	0.1	<.01
FFQ Year 2	612	4.5	2.6	824	3.5	2.2	1.0	0.1	<.01
FFQ Year 3	350	4.7	2.7	514	3.7	2.3	1.0	0.2	<.01
FFQ Year 4	485	4.8	2.7	775	3.4	2.1	1.3	0.1	<.01
FFQ Year 5	576	4.6	2.7	855	3.5	2.1	1.1	0.1	<.01
FFQ Year 6	670	4.6	2.6	990	3.5	2.2	1.1	0.1	<.01
FFQ Year 7	239	4.4	2.7	368	3.5	2.1	1.0	0.2	<.01
FFQ Year 8	117	4.5	2.5	154	3.2	2.0	1.3	0.3	<.01
FFQ Year 9	22	4.3	2.6	43	4.1	2.4	0.2	0.6	0.86
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	2132	4.5	2.7	3122	4.4	2.8	0.1	0.1	0.32
FFQ Year 1	1853	4.4	2.8	2621	3.8	2.5	0.6	0.1	<.01
FFQ Year 2	612	4.2	2.6	823	3.7	2.4	0.5	0.1	<.01
FFQ Year 3	350	4.2	2.7	514	3.8	2.5	0.4	0.2	0.01
FFQ Year 4	485	4.0	2.5	773	3.6	2.4	0.4	0.1	<.01
FFQ Year 5	575	3.8	2.5	854	3.4	2.2	0.4	0.1	<.01
FFQ Year 6	670	3.6	2.1	986	3.4	2.1	0.3	0.1	<.01
FFQ Year 7	239	3.6	2.3	368	3.5	2.3	0.2	0.2	0.22
FFQ Year 8	117	3.6	2.6	154	3.5	2.4	0.1	0.3	0.72
FFQ Year 9	22	3.0	1.8	42	3.0	1.7	0.0	0.4	0.83

(continues)

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

Table 3.3 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	751	39.3	5.1	1094	39.0	5.1	0.4	0.2	0.13
FFQ Year 1[3]	617	27.9	8.0	914	36.1	7.4	8.2	0.4	<.01
FFQ Year 2[4]	226	27.7	8.3	304	36.9	7.5	9.2	0.7	<.01
FFQ Year 3[5]	131	29.9	8.9	195	37.2	7.3	7.3	0.9	<.01
FFQ Year 4[6]	163	30.9	8.3	296	36.9	7.2	6.0	0.7	<.01
FFQ Year 5[7]	188	29.9	8.5	302	36.3	7.4	6.3	0.7	<.01
FFQ Year 6[8]	185	30.7	8.0	339	37.1	6.9	6.4	0.7	<.01
FFQ Year 7[9]	86	30.9	9.4	122	37.5	7.5	6.5	1.2	<.01
FFQ Year 8[10]	25	27.8	7.0	49	37.3	7.3	9.6	1.8	<.01
FFQ Year 9[11]	16	31.6	7.3	17	36.9	5.8	5.3	2.3	0.03
4DFR Baseline	96	32.4	5.7	134	32.4	6.5	0.1	0.8	0.95
4DFR Year 1	82	23.1	7.4	110	32.0	7.3	8.9	1.1	<.01
Total Energy (kcal)									
FFQ Baseline	751	1846.5	836.1	1094	1859.3	870.7	12.8	40.6	0.86
FFQ Year 1	617	1418.6	665.0	914	1569.9	862.5	151.2	41.1	<.01
FFQ Year 2	226	1411.2	614.8	304	1625.8	772.1	214.6	62.3	<.01
FFQ Year 3	131	1534.3	638.4	195	1576.7	710.7	42.4	77.1	0.80
FFQ Year 4	163	1385.3	651.8	296	1528.0	756.5	142.7	70.3	0.04
FFQ Year 5	188	1377.7	655.7	302	1584.0	917.3	206.4	76.8	0.03
FFQ Year 6	185	1327.4	653.2	339	1513.7	756.7	186.2	66.0	<.01
FFQ Year 7	86	1294.5	561.8	122	1503.6	809.2	209.2	101.0	0.13
FFQ Year 8	25	1321.9	557.1	49	1411.8	613.4	89.9	146.3	0.60
FFQ Year 9	16	1208.4	682.7	17	1344.0	471.6	135.6	203.2	0.25
4DFR Baseline	96	1643.3	446.4	134	1748.5	460.0	105.2	60.8	0.06
4DFR Year 1	82	1399.8	412.1	110	1627.1	448.8	227.3	63.3	<.01
Total Fat (g)									
FFQ Baseline	751	81.6	41.0	1094	80.8	40.5	0.8	1.9	0.56
FFQ Year 1	617	44.5	27.2	914	64.3	41.2	19.8	1.9	<.01
FFQ Year 2	226	43.7	24.3	304	68.3	38.6	24.5	2.9	<.01
FFQ Year 3	131	52.3	31.8	195	66.1	34.8	13.8	3.8	<.01
FFQ Year 4	163	48.1	27.8	296	63.5	35.4	15.5	3.2	<.01
FFQ Year 5	188	46.9	30.0	302	66.1	44.7	19.1	3.7	<.01
FFQ Year 6	185	45.6	25.9	339	63.4	36.3	17.8	3.0	<.01
FFQ Year 7	86	45.1	27.4	122	62.5	36.8	17.4	4.7	<.01
FFQ Year 8	25	39.5	15.2	49	58.3	25.9	18.8	5.6	<.01
FFQ Year 9	16	42.1	25.4	17	54.3	18.8	12.1	7.8	0.07
4DFR Baseline	96	59.6	20.1	134	64.1	25.6	4.5	3.1	0.22
4DFR Year 1	82	36.4	17.7	110	58.9	24.5	22.5	3.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 106 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 1.
[4] 45 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.
[5] 14 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3.
[6] 16 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 24 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 19 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 11 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.
[10] 3 (12%) Hispanic/Latino Intervention women had <=20% energy from fat at year 8.
[11] 1 (6%) Hispanic/Latino Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	751	27.8	14.9	1094	27.7	15.1	0.1	0.7	0.65
FFQ Year 1	617	15.0	9.8	914	21.7	14.3	6.7	0.7	<.01
FFQ Year 2	226	14.4	8.4	304	23.1	14.2	8.7	1.1	<.01
FFQ Year 3	131	17.4	12.0	195	22.1	12.5	4.8	1.4	<.01
FFQ Year 4	163	15.7	9.9	296	21.1	12.3	5.4	1.1	<.01
FFQ Year 5	188	15.5	10.4	302	22.5	15.9	6.9	1.3	<.01
FFQ Year 6	185	14.8	9.2	339	21.5	13.0	6.7	1.1	<.01
FFQ Year 7	86	15.0	10.6	122	20.8	13.3	5.8	1.7	<.01
FFQ Year 8	25	13.3	6.0	49	19.9	9.7	6.6	2.1	<.01
FFQ Year 9	16	14.5	9.3	17	18.3	7.3	3.8	2.9	0.08
4DFR Baseline	96	19.8	7.6	134	20.9	10.0	1.1	1.2	0.57
4DFR Year 1	82	11.5	6.7	110	19.4	8.9	7.9	1.2	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	751	15.9	8.4	1094	15.7	8.2	0.2	0.4	0.48
FFQ Year 1	617	8.6	5.5	914	12.7	8.6	4.2	0.4	<.01
FFQ Year 2	226	8.7	5.3	304	13.4	8.2	4.7	0.6	<.01
FFQ Year 3	131	10.4	6.5	195	12.9	7.4	2.5	0.8	<.01
FFQ Year 4	163	9.4	5.7	296	12.4	7.1	3.1	0.6	<.01
FFQ Year 5	188	9.2	6.5	302	12.7	9.3	3.5	0.8	<.01
FFQ Year 6	185	9.1	5.5	339	12.2	7.3	3.1	0.6	<.01
FFQ Year 7	86	8.7	5.0	122	12.3	7.9	3.6	1.0	<.01
FFQ Year 8	25	7.7	3.7	49	10.9	5.7	3.1	1.3	0.02
FFQ Year 9	16	7.5	4.5	17	10.9	4.5	3.3	1.6	0.04
4DFR Baseline	96	11.5	4.6	134	13.4	6.2	1.9	0.7	0.02
4DFR Year 1	82	7.8	4.1	110	12.0	6.3	4.2	0.8	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	748	3.0	1.9	1094	2.9	1.8	0.1	0.1	0.27
FFQ Year 1	614	4.2	2.3	914	3.1	1.9	1.0	0.1	<.01
FFQ Year 2	224	4.4	2.4	304	3.2	1.7	1.2	0.2	<.01
FFQ Year 3	130	4.6	2.9	195	3.4	2.0	1.3	0.3	<.01
FFQ Year 4	163	4.7	2.7	296	3.1	2.1	1.5	0.2	<.01
FFQ Year 5	187	4.4	2.5	302	3.3	2.1	1.1	0.2	<.01
FFQ Year 6	183	4.4	2.5	339	3.1	2.0	1.3	0.2	<.01
FFQ Year 7	86	4.1	2.6	122	3.3	2.2	0.8	0.3	<.01
FFQ Year 8	25	4.8	2.5	49	3.0	1.4	1.8	0.5	<.01
FFQ Year 9	16	4.1	2.7	17	3.2	2.4	0.8	0.9	0.40
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	748	5.5	3.3	1094	5.7	3.5	0.2	0.2	0.54
FFQ Year 1	614	5.1	3.3	914	4.8	3.4	0.3	0.2	0.06
FFQ Year 2	224	5.0	3.5	304	4.9	3.1	0.0	0.3	0.48
FFQ Year 3	130	5.1	3.0	195	4.7	2.9	0.4	0.3	0.32
FFQ Year 4	163	4.3	2.9	296	4.6	2.9	0.3	0.3	0.18
FFQ Year 5	187	4.3	3.0	302	4.8	3.4	0.5	0.3	0.12
FFQ Year 6	183	4.3	3.2	339	4.4	3.1	0.1	0.3	0.79
FFQ Year 7	86	4.0	2.4	122	4.4	3.3	0.4	0.4	0.48
FFQ Year 8	25	4.6	2.9	49	4.3	3.0	0.2	0.7	0.51
FFQ Year 9	16	3.6	2.7	17	4.2	1.9	0.7	0.8	0.16

(continues)

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

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	15871	38.7	5.0	23891	38.7	4.9	0.0	0.1	0.93
FFQ Year 1[3]	14900	24.6	7.3	22154	36.0	6.8	11.3	0.1	<.01
FFQ Year 2[4]	4834	25.8	7.5	7168	36.2	7.0	10.4	0.1	<.01
FFQ Year 3[5]	2589	27.3	7.8	3928	37.2	7.1	9.9	0.2	<.01
FFQ Year 4[6]	4206	28.2	8.0	6480	37.6	7.1	9.5	0.1	<.01
FFQ Year 5[7]	4792	28.8	8.1	7465	37.9	7.2	9.1	0.1	<.01
FFQ Year 6[8]	4668	29.3	8.2	7129	37.8	7.1	8.5	0.1	<.01
FFQ Year 7[9]	2549	29.9	8.3	3909	38.0	7.3	8.1	0.2	<.01
FFQ Year 8[10]	1060	30.2	8.0	1737	38.3	7.2	8.0	0.3	<.01
FFQ Year 9[11]	412	30.3	8.4	630	39.0	7.6	8.8	0.5	<.01
4DFR Baseline	442	32.6	6.5	669	32.6	6.7	0.1	0.4	0.88
4DFR Year 1	405	20.4	6.7	610	32.5	6.6	12.1	0.4	<.01
Total Energy (kcal)									
FFQ Baseline	15871	1795.1	687.8	23891	1797.1	677.4	2.0	7.0	0.62
FFQ Year 1	14900	1485.5	509.0	22154	1599.0	611.4	113.5	6.1	<.01
FFQ Year 2	4834	1492.7	497.0	7168	1590.7	597.6	98.0	10.4	<.01
FFQ Year 3	2589	1484.4	511.7	3928	1583.1	618.6	98.8	14.6	<.01
FFQ Year 4	4206	1457.4	515.8	6480	1580.1	611.2	122.7	11.4	<.01
FFQ Year 5	4792	1462.0	514.8	7465	1574.7	607.6	112.7	10.6	<.01
FFQ Year 6	4668	1444.6	526.5	7129	1555.4	601.9	110.9	10.8	<.01
FFQ Year 7	2549	1440.6	533.7	3909	1564.8	617.4	124.2	14.9	<.01
FFQ Year 8	1060	1433.6	541.4	1737	1561.8	615.6	128.2	22.9	<.01
FFQ Year 9	412	1437.4	564.8	630	1550.3	572.1	112.9	36.1	<.01
4DFR Baseline	442	1744.2	422.9	669	1740.7	447.9	3.6	26.9	0.68
4DFR Year 1	405	1461.2	331.5	610	1652.6	428.1	191.4	25.2	<.01
Total Fat (g)									
FFQ Baseline	15871	77.8	34.1	23891	77.9	33.4	0.0	0.3	0.65
FFQ Year 1	14900	40.9	20.6	22154	64.8	30.5	23.9	0.3	<.01
FFQ Year 2	4834	42.9	20.2	7168	64.9	30.1	21.9	0.5	<.01
FFQ Year 3	2589	45.3	22.5	3928	66.3	31.5	21.0	0.7	<.01
FFQ Year 4	4206	46.0	23.2	6480	67.0	31.5	21.0	0.6	<.01
FFQ Year 5	4792	47.2	23.5	7465	67.3	31.6	20.1	0.5	<.01
FFQ Year 6	4668	47.3	23.4	7129	66.2	31.0	18.9	0.5	<.01
FFQ Year 7	2549	48.4	25.4	3909	67.1	32.3	18.7	0.8	<.01
FFQ Year 8	1060	48.6	24.7	1737	67.2	31.6	18.6	1.1	<.01
FFQ Year 9	412	49.3	29.0	630	68.0	30.6	18.7	1.9	<.01
4DFR Baseline	442	64.1	23.9	669	64.0	23.5	0.2	1.5	0.81
4DFR Year 1	405	33.0	13.0	610	60.5	22.3	27.5	1.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4374 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1098 (23%) White Intervention women had <=20% energy from fat at year 2.
[5] 482 (19%) White Intervention women had <=20% energy from fat at year 3.
[6] 671 (16%) White Intervention women had <=20% energy from fat at year 4.
[7] 681 (14%) White Intervention women had <=20% energy from fat at year 5.
[8] 531 (11%) White Intervention women had <=20% energy from fat at year 6.
[9] 264 (10%) White Intervention women had <=20% energy from fat at year 7.
[10] 104 (10%) White Intervention women had <=20% energy from fat at year 8.
[11] 38 (9%) White Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	15871	27.7	13.2	23891	27.6	12.8	0.1	0.1	0.95
FFQ Year 1	14900	14.1	7.8	22154	22.9	11.6	8.8	0.1	<.01
FFQ Year 2	4834	14.7	7.5	7168	22.9	11.4	8.1	0.2	<.01
FFQ Year 3	2589	15.5	8.6	3928	23.3	12.0	7.9	0.3	<.01
FFQ Year 4	4206	15.8	8.8	6480	23.7	12.1	7.9	0.2	<.01
FFQ Year 5	4792	16.3	9.0	7465	23.8	12.1	7.5	0.2	<.01
FFQ Year 6	4668	16.2	8.7	7129	23.4	12.0	7.2	0.2	<.01
FFQ Year 7	2549	16.7	9.5	3909	23.6	12.5	6.9	0.3	<.01
FFQ Year 8	1060	16.8	9.3	1737	23.9	12.5	7.1	0.4	<.01
FFQ Year 9	412	16.9	10.6	630	24.0	11.4	7.0	0.7	<.01
4DFR Baseline	442	21.7	9.2	669	21.6	9.1	0.1	0.6	0.64
4DFR Year 1	405	10.4	4.7	610	20.2	8.3	9.8	0.5	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	15871	15.2	7.4	23891	15.2	7.3	0.0	0.1	0.48
FFQ Year 1	14900	7.7	4.1	22154	12.4	6.4	4.7	0.1	<.01
FFQ Year 2	4834	8.1	4.1	7168	12.3	6.2	4.2	0.1	<.01
FFQ Year 3	2589	8.6	4.4	3928	12.7	6.5	4.1	0.1	<.01
FFQ Year 4	4206	8.8	4.7	6480	12.8	6.5	4.0	0.1	<.01
FFQ Year 5	4792	9.0	4.7	7465	12.9	6.6	3.8	0.1	<.01
FFQ Year 6	4668	9.1	4.9	7129	12.7	6.3	3.5	0.1	<.01
FFQ Year 7	2549	9.2	5.2	3909	12.9	6.6	3.7	0.2	<.01
FFQ Year 8	1060	9.3	4.8	1737	12.8	6.3	3.5	0.2	<.01
FFQ Year 9	412	9.5	5.9	630	13.2	6.7	3.8	0.4	<.01
4DFR Baseline	442	12.9	5.5	669	13.2	5.7	0.3	0.3	0.51
4DFR Year 1	405	7.1	3.1	610	12.4	5.6	5.3	0.3	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	15809	3.7	1.8	23818	3.7	1.8	0.0	0.0	0.17
FFQ Year 1	14831	5.2	2.3	22079	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	4815	5.2	2.3	7141	4.0	2.0	1.2	0.0	<.01
FFQ Year 3	2584	5.3	2.4	3914	4.0	2.0	1.3	0.1	<.01
FFQ Year 4	4198	5.2	2.4	6466	3.9	2.0	1.3	0.0	<.01
FFQ Year 5	4773	5.2	2.4	7440	3.9	2.0	1.2	0.0	<.01
FFQ Year 6	4648	5.1	2.4	7106	3.9	2.0	1.2	0.0	<.01
FFQ Year 7	2531	5.0	2.4	3896	3.8	1.9	1.1	0.1	<.01
FFQ Year 8	1052	4.9	2.4	1729	3.8	2.0	1.1	0.1	<.01
FFQ Year 9	408	4.9	2.4	626	3.8	2.0	1.1	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15807	4.7	2.4	23817	4.8	2.4	0.0	0.0	0.21
FFQ Year 1	14828	5.1	2.6	22071	4.2	2.2	0.9	0.0	<.01
FFQ Year 2	4814	5.0	2.4	7136	4.1	2.1	0.8	0.0	<.01
FFQ Year 3	2583	4.6	2.5	3909	3.9	2.1	0.7	0.1	<.01
FFQ Year 4	4194	4.4	2.3	6456	3.9	2.1	0.6	0.0	<.01
FFQ Year 5	4770	4.3	2.2	7430	3.8	2.0	0.5	0.0	<.01
FFQ Year 6	4646	4.2	2.4	7097	3.7	2.0	0.5	0.0	<.01
FFQ Year 7	2529	4.1	2.2	3892	3.7	2.0	0.3	0.1	<.01
FFQ Year 8	1052	4.0	2.2	1726	3.7	2.0	0.3	0.1	<.01
FFQ Year 9	407	4.0	2.2	624	3.6	1.9	0.4	0.1	0.04

(continues)

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

Table 3.3 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO Baseline	265	39.1	5.3	394	39.2	5.1	0.1	0.4	0.79
FFQ Year 1[3]	240	27.7	8.0	354	35.9	7:7	8.3	0.7	<.01
FFQ Year 2[4]	79	27.2	7.9	123	37.3	6.9	10.2	1.1	<.01
FFQ Year 3[5]	46	29.1	7.4	59	37.8	8.2	8.6	1.5	<.01
FFQ Year 4[6]	72	29.2	8.2	112	37.1	7.2	7.9	1.1	<.01
FFQ Year 5[7]	78	29.2	8.1	107	38.2	7.7	9.1	1.2	<.01
FFQ Year 6[8]	66	31.0	8.5	115	38.6	6.7	7.6	1.1	<.01
FFQ Year 7[9]	30	32.9	8.8	32	37.9	8.3	5.1	2.2	0.02
FFQ Year 8[10]	8	31.3	7.5	20	38.1	8.4	6.8	3.4	0.05
FFQ Year 9[11]	3	30.4	4.0	8	33.7	9.1	3.3	5.6	0.43
4DFR Baseline	17	32.2	5.5	29	32.8	5.6	0.6	1.7	0.71
4DFR Year 1	13	22.8	8.9	24	33.6	6.5	10.8	2.6	<.01
Total Energy (kcal)									
FFO Baseline	265	1796.2	774.8	394	1726.3	769.8	70.0	61.3	0.23
FFQ Year 1	240	1505.5	628.2	354	1501.5	639.0	4.1	53.1	0.66
FFQ Year 2	79	1463.9	583.5	123	1571.6	674.2	107.8	92.3	0.33
FFQ Year 3	46	1463.7	598.3	59	1477.1	725.4	13.4	132.3	1.00
FFQ Year 4	72	1374.9	623.0	112	1495.4	657.4	120.5	97.3	0.23
FFQ Year 5	78	1459.7	553.9	107	1439.6	633.2	20.1	89.5	0.42
FFQ Year 6	66	1573.0	536.6	115	1524.3	632.3	48.7	92.5	0.31
FFQ Year 7	30	1323.1	585.6	32	1508.3	826.3	185.1	183.0	0.41
FFQ Year 8	8	1598.8	541.1	20	1281.4	454.4	317.4	200.5	0.14
FFQ Year 9	3	1109.0	326.5	8	1449.4	721.1	340.4	443.0	0.46
4DFR Baseline	17	1504.1	288.3	29	1693.4	404.8	189.3	112.0	0.10
4DFR Year 1	13	1334.5	469.5	24	1541.7	334.5	207.2	133.0	0.13
Total Fat (g)									
FFO Baseline	265	79.0	39.4	394	75.9	38.4	3.1	3.1	0.31
FFQ Year 1	240	46.7	28.0	354	60.7	31.5	14.0	2.5	<.01
FFQ Year 2	79	44.9	29.0	123	66.7	35.1	21.8	4.7	<.01
FFQ Year 3	46	46.2	21.0	59	62.8	35.9	16.6	6.0	<.01
FFQ Year 4	72	45.7	30.4	112	63.1	33.2	17.4	4.9	<.01
FFQ Year 5	78	48.2	26.0	107	61.9	31.8	13.7	4.4	<.01
FFQ Year 6	66	54.7	26.5	115	65.9	33.2	11.2	4.8	0.01
FFQ Year 7	30	46.7	20.6	32	63.8	37.9	17.1	7.8	0.06
FFQ Year 8	8	54.9	20.8	20	56.2	26.8	1.3	10.6	0.86
FFQ Year 9	3	36.8	9.5	8	52.0	22.7	15.1	13.9	0.26
4DFR Baseline	17	54.4	16.8	29	61.8	17.4	7.4	5.2	0.18
4DFR Year 1	13	33.7	19.1	24	57.9	17.3	24.2	6.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Unknown Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Unknown Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Unknown Intervention women had <=20% energy from fat at year 3.
[6] 11 (15%) Unknown Intervention women had <=20% energy from fat at year 4.
[7] 12 (15%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 8 (12%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 2 (7%) Unknown Intervention women had <=20% energy from fat at year 7.
[10] 1 (13%) Unknown Intervention women had <=20% energy from fat at year 8.
[11] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: August 31, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	265	27.2	14.6	394	26.3	14.2	0.9	1.1	0.47
FFQ Year 1[3]	240	15.4	9.4	354	20.9	11.7	5.5	0.9	<.01
FFQ Year 2[4]	79	15.3	10.7	123	23.2	12.6	7.9	1.7	<.01
FFQ Year 3[5]	46	15.3	7.9	59	20.9	13.0	5.6	2.2	0.01
FFQ Year 4[6]	72	15.1	10.3	112	21.8	12.2	6.7	1.7	<.01
FFQ Year 5[7]	78	15.7	9.2	107	21.1	11.3	5.3	1.6	<.01
FFQ Year 6[8]	66	18.1	10.4	115	22.3	12.4	4.2	1.8	<.01
FFQ Year 7[9]	30	15.6	7.3	32	22.6	14.8	7.0	3.0	0.06
FFQ Year 8[10]	8	18.5	8.6	20	19.5	11.4	1.0	4.5	0.96
FFQ Year 9[11]	3	11.7	2.0	8	20.8	10.4	9.0	6.3	0.07
4DFR Baseline	17	17.6	6.7	29	21.0	7.2	3.4	2.1	0.10
4DFR Year 1	13	11.3	8.7	24	18.9	5.7	7.6	2.4	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	265	15.9	8.7	394	15.0	8.6	0.9	0.7	0.19
FFQ Year 1	240	9.0	6.0	354	11.9	6.8	2.8	0.5	<.01
FFQ Year 2	79	8.4	5.6	123	12.8	7.8	4.5	1.0	<.01
FFQ Year 3	46	9.0	4.1	59	13.1	7.9	4.1	1.3	<.01
FFQ Year 4	72	9.2	6.5	112	12.4	7.4	3.3	1.1	<.01
FFQ Year 5	78	9.8	5.4	107	12.3	7.1	2.4	1.0	0.02
FFQ Year 6	66	11.2	5.4	115	13.0	6.4	1.8	0.9	0.06
FFQ Year 7	30	9.1	4.5	32	12.1	7.8	2.9	1.6	0.12
FFQ Year 8	8	10.8	3.7	20	10.4	4.9	0.4	1.9	0.50
FFQ Year 9	3	7.3	3.3	8	8.6	3.5	1.3	2.3	0.63
4DFR Baseline	17	11.7	3.7	29	12.5	4.4	0.8	1.3	0.59
4DFR Year 1	13	6.6	3.1	24	11.8	4.3	5.2	1.4	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	264	3.7	2.0	393	3.4	2.0	0.2	0.2	0.04
FFQ Year 1	239	4.9	2.4	353	3.6	2.0	1.3	0.2	<.01
FFQ Year 2	78	5.0	2.2	123	3.9	2.3	1.1	0.3	<.01
FFQ Year 3	46	5.0	2.6	59	3.7	1.9	1.3	0.4	<.01
FFQ Year 4	71	5.0	2.7	112	4.0	2.1	1.1	0.4	0.02
FFQ Year 5	78	5.0	2.5	107	3.6	2.3	1.4	0.4	<.01
FFQ Year 6	65	5.5	2.3	115	4.0	2.0	1.5	0.3	<.01
FFQ Year 7	30	4.1	2.2	32	4.8	3.5	0.6	0.7	0.93
FFQ Year 8	8	5.3	2.5	20	3.7	2.1	1.6	0.9	0.11
FFQ Year 9	2	4.0	1.5	8	4.3	2.8	0.3	2.1	0.82
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	264	4.7	2.7	393	4.7	2.7	0.1	0.2	0.67
FFQ Year 1	239	5.0	2.9	353	4.1	2.4	0.8	0.2	<.01
FFQ Year 2	78	4.6	2.4	123	4.2	2.3	0.4	0.3	0.30
FFQ Year 3	46	4.6	3.0	59	4.1	2.8	0.5	0.6	0.38
FFQ Year 4	71	4.1	2.5	112	3.8	2.1	0.3	0.3	0.64
FFQ Year 5	78	4.5	2.3	107	3.7	2.2	0.9	0.3	<.01
FFQ Year 6	65	4.5	2.4	115	3.8	2.5	0.7	0.4	0.02
FFQ Year 7	30	4.0	2.7	32	3.5	2.0	0.5	0.6	0.76
FFQ Year 8	8	5.1	2.7	20	2.6	1.6	2.5	0.8	<.01
FFQ Year 9	2	3.0	1.7	8	3.0	2.0	0.0	1.6	0.83

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

Table 3.4
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]

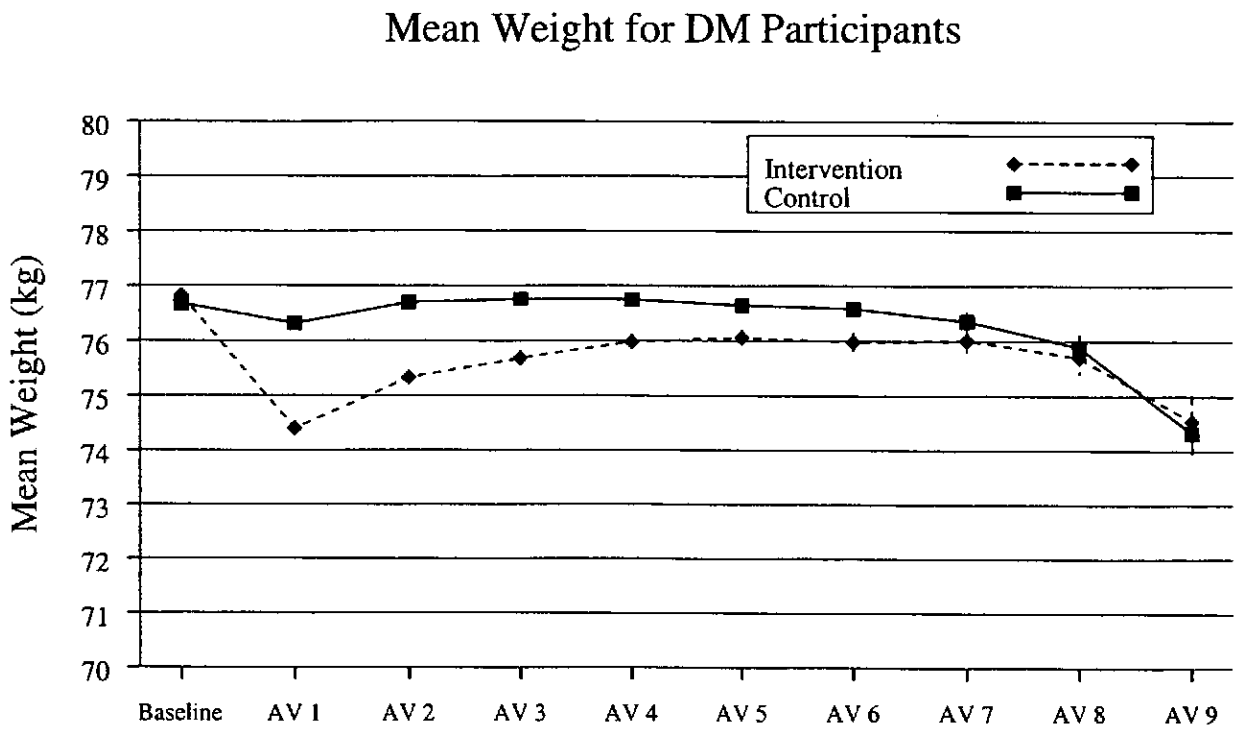
Data as of: August 31, 2003

	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			17.7%				17.7%				17.7%	
Age												
60-69	6498				6498				6498			
50-54 vs. 60-69	2031	0.60			2031	0.62			2031	0.76		
55-59 vs. 60-69	3243	0.49			3243	0.47			3243	0.59		
70-79 vs. 60-69	2167	-0.86 *			2167	-0.79 *			2167	-0.70		
Ethnicity												
White	11492				11492				11492			
American Indian vs. White	62	0.41			62	0.06			62	0.64		
Asian/Pacific Islander vs. White	324	0.00			324	0.26			324	0.17		
Black vs. White	1384	-1.92 **			1384	-1.75 **			1384	-1.61 **		
Hispanic vs. White	492	-1.41			492	-1.33			492	-1.41		
Unknown vs. White	185	-0.44			185	-0.14			185	0.26		
Education												
Post H.S.	10945				10945				10945			
0-8 Years vs. Post H.S.	147	0.50			147	0.89			147	0.84		
Some H.S. or Diploma vs. Post H.S.	2847	0.32			2847	0.33			2847	0.35		
Family Income												
>75K	2577				2577				2577			
<20K vs. >75K	2368	-1.16 *			2368	-1.02 *			2368	-0.83		
20-35K vs. >75K	3276	-0.87 *			3276	-0.57			3276	-0.69		
35-50K vs. >75K	2906	-0.94 *			2906	-0.79			2906	-0.73		
50-75K vs. >75K	2812	-0.63			2812	-0.55			2812	-0.63		
HRT Randomized												
No	11732				11732				11732			
Yes vs. No	2207	0.10			2207	0.05			2207	0.06		
Visit			18.0%	(0.3%)			18.0%	(0.3%)			18.0%	(0.3%)
Visit Year												
AV-6	4900				4900				4900			
AV-5 vs. AV-6	2189	0.02			2189	-0.03			2189	0.10		
AV-7 vs. AV-6	3508	-0.20			3508	-0.33			3508	-0.16		
AV-8 vs. AV-6	2141	-0.61			2141	-0.76 *			2141	-0.64		
AV-9 vs. AV-6	1135	3.62 **			1135	4.89 **			1135	3.37 **		
Clinic Effect			23.0%	(5.0%)			23.0%	(5.0%)			23.0%	(5.0%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			26.8%	(3.8%)								
None	10626											
1 vs. None	593	4.01 **										
2 vs. None	767	5.35 **										
3 vs. None	1063	6.36 **										
4+ vs. None	890	7.10 **										
# Sessions Completed in Previous 12 Months							27.0%	(4.0%)				
None					9705							
1 vs. None					355	1.17 *						
2 vs. None					435	3.69 **						
3 vs. None					746	5.19 **						
4+ vs. None					2698	7.80 **						
# Fat Scores Provided in Previous 12 Months											28.0%	(5.0%)
None									10836			
1 vs. None									534	3.13 **		
2 vs. None									472	4.67 **		
3 vs. None									625	6.40 **		
4+ vs. None									1472	8.00 **		

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

Data as of: August 31, 2003



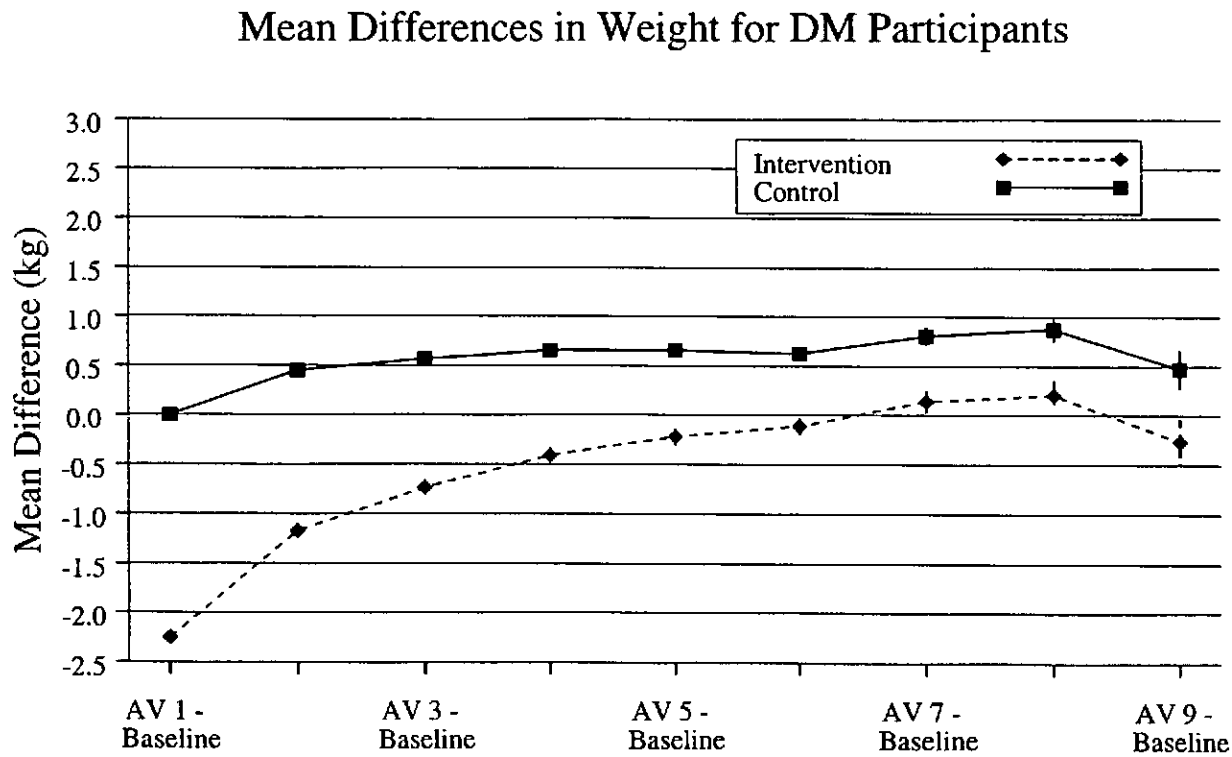


Table 3.5
Reasons for Stopping DM[1]

Data as of: August 31, 2003

Reasons[2]	(N = 2594)	
Personal/family		
Demands of work	236	9.1%
Family illness, emergency, or other family demands[3]	279	10.8%
Financial problems	9	0.3%
Lack of cooperation/support from family/friends[4]	49	1.9%
Living in nursing home	28	1.1%
Issues of interest in study[5]	257	9.9%
Travel		
Too far to CC	118	4.5%
Moved out of area or refuses to be followed at another CC	23	0.9%
Other Travel Issues[6]	63	2.4%
Visits & Procedures		
Doesn't like visits/calls	54	2.1%
Doesn't like required forms or safety procedures[7]	45	1.7%
Problems with other procedures[8]	12	0.5%
Worried about health effects of medical tests/procedures	3	0.1%
Wants test results[9]	0	0.0%
Problems with the CC[10]	29	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 3.5 (continued)
Reasons for Stopping DM[1]

Data as of: August 31, 2003

Reasons[2]	(N = 2594)	
Symptoms		
GI Problems[3]	3	0.1%
Hair/Skin Changes	1	< 0.1%
Weight loss/gain	5	0.2%
HRT Related Symptoms[4]	4	0.2%
Other[5]	9	0.3%
Health Conditions		
Disease and/or health conditions[6]	106	4.1%
Communication difficulties[7]	66	2.5%
Intervention		
Doesn't like randomized nature of intervention	11	0.4%
Expected some benefit from intervention	31	1.2%
Feels guilty/unhappy or like a failure for not meeting study goals	19	0.7%
Pill Issues[8]	6	0.2%
CaD Issues[9]	1	< 0.1%
HRT Issues[10]	2	< 0.1%
Problem with DM group nutritionist or group members	29	1.1%
Doesn't like attending DM intervention classes	73	2.8%
Doesn't like self-monitoring	52	2.0%
Doesn't like budgeting fat grams	9	0.3%
Health concerns regarding long-term risk/benefits of low fat diet	24	0.9%
Unhappy that not losing weight	21	0.8%
Not in control of meal preparation	15	0.6%
Too difficult to meet or maintain dietary goals	52	2.0%
Doesn't like eating low fat diet	37	1.4%
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	33	1.3%
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]	22	0.8%
Study conflicts with other health issues[12]	31	1.2%
Other		
Other reasons not listed above	461	17.8%
Refuses to give a reason	98	3.8%

[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 3.6
Reasons for Stopping DM by Age at Screening and Race/Ethnicity[1]

Data as of: August 31, 2003

	Age at Screening									
	All (N = 19,541)		50 – 54 (N = 2,783)		55 – 59 (N = 4,423)		60 – 69 (N = 9,084)		70 – 79 (N = 3,250)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	2594	13.3%	409	14.7%	561	12.7%	1053	11.6%	571	17.6%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	279	10.8%	45	11.0%	71	12.7%	109	10.4%	54	9.5%
Demands of work	236	9.1%	74	18.1%	72	12.8%	74	7.0%	16	2.8%
Issues of interest in study[6]	257	9.9%	40	9.8%	58	10.3%	108	10.3%	51	8.9%
Too far to CC	118	4.5%	24	5.9%	33	5.9%	43	4.1%	18	3.2%
Other ("Other reasons not listed above")	461	17.8%	79	19.3%	127	22.6%	181	17.2%	74	13.0%

	Race/Ethnicity											
	American Indian/ Alaskan (N = 88)		Asian/Pacific Islander (N = 431)		Black/African American (N = 2,135)		Hispanic/Latino (N = 751)		White (N = 15,871)		Unknown (N = 265)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	23	26.1%	66	15.3%	347	16.3%	168	22.4%	1939	12.2%	51	19.2%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	2	8.7%	3	4.5%	32	9.2%	21	12.5%	216	11.1%	5	9.8%
Demands of work	1	4.3%	5	7.6%	45	13.0%	16	9.5%	165	8.5%	4	7.8%
Issues of interest in study[6]	3	13.0%	7	10.6%	38	11.0%	7	4.2%	199	10.3%	3	5.9%
Too far to CC	2	8.7%	2	3.0%	6	1.7%	6	3.6%	101	5.2%	1	2.0%
Other ("Other reasons not listed above")	5	21.7%	9	13.6%	49	14.1%	48	28.6%	340	17.5%	10	19.6%

[1] Does not include reasons reported by women who stopped and later restarted DM intervention.
[2] Percentages are of DM intervention participants in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of DM intervention participants in the same age or race/ethnicity category who stopped DM intervention.
[5] 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."
[6] 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."

Table 3.7
Bone Mineral Density[1] Analysis: DM Participants

Data as of: August 31, 2003

	N	Mean	S.D.
Whole Body Scan			
Baseline	3622	1.03	0.11
AV1	3277	1.03	0.11
AV3	3101	1.04	0.11
AV6	2760	1.05	0.12
AV9	401	1.04	0.13
AV1 % Change from baseline BMD[2]	3249	0.18	2.50
AV3 % Change from baseline BMD[2]	3074	1.30	3.62
AV6 % Change from baseline BMD[2]	2735	2.11	5.33
AV9 % Change from baseline BMD[2]	400	1.88	6.40
Spine Scan			
Baseline	3510	0.99	0.17
AV1	3177	1.00	0.17
AV3	3017	1.01	0.17
AV6	2666	1.02	0.18
AV9	373	0.99	0.17
AV1 % Change from baseline BMD[2]	3156	0.73	3.82
AV3 % Change from baseline BMD[2]	2992	2.13	5.20
AV6 % Change from baseline BMD[2]	2648	3.29	6.89
AV9 % Change from baseline BMD[2]	373	2.76	7.89
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3275	0.87	0.14
AV3	3099	0.88	0.14
AV6	2786	0.88	0.14
AV9	397	0.85	0.14
AV1 % Change from baseline BMD[2]	3254	-0.04	2.76
AV3 % Change from baseline BMD[2]	3071	0.98	4.18
AV6 % Change from baseline BMD[2]	2756	0.22	5.27
AV9 % Change from baseline BMD[2]	394	-1.46	6.17

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

Table 3.8
Bone Mineral Density[1] Analysis: DM Participants by Race/Ethnicicty

Data as of: August 31, 2003

	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	2787	1.01	0.11
AV1	513	1.09	0.11	152	1.05	0.11	2569	1.01	0.10
AV3	496	1.10	0.12	152	1.05	0.12	2411	1.03	0.11
AV6	439	1.09	0.12	147	1.09	0.14	2129	1.04	0.12
AV1 % Change from baseline BMD[2]	507	0.98	2.96	151	-0.33	2.24	2549	0.06	2.38
AV3 % Change from baseline BMD[2]	491	2.02	2.94	151	0.65	4.45	2391	1.20	3.68
AV6 % Change from baseline BMD[2]	434	0.41	3.41	147	4.44	7.56	2110	2.29	5.38
Spine Scan									
Baseline	576	1.07	0.18	188	0.97	0.15	2689	0.97	0.16
AV1	506	1.08	0.18	146	0.98	0.16	2482	0.98	0.16
AV3	491	1.09	0.19	147	0.96	0.15	2337	1.00	0.17
AV6	412	1.10	0.19	144	0.98	0.16	2065	1.01	0.17
AV1 % Change from baseline BMD[2]	501	0.80	4.31	145	0.15	4.38	2468	0.75	3.66
AV3 % Change from baseline BMD[2]	487	2.10	5.25	146	0.08	5.92	2318	2.29	5.13
AV6 % Change from baseline BMD[2]	408	2.15	6.75	144	1.06	6.99	2052	3.69	6.87
Hip Scan									
Baseline	584	0.97	0.15	195	0.88	0.14	2784	0.85	0.13
AV1	514	0.98	0.15	152	0.87	0.14	2566	0.85	0.13
AV3	496	0.99	0.15	152	0.88	0.14	2409	0.86	0.13
AV6	445	0.97	0.15	149	0.89	0.14	2147	0.86	0.13
AV1 % Change from baseline BMD[2]	510	0.84	2.87	151	-0.62	2.94	2551	-0.18	2.66
AV3 % Change from baseline BMD[2]	492	1.40	3.83	150	0.80	5.76	2388	0.90	4.10
AV6 % Change from baseline BMD[2]	440	-1.43	4.75	147	1.93	6.10	2125	0.43	5.20

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

Table 3.9
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 31, 2003

	DM Participants (N = 48,835)	
	N	%
Vital Status/Participation		
Deceased	1670	3.4
Alive: Current Participation[1]	44672	91.5
Alive: Recent Participation[2]	611	1.3
Alive: Past/Unknown Participation[3]	22	0.0
Stopped Follow-Up[4]	1216	2.5
Lost to Follow-Up[5]	644	1.3

[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 3.10
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 31, 2003

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11040		22710		8124	
Mean follow-up (months)	79.1		85.7		81.6		77.1		75.8	
Cancer										
Breast cancer	1705	(0.53%)	195	(0.39%)	388	(0.52%)	811	(0.56%)	311	(0.61%)
Invasive breast cancer	1366	(0.42%)	141	(0.28%)	314	(0.42%)	662	(0.45%)	249	(0.49%)
Non-invasive breast cancer	345	(0.11%)	56	(0.11%)	75	(0.10%)	151	(0.10%)	63	(0.12%)
Ovarian cancer	142	(0.04%)	15	(0.03%)	30	(0.04%)	63	(0.04%)	34	(0.07%)
Endometrial cancer[1]	233	(0.13%)	24	(0.09%)	53	(0.12%)	110	(0.14%)	46	(0.16%)
Colorectal cancer	397	(0.12%)	25	(0.05%)	65	(0.09%)	200	(0.14%)	107	(0.21%)
Other cancer[2]	1528	(0.47%)	135	(0.27%)	260	(0.35%)	751	(0.51%)	382	(0.74%)
Total cancer	3867	(1.20%)	384	(0.77%)	767	(1.02%)	1866	(1.28%)	850	(1.66%)
Cardiovascular										
CHD[3]	1026	(0.32%)	54	(0.11%)	121	(0.16%)	487	(0.33%)	364	(0.71%)
CHD death[4]	236	(0.07%)	10	(0.02%)	19	(0.03%)	105	(0.07%)	102	(0.20%)
Total MI[5]	877	(0.27%)	45	(0.09%)	107	(0.14%)	421	(0.29%)	304	(0.59%)
Clinical MI	831	(0.26%)	38	(0.08%)	101	(0.13%)	402	(0.28%)	290	(0.56%)
Evolving Q-wave MI[6]	48	(0.01%)	7	(0.01%)	6	(0.01%)	21	(0.01%)	14	(0.03%)
Possible evolving Q-wave MI[6]	188	(0.06%)	22	(0.04%)	32	(0.04%)	87	(0.06%)	47	(0.09%)
Angina	1294	(0.40%)	72	(0.14%)	178	(0.24%)	676	(0.46%)	368	(0.72%)
CABG/PTCA	1358	(0.42%)	57	(0.11%)	172	(0.23%)	720	(0.49%)	409	(0.80%)
Carotid artery disease	210	(0.07%)	7	(0.01%)	24	(0.03%)	107	(0.07%)	72	(0.14%)
Congestive heart failure	800	(0.25%)	37	(0.07%)	85	(0.11%)	362	(0.25%)	316	(0.62%)
Stroke	778	(0.24%)	36	(0.07%)	69	(0.09%)	364	(0.25%)	309	(0.60%)
PVD	185	(0.06%)	6	(0.01%)	21	(0.03%)	88	(0.06%)	70	(0.14%)
CHD[3]/Possible evolving Q-wave MI	1206	(0.37%)	76	(0.15%)	152	(0.20%)	569	(0.39%)	409	(0.80%)
Coronary disease[7]	2983	(0.93%)	168	(0.34%)	386	(0.51%)	1487	(1.02%)	942	(1.83%)
Total cardiovascular disease	3894	(1.21%)	210	(0.42%)	475	(0.63%)	1943	(1.33%)	1266	(2.47%)
Fractures										
Hip fracture	331	(0.10%)	8	(0.02%)	25	(0.03%)	129	(0.09%)	169	(0.33%)
Vertebral fracture	388	(0.12%)	16	(0.03%)	45	(0.06%)	167	(0.11%)	160	(0.31%)
Other fracture[2]	4198	(1.30%)	529	(1.06%)	848	(1.13%)	1960	(1.34%)	861	(1.68%)
Total fracture	4737	(1.47%)	551	(1.11%)	909	(1.21%)	2178	(1.49%)	1099	(2.14%)
Deaths										
Cardiovascular deaths	471	(0.15%)	18	(0.04%)	36	(0.05%)	206	(0.14%)	211	(0.41%)
Cancer deaths	751	(0.23%)	47	(0.09%)	103	(0.14%)	364	(0.25%)	237	(0.46%)
Other known cause	270	(0.08%)	16	(0.03%)	31	(0.04%)	117	(0.08%)	106	(0.21%)
Unknown cause	86	(0.03%)	4	(0.01%)	9	(0.01%)	44	(0.03%)	29	(0.06%)
Not yet adjudicated	93	(0.03%)	7	(0.01%)	17	(0.02%)	36	(0.02%)	33	(0.06%)
Total death	1670	(0.52%)	92	(0.19%)	195	(0.26%)	767	(0.53%)	616	(1.20%)

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

Data as of: August 31, 2003

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)	78.0	75.6	77.4	74.7	79.7	74.7
Cancer						
Breast cancer	4 (0.30%)	40 (0.57%)	119 (0.35%)	46 (0.40%)	1477 (0.56%)	19 (0.46%
Invasive breast cancer	4 (0.30%)	30 (0.43%)	91 (0.27%)	37 (0.32%)	1189 (0.45%)	15 (0.37%
Non-invasive breast cancer	0 (0.00%)	10 (0.14%)	28 (0.08%)	9 (0.08%)	294 (0.11%)	4 (0.10%
Ovarian cancer	1 (0.08%)	3 (0.04%)	9 (0.03%)	3 (0.03%)	123 (0.05%)	3 (0.07%
Endometrial cancer[1]	0 (0.00%)	3 (0.07%)	14 (0.09%)	7 (0.11%)	204 (0.13%)	5 (0.22%
Colorectal cancer	4 (0.30%)	6 (0.09%)	45 (0.13%)	14 (0.12%)	321 (0.12%)	7 (0.17%
Other cancer[2]	5 (0.38%)	20 (0.29%)	114 (0.34%)	33 (0.29%)	1337 (0.51%)	19 (0.46%
Total cancer	14 (1.07%)	69 (0.99%)	291 (0.86%)	97 (0.84%)	3347 (1.27%)	49 (1.19%
Cardiovascular						
CHD[3]	2 (0.15%)	12 (0.17%)	111 (0.33%)	16 (0.14%)	875 (0.33%)	10 (0.24%
CHD death[4]	0 (0.00%)	3 (0.04%)	37 (0.11%)	3 (0.03%)	190 (0.07%)	3 (0.07%
Total MI[5]	2 (0.15%)	12 (0.17%)	87 (0.26%)	15 (0.13%)	751 (0.28%)	10 (0.24%
Clinical MI	2 (0.15%)	11 (0.16%)	83 (0.24%)	15 (0.13%)	711 (0.27%)	9 (0.22%
Evolving Q-wave MI[6]	0 (0.00%)	1 (0.01%)	4 (0.01%)	0 (0.00%)	42 (0.02%)	1 (0.02%
Possible evolving Q-wave MI[6]	2 (0.15%)	7 (0.10%)	23 (0.07%)	6 (0.05%)	148 (0.06%)	2 (0.05%
Angina	4 (0.30%)	14 (0.20%)	175 (0.52%)	38 (0.33%)	1042 (0.39%)	21 (0.51%
CABG/PTCA	1 (0.08%)	10 (0.14%)	129 (0.38%)	25 (0.22%)	1180 (0.45%)	13 (0.32%
Carotid artery disease	2 (0.15%)	1 (0.01%)	18 (0.05%)	2 (0.02%)	185 (0.07%)	2 (0.05%
Congestive heart failure	1 (0.08%)	6 (0.09%)	137 (0.40%)	22 (0.19%)	623 (0.24%)	11 (0.27%
Stroke	4 (0.30%)	17 (0.24%)	97 (0.29%)	17 (0.15%)	633 (0.24%)	10 (0.24%
PVD	1 (0.08%)	2 (0.03%)	32 (0.09%)	2 (0.02%)	145 (0.05%)	3 (0.07%
CHD[3]/Possible evolving Q-wave MI	4 (0.30%)	18 (0.26%)	134 (0.39%)	22 (0.19%)	1016 (0.38%)	12 (0.29%
Coronary disease[7]	9 (0.69%)	34 (0.49%)	395 (1.16%)	73 (0.64%)	2433 (0.92%)	39 (0.95%
Total cardiovascular disease	15 (1.14%)	52 (0.75%)	500 (1.47%)	93 (0.81%)	3183 (1.20%)	51 (1.24%
Fractures						
Hip fracture	1 (0.08%)	1 (0.01%)	9 (0.03%)	5 (0.04%)	311 (0.12%)	4 (0.10%
Vertebral fracture	1 (0.08%)	9 (0.13%)	5 (0.01%)	6 (0.05%)	363 (0.14%)	4 (0.10%
Other fracture[2]	15 (1.14%)	65 (0.93%)	252 (0.74%)	98 (0.85%)	3722 (1.41%)	46 (1.12%
Total fracture	16 (1.22%)	75 (1.08%)	263 (0.77%)	107 (0.93%)	4222 (1.60%)	54 (1.32%
Deaths						
Cardiovascular deaths	3 (0.23%)	8 (0.11%)	68 (0.20%)	8 (0.07%)	379 (0.14%)	5 (0.12%
Cancer deaths	6 (0.46%)	9 (0.13%)	71 (0.21%)	21 (0.18%)	633 (0.24%)	11 (0.27%
Other known cause	4 (0.30%)	1 (0.01%)	40 (0.12%)	5 (0.04%)	217 (0.08%)	3 (0.07%
Unknown cause	1 (0.08%)	0 (0.00%)	10 (0.03%)	5 (0.04%)	70 (0.03%)	0 (0.00%
Not yet adjudicated	0 (0.00%)	2 (0.03%)	10 (0.03%)	6 (0.05%)	73 (0.03%)	2 (0.05%
Total death	14 (1.07%)	20 (0.29%)	199 (0.59%)	44 (0.38%)	1372 (0.52%)	21 (0.51%

[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 3.11
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, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11040	22710	8124
Mean follow-up (months)	79.1	85.7	81.6	77.1	75.8
Hospitalizations					
Ever	21204 (6.59%)	2252 (4.53%)	4031 (5.37%)	10303 (7.06%)	4618 (8.99%)
Two or more	10565 (3.28%)	928 (1.87%)	1789 (2.38%)	5167 (3.54%)	2681 (5.22%)
Other					
DVT[1]	431 (0.14%)	26 (0.05%)	65 (0.09%)	204 (0.15%)	136 (0.28%)
Pulmonary embolism	277 (0.09%)	17 (0.03%)	41 (0.06%)	148 (0.10%)	71 (0.14%)
Diabetes (treated)	2952 (0.96%)	405 (0.84%)	658 (0.91%)	1369 (0.99%)	520 (1.07%)
Gallbladder disease[2]	3217 (1.19%)	491 (1.11%)	755 (1.18%)	1507 (1.26%)	464 (1.12%)
Hysterectomy	1312 (0.72%)	189 (0.67%)	301 (0.66%)	623 (0.77%)	199 (0.71%)
Glaucoma	4240 (1.37%)	425 (0.87%)	865 (1.18%)	2075 (1.48%)	875 (1.84%)
Osteoporosis	8574 (2.82%)	906 (1.86%)	1584 (2.18%)	4243 (3.11%)	1841 (4.02%)
Osteoarthritis[3]	8048 (4.07%)	1178 (3.21%)	1876 (3.68%)	3700 (4.37%)	1294 (5.06%)
Rheumatoid arthritis	2342 (0.76%)	322 (0.67%)	529 (0.73%)	1089 (0.78%)	402 (0.82%)
Intestinal polyps	6254 (2.09%)	778 (1.62%)	1365 (1.91%)	3148 (2.35%)	963 (2.11%)
Lupus	395 (0.12%)	60 (0.12%)	96 (0.13%)	185 (0.13%)	54 (0.11%)
Kidney stones[3]	1008 (0.39%)	134 (0.35%)	226 (0.38%)	487 (0.40%)	161 (0.38%)
Cataracts[3]	12665 (5.33%)	827 (2.11%)	2172 (3.64%)	7022 (6.45%)	2644 (8.88%)
Pills for hypertension	10264 (4.57%)	1364 (3.41%)	2276 (4.02%)	4825 (4.94%)	1799 (5.91%)

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)	78.0	75.6	77.4	74.7	79.7	74.7
Hospitalizations						
Ever	82 (6.25%)	317 (4.55%)	2261 (6.66%)	662 (5.76%)	17618 (6.67%)	264 (6.44%)
Two or more	51 (3.89%)	120 (1.72%)	1158 (3.41%)	305 (2.66%)	8794 (3.33%)	137 (3.34%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	39 (0.12%)	6 (0.05%)	379 (0.15%)	7 (0.18%)
Pulmonary embolism	2 (0.15%)	1 (0.01%)	27 (0.08%)	2 (0.02%)	241 (0.09%)	4 (0.10%)
Diabetes (treated)	15 (1.23%)	86 (1.31%)	550 (1.83%)	163 (1.51%)	2094 (0.82%)	44 (1.13%)
Gallbladder disease[2]	11 (1.18%)	47 (0.75%)	252 (0.83%)	133 (1.53%)	2734 (1.24%)	40 (1.14%)
Hysterectomy	4 (0.64%)	26 (0.59%)	83 (0.55%)	39 (0.64%)	1152 (0.75%)	8 (0.35%)
Glaucoma	22 (1.75%)	84 (1.25%)	614 (1.94%)	155 (1.39%)	3314 (1.30%)	51 (1.32%)
Osteoporosis	39 (3.12%)	212 (3.22%)	511 (1.56%)	319 (2.99%)	7381 (2.97%)	112 (2.95%)
Osteoarthritis[3]	38 (5.08%)	186 (3.71%)	813 (4.02%)	340 (4.38%)	6553 (4.06%)	118 (4.71%)
Rheumatoid arthritis	18 (1.53%)	42 (0.63%)	426 (1.34%)	190 (1.74%)	1626 (0.64%)	40 (1.03%)
Intestinal polyps	31 (2.55%)	135 (2.11%)	687 (2.17%)	201 (1.83%)	5111 (2.08%)	89 (2.37%)
Lupus	3 (0.23%)	5 (0.07%)	56 (0.17%)	14 (0.12%)	311 (0.12%)	6 (0.15%)
Kidney stones[3]	7 (0.69%)	18 (0.31%)	98 (0.36%)	46 (0.49%)	825 (0.39%)	14 (0.42%)
Cataracts[3]	52 (5.57%)	247 (4.72%)	1218 (4.82%)	425 (4.71%)	10553 (5.44%)	170 (5.58%)
Pills for hypertension	38 (4.51%)	218 (4.68%)	1107 (6.52%)	427 (4.99%)	8343 (4.37%)	131 (4.76%)

[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 generally remained steady since the last report (see *Figure 4.1 – CaD Adherence Summary*) at 54%-62%. At AV-5, which is nearly complete, 95% of visits due have been conducted, and of those women who have completed visits, 4% have stopped taking the CaD study medication, and 86% completed the pill collection procedure. While adherence rates held steady, most annual visits that are still in progress, the AV-5 adherence summary declined over the most recent time interval from 69% to 61% (*Figure 4.1*). About 23-38% 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 3.1-5.4%, which compares favorably to the 5.9% design assumption. At AV-5, the cumulative drop-out rate was 20.3% (design assumption was 24.0%). From AV-6 through AV-8, observed cumulative rates are below the design assumption by > 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. 1016 women (10.3%) reported other health problems or diseases, 2192 women (22.3%) reported symptoms, and 514 women (5.2%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (10.7%) followed by want to take her own calcium (4.0%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 20.8% of women. Four common reasons for stopping CaD are shown

first by age, and then by race/ethnicity, in *Table 4.5 – Reasons for Stopping CaD*. No strong associations by race/ethnicity are present, though "being advised by one's health care provider not to participate" and "study conflicts with other health issues" were slightly more common among white women. These reasons were reported with similar frequency by women in the various age groups.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of August 31, 2003, 2733 (7.5%) of women were taking alendronate, 346 (1.0%) were taking risendronate, 280 (0.8%) were taking calcitonin, and 774 (2.1%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 – 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 has 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 0.30%, 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%, whereas hip BMD declined by -0.41%. *Table 4.7 – 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 1-6% 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 4.8 – 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, 2.2% of the participants are lost-to-follow-up or have stopped follow-up, and 3.0% 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 5.5 years, suggesting that approximately 15.4% could be expected to be dead or lost-to-follow-up. Our overall rates compare very favorably to design assumptions.

4.5 Outcomes

Table 4.9 –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. Thus, 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. See *Section 6 – Outcomes* for detailed procedures. The use of centrally adjudicated outcomes has resulted in a decrease of cases of ovarian cancer for some components. This is explained in detail in *Section 6*. 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 237 cases of hip fracture locally verified, we have observed only about 40% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (250 cases) is approximately 75%, the number of invasive breast cancer cases (856 cases) is approximately 120%, and the number of CHD cases is about 70% of what was expected (681 cases).

Table 4.10 - 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, 2003

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5,154	118%	14%	10
55-59	8,267	94%	23%	20
60-69	16,519	84%	46%	45
70-79	6,342	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

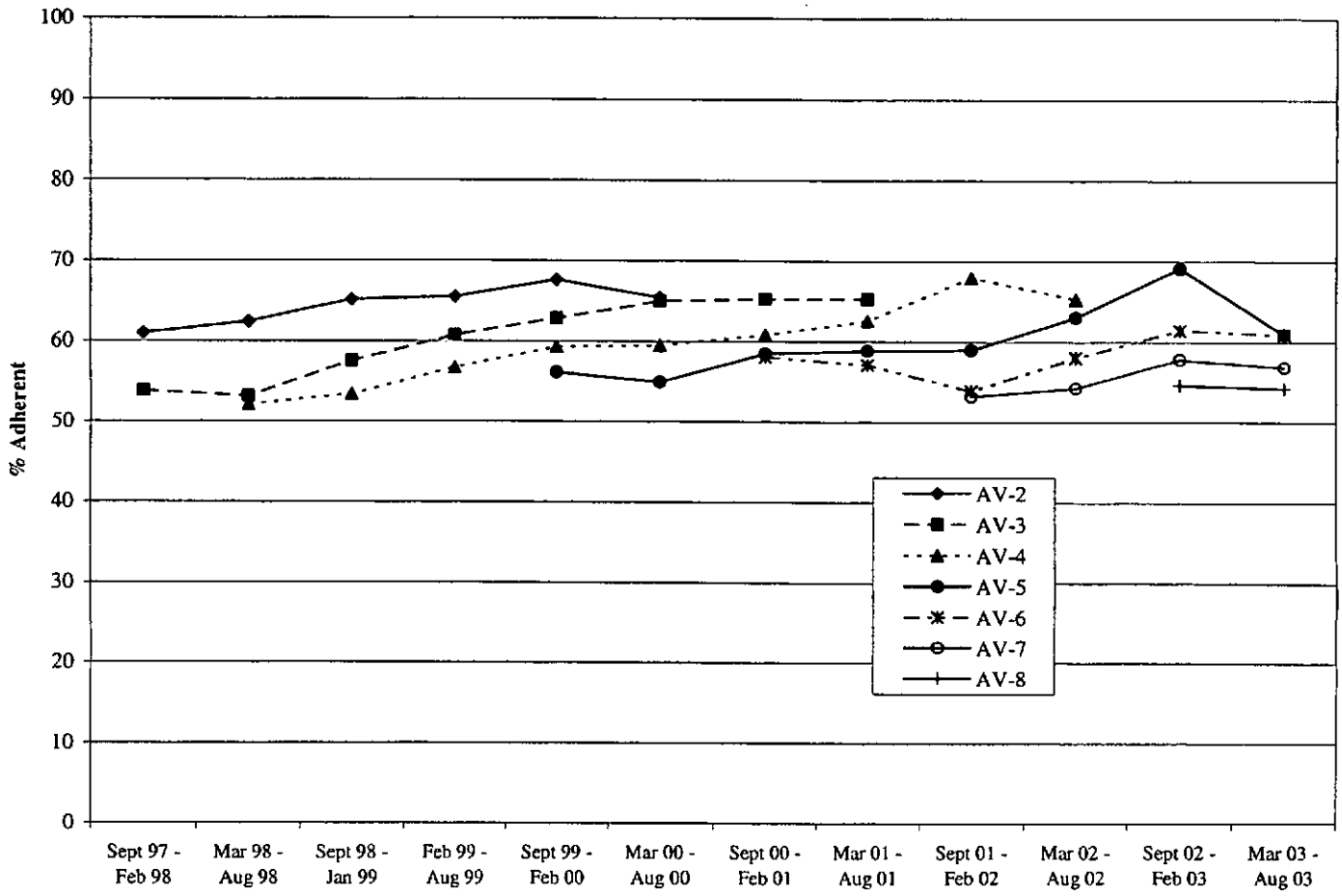
Data as of: August 31, 2003

	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	25859	78	2406	7	151	0	32649	100	5717	17	7009	21	19923	61	60
Annual Visit - 3	36282	35240	97	26512	74	1944	5	416	1	33321	99	5282	16	5707	17	22332	66	62
Annual Visit - 4	36282	34766	96	24602	69	1602	4	476	1	31306	99	4172	13	4791	15	22343	70	62
Annual Visit - 5	36246	34430	95	23080	65	1422	4	514	2	29628	98	3530	12	4166	14	21932	73	62
Annual Visit - 6	28799	27168	94	17268	61	981	3	446	2	22304	98	2451	11	3009	13	16844	74	60
Annual Visit - 7	16560	15386	93	9416	58	495	3	290	2	12264	98	1307	10	1657	13	9300	74	58
Annual Visit - 8	7297	6731	92	3985	56	216	3	155	3	5178	97	531	10	684	13	3963	74	56
Annual Visit - 9	1966	1790	91	1092	58	84	4	47	3	1359	97	146	10	193	14	1020	73	54

[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, 2003



[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, 2003

	Design		Observed			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-2	8.8	8.8	7.3	0.2	7.3	7.2
AV-3	5.9	14.2	5.4	0.4	5.4	12.2
AV-4	5.9	19.2	4.5	0.6	4.5	16.4
AV-5	5.9	24.0	4.0	0.7	4.0	20.3
AV-6	5.9	28.5	3.5	0.7	3.5	23.8
AV-7	5.9	32.7	3.1	0.8	3.1	26.8
AV-8	5.9	36.7	3.1	0.8	3.1	29.8

[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, 2003

Reasons[2]	(N = 9825)	
Personal/family		
Demands of work	206	2.1%
Family illness, emergency or other family demands[3]	370	3.8%
Financial problems	15	0.2%
Lack of cooperation/support from family/friends[4]	75	0.8%
Living in nursing home	57	0.6%
Issues of interest in study[5]	368	3.7%
Travel		
Too far to CC	246	2.5%
Moved out of area or refuses to be followed at another CC	93	0.9%
Other travel issues[6]	97	1.0%
Visits & Procedures		
Doesn't like visits, calls	91	0.9%
Doesn't like required forms or safety procedures[7]	84	0.9%
Problems with other procedures[8]	35	0.4%
Worried about health effects of medical tests/procedures	34	0.3%
Wants results of blood analyses	4	<0.1%
Wants results of bone mineral density	2	<0.1%
Problems with CC[9]	57	0.6%

(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, 2003

Reasons[2]	(N = 9825)	
Symptoms		
Bloating/gas	190	1.9%
Constipation	213	2.2%
Other gastrointestinal problems	252	2.6%
HRT Related Symptoms[3]	37	0.4%
Other[4]	2192	22.3%
Health Conditions		
Hypercalcemia	242	2.5%
Renal calculi	225	2.3%
Osteoporosis	86	0.9%
Other Diseases/Health Conditions[5]	1016	10.3%
Communication difficulties[6]	136	1.4%
Intervention		
Doesn't like randomized nature of intervention	363	3.7%
Expected some benefit from intervention	59	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	19	0.2%
Takes too many pills	326	3.3%
Other pill issues[7]	1053	10.7%
HRT Issues[8]	155	1.6%
DM Issues[9]	16	0.2%
Wants to take her own calcium	393	4.0%
Feels diet is already sufficient in calcium/Vit D	47	0.5%
Taking more than the max allowable IU of Vit D	40	0.4%
Taking Calcitrol	23	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	10	0.1%
Expected more health care	24	0.2%
Advised not to participate by health care provider[10]	765	7.8%
Study conflicts with other health issues[11]	514	5.2%
Other		
Other reasons not listed above	2040	20.8%
Refuses to give a reason	157	1.6%

[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
Reasons for Stopping CaD by Age at Screening and Race/Ethnicity[1]

Data as of: August 31, 2003

	All (N = 36,282)		Age at Screening: 50 – 54 (N = 5,154)		55 – 59 (N = 8,267)		60 – 69 (N = 16,519)		70 – 79 (N = 6,342)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	9825	27.1%	1513	29.4%	2150	26.0%	4193	25.4%	1969	31.0%
REASONS FOR STOPPING[3]										
Doesn't like randomized nature of intervention	363	3.7%	59	3.9%	83	3.9%	163	3.9%	58	2.9%
Other pill issues[4]	1053	10.7%	162	10.7%	246	11.4%	454	10.8%	191	9.7%
Advised not to participate by health care provider[5]	765	7.8%	83	5.5%	161	7.5%	354	8.4%	167	8.5%
Study conflicts with other health issues[6]	514	5.2%	66	4.4%	98	4.6%	224	5.3%	126	6.4%

	Race/Ethnicity: American Indian/ Alaskan Native (N = 149)		Asian/Pacific Islander (N = 721)		Black/African American (N = 3,315)		Hispanic/Latino (N = 1,502)		White (N = 30,155)		Unknown (N = 440)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	46	30.9%	195	27.0%	1037	31.3%	477	31.8%	7941	26.3%	129	29.3%
REASONS FOR STOPPING[3]												
Doesn't like randomized nature of intervention	0	0.0%	3	1.5%	31	3.0%	9	1.9%	316	4.0%	4	3.1%
Other pill issues[4]	6	13.0%	24	12.3%	97	9.4%	52	10.9%	863	10.9%	11	8.5%
Advised not to participate by health care provider[5]	2	4.3%	8	4.1%	62	6.0%	35	7.3%	650	8.2%	8	6.2%
Study conflicts with other health issues[6]	1	2.2%	7	3.6%	40	3.9%	20	4.2%	439	5.5%	7	5.4%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Percentages are of CaD participants in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Combines "Doesn't like taking pills", "Doesn't like taste of pills", and "Unable to swallow pills."
[5] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
[6] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 4.6
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: August 31, 2003

	N	Mean	S.D.
Whole Body Scan			
AV1	2440	1.02	0.11
AV3	2284	1.03	0.11
AV6	1981	1.05	0.12
AV9	277	1.05	0.13
AV3 % Change from AV1 BMD[2]	2211	1.46	3.39
AV6 % Change from AV1 BMD[2]	1916	2.22	5.29
AV9 % Change from AV1 BMD[2]	270	3.29	6.62
Spine Scan			
AV1	2355	0.99	0.16
AV3	2225	1.01	0.17
AV6	1918	1.02	0.17
AV9	257	1.00	0.16
AV3 % Change from AV1 BMD[2]	2156	1.58	4.21
AV6 % Change from AV1 BMD[2]	1855	2.76	5.98
AV9 % Change from AV1 BMD[2]	250	3.06	7.37
Hip Scan			
AV1	2431	0.86	0.14
AV3	2285	0.87	0.14
AV6	1999	0.87	0.14
AV9	273	0.85	0.14
AV3 % Change from AV1 BMD[2]	2211	1.27	3.54
AV6 % Change from AV1 BMD[2]	1925	0.30	5.09
AV9 % Change from AV1 BMD[2]	266	-0.41	6.16

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

Table 4.7
Bone Mineral Density[1] Analysis: CaD Participants by Race/Ethnicity

Data as of: August 31, 2003

	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	224	1.08	0.12	107	1.10	0.15	1616	1.04	0.12
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]	220	-0.33	3.77	89	5.69	7.04	1576	2.39	5.20
Spine Scan									
AV1	274	1.07	0.18	119	0.98	0.16	1924	0.98	0.16
AV3	260	1.08	0.19	113	0.97	0.15	1816	1.00	0.17
AV6	209	1.08	0.18	106	0.99	0.16	1569	1.01	0.17
AV3 % Change from AV1 BMD[2]	256	1.15	4.40	101	0.39	3.99	1765	1.75	4.18
AV6 % Change from AV1 BMD[2]	205	1.01	6.17	88	1.58	5.53	1531	3.07	5.95
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	228	0.96	0.14	109	0.90	0.14	1628	0.86	0.13
AV3 % Change from AV1 BMD[2]	260	0.85	3.16	103	1.68	4.67	1814	1.31	3.51
AV6 % Change from AV1 BMD[2]	223	-1.96	4.35	90	2.93	5.20	1581	0.50	5.04

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

Table 4.8
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: August 31, 2003

	CaD Participants (N=36,282)	
	N	%
Vital Status/Participation		
Deceased	1073	3.0
Alive: Current Participation[1]	34018	93.8
Alive: Recent Participation[2]	382	1.1
Alive: Past/Unknown Participation[3]	8	0.0
Stopped Follow-Up[4]	518	1.4
Lost to Follow-Up[5]	283	0.8

[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 4.9
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: August 31, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5154	8267	16519	6342
Mean follow-up (months)	66.4	72.1	68.7	64.6	63.2
Fractures					
Hip fracture	237 (0.12%)	4 (0.01%)	23 (0.05%)	85 (0.10%)	125 (0.37%)
Vertebral fracture	253 (0.13%)	7 (0.02%)	29 (0.06%)	105 (0.12%)	112 (0.34%)
Other fracture[1]	2798 (1.39%)	352 (1.14%)	566 (1.20%)	1272 (1.43%)	608 (1.82%)
Total fracture	3165 (1.58%)	362 (1.17%)	611 (1.29%)	1404 (1.58%)	788 (2.36%)
Cancer					
Colorectal cancer	250 (0.12%)	17 (0.05%)	36 (0.08%)	122 (0.14%)	75 (0.22%)
Breast cancer	1078 (0.54%)	120 (0.39%)	255 (0.54%)	513 (0.58%)	190 (0.57%)
Invasive breast cancer	856 (0.43%)	87 (0.28%)	205 (0.43%)	414 (0.47%)	150 (0.45%)
Non-invasive breast cancer	224 (0.11%)	33 (0.11%)	50 (0.11%)	100 (0.11%)	41 (0.12%)
Ovarian cancer	86 (0.04%)	8 (0.03%)	24 (0.05%)	36 (0.04%)	18 (0.05%)
Endometrial cancer[2]	140 (0.12%)	15 (0.08%)	32 (0.11%)	65 (0.13%)	28 (0.15%)
Other cancer[1]	1008 (0.50%)	92 (0.30%)	174 (0.37%)	478 (0.54%)	264 (0.79%)
Total cancer	2491 (1.24%)	248 (0.80%)	510 (1.08%)	1178 (1.32%)	555 (1.66%)
Cardiovascular					
CHD[3]	681 (0.34%)	41 (0.13%)	75 (0.16%)	322 (0.36%)	243 (0.73%)
CHD death[4]	167 (0.08%)	10 (0.03%)	14 (0.03%)	64 (0.07%)	79 (0.24%)
Total MI[5]	571 (0.28%)	33 (0.11%)	64 (0.14%)	283 (0.32%)	191 (0.57%)
Clinical MI	526 (0.26%)	29 (0.09%)	59 (0.12%)	263 (0.30%)	175 (0.52%)
Evolving Q-wave MI[6]	47 (0.02%)	4 (0.01%)	5 (0.01%)	22 (0.02%)	16 (0.05%)
Possible evolving Q-wave MI[6]	151 (0.08%)	19 (0.06%)	26 (0.05%)	61 (0.07%)	45 (0.13%)
Angina	853 (0.43%)	36 (0.12%)	117 (0.25%)	434 (0.49%)	266 (0.80%)
CABG/PTCA	926 (0.46%)	40 (0.13%)	114 (0.24%)	479 (0.54%)	293 (0.88%)
Carotid artery disease	153 (0.08%)	7 (0.02%)	14 (0.03%)	86 (0.10%)	46 (0.14%)
Congestive heart failure	533 (0.27%)	21 (0.07%)	57 (0.12%)	253 (0.28%)	202 (0.60%)
Stroke	531 (0.26%)	26 (0.08%)	49 (0.10%)	240 (0.27%)	216 (0.65%)
PVD	138 (0.07%)	5 (0.02%)	16 (0.03%)	65 (0.07%)	52 (0.16%)
CHD[3]/Possible evolving Q-wave MI	825 (0.41%)	60 (0.19%)	100 (0.21%)	379 (0.43%)	286 (0.86%)
Coronary disease[7]	2015 (1.00%)	109 (0.35%)	261 (0.55%)	973 (1.09%)	672 (2.01%)
Total cardiovascular disease	2660 (1.33%)	142 (0.46%)	324 (0.68%)	1297 (1.46%)	897 (2.69%)
Deaths					
Cardiovascular deaths	304 (0.15%)	15 (0.05%)	25 (0.05%)	121 (0.14%)	143 (0.43%)
Cancer deaths	483 (0.24%)	36 (0.12%)	63 (0.13%)	234 (0.26%)	150 (0.45%)
Other known cause	166 (0.08%)	7 (0.02%)	23 (0.05%)	79 (0.09%)	57 (0.17%)
Unknown cause	54 (0.03%)	3 (0.01%)	9 (0.02%)	26 (0.03%)	16 (0.05%)
Not yet adjudicated	66 (0.03%)	6 (0.02%)	12 (0.03%)	22 (0.02%)	26 (0.08%)
Total death	1073 (0.53%)	67 (0.22%)	132 (0.28%)	482 (0.54%)	392 (1.17%)

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

Data as of: August 31, 2003

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)	66.5	62.6	65.0	64.6	66.7	62.7
Fractures						
Hip fracture	1 (0.12%)	4 (0.11%)	4 (0.02%)	2 (0.02%)	226 (0.13%)	0 (0.00%
Vertebral fracture	1 (0.12%)	3 (0.08%)	3 (0.02%)	5 (0.06%)	236 (0.14%)	5 (0.22%
Other fracture[1]	14 (1.70%)	35 (0.93%)	141 (0.79%)	65 (0.80%)	2517 (1.50%)	26 (1.13%
Total fracture	16 (1.94%)	41 (1.09%)	147 (0.82%)	72 (0.89%)	2859 (1.70%)	30 (1.30%
Cancer						
Colorectal cancer	3 (0.36%)	4 (0.11%)	22 (0.12%)	9 (0.11%)	209 (0.12%)	3 (0.13%
Breast cancer	3 (0.36%)	23 (0.61%)	67 (0.37%)	33 (0.41%)	943 (0.56%)	9 (0.39%
Invasive breast cancer	3 (0.36%)	15 (0.40%)	52 (0.29%)	27 (0.33%)	750 (0.45%)	9 (0.39%
Non-invasive breast cancer	0 (0.00%)	8 (0.21%)	15 (0.08%)	6 (0.07%)	195 (0.12%)	0 (0.00%
Ovarian cancer	0 (0.00%)	2 (0.05%)	6 (0.03%)	1 (0.01%)	76 (0.05%)	1 (0.04%
Endometrial cancer[2]	1 (0.29%)	2 (0.08%)	3 (0.04%)	2 (0.04%)	130 (0.13%)	2 (0.15%
Other cancer[1]	3 (0.36%)	17 (0.45%)	61 (0.34%)	21 (0.26%)	896 (0.53%)	10 (0.43%
Total cancer	10 (1.21%)	46 (1.22%)	158 (0.88%)	61 (0.75%)	2191 (1.31%)	25 (1.09%
Cardiovascular						
CHD[3]	2 (0.24%)	3 (0.08%)	70 (0.39%)	14 (0.17%)	581 (0.35%)	11 (0.48%
CHD death[4]	1 (0.12%)	1 (0.03%)	29 (0.16%)	2 (0.02%)	131 (0.08%)	3 (0.13%
Total MI[5]	2 (0.24%)	3 (0.08%)	47 (0.26%)	13 (0.16%)	496 (0.30%)	10 (0.43%
Clinical MI	2 (0.24%)	3 (0.08%)	44 (0.25%)	13 (0.16%)	455 (0.27%)	9 (0.39%
Evolving Q-wave MI[6]	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	43 (0.03%)	1 (0.04%
Possible evolving Q-wave MI[6]	0 (0.00%)	5 (0.13%)	20 (0.11%)	5 (0.06%)	121 (0.07%)	0 (0.00%
Angina	2 (0.24%)	10 (0.27%)	89 (0.50%)	32 (0.40%)	708 (0.42%)	12 (0.52%
CABG/PTCA	1 (0.12%)	7 (0.19%)	78 (0.43%)	29 (0.36%)	797 (0.48%)	14 (0.61%
Carotid artery disease	1 (0.12%)	1 (0.03%)	7 (0.04%)	2 (0.02%)	142 (0.08%)	0 (0.00%
Congestive heart failure	2 (0.24%)	4 (0.11%)	74 (0.41%)	19 (0.23%)	429 (0.26%)	5 (0.22%
Stroke	5 (0.61%)	15 (0.40%)	54 (0.30%)	13 (0.16%)	436 (0.26%)	8 (0.35%
PVD	1 (0.12%)	1 (0.03%)	17 (0.09%)	1 (0.01%)	117 (0.07%)	1 (0.04%
CHD[3]/Possible evolving Q-wave MI	2 (0.24%)	8 (0.21%)	89 (0.50%)	19 (0.23%)	696 (0.42%)	11 (0.48%
Coronary disease[7]	5 (0.61%)	20 (0.53%)	224 (1.25%)	61 (0.75%)	1681 (1.00%)	24 (1.04%
Total cardiovascular disease	9 (1.09%)	35 (0.93%)	283 (1.58%)	78 (0.96%)	2222 (1.32%)	33 (1.43%
Deaths						
Cardiovascular deaths	2 (0.24%)	6 (0.16%)	45 (0.25%)	5 (0.06%)	243 (0.14%)	3 (0.13%
Cancer deaths	1 (0.12%)	11 (0.29%)	37 (0.21%)	11 (0.14%)	417 (0.25%)	6 (0.26%
Other known cause	3 (0.36%)	0 (0.00%)	21 (0.12%)	1 (0.01%)	139 (0.08%)	2 (0.09%
Unknown cause	0 (0.00%)	0 (0.00%)	12 (0.07%)	2 (0.02%)	39 (0.02%)	1 (0.04%
Not yet adjudicated	0 (0.00%)	2 (0.05%)	6 (0.03%)	1 (0.01%)	56 (0.03%)	1 (0.04%
Total death	6 (0.73%)	19 (0.51%)	121 (0.67%)	20 (0.25%)	894 (0.53%)	13 (0.57%

[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 4.10
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, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5154	8267	16519	6342
Mean follow-up (months)	66.4	72.1	68.7	64.6	63.2
Hospitalizations					
Ever	14081 (7.02%)	1455 (4.70%)	2678 (5.66%)	6718 (7.55%)	3230 (9.67%)
Two or more	6489 (3.23%)	562 (1.82%)	1111 (2.35%)	3096 (3.48%)	1720 (5.15%)
Other					
DVT[1]	306 (0.16%)	17 (0.06%)	52 (0.11%)	137 (0.16%)	100 (0.31%)
Pulmonary embolism	184 (0.09%)	12 (0.04%)	31 (0.07%)	99 (0.11%)	42 (0.13%)
Diabetes (treated)	2109 (1.10%)	313 (1.04%)	475 (1.04%)	958 (1.13%)	363 (1.15%)
Gallbladder disease[2]	2004 (1.18%)	308 (1.13%)	496 (1.22%)	914 (1.24%)	286 (1.05%)
Hysterectomy	779 (0.66%)	106 (0.60%)	187 (0.64%)	365 (0.71%)	121 (0.65%)
Glaucoma	2849 (1.47%)	292 (0.96%)	570 (1.23%)	1373 (1.61%)	614 (1.97%)
Osteoporosis	5749 (3.01%)	570 (1.87%)	1050 (2.28%)	2786 (3.30%)	1343 (4.42%)
Osteoarthritis[3]	5407 (4.32%)	793 (3.45%)	1265 (3.91%)	2446 (4.64%)	903 (5.29%)
Rheumatoid arthritis	1470 (0.76%)	214 (0.71%)	356 (0.78%)	644 (0.75%)	256 (0.81%)
Intestinal polyps	4028 (2.15%)	501 (1.67%)	871 (1.93%)	1978 (2.40%)	678 (2.27%)
Lupus	263 (0.13%)	45 (0.15%)	64 (0.14%)	105 (0.12%)	49 (0.15%)
Kidney stones[3]	579 (0.34%)	80 (0.32%)	135 (0.35%)	261 (0.34%)	103 (0.36%)
Cataracts[3]	9015 (6.07%)	596 (2.44%)	1569 (4.15%)	4885 (7.33%)	1965 (10.06%)
Pills for hypertension	7593 (5.29%)	1009 (3.99%)	1678 (4.60%)	3492 (5.72%)	1414 (6.89%)

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)	66.5	62.6	65.0	64.6	66.7	62.7
Hospitalizations						
Ever	62 (7.51%)	187 (4.97%)	1315 (7.32%)	483 (5.97%)	11865 (7.07%)	169 (7.35%)
Two or more	38 (4.60%)	70 (1.86%)	622 (3.46%)	194 (2.40%)	5482 (3.27%)	83 (3.61%)
Other						
DVT[1]	2 (0.25%)	0 (0.00%)	24 (0.14%)	5 (0.06%)	272 (0.17%)	3 (0.13%)
Pulmonary embolism	3 (0.37%)	0 (0.00%)	14 (0.08%)	2 (0.02%)	162 (0.10%)	3 (0.13%)
Diabetes (treated)	9 (1.18%)	62 (1.75%)	329 (2.05%)	144 (1.89%)	1532 (0.94%)	33 (1.53%)
Gallbladder disease[2]	8 (1.28%)	30 (0.88%)	135 (0.83%)	96 (1.54%)	1711 (1.22%)	24 (1.24%)
Hysterectomy	2 (0.57%)	12 (0.49%)	37 (0.48%)	25 (0.56%)	698 (0.69%)	5 (0.38%)
Glaucoma	16 (2.03%)	45 (1.25%)	364 (2.17%)	136 (1.73%)	2264 (1.40%)	24 (1.10%)
Osteoporosis	21 (2.67%)	119 (3.28%)	301 (1.74%)	232 (3.06%)	5010 (3.14%)	66 (3.07%)
Osteoarthritis[3]	32 (6.15%)	108 (3.96%)	470 (4.31%)	265 (4.80%)	4453 (4.29%)	79 (5.26%)
Rheumatoid arthritis	13 (1.77%)	21 (0.58%)	246 (1.48%)	126 (1.63%)	1045 (0.64%)	19 (0.88%)
Intestinal polyps	24 (3.16%)	70 (2.02%)	393 (2.34%)	131 (1.69%)	3366 (2.15%)	44 (2.08%)
Lupus	4 (0.49%)	1 (0.03%)	29 (0.16%)	9 (0.11%)	218 (0.13%)	2 (0.09%)
Kidney stones[3]	4 (0.59%)	12 (0.37%)	46 (0.31%)	29 (0.43%)	481 (0.34%)	7 (0.36%)
Cataracts[3]	43 (6.90%)	144 (5.11%)	736 (5.50%)	357 (5.63%)	7634 (6.18%)	101 (5.79%)
Pills for hypertension	31 (5.97%)	144 (5.57%)	734 (7.87%)	361 (5.79%)	6241 (5.06%)	82 (5.62%)

[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 attend a clinic follow-up visit. Participants at the 3 bone density sites also attend 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 2 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 year 3 clinic visit was incorporated to assess change in physical measures, blood analytes, diet, and use of medications and supplements. These visits began in the first CCs in Fall 1997. Year 6 visits at bone density sites started in 2000 and year 9 started in 2003.

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.

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, and 7 the rates of 94.0% (Y2), 93.6% (Y4), 94.2% (Y5), 93.4% (Y6), and 94.5% (Y7) exceed or meet the 94% (Y2), 92% (Y4), 91% (Y5), 90% (Y6), and 90% (Y7) goals for the *Exposure Update*. These rates fall slightly short of the optimal goals (98% at Y1 with a 0.5% annual decline to 95% by Y7) 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. Of those participants due for the year 3 visit through 8/31/03, 96.1% overall completed *Form 33 – Medical History Updates* and 82.7% provided *Form 100 – Blood Samples*. Of those participants at the 3 bone densitometry substudy clinics due for the year 6 visit, 86.9% completed *Form 33 – Medical History Updates* and 77.1% 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 will allow us to address hypotheses regarding racial/ethnic differences. Bone scans are given at baseline and years 1, 3, 6, and 9 in these centers.

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 A-V9, 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 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, 1.8% of the participants are lost-to-follow-up, and an additional 1.8% of the participants have stopped follow-up. 4.3% of the OS participants are deceased.

5.7 Outcomes

Table 5.7 – Verified Outcomes (Annualized Percentages) by Age 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. Thus, 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. See *Section 6 – Outcomes* for detailed procedures. The use of centrally adjudicated outcomes has resulted in a decrease of cases of ovarian cancer for some components. This is explained in detail in *Section 6*. Compared to the incidence rates used in the CT design, we have about 130% of the expected number of breast cancers, 65% of the expected number of colorectal cancers, about 50% of the expected number of CHD events, and about 35% 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, 2003

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12,383	13%
55-59	17,322	18%
60-69	41,198	44%
70-79	22,773	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, 2003

	# Due[1]	Mailings Initiated[2] N	Mailings Initiated[2] %	Response to Mailings N	Response to Mailings %[3]	Response to CC follow-up N	Response to CC follow-up %[4]	Total Responses N	Total Responses %[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	93,040	91,401	98.2%	86,194	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	51,582	50,690	98.3%	47,777	94.3%	N/A		48,437	93.9%
Year 4	91,033	89,322	98.1%	83,360	93.3%	N/A		85,211	93.6%
VCC	40,887	40,102	98.1%	37,224	92.8%	N/A		38,002	92.9%
NCC	50,146	49,220	98.2%	46,136	93.7%	N/A		47,209	94.1%
Year 5	64,237	62,959	98.0%	59,073	93.8%	1,435	36.9%	60,508	94.2%
VCC	30,066	29,576	98.4%	27,557	93.2%	662	32.8%	28,219	93.9%
NCC	34,171	33,383	97.7%	31,516	94.4%	773	41.4%	32,289	94.5%
Year 6[6]	36,836	35,929	97.5%	33,664	93.7%	N/A		34,395	93.4%
VCC	15,475	15,140	97.8%	14,066	92.9%	N/A		14,304	92.4%
NCC	21,361	20,789	97.3%	19,598	94.3%	N/A		20,091	94.1%
Year 7	13,559	13,184	97.2%	12,550	95.2%	266	42.0%	12,816	94.5%
VCC	8,525	8,308	97.5%	7,862	94.6%	164	36.8%	8,026	94.1%
NCC	5,034	4,876	96.9%	4,688	96.1%	102	54.3%	4,790	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, 2003

	Task	# Due[1]	# Done[2]	% Done
Year 3	Form 33 - Medical History Update	92,488	88,856	96.1%
	Form 38 - Daily Life	92,488	82,338	89.0%
	Form 44 - Current Medications	92,488	79,267	85.7%
	Form 45 - Current Supplements	92,488	79,166	85.6%
	Form 60 - Food Frequency Quest	92,488	82,499	89.2%
	Form 80 - Physical Measures	92,488	77,386	83.7%
	Form 100 - Blood Collection	92,488	76,489	82.7%
	Form 143 - Follow-up	92,488	81,973	88.6%
Year 6[3]	Form 33 - Medical History Update	4,782	4,156	86.9%
	Form 80 - Physical Measures	4,782	3,698	77.3%
	Form 87 - Bone Densitometry	4,782	3,686	77.1%
	Form 146 - Follow-up	4,782	3,949	82.6%

[1] Includes all Year 3/6 contacts due through 10/31/02. 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, 2003

	N	Mean	S.D.
Whole Body Scan			
Baseline	6414	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5103	1.01	0.11
Baseline (for ppts. with an AV6 scan)	4181	1.01	0.11
Baseline (for ppts. with an AV9 scan)	107	1.01	0.09
AV3	5158	1.02	0.11
AV6	4210	1.03	0.12
AV9	108	1.02	0.10
AV3 % Change from baseline BMD[2]	5096	0.95	3.70
AV6 % Change from baseline BMD[2]	4173	1.95	5.59
AV9 % Change from baseline BMD[2]	107	1.00	5.13
Spine Scan			
Baseline	6250	0.98	0.17
Baseline (for ppts. with an AV3 scan)	5011	0.97	0.17
Baseline (for ppts. with an AV6 scan)	4028	0.97	0.17
Baseline (for ppts. with an AV9 scan)	106	0.96	0.14
AV3	5049	0.99	0.18
AV6	4048	1.01	0.18
AV9	107	1.01	0.18
AV3 % Change from baseline BMD[2]	5003	1.67	5.15
AV6 % Change from baseline BMD[2]	4019	3.35	6.96
AV9 % Change from baseline BMD[2]	106	5.45	8.98
Hip Scan			
Baseline	6418	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5146	0.84	0.14
Baseline (for ppts. with an AV6 scan)	4217	0.84	0.14
Baseline (for ppts. with an AV9 scan)	112	0.84	0.13
AV3	5186	0.85	0.14
AV6	4237	0.84	0.14
AV9	113	0.82	0.14
AV3 % Change from baseline BMD[2]	5114	0.48	4.34
AV6 % Change from baseline BMD[2]	4176	-0.06	5.49
AV9 % Change from baseline BMD[2]	112	-1.88	7.47

[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, 2003

	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	463	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)	51	1.03	0.12	15	1.02	0.07	491	1.05	0.11	274	1.02	0.10	3327	1.01	0.10	23	0.99	0.12
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	52	1.03	0.13	15	1.04	0.12	494	1.05	0.11	277	1.06	0.13	3348	1.03	0.12	24	0.99	0.13
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	491	0.01	3.91	272	3.41	6.27	3321	2.15	5.67	23	0.03	3.85
Spine Scan																		
Baseline	109	0.99	0.17	24	0.95	0.12	819	1.04	0.18	450	0.95	0.16	4803	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	3988	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	52	0.99	0.17	14	0.94	0.10	463	1.04	0.17	268	0.96	0.16	3208	0.97	0.16	23	0.97	0.23
AV3	81	1.00	0.16	21	0.96	0.12	579	1.05	0.19	328	0.95	0.16	4005	0.98	0.17	35	0.95	0.17
AV6	53	1.00	0.17	14	0.96	0.11	463	1.05	0.19	272	0.97	0.17	3222	1.00	0.18	24	1.00	0.24
AV3 % Change from baseline BMD[2]	77	0.16	5.83	21	0.42	4.57	576	1.15	5.59	314	0.22	5.42	3981	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	463	1.54	6.58	266	1.19	6.92	3201	3.84	6.92	23	3.09	7.29
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	463	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)	51	0.90	0.16	15	0.79	0.08	494	0.93	0.15	277	0.84	0.12	3356	0.83	0.13	24	0.82	0.15
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	52	0.88	0.17	15	0.81	0.09	496	0.91	0.15	281	0.85	0.13	3368	0.83	0.13	25	0.81	0.15
AV3 % Change from baseline BMD[2]	77	-0.36	4.85	22	0.72	4.21	582	0.36	4.00	322	1.68	5.00	4075	0.43	4.30	36	-0.81	4.76
AV6 % Change from baseline BMD[2]	50	-1.19	7.58	15	2.34	5.68	492	-2.39	4.84	274	1.38	5.99	3321	0.18	5.39	24	-1.51	6.61

[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, 2003

	OS Participants (N=93,676)	
	N	%
Vital Status/Participation		
Deceased	3909	4.2
Alive: Current Participation[1]	84025	89.7
Alive: Recent Participation[2]	2141	2.3
Alive: Past/Unknown Participation[3]	226	0.2
Stopped Follow-Up[4]	1690	1.8
Lost to Follow-Up[5]	1685	1.8

[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, 2003

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number enrolled	93676		12383		17322		41198		22773	
Mean follow-up (months)	72.1		76.2		74.9		71.1		69.5	
Cardiovascular										
CHD[1]	1659	(0.29%)	54	(0.07%)	134	(0.12%)	680	(0.28%)	791	(0.60%)
CHD death[2]	466	(0.08%)	9	(0.01%)	24	(0.02%)	158	(0.06%)	275	(0.21%)
Clinical MI	1336	(0.24%)	47	(0.06%)	117	(0.11%)	567	(0.23%)	605	(0.46%)
Angina	2240	(0.40%)	98	(0.12%)	238	(0.22%)	1040	(0.43%)	864	(0.66%)
CABG/PTCA	2290	(0.41%)	81	(0.10%)	231	(0.21%)	1089	(0.45%)	889	(0.67%)
Carotid artery disease	431	(0.08%)	24	(0.03%)	32	(0.03%)	163	(0.07%)	212	(0.16%)
Congestive heart failure	1592	(0.28%)	55	(0.07%)	124	(0.11%)	625	(0.26%)	788	(0.60%)
Stroke	1351	(0.24%)	36	(0.05%)	100	(0.09%)	513	(0.21%)	702	(0.53%)
PVD	372	(0.07%)	14	(0.02%)	34	(0.03%)	152	(0.06%)	172	(0.13%)
Coronary disease[3]	4971	(0.88%)	197	(0.25%)	466	(0.43%)	2159	(0.88%)	2149	(1.63%)
Total cardiovascular disease	6733	(1.20%)	262	(0.33%)	604	(0.56%)	2833	(1.16%)	3034	(2.30%)
Cancer										
Breast cancer	3166	(0.56%)	320	(0.41%)	579	(0.54%)	1452	(0.59%)	815	(0.62%)
Invasive breast cancer	2662	(0.47%)	262	(0.33%)	477	(0.44%)	1225	(0.50%)	698	(0.53%)
Non-invasive breast cancer	515	(0.09%)	61	(0.08%)	104	(0.10%)	232	(0.10%)	118	(0.09%)
Ovarian cancer	267	(0.05%)	27	(0.03%)	41	(0.04%)	123	(0.05%)	76	(0.06%)
Endometrial cancer[4]	422	(0.13%)	32	(0.07%)	60	(0.09%)	196	(0.14%)	134	(0.18%)
Colorectal cancer	656	(0.12%)	38	(0.05%)	74	(0.07%)	297	(0.12%)	247	(0.19%)
Other cancer[5]	2895	(0.51%)	206	(0.26%)	365	(0.34%)	1315	(0.54%)	1009	(0.77%)
Total cancer	7129	(1.27%)	610	(0.78%)	1082	(1.00%)	3253	(1.33%)	2184	(1.66%)
Fractures										
Hip fracture	702	(0.12%)	20	(0.03%)	54	(0.05%)	224	(0.09%)	404	(0.31%)
Vertebral fracture[6]	83	(0.19%)	4	(0.06%)	6	(0.08%)	29	(0.16%)	44	(0.43%)
Other fracture[5, 6]	563	(1.32%)	71	(1.13%)	93	(1.17%)	226	(1.23%)	173	(1.70%)
Total fracture[7]	1305	N/A	93	N/A	149	N/A	465	N/A	598	N/A
Deaths										
Cardiovascular deaths	1031	(0.18%)	27	(0.03%)	58	(0.05%)	338	(0.14%)	608	(0.46%)
Cancer deaths	1692	(0.30%)	94	(0.12%)	197	(0.18%)	731	(0.30%)	670	(0.51%)
Other known cause	710	(0.13%)	36	(0.05%)	78	(0.07%)	255	(0.10%)	341	(0.26%)
Unknown cause	248	(0.04%)	6	(0.01%)	21	(0.02%)	88	(0.04%)	133	(0.10%)
Not yet adjudicated	229	(0.04%)	7	(0.01%)	18	(0.02%)	90	(0.04%)	114	(0.09%)
Total death	3909	(0.69%)	170	(0.22%)	371	(0.34%)	1502	(0.62%)	1866	(1.42%)

[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, 2003

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)	67.8	69.8	67.8	64.5	73.0	69.4
Cardiovascular						
CHD[1]	9 (0.38%)	31 (0.20%)	148 (0.34%)	27 (0.14%)	1417 (0.30%)	27 (0.35%)
CHD death[2]	4 (0.17%)	8 (0.05%)	63 (0.15%)	6 (0.03%)	378 (0.08%)	7 (0.09%)
Clinical MI	6 (0.25%)	26 (0.17%)	102 (0.24%)	24 (0.12%)	1156 (0.24%)	22 (0.29%)
Angina	14 (0.59%)	35 (0.23%)	194 (0.45%)	62 (0.32%)	1914 (0.40%)	21 (0.27%)
CABG/PTCA	12 (0.50%)	42 (0.27%)	148 (0.34%)	57 (0.29%)	1998 (0.42%)	33 (0.43%)
Carotid artery disease	3 (0.13%)	4 (0.03%)	20 (0.05%)	10 (0.05%)	388 (0.08%)	6 (0.08%)
Congestive heart failure	11 (0.46%)	19 (0.12%)	172 (0.40%)	32 (0.17%)	1332 (0.28%)	26 (0.34%)
Stroke	9 (0.38%)	34 (0.22%)	141 (0.33%)	26 (0.13%)	1121 (0.24%)	20 (0.26%)
PVD	2 (0.08%)	4 (0.03%)	37 (0.09%)	4 (0.02%)	316 (0.07%)	9 (0.12%)
Coronary disease[3]	29 (1.22%)	82 (0.53%)	452 (1.05%)	115 (0.59%)	4232 (0.89%)	61 (0.80%)
Total cardiovascular disease	37 (1.55%)	122 (0.78%)	630 (1.46%)	149 (0.77%)	5700 (1.20%)	95 (1.24%)
Cancer						
Breast cancer	8 (0.34%)	67 (0.43%)	198 (0.46%)	79 (0.41%)	2783 (0.59%)	31 (0.40%)
Invasive breast cancer	6 (0.25%)	56 (0.36%)	164 (0.38%)	68 (0.35%)	2342 (0.49%)	26 (0.34%)
Non-invasive breast cancer	2 (0.08%)	11 (0.07%)	36 (0.08%)	12 (0.06%)	449 (0.09%)	5 (0.07%)
Ovarian cancer	1 (0.04%)	5 (0.03%)	14 (0.03%)	7 (0.04%)	239 (0.05%)	1 (0.01%)
Endometrial cancer[4]	0 (0.00%)	6 (0.06%)	15 (0.08%)	7 (0.07%)	385 (0.14%)	9 (0.20%)
Colorectal cancer	2 (0.08%)	9 (0.06%)	82 (0.19%)	14 (0.07%)	541 (0.11%)	8 (0.10%)
Other cancer[5]	12 (0.50%)	53 (0.34%)	189 (0.44%)	61 (0.31%)	2534 (0.53%)	46 (0.60%)
Total cancer	23 (0.97%)	134 (0.86%)	477 (1.11%)	164 (0.85%)	6242 (1.32%)	89 (1.16%)
Fractures						
Hip fracture	4 (0.17%)	7 (0.05%)	18 (0.04%)	7 (0.04%)	657 (0.14%)	9 (0.12%)
Vertebral fracture[6]	1 (0.18%)	0 (0.00%)	2 (0.04%)	2 (0.07%)	78 (0.23%)	0 (0.00%)
Other fracture[5, 6]	8 (1.40%)	3 (1.82%)	35 (0.65%)	30 (1.04%)	482 (1.44%)	5 (1.82%)
Total fracture[7]	12 N/A	10 N/A	52 N/A	38 N/A	1179 N/A	14 N/A
Deaths						
Cardiovascular deaths	8 (0.34%)	24 (0.15%)	128 (0.30%)	20 (0.10%)	836 (0.18%)	15 (0.20%)
Cancer deaths	8 (0.34%)	31 (0.20%)	144 (0.33%)	43 (0.22%)	1444 (0.30%)	22 (0.29%)
Other known cause	11 (0.46%)	12 (0.08%)	72 (0.17%)	32 (0.17%)	575 (0.12%)	8 (0.10%)
Unknown cause	0 (0.00%)	4 (0.03%)	41 (0.09%)	6 (0.03%)	194 (0.04%)	3 (0.04%)
Not yet adjudicated	1 (0.04%)	6 (0.04%)	22 (0.05%)	6 (0.03%)	192 (0.04%)	2 (0.03%)
Total death	28 (1.18%)	77 (0.50%)	406 (0.94%)	107 (0.55%)	3241 (0.68%)	50 (0.65%)

[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, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12383	17322	41198	22773
Mean follow-up (months)	72.1	76.2	74.9	71.1	69.5
Hospitalizations					
Ever	37022 (6.58%)	3402 (4.33%)	5360 (4.96%)	16637 (6.81%)	11623 (8.82%)
Two or more	17116 (3.04%)	1305 (1.66%)	2080 (1.93%)	7640 (3.13%)	6091 (4.62%)
Other					
DVT[1]	576 (0.11%)	46 (0.06%)	67 (0.06%)	264 (0.11%)	199 (0.16%)
Pulmonary embolism	354 (0.06%)	33 (0.04%)	46 (0.04%)	154 (0.06%)	121 (0.09%)
Diabetes (treated)	3884 (0.72%)	481 (0.63%)	719 (0.69%)	1757 (0.75%)	927 (0.74%)
Gallbladder disease[2]	4550 (0.96%)	688 (0.99%)	898 (0.96%)	2047 (1.00%)	917 (0.85%)
Hysterectomy	2481 (0.75%)	346 (0.74%)	486 (0.72%)	1156 (0.82%)	493 (0.67%)
Glaucoma	6297 (1.17%)	615 (0.80%)	947 (0.90%)	2918 (1.25%)	1817 (1.50%)
Osteoporosis	17338 (3.37%)	1676 (2.21%)	2718 (2.64%)	8018 (3.60%)	4926 (4.33%)
Osteoarthritis[3]	12667 (3.87%)	1583 (2.79%)	2271 (3.21%)	5680 (4.16%)	3133 (4.93%)
Rheumatoid arthritis	3679 (0.69%)	503 (0.66%)	714 (0.69%)	1513 (0.65%)	949 (0.77%)
Intestinal polyps	10300 (2.02%)	1185 (1.58%)	1934 (1.91%)	4812 (2.19%)	2369 (2.08%)
Lupus	800 (0.14%)	118 (0.15%)	162 (0.15%)	352 (0.14%)	168 (0.13%)
Kidney stones[3]	1738 (0.38%)	228 (0.37%)	320 (0.37%)	734 (0.36%)	456 (0.42%)
Cataracts[3]	21507 (5.50%)	1195 (1.92%)	2971 (3.50%)	11210 (6.43%)	6131 (8.84%)
Pills for hypertension	17180 (4.27%)	1937 (2.97%)	3037 (3.61%)	7503 (4.42%)	4703 (5.69%)

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)	67.8	69.8	67.8	64.5	73.0	69.4
Hospitalizations						
Ever	191 (8.03%)	668 (4.30%)	2892 (6.70%)	1065 (5.49%)	31710 (6.68%)	496 (6.48%)
Two or more	103 (4.33%)	251 (1.61%)	1339 (3.10%)	390 (2.01%)	14802 (3.12%)	231 (3.02%)
Other						
DVT[1]	3 (0.13%)	4 (0.03%)	54 (0.13%)	9 (0.05%)	501 (0.11%)	5 (0.07%)
Pulmonary embolism	1 (0.04%)	3 (0.02%)	28 (0.07%)	2 (0.01%)	317 (0.07%)	3 (0.04%)
Diabetes (treated)	39 (1.93%)	140 (0.95%)	609 (1.60%)	253 (1.40%)	2787 (0.60%)	56 (0.77%)
Gallbladder disease[2]	26 (1.39%)	63 (0.45%)	302 (0.79%)	192 (1.27%)	3905 (0.98%)	62 (0.97%)
Hysterectomy	5 (0.42%)	42 (0.41%)	100 (0.51%)	84 (0.79%)	2207 (0.78%)	43 (0.97%)
Glaucoma	36 (1.65%)	207 (1.40%)	748 (1.89%)	226 (1.23%)	4991 (1.10%)	89 (1.22%)
Osteoporosis	77 (3.54%)	528 (3.72%)	820 (2.00%)	594 (3.33%)	15059 (3.48%)	260 (3.71%)
Osteoarthritis[3]	53 (3.97%)	394 (3.60%)	1042 (4.17%)	590 (4.63%)	10392 (3.81%)	196 (4.22%)
Rheumatoid arthritis	31 (1.42%)	83 (0.56%)	544 (1.39%)	316 (1.76%)	2635 (0.58%)	70 (0.98%)
Intestinal polyps	36 (1.65%)	260 (1.87%)	819 (2.07%)	318 (1.75%)	8731 (2.04%)	136 (1.97%)
Lupus	7 (0.30%)	14 (0.09%)	79 (0.18%)	47 (0.24%)	642 (0.14%)	11 (0.14%)
Kidney stones[3]	15 (0.78%)	31 (0.24%)	207 (0.57%)	104 (0.64%)	1347 (0.35%)	34 (0.54%)
Cataracts[3]	84 (5.08%)	553 (5.19%)	1553 (5.01%)	700 (4.70%)	18302 (5.59%)	315 (5.92%)
Pills for hypertension	81 (5.37%)	466 (4.26%)	1386 (6.56%)	710 (4.88%)	14281 (4.10%)	256 (4.78%)

[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, 2003

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	756	903
CHD death[3]	174	292
Clinical MI	639	697
Angina	1269	971
CABG/PTCA	1164	1126
Carotid artery disease	221	210
Congestive heart failure	715	877
Stroke	572	779
PVD	198	174
Coronary disease[4]	2577	2394
Total cardiovascular disease	3437	3296
Cancer		
Breast cancer	1590	1576
Invasive breast cancer	1331	1331
Non-invasive breast cancer	281	264
Ovarian cancer	132	135
Endometrial cancer	212	210
Colorectal cancer	331	325
Other cancer[5]	1419	1476
Total cancer	3609	3520
Fractures		
Hip fracture[6]	294	408
Vertebral fracture[6]	35	48
Other fracture[5, 6]	275	288
Total fracture[6]	593	712
Deaths		
Cardiovascular deaths	368	663
Cancer deaths	614	1078
Deaths: other known cause	221	489
Deaths: unknown cause	56	192
Deaths: not yet adjudicated	6	222
Total death	1265	2644

[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, 2003

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19161	17861
DVT[2]	227	349
Pulmonary embolism	130	224
Diabetes (treated)	1740	2144
Gallbladder disease[3]	2137	2413
Hysterectomy	1246	1235
Glaucoma	2755	3542
Osteoporosis	8702	8636
Osteoarthritis[4]	6338	6329
Rheumatoid arthritis	1724	1955
Intestinal polyps	4396	5904
Lupus	348	452
Kidney stones[4]	646	1092
Cataracts[4]	9146	12361
Pills for hypertension	8142	9038

[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.

For the first time in this report we use data from central adjudicated cases for those outcomes where 100% of all self-reports and the locally verified outcomes is centrally adjudicated in *Sections 2, 3, 4, and 5.* A detailed description of the implications can be found in *Section 6.3.*

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, 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.

For the first time in this report we use data from central adjudicated cases for those outcomes where 100% of all self-reports and the locally verified outcomes is 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.

We have carefully compared data for all outcomes on which local and central data is available. In general, there is no noticeable difference between the old and the new method of reporting as typically the number of locally verified cases that are centrally denied is approximately the same as the number of locally denied cases that are centrally confirmed. There are two exceptions:

1. The number of cases in "other" and "unknown" death subclasses has reduced in some tables, as central adjudicators are able to determine the exact cause of death for a larger number of the cases.

2. The number of ovarian cancers has reduced for several of the arms. Reason for this is that the one outcome where many more locally confirmed ovarian cancers are centrally classified different, than that locally classified other cancers are centrally classified as ovarian. For example, in the CT 28 participants (distributed over all trials) were classified in the previous report as having ovarian cancer. In the current report these 28 are classified as:

   - 12 as peritoneal cancer
   - 1 as fallopian tube cancer
   - 1 as pelvic cancer
   - 1 as appendix cancer
   - 1 as endometrial cancer
   - 6 as unknown cancer
   - 4 as benign tumors (no outcome)
   - 1 was originally classified as an ovarian cancer death on the preliminary death adjudication, and was reclassified locally as a gastric cancer on the final local death adjudication; central adjudication confirmed the gastric cancer as cause of death
   - 1 was denied for insufficient documentation

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 96% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 59% of the outcomes in the CT and 60% of the outcomes in the OS have been closed within 90 days of self-report and 78% (CT) and 80% (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.)

Over the last six months the number of open adjudication cases has increased slightly. This is for the first time in several years that we have observed such an increase. It is quite well possible that this increase is temporary, caused by the enactment of HIPAA last April. The Outcomes PMC is closely monitoring the outcomes processing. As only about a year is left before the close-out of the CT starts, the OPMC has increased the of targeted intervention phone calls, and the CCC has send out outcomes liaisons to trouble-shoot clinics on a regular basis.

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 87% (93% for the primary cancers), and fracture outcomes have an agreement rate of 80% 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 is 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 94% of the cardiovascular outcomes have been adjudicated and about 96% 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 12%(CT)-19%(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 andRace/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 35% 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.

During the summer of 2001, we completed the first NDI search. Results of this investigation are detailed in *Table 6.16 – Results of NDI Search.* The NDI search identified 22 women as dead, whose death had not otherwise been ascertained by WHI. A second NDI search is currently under way.

As of the February 28 database, there were 2,511 deaths in the CT and 3,909 in the OS.

Table 6.17 – 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 4.2% of the CT participants are deceased; we do not know the vital status of about 1.3% of the CT participants, and 2.5% of the participants request no further follow-up. In addition, we lack recent outcomes information on an additional 27 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 6.7 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 0.1 to 7.8%.

Table 6.18 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.17* 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 3.6% 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, 2003

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	3986	270	7%	781	20%	3984	100%	2	<1%
1996 July-December	1385	308	22%	715	52%	1385	100%	0	0%
1997 January-June	2182	764	35%	1328	61%	2180	100%	2	<1%
1997 July-December	2552	980	38%	1518	59%	2551	100%	1	<1%
1998 January-June	3576	1664	47%	2777	78%	3576	100%	0	0%
1998 July-December	4162	2360	57%	3331	80%	4161	100%	1	<1%
1999 January-June	4607	2828	61%	3802	83%	4607	100%	0	0%
1999 July-December	4483	2868	64%	3691	82%	4483	100%	0	0%
2000 January-June	4716	3102	66%	3960	84%	4715	100%	1	<1%
2000 July-December	4411	2985	68%	3811	86%	4409	100%	2	<1%
2001 January- June	5212	3647	70%	4543	87%	5209	100%	3	<1%
2001 July-December	4767	3233	68%	4290	90%	4759	100%	8	<1%
2002 January - June	5281	3962	75%	4771	90%	5244	99%	37	1%
2002 July	1068	823	77%	991	93%	1060	99%	8	1%
2002 August	965	739	77%	893	93%	949	98%	16	2%
2002 September	814	599	74%	744	91%	793	97%	21	3%
2002 October	970	728	75%	880	91%	948	98%	22	2%
2002 November	751	567	75%	689	92%	727	97%	24	3%
2002 December	705	536	76%	663	94%	683	97%	22	3%
2003 January	949	758	80%	887	93%	912	96%	37	4%
2003 February	879	694	79%	823	94%	836	95%	43	5%
2003 March	912	660	72%	836	92%	836	92%	76	8%
2003 April	927	701	76%	827	89%	827	89%	100	11%
2003 May	910	650	71%	723	79%	723	79%	187	21%
2003 June	835	600	72%	600	72%	600	72%	235	28%
2003 July	916	433	47%	433	47%	433	47%	483	53%
2003 August	658	86	13%	86	13%	86	13%	572	87%
Total	63579	37545	59%	49393	78%	61676	97%	1903	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, 2003

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	238	83	35%	126	53%	238	100%	0	0%
1996 July-December	1311	307	23%	701	53%	1310	100%	1	<1%
1997 January-June	2155	845	39%	1401	65%	2155	100%	0	0%
1997 July-December	2297	709	31%	1354	59%	2297	100%	0	0%
1998 January-June	2835	1268	45%	2037	72%	2835	100%	0	0%
1998 July-December	3807	2002	53%	2897	76%	3806	100%	1	<1%
1999 January-June	4754	2843	60%	3923	83%	4754	100%	0	0%
1999 July-December	4226	2522	60%	3408	81%	4226	100%	0	0%
2000 January-June	5931	3777	64%	4887	82%	5930	100%	1	<1%
2000 July-December	4318	2830	66%	3631	84%	4317	100%	1	<1%
2001 January- June	5380	3568	66%	4587	85%	5375	100%	5	<1%
2001 July-December	4707	3124	66%	4133	88%	4692	100%	15	<1%
2002 January - June	5766	4114	71%	5149	89%	5706	99%	60	1%
2002 July	969	708	73%	861	89%	940	97%	29	3%
2002 August	1000	700	70%	881	88%	967	97%	33	3%
2002 September	793	577	73%	698	88%	768	97%	25	3%
2002 October	826	588	71%	725	88%	803	97%	23	3%
2002 November	658	467	71%	586	89%	621	94%	37	6%
2002 December	676	485	72%	604	89%	636	94%	40	6%
2003 January	902	712	79%	841	93%	864	96%	38	4%
2003 February	895	694	78%	835	93%	850	95%	45	5%
2003 March	971	701	72%	899	93%	899	93%	72	7%
2003 April	1100	814	74%	957	87%	957	87%	143	13%
2003 May	920	613	67%	702	76%	702	76%	218	24%
2003 June	1011	688	68%	688	68%	688	68%	323	32%
2003 July	1113	501	45%	501	45%	501	45%	612	55%
2003 August	756	112	15%	112	15%	112	15%	644	85%
Total	60315	36352	60%	48124	80%	57949	96%	2366	4%

[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

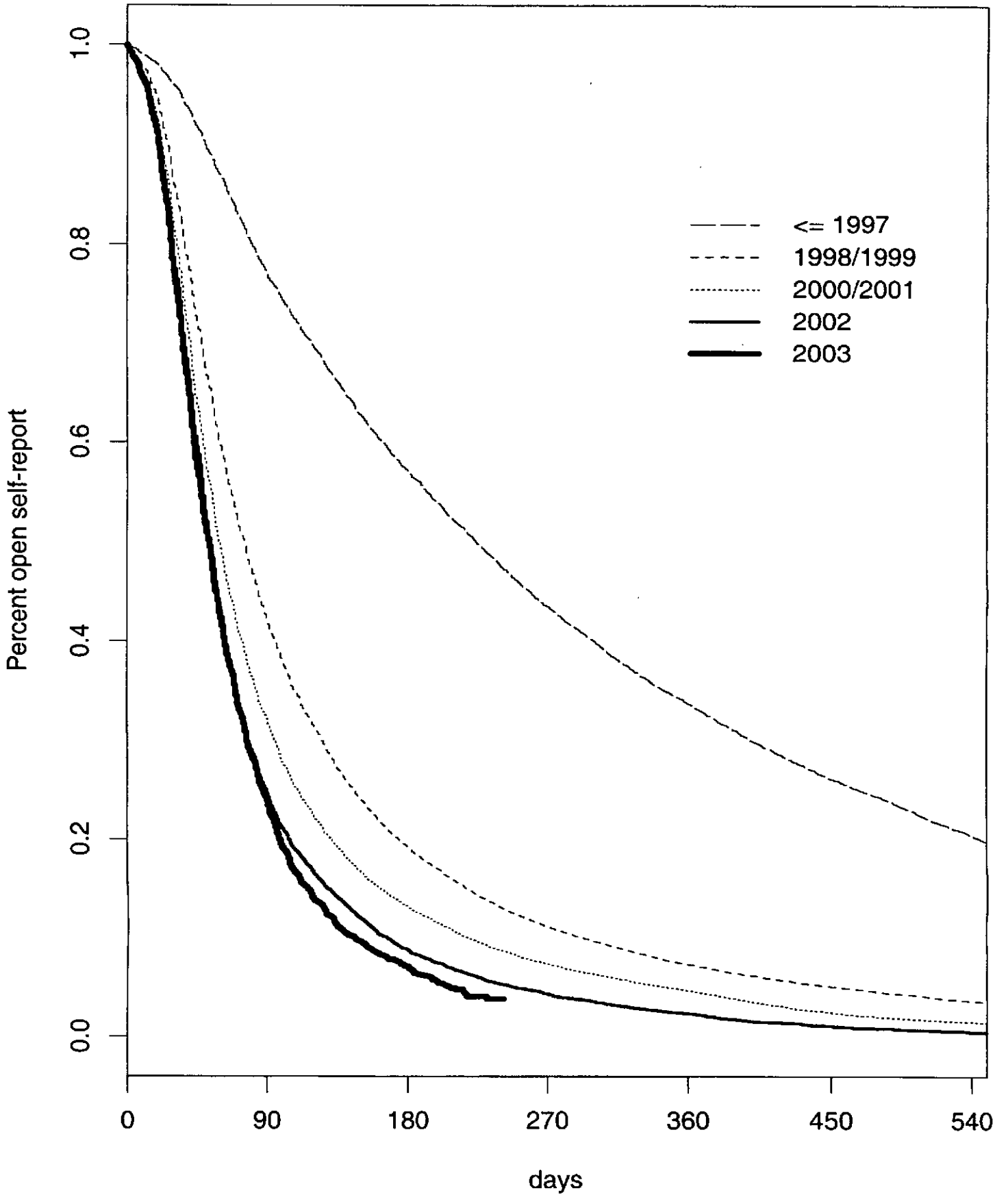


Figure 6.2 Observational Study Timeliness per Period of Self-Report

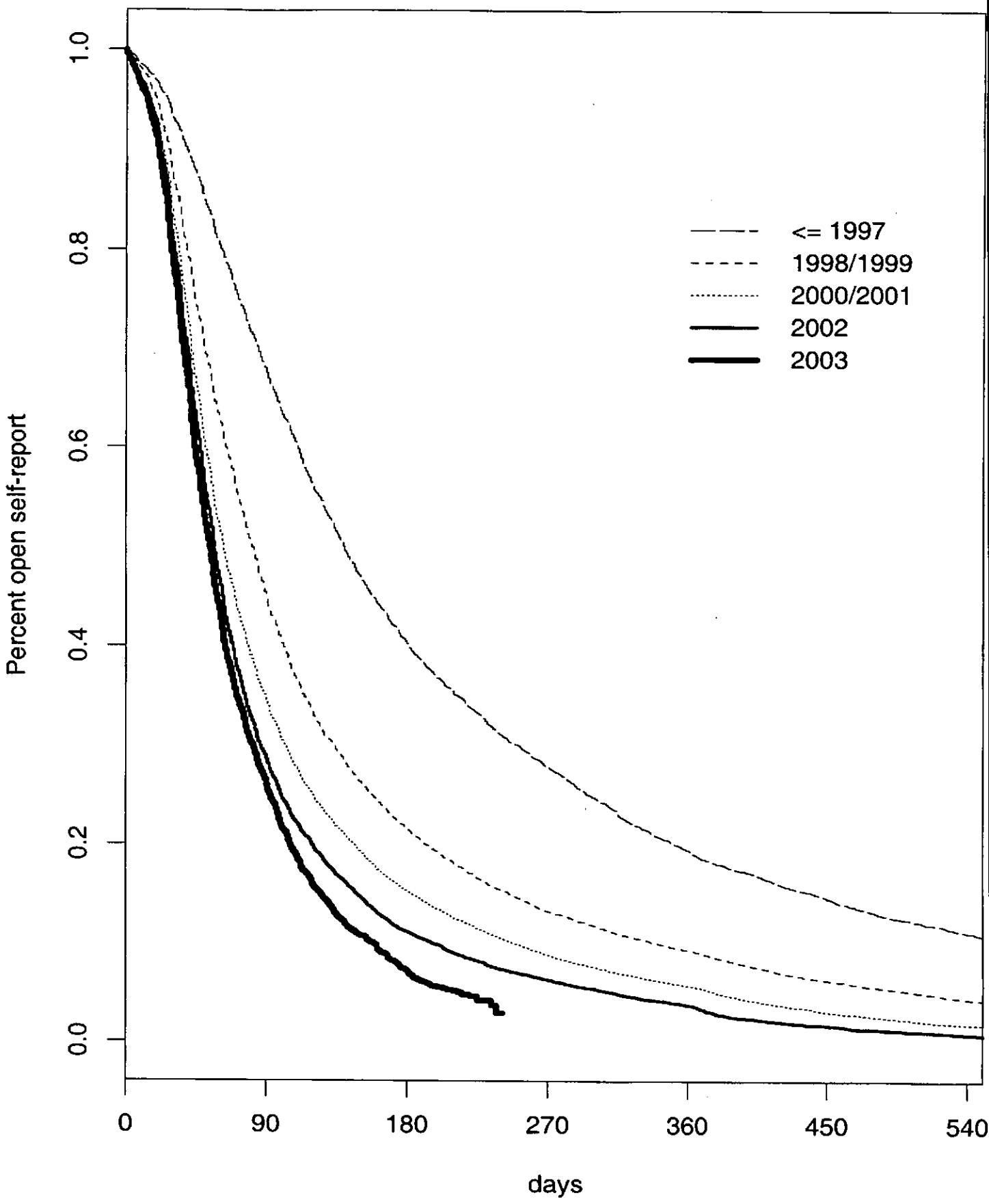


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: August 31, 2003

	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	1128	1072	95%	758	(71%)	170	(16%)	130	(12%)	14	(1%)
Angina[2]	2163	2085	96%	997	(48%)	96	(5%)	955	(46%)	37	(2%)
Congestive heart failure	766	736	96%	542	(74%)	42	(6%)	142	(19%)	10	(1%)
CABG/PTCA	2512	2392	95%	1894	(79%)	198	(8%)	271	(11%)	29	(1%)
Carotid artery disease[3]	334	316	95%	268	(85%)	24	(8%)	20	(6%)	4	(1%)
Stroke/TIA[4]	1883	1783	95%	1376	(77%)	82	(5%)	298	(17%)	27	(2%)
PVD	244	235	96%	136	(58%)	30	(13%)	64	(27%)	5	(2%)
DVT[5]	373	352	94%	240	(68%)	47	(13%)	57	(16%)	8	(2%)
Pulmonary embolism[5]	182	166	91%	141	(85%)	8	(5%)	16	(10%)	1	(1%)
Cancers											
Breast cancer	2339	2245	96%	2168	(97%)	1	(<1%)	64	(3%)	12	(1%)
Ovarian cancer	215	209	97%	153	(73%)	39	(19%)	11	(5%)	6	(3%)
Endometrial cancer	274	266	97%	207	(78%)	33	(12%)	23	(9%)	3	(1%)
Colorectal cancer	615	584	95%	506	(87%)	35	(6%)	41	(7%)	2	(<1%)
Other cancer[6]	2562	2432	95%	1837	(76%)	131	(5%)	422	(17%)	42	(2%)
Fractures											
Hip fracture	565	530	94%	433	(82%)	43	(8%)	49	(9%)	5	(1%)
Vertebral fracture	903	856	95%	472	(55%)	34	(4%)	323	(38%)	27	(3%)
Other fracture	7313	7079	97%	5793	(82%)	78	(1%)	1022	(14%)	186	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 250 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 415 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, 2003

	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	1097	1038	95%	702	(68%)	177	(17%)	138	(13%)	21	(2%)
Angina[2]	2528	2416	96%	1085	(45%)	153	(6%)	1127	(47%)	51	(2%)
Congestive heart failure	957	900	94%	676	(75%)	53	(6%)	154	(17%)	17	(2%)
CABG/PTCA	2827	2679	95%	2064	(77%)	255	(10%)	314	(12%)	46	(2%)
Carotid artery disease[3]	398	381	96%	313	(82%)	33	(9%)	30	(8%)	5	(1%)
Stroke/TIA[4]	2290	2134	93%	1562	(73%)	90	(4%)	421	(20%)	61	(3%)
PVD	340	323	95%	187	(58%)	41	(13%)	88	(27%)	7	(2%)
Cancers											
Breast cancer	3376	3212	95%	2946	(92%)	16	(<1%)	202	(6%)	48	(1%)
Ovarian cancer	298	286	96%	199	(70%)	47	(16%)	38	(13%)	2	(1%)
Endometrial cancer	368	350	95%	271	(77%)	49	(14%)	23	(7%)	7	(2%)
Colorectal	711	686	96%	578	(84%)	39	(6%)	56	(8%)	13	(2%)
Other cancer[5]	3504	3288	94%	2271	(69%)	229	(7%)	697	(21%)	91	(3%)
Fractures											
Hip fracture	782	725	93%	572	(79%)	5	(1%)	129	(18%)	19	(3%)
Vertebral fracture	115	108	94%	69	(64%)	6	(6%)	27	(25%)	6	(6%)
Other fracture	816	791	97%	584	(74%)	15	(2%)	156	(20%)	36	(5%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 253 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, 8 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 505 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, 2003

	Locally confirmed N	Called forward for central adjudication N	% [1]	Centrally adjudicated N	% [2]	In agreement N	% [3]
Cardiovascular							
Clinical MI	1226	927	76%	870	94%	784	90%
Angina [4]	1960	1555	79%	1471	95%	1124	76%
Congestive heart failure	1198	897	75%	827	92%	641	78%
CABG/PTCA	2034	1542	76%	1448	94%	1405	97%
DVT [5]	309	309	100%	297	96%	287	97%
Pulmonary embolism [5]	193	193	100%	189	98%	187	99%
Stroke	1125	552	49%	493	89%	448	91%
Cancers							
Breast cancer	2193	2193	100%	2114	96%	2109	100%
Invasive	1728	1728	100%	1662	96%	1627	98%
Non-invasive	465	465	100%	452	97%	390	86%
Ovarian cancer	188	188	100%	179	95%	145	81%
Endometrial cancer	266	266	100%	257	97%	246	96%
Colorectal cancer	562	562	100%	550	98%	532	97%
Fractures							
Hip fracture	532	532	100%	423	80%	397	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.

Table 6.6
Agreement of Central Adjudications with Local Adjudications — OS Participants

Data as of: August 31, 2003

	Locally confirmed N	Called forward for central adjudication N	% [1]	Centrally adjudicated N	% [2]	In agreement N	% [3]
Cardiovascular							
Clinical MI	1336	753	56%	703	93%	579	82%
Angina [4]	2240	1429	64%	1362	95%	1074	79%
Congestive heart failure	1592	862	54%	789	92%	631	80%
CABG/PTCA	2290	1344	59%	1265	94%	1211	96%
Cancers							
Breast cancer	3035	3035	100%	2915	96%	2858	98%
Invasive	2483	2483	100%	2377	96%	2269	95%
Non-Invasive	552	552	100%	538	97%	430	80%
Ovarian cancer	252	252	100%	232	92%	195	84%
Endometrial cancer	384	384	100%	362	94%	338	93%
Colorectal cancer	645	645	100%	621	96%	586	94%
Fractures							
Hip fracture	708	708	100%	555	78%	537	97%

[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, 2003

	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	882	770	87%	106	12%	6	1%	107
Angina	1402	1110	79%	273	19%	19	1%	N/A
Congestive heart failure	735	624	85%	106	14%	5	1%	N/A
CABG/PTCA	1446	1387	96%	55	4%	4	0%	N/A
DVT	295	285	97%	7	2%	3	1%	70
Pulmonary embolism	194	187	96%	3	2%	4	2%	14
Stroke	485	441	91%	27	6%	17	4%	285
Cancers								
Breast cancer	2121	2113	100%	3	0%	5	0%	78
Ovarian cancer	156	145	93%	8	5%	3	2%	21
Endometrial cancer	271	245	90%	24	9%	2	1%	29
Colorectal cancer	541	531	98%	4	1%	6	1%	60
Fractures								
Hip fracture	411	397	97%	7	2%	7	2%	58

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

Data as of: August 31, 2003

	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	702	565	80%	134	19%	3	0%	72
Angina	1332	1082	81%	239	18%	11	1%	N/A
Congestive heart failure	708	622	88%	82	12%	4	1%	N/A
CABG/PTCA	1249	1193	96%	52	4%	4	0%	N/A
Cancers								
Breast cancer	2882	2862	99%	3	0%	17	1%	147
Ovarian cancer	205	195	95%	8	4%	2	1%	48
Endometrial cancer	384	337	88%	42	11%	5	1%	35
Colorectal cancer	596	586	98%	4	1%	6	1%	81
Fractures								
Hip fracture	547	537	98%	2	0%	8	1%	85

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

Data as of: August 31, 2003

	Closed Local[1]	Closed Central		Confirmed Cause		Related Cause		Unrelated Cause	
		N	%	N	%[2]	N	%[2]	N	%[2]
Final adjudicated death	2203	1993	90%	1775	(89%)	112	(6%)	106	(5%)
Cardiovascular									
Atherosclerotic cardiac[3]	344	311	90%	291	(94%)	9	(3%)	11	(4%)
Cerebrovascular	163	146	90%	137	(94%)	3	(2%)	6	(4%)
Pulmonary embolism	15	13	87%	13	(100%)	0	(0%)	0	(0%)
Other cardiovascular	129	103	80%	68	(66%)	24	(23%)	11	(11%)
Unknown cardiovascular	32	26	81%	3	(12%)	16	(62%)	7	(27%)
Total cardiovascular deaths	683	599	88%	512	(85%)	52	(9%)	35	(6%)
Cancer									
Breast cancer	47	42	89%	41	(98%)	1	(2%)	0	(0%)
Ovarian cancer	84	81	96%	73	(90%)	7	(9%)	1	(1%)
Endometrial cancer	10	10	100%	9	(90%)	1	(10%)	0	(0%)
Colorectal cancer	103	97	94%	96	(99%)	0	(0%)	1	(1%)
Other cancer	750	710	95%	686	(97%)	18	(3%)	6	(1%)
Unknown cancer site	44	42	95%	29	(69%)	12	(29%)	1	(2%)
Total cancer deaths	1038	982	95%	934	(95%)	39	(4%)	9	(1%)
Accident/injury									
Homicide	5	5	100%	4	(80%)	1	(20%)	0	(0%)
Accident	59	53	90%	48	(91%)	4	(8%)	1	(2%)
Suicide	10	7	70%	7	(100%)	0	(0%)	0	(0%)
Other injury	6	4	67%	0	(0%)	3	(75%)	1	(25%)
Total accidental deaths	80	69	86%	59	(86%)	8	(12%)	2	(3%)
Other									
Other known cause	331	282	85%	239	(85%)	5	(2%)	38	(13%)
Unknown cause	71	61	86%	31	(51%)	8	(13%)	22	(36%)
Total deaths - other causes	402	343	85%	270	(79%)	13	(4%)	60	(17%)

[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 <u>All OS Participants</u>

Data as of: August 31, 2003

	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	3420	2036	60%	1653	(81%)	168	(8%)	215	(11%)
Cardiovascular									
Atherosclerotic cardiac[3]	446	276	62%	218	(79%)	20	(7%)	38	(14%)
Cerebrovascular	259	132	51%	117	(89%)	5	(4%)	10	(8%)
Pulmonary embolism	29	14	48%	10	(71%)	0	(0%)	4	(29%)
Other cardiovascular	213	135	63%	58	(43%)	55	(41%)	22	(16%)
Unknown cardiovascular	40	26	65%	1	(4%)	17	(65%)	8	(31%)
Total cardiovascular deaths	987	583	59%	404	(69%)	97	(17%)	82	(14%)
Cancer									
Breast cancer	228	126	55%	118	(94%)	4	(3%)	4	(3%)
Ovarian cancer	115	67	58%	61	(91%)	4	(6%)	2	(3%)
Endometrial cancer	35	17	49%	12	(71%)	5	(29%)	0	(0%)
Colorectal cancer	133	87	65%	80	(92%)	3	(3%)	4	(5%)
Other cancer	1021	645	63%	599	(93%)	21	(3%)	25	(4%)
Unknown cancer site	88	60	68%	44	(73%)	15	(25%)	1	(2%)
Total cancer deaths	1620	1002	62%	914	(91%)	52	(5%)	36	(4%)
Accident/injury									
Homicide	7	5	71%	5	(100%)	0	(0%)	0	(0%)
Accident	73	52	71%	44	(85%)	2	(4%)	6	(12%)
Suicide	20	17	85%	14	(82%)	1	(6%)	2	(12%)
Other injury	5	3	60%	2	(67%)	1	(33%)	0	(0%)
Total accidental deaths	105	77	73%	65	(84%)	4	(5%)	8	(10%)
Other									
Other known cause	575	290	50%	232	(80%)	4	(1%)	54	(19%)
Unknown cause	133	84	63%	38	(45%)	11	(13%)	35	(42%)
Total deaths - other causes	708	374	53%	270	(72%)	15	(4%)	89	(24%)

[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, 2003

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14663		31387		12894	
Mean follow-up (months)	78.2		84.6		80.8		76.5		74.9	
Cardiovascular										
CHD[1]	1565	(0.35%)	81	(0.13%)	171	(0.17%)	715	(0.36%)	598	(0.74%)
CHD death[2]	390	(0.09%)	16	(0.02%)	32	(0.03%)	160	(0.08%)	182	(0.23%)
Total MI[3]	1303	(0.29%)	68	(0.10%)	146	(0.15%)	604	(0.30%)	485	(0.60%)
Clinical MI	1235	(0.28%)	61	(0.09%)	139	(0.14%)	574	(0.29%)	461	(0.57%)
Evolving Q-wave MI[4]	70	(0.02%)	7	(0.01%)	7	(0.01%)	32	(0.02%)	24	(0.03%)
Possible evolving Q-wave MI[4]	282	(0.06%)	32	(0.05%)	43	(0.04%)	117	(0.06%)	90	(0.11%)
Angina	1941	(0.44%)	95	(0.15%)	258	(0.26%)	968	(0.48%)	620	(0.77%)
CABG/PTCA	2034	(0.46%)	85	(0.13%)	245	(0.25%)	1033	(0.52%)	671	(0.83%)
Carotid artery disease	339	(0.08%)	10	(0.02%)	38	(0.04%)	174	(0.09%)	117	(0.15%)
Congestive heart failure	1198	(0.27%)	56	(0.09%)	128	(0.13%)	512	(0.26%)	502	(0.62%)
Stroke	1164	(0.26%)	47	(0.07%)	107	(0.11%)	526	(0.26%)	484	(0.60%)
PVD	303	(0.07%)	12	(0.02%)	33	(0.03%)	144	(0.07%)	114	(0.14%)
CHD[1]/Possible evolving Q-wave MI	1834	(0.41%)	113	(0.17%)	213	(0.22%)	827	(0.41%)	681	(0.85%)
Coronary disease[5]	4475	(1.01%)	242	(0.37%)	553	(0.56%)	2133	(1.07%)	1547	(1.92%)
Total cardiovascular disease	5860	(1.32%)	299	(0.46%)	686	(0.69%)	2807	(1.40%)	2068	(2.57%)
Cancer										
Breast cancer	2206	(0.50%)	234	(0.36%)	474	(0.48%)	1050	(0.52%)	448	(0.56%)
Invasive breast cancer	1770	(0.40%)	174	(0.27%)	387	(0.39%)	845	(0.42%)	364	(0.45%)
Non-invasive breast cancer	446	(0.10%)	62	(0.10%)	89	(0.09%)	210	(0.10%)	85	(0.11%)
Ovary cancer	187	(0.04%)	16	(0.02%)	40	(0.04%)	88	(0.04%)	43	(0.05%)
Endometrial cancer[6]	280	(0.11%)	25	(0.07%)	60	(0.10%)	138	(0.12%)	57	(0.13%)
Colorectal cancer	560	(0.13%)	32	(0.05%)	79	(0.08%)	283	(0.14%)	166	(0.21%)
Other cancer[7]	2191	(0.49%)	176	(0.27%)	353	(0.36%)	1051	(0.53%)	611	(0.76%)
Total cancer	5236	(1.18%)	471	(0.73%)	973	(0.99%)	2514	(1.26%)	1278	(1.59%)
Fractures										
Hip fracture	520	(0.12%)	10	(0.02%)	33	(0.03%)	185	(0.09%)	292	(0.36%)
Vertebral fracture	572	(0.13%)	20	(0.03%)	64	(0.06%)	238	(0.12%)	250	(0.31%)
Other fracture[7]	6055	(1.36%)	717	(1.11%)	1124	(1.14%)	2829	(1.41%)	1385	(1.72%)
Total fracture	6872	(1.55%)	743	(1.15%)	1204	(1.22%)	3137	(1.57%)	1788	(2.22%)
Deaths										
Cardiovascular deaths	729	(0.16%)	25	(0.04%)	56	(0.06%)	297	(0.15%)	351	(0.44%)
Cancer deaths	1102	(0.25%)	63	(0.10%)	142	(0.14%)	535	(0.27%)	362	(0.45%)
Other known cause	415	(0.09%)	25	(0.04%)	47	(0.05%)	176	(0.09%)	167	(0.21%)
Unknown cause	136	(0.03%)	8	(0.01%)	13	(0.01%)	62	(0.03%)	53	(0.07%)
Not yet adjudicated	130	(0.03%)	8	(0.01%)	20	(0.02%)	47	(0.02%)	55	(0.07%)
Total death	2511	(0.57%)	129	(0.20%)	277	(0.28%)	1117	(0.56%)	988	(1.23%)

[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, 2003

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)	76.4	74.8	76.9	74.3	78.8	74.0
Cardiovascular						
CHD[1]	4 (0.22%)	19 (0.20%)	165 (0.37%)	29 (0.16%)	1324 (0.36%)	24 (0.41%
CHD death[2]	2 (0.11%)	6 (0.06%)	66 (0.15%)	5 (0.03%)	306 (0.08%)	5 (0.09%
Total MI[3]	3 (0.16%)	18 (0.19%)	119 (0.27%)	26 (0.15%)	1115 (0.31%)	22 (0.38%
Clinical MI	3 (0.16%)	17 (0.18%)	115 (0.26%)	26 (0.15%)	1054 (0.29%)	20 (0.35%
Evolving Q-wave MI[4]	0 (0.00%)	1 (0.01%)	4 (0.01%)	0 (0.00%)	63 (0.02%)	2 (0.03%
Possible evolving Q-wave MI[4]	2 (0.11%)	9 (0.10%)	32 (0.07%)	10 (0.06%)	226 (0.06%)	3 (0.05%
Angina	7 (0.38%)	26 (0.27%)	238 (0.53%)	62 (0.35%)	1582 (0.43%)	26 (0.45%
CABG/PTCA	5 (0.27%)	17 (0.18%)	188 (0.42%)	50 (0.28%)	1750 (0.48%)	24 (0.41%
Carotid artery disease	3 (0.16%)	2 (0.02%)	24 (0.05%)	3 (0.02%)	305 (0.08%)	2 (0.03%
Congestive heart failure	4 (0.22%)	12 (0.13%)	188 (0.42%)	32 (0.18%)	946 (0.26%)	16 (0.28%
Stroke	7 (0.38%)	25 (0.26%)	147 (0.33%)	32 (0.18%)	936 (0.26%)	17 (0.29%
PVD	3 (0.16%)	2 (0.02%)	42 (0.09%)	4 (0.02%)	249 (0.07%)	3 (0.05%
CHD[1]/Possible evolving Q-wave MI	6 (0.32%)	27 (0.29%)	196 (0.44%)	39 (0.22%)	1539 (0.42%)	27 (0.47%
Coronary disease[5]	16 (0.86%)	57 (0.60%)	542 (1.21%)	123 (0.69%)	3677 (1.01%)	60 (1.04%
Total cardiovascular disease	25 (1.35%)	83 (0.88%)	699 (1.56%)	159 (0.89%)	4816 (1.32%)	78 (1.35%
Cancer						
Breast cancer	6 (0.32%)	55 (0.58%)	162 (0.36%)	59 (0.33%)	1903 (0.52%)	21 (0.36%
Invasive breast cancer	6 (0.32%)	41 (0.43%)	128 (0.29%)	48 (0.27%)	1530 (0.42%)	17 (0.29%
Non-invasive breast cancer	0 (0.00%)	14 (0.15%)	34 (0.08%)	11 (0.06%)	383 (0.11%)	4 (0.07%
Ovary cancer	1 (0.05%)	3 (0.03%)	13 (0.03%)	3 (0.02%)	163 (0.04%)	4 (0.07%
Endometrial cancer[6]	1 (0.12%)	3 (0.05%)	14 (0.07%)	8 (0.08%)	249 (0.11%)	5 (0.15%
Colorectal cancer	5 (0.27%)	11 (0.12%)	59 (0.13%)	21 (0.12%)	455 (0.12%)	9 (0.16%
Other cancer[7]	9 (0.48%)	33 (0.35%)	159 (0.36%)	52 (0.29%)	1913 (0.52%)	25 (0.43%
Total cancer	22 (1.18%)	102 (1.08%)	393 (0.88%)	135 (0.76%)	4524 (1.24%)	60 (1.04%
Fractures						
Hip fracture	1 (0.05%)	4 (0.04%)	14 (0.03%)	8 (0.04%)	488 (0.13%)	5 (0.09%
Vertebral fracture	2 (0.11%)	11 (0.12%)	7 (0.02%)	6 (0.03%)	541 (0.15%)	5 (0.09%
Other fracture[7]	23 (1.24%)	94 (0.99%)	337 (0.75%)	156 (0.88%)	5385 (1.48%)	60 (1.04%
Total fracture	25 (1.35%)	108 (1.14%)	354 (0.79%)	166 (0.93%)	6151 (1.69%)	68 (1.17%
Deaths						
Cardiovascular deaths	6 (0.32%)	14 (0.15%)	110 (0.25%)	10 (0.06%)	582 (0.16%)	7 (0.12%
Cancer deaths	7 (0.38%)	20 (0.21%)	98 (0.22%)	30 (0.17%)	933 (0.26%)	14 (0.24%
Other known cause	5 (0.27%)	2 (0.02%)	56 (0.13%)	6 (0.03%)	343 (0.09%)	3 (0.05%
Unknown cause	1 (0.05%)	0 (0.00%)	19 (0.04%)	8 (0.04%)	106 (0.03%)	2 (0.03%
Not yet adjudicated	0 (0.00%)	3 (0.03%)	11 (0.02%)	6 (0.03%)	107 (0.03%)	3 (0.05%
Total death	19 (1.02%)	39 (0.41%)	294 (0.66%)	59 (0.33%)	2071 (0.57%)	29 (0.50%

[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, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14663	31387	12894
Mean follow-up (months)	78.2	84.6	80.8	76.5	74.9
Hospitalizations					
Ever	29713 (6.69%)	2947 (4.55%)	5299 (5.36%)	14180 (7.09%)	7287 (9.06%)
Two or more	14942 (3.36%)	1247 (1.92%)	2362 (2.39%)	7117 (3.56%)	4216 (5.24%)
Other					
DVT[1]	654 (0.15%)	38 (0.06%)	95 (0.10%)	299 (0.15%)	222 (0.29%)
Pulmonary embolism	395 (0.09%)	23 (0.04%)	55 (0.06%)	203 (0.10%)	114 (0.14%)
Diabetes (treated)	4142 (0.98%)	564 (0.90%)	862 (0.91%)	1918 (1.01%)	798 (1.05%)
Gallbladder disease[2]	4397 (1.18%)	637 (1.11%)	996 (1.18%)	2056 (1.25%)	708 (1.09%)
Hysterectomy	1740 (0.67%)	221 (0.59%)	377 (0.61%)	843 (0.73%)	299 (0.66%)
Glaucoma	6024 (1.41%)	557 (0.87%)	1148 (1.19%)	2923 (1.52%)	1396 (1.88%)
Osteoporosis	12283 (2.93%)	1165 (1.84%)	2115 (2.21%)	5988 (3.19%)	3015 (4.19%)
Osteoarthritis[3]	10849 (5.48%)	1498 (3.11%)	2410 (3.57%)	4968 (4.25%)	1973 (4.88%)
Rheumatoid arthritis	3288 (0.77%)	438 (0.70%)	735 (0.77%)	1487 (0.78%)	628 (0.82%)
Intestinal polyps	8447 (2.05%)	981 (1.56%)	1733 (1.84%)	4245 (2.30%)	1488 (2.09%)
Lupus	577 (0.13%)	87 (0.14%)	134 (0.14%)	262 (0.13%)	94 (0.12%)
Kidney stones[3]	1423 (0.54%)	185 (0.37%)	297 (0.37%)	670 (0.40%)	271 (0.41%)
Cataracts[3]	17692 (7.45%)	1054 (2.06%)	2812 (3.56%)	9700 (6.50%)	4126 (8.88%)
Pills for hypertension	14587 (4.67%)	1807 (3.45%)	3030 (4.03%)	6783 (4.99%)	2967 (6.07%)

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)	76.4	74.8	76.9	74.3	78.8	74.0
Hospitalizations						
Ever	130 (7.00%)	444 (4.69%)	3071 (6.86%)	1003 (5.63%)	24686 (6.77%)	379 (6.55%)
Two or more	76 (4.09%)	180 (1.90%)	1584 (3.54%)	452 (2.54%)	12460 (3.42%)	190 (3.28%)
Other						
DVT[1]	2 (0.11%)	1 (0.01%)	61 (0.14%)	10 (0.06%)	573 (0.16%)	7 (0.12%)
Pulmonary embolism	4 (0.22%)	2 (0.02%)	35 (0.08%)	3 (0.02%)	346 (0.10%)	5 (0.09%)
Diabetes (treated)	21 (1.25%)	117 (1.32%)	736 (1.86%)	274 (1.65%)	2929 (0.83%)	65 (1.20%)
Gallbladder disease[2]	18 (1.32%)	69 (0.80%)	348 (0.87%)	198 (1.46%)	3701 (1.22%)	63 (1.28%)
Hysterectomy	5 (0.60%)	30 (0.49%)	106 (0.54%)	56 (0.56%)	1531 (0.70%)	12 (0.36%)
Glaucoma	31 (1.76%)	122 (1.34%)	801 (1.93%)	259 (1.51%)	4733 (1.35%)	78 (1.44%)
Osteoporosis	55 (3.12%)	305 (3.40%)	681 (1.58%)	492 (2.97%)	10582 (3.08%)	168 (3.11%)
Osteoarthritis[3]	57 (0.12%)	258 (0.38%)	1063 (0.91%)	542 (1.34%)	8758 (5.42%)	171 (6.82%)
Rheumatoid arthritis	24 (1.43%)	62 (0.68%)	575 (1.38%)	303 (1.78%)	2267 (0.64%)	57 (1.04%)
Intestinal polyps	42 (2.46%)	174 (2.00%)	885 (2.12%)	299 (1.76%)	6938 (2.05%)	109 (2.05%)
Lupus	5 (0.27%)	9 (0.10%)	74 (0.17%)	26 (0.15%)	456 (0.13%)	7 (0.12%)
Kidney stones[3]	10 (0.02%)	34 (0.04%)	135 (0.08%)	74 (0.11%)	1150 (0.54%)	20 (0.60%)
Cataracts[3]	76 (0.15%)	346 (0.44%)	1631 (1.09%)	660 (1.42%)	14743 (7.60%)	236 (7.75%)
Pills for hypertension	65 (5.38%)	311 (4.83%)	1455 (6.52%)	674 (5.06%)	11901 (4.48%)	181 (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, 2003

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	78.2		72.1	
Ppts with other cancer	2191	(0.49%)	2895	(0.51%)
Accessory sinus	0	(0.00%)	1	(<0.01%)
Adrenal gland	2	(<0.01%)	4	(<0.01%)
Anus	9	(<0.01%)	12	(<0.01%)
Appendix	3	(<0.01%)	7	(<0.01%)
Biliary tract, parts of (other/unspecified)	29	(0.01%)	25	(<0.01%)
Bladder	124	(0.03%)	163	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	6	(<0.01%)
Bones/joints/articular cartilage (other)	4	(<0.01%)	3	(<0.01%)
Brain	61	(0.01%)	65	(0.01%)
Cervix	41	(0.01%)	35	(0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	1	(<0.01%)
Connective/subcutaneous/soft tissues	19	(<0.01%)	32	(0.01%)
Endocrine glands, related structures	5	(<0.01%)	3	(<0.01%)
Esophagus	25	(0.01%)	25	(<0.01%)
Eye and adnexa	13	(<0.01%)	9	(<0.01%)
Genital organs	23	(0.01%)	17	(<0.01%)
Kidney	104	(0.02%)	131	(0.02%)
Larynx	11	(<0.01%)	9	(<0.01%)
Leukemia	98	(0.02%)	128	(0.02%)
Liver	25	(0.01%)	30	(0.01%)
Lung	436	(0.10%)	534	(0.09%)
Lymph nodes	12	(<0.01%)	9	(<0.01%)
Lymphoma,Hodgkins	12	(<0.01%)	13	(<0.01%)
Lymphoma,Non-Hodgkins	181	(0.04%)	262	(0.05%)
Melanoma of the skin	289	(0.07%)	387	(0.07%)
Multiple myeloma	81	(0.02%)	70	(0.01%)
Oral (mouth)	15	(<0.01%)	13	(<0.01%)
Palate	3	(<0.01%)	6	(<0.01%)
Pancreas	111	(0.02%)	130	(0.02%)
Parotid gland (Stensen's duct)	8	(<0.01%)	15	(<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	11	(<0.01%)	13	(<0.01%)
Salivary glands, major (other/unspecified)	2	(<0.01%)	9	(<0.01%)
Stomach	32	(0.01%)	35	(0.01%)
Thyroid	68	(0.02%)	78	(0.01%)
Tongue, part of (other/unspecified)	17	(<0.01%)	16	(<0.01%)
Urinary organs (other/unspecified)	6	(<0.01%)	16	(<0.01%)
Uterus, not otherwise specified	31	(0.01%)	58	(0.01%)
Other/unknown site of cancer	177	(0.04%)	224	(0.04%)
Other/unknown cancers reported on death form	154	(0.03%)	347	(0.06%)

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

Data as of: August 31, 2003

	CT		OS[1]	
Locally Verified				
Number of participants	68132		6365	
Mean follow-up time (months)	78.2		80.5	
Ppts with other fractures[2]	6055	(1.36%)	563	(1.32%)
Ankle	1087	(0.24%)	99	(0.23%)
Carpal bone(s) in wrist	152	(0.03%)	10	(0.02%)
Clavicle or collar bone	108	(0.02%)	10	(0.02%)
Elbow, not otherwise specified	18	(<0.01%)	1	(<0.01%)
Humerus, shaft/unspecified	65	(0.01%)	6	(0.01%)
Humerus, upper end	643	(0.14%)	50	(0.12%)
Humerus, lower end	73	(0.02%)	7	(0.02%)
Metacarpal bone(s)	210	(0.05%)	19	(0.04%)
Patella	272	(0.06%)	25	(0.06%)
Pelvis	239	(0.05%)	34	(0.08%)
Radius or ulna	1694	(0.38%)	172	(0.40%)
Sacrum and coccyx	74	(0.02%)	8	(0.02%)
Scapula	28	(0.01%)	4	(0.01%)
Shaft of femur	86	(0.02%)	7	(0.02%)
Tarsal/metatarsal bones	1024	(0.23%)	108	(0.25%)
Tibia and fibula	507	(0.11%)	28	(0.07%)
Tibial plateau	127	(0.03%)	9	(0.02%)
Upper radius/ulna	312	(0.07%)	30	(0.07%)
Unknown other fracture	1	(<0.01%)	0	(0.00%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			72.1	
Elbow			520	(0.09%)
Foot			1845	(0.33%)
Hand			340	(0.06%)
Knee			597	(0.11%)
Lower Arm			2640	(0.47%)
Lower Leg			2069	(0.37%)
Pelvis			482	(0.09%)
Tailbone			140	(0.02%)
Upper Arm			1092	(0.19%)
Upper Leg			282	(0.05%)
Vertebra			1191	(0.21%)
Other Fracture			2137	(0.38%)

[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, 2003

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	78.2		72.1	
Total death	2511	(0.57%)	3909	(0.69%)
Adjudicated death	2382	(0.54%)	3681	(0.65%)
Centrally adjudicated death	1988	(0.45%)	0	(0.00%)
Locally adjudicated death (final)	210	(0.05%)	3404	(0.60%)
Temporary adjudicated death	178	(0.04%)	261	(0.05%)
Identified by NDI search	6	(<0.01%)	16	(<0.01%)
Cardiovascular				
Atherosclerotic cardiac	390	(0.09%)	466	(0.08%)
CHD deaths adjudicated before 10/99	10	(<0.01%)	82	(0.01%)
Definite CHD deaths adjudicated after 10/99	186	(0.04%)	191	(0.03%)
Possible CHD deaths adjudicated after 10/99	194	(0.04%)	193	(0.03%)
Cerebrovascular	178	(0.04%)	269	(0.05%)
Pulmonary embolism	25	(0.01%)	29	(0.01%)
Other cardiovascular	118	(0.03%)	223	(0.04%)
Unknown cardiovascular	18	(<0.01%)	44	(0.01%)
Total cardiovascular deaths	729	(0.16%)	1031	(0.18%)
Cancer				
Breast cancer	54	(0.01%)	241	(0.04%)
Ovarian cancer	79	(0.02%)	119	(0.02%)
Endometrial cancer	11	(<0.01%)	35	(0.01%)
Colorectal cancer	105	(0.02%)	137	(0.02%)
Other cancer	799	(0.18%)	1069	(0.19%)
Unknown cancer site	54	(0.01%)	91	(0.02%)
Total cancer deaths	1102	(0.25%)	1692	(0.30%)
Accident/injury				
Homicide	5	(<0.01%)	7	(<0.01%)
Accident	61	(0.01%)	75	(0.01%)
Suicide	13	(<0.01%)	20	(<0.01%)
Other injury	6	(<0.01%)	5	(<0.01%)
Total accidental deaths	85	(0.02%)	107	(0.02%)
Other				
Other known cause	330	(0.07%)	603	(0.11%)
Unknown cause	136	(0.03%)	248	(0.04%)
Total deaths – other causes	466	(0.10%)	851	(0.15%)

Table 6.16
Results of NDI Search[1]

	Known dead[2]		Lost to follow-up[3]		Known alive[4]	
	N	%	N	%	N	%
Submitted to NDI	1252		2249		500	
NDI returned matches	1235	98.6	731	32.5	149	29.8
Matches satisfying WHI criteria	1224	97.8	53	2.4	0	0.0
Reported dead to WHI after 8/31/2000	N/A		29	1.3[5]	N/A	
Reported alive to WHI after 8/31/2000[6]	N/A		2	<1.0[7]	N/A	
Only identified using NDI	N/A		22	1.0[8]	N/A	

[1] Analysis has not been updated from that of August 31, 2001.
[2] Participants having a Form 120 or Form 124 with date of death before 1/1/2000.
[3] Participants who were lost-to-follow-up or no-follow-up by 8/31/2000, for whom contact was before 1/1/2000.
[4] Randomly selected participants with whom there was clinic contact after 1/1/2000.
[5] 2 of these participants were CT participants, 27 were OS participants.
[6] Not counted as dead in this report or DSMB report.
[7] 1 of these participants was a CT participant, 1 was an OS participant.
[8] 6 of these participants were CT participants, 16 were OS participants.

Table 6.17
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: August 31, 2003

	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	71	4.1	1596	92.8	13	0.8	0	0.0	24	1.4	16	0.9	1720
Birmingham	84	4.6	1669	91.1	36	2.0	0	0.0	24	1.3	19	1.0	1832
Bowman	60	3.9	1366	89.3	13	0.8	0	0.0	59	3.9	32	2.1	1530
Brigham	73	3.2	2169	94.3	19	0.8	0	0.0	1	0.0	39	1.7	2301
Buffalo	66	4.1	1496	93.5	10	0.6	0	0.0	27	1.7	1	0.1	1600
Chapel Hill	55	3.6	1449	94.2	2	0.1	0	0.0	31	2.0	1	0.1	1538
Chicago	68	4.2	1468	90.4	19	1.2	0	0.0	47	2.9	22	1.4	1624
Chi-Rush	55	4.2	1162	87.8	32	2.4	0	0.0	37	2.8	38	2.9	1324
Cincinnati	37	2.7	1293	93.0	6	0.4	0	0.0	49	3.5	5	0.4	1390
Columbus	58	3.7	1448	93.5	1	0.1	0	0.0	35	2.3	7	0.5	1549
Detroit	26	1.9	1199	86.9	12	0.9	2	0.1	107	7.8	33	2.4	1379
GWU-DC	44	2.9	1421	93.6	34	2.2	2	0.1	11	0.7	6	0.4	1518
Gainesville	75	3.6	1920	92.2	20	1.0	1	0.0	53	2.5	13	0.6	2082
Honolulu	41	2.9	1255	89.3	30	2.1	2	0.1	56	4.0	21	1.5	1405
Houston	32	2.5	1108	87.0	58	4.6	1	0.1	59	4.6	15	1.2	1273
Iowa City	94	3.9	2282	93.8	10	0.4	0	0.0	27	1.1	20	0.8	2433
Irvine	46	2.8	1470	90.6	11	0.7	0	0.0	64	3.9	31	1.9	1622
L.A.	60	3.6	1546	92.1	13	0.8	0	0.0	45	2.7	15	0.9	1679
La Jolla	92	4.3	1866	86.2	55	2.5	3	0.1	42	1.9	106	4.9	2164
Madison	34	2.2	1492	95.9	8	0.5	0	0.0	18	1.2	3	0.2	1555
Medlantic	63	4.2	1335	89.7	19	1.3	0	0.0	43	2.9	29	1.9	1489
Memphis	85	4.9	1573	90.5	3	0.2	0	0.0	72	4.1	5	0.3	1738
Miami	44	3.0	1245	83.7	16	1.1	0	0.0	61	4.1	122	8.2	1488
Milwaukee	54	3.3	1532	92.9	6	0.4	0	0.0	50	3.0	7	0.4	1649
Minneapolis	71	3.6	1869	94.0	24	1.2	0	0.0	23	1.2	2	0.1	1989
NY-City	68	3.6	1691	89.9	66	3.5	8	0.4	31	1.6	18	1.0	1882
Nevada	71	4.8	1374	93.0	8	0.5	0	0.0	18	1.2	6	0.4	1477
Newark	81	3.3	2190	89.6	56	2.3	1	0.0	83	3.4	34	1.4	2445
Oakland	53	3.4	1468	94.3	7	0.4	1	0.1	20	1.3	8	0.5	1557
Pawtucket	92	3.5	2450	92.6	20	0.8	0	0.0	61	2.3	23	0.9	2646
Pittsburgh	73	4.4	1528	92.2	26	1.6	0	0.0	29	1.8	1	0.1	1657
Portland	65	4.0	1464	89.5	40	2.4	0	0.0	34	2.1	33	2.0	1636
San Antonio	32	2.3	1234	88.7	11	0.8	0	0.0	97	7.0	17	1.2	1391
Seattle	80	4.4	1616	89.4	38	2.1	1	0.1	38	2.1	34	1.9	1807
Stanford	55	3.1	1625	92.9	8	0.5	0	0.0	46	2.6	15	0.9	1749
Stonybrook	48	3.5	1255	92.8	22	1.6	0	0.0	26	1.9	2	0.1	1353
Torrance	35	3.5	879	87.7	24	2.4	3	0.3	43	4.3	18	1.8	1002
Tucson	115	5.5	1822	86.9	19	0.9	0	0.0	104	5.0	36	1.7	2096
U.C. Davis	99	5.1	1728	89.3	43	2.2	2	0.1	37	1.9	26	1.3	1935
Worcester	56	3.4	1535	94.3	21	1.3	0	0.0	5	0.3	11	0.7	1628
Total	2511	3.7	62088	91.1	879	1.3	27	0.0	1737	2.5	890	1.3	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 6.18
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: August 31, 2003

	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	90	3.7	2307	93.7	41	1.7	0	0.0	10	0.4	15	0.6	2463
Birmingham	128	5.1	2204	87.1	105	4.2	0	0.0	55	2.2	37	1.5	2529
Bowman	86	3.9	2023	90.8	43	1.9	0	0.0	38	1.7	37	1.7	2227
Brigham	65	2.2	2719	92.3	95	3.2	0	0.0	1	0.0	66	2.2	2946
Buffalo	136	6.0	2053	91.3	33	1.5	0	0.0	21	0.9	5	0.2	2248
Chapel Hill	70	3.4	1976	94.9	15	0.7	0	0.0	17	0.8	5	0.2	2083
Chicago	82	4.3	1688	89.4	48	2.5	5	0.3	29	1.5	37	2.0	1889
Chi-Rush	101	4.9	1782	87.0	37	1.8	20	1.0	48	2.3	61	3.0	2049
Cincinnati	93	4.1	1979	88.0	56	2.5	10	0.4	52	2.3	59	2.6	2249
Columbus	76	3.4	2084	93.9	36	1.6	0	0.0	19	0.9	4	0.2	2219
Detroit	65	3.1	1831	86.7	63	3.0	2	0.1	84	4.0	67	3.2	2112
GWU-DC	91	4.0	2108	93.8	31	1.4	3	0.1	6	0.3	8	0.4	2247
Gainesville	120	4.3	2544	91.1	29	1.0	5	0.2	67	2.4	27	1.0	2792
Honolulu	58	2.7	1819	86.1	53	2.5	11	0.5	91	4.3	81	3.8	2113
Houston	110	5.2	1900	89.2	21	1.0	3	0.1	79	3.7	17	0.8	2130
Iowa City	98	3.1	2896	92.8	44	1.4	0	0.0	44	1.4	38	1.2	3120
Irvine	85	3.8	2030	91.0	22	1.0	1	0.0	55	2.5	37	1.7	2230
L.A.	80	3.6	2044	93.1	25	1.1	0	0.0	31	1.4	15	0.7	2195
La Jolla	189	5.5	2980	86.1	96	2.8	10	0.3	38	1.1	150	4.3	3463
Madison	85	4.3	1864	94.1	17	0.9	0	0.0	15	0.8	0	0.0	1981
Medlantic	93	4.2	1992	90.8	28	1.3	2	0.1	35	1.6	43	2.0	2193
Memphis	113	4.5	2152	85.5	109	4.3	3	0.1	100	4.0	39	1.6	2516
Miami	55	4.0	1030	75.0	76	5.5	1	0.1	34	2.5	178	13.0	1374
Milwaukee	78	3.5	2039	90.8	40	1.8	1	0.0	39	1.7	49	2.2	2246
Minneapolis	87	3.2	2490	91.3	67	2.5	1	0.0	33	1.2	49	1.8	2727
NY-City	121	4.2	2481	85.5	136	4.7	5	0.2	13	0.4	147	5.1	2903
Nevada	147	6.8	1989	91.5	13	0.6	0	0.0	18	0.8	7	0.3	2174
Newark	108	3.2	3008	89.2	119	3.5	9	0.3	71	2.1	58	1.7	3373
Oakland	101	4.9	1888	92.0	33	1.6	0	0.0	23	1.1	8	0.4	2053
Pawtucket	129	3.6	3185	88.8	101	2.8	105	2.9	48	1.3	20	0.6	3588
Pittsburgh	100	5.2	1673	87.3	56	2.9	0	0.0	63	3.3	25	1.3	1917
Portland	83	3.7	1981	88.8	76	3.4	1	0.0	37	1.7	54	2.4	2232
San Antonio	68	3.5	1680	86.5	61	3.1	0	0.0	106	5.5	27	1.4	1942
Seattle	94	5.7	1434	86.2	52	3.1	9	0.5	17	1.0	57	3.4	1663
Stanford	117	4.4	2423	90.8	64	2.4	2	0.1	56	2.1	7	0.3	2669
Stonybrook	70	3.5	1900	93.7	35	1.7	0	0.0	13	0.6	10	0.5	2028
Torrance	67	4.5	1310	87.2	40	2.7	9	0.6	39	2.6	38	2.5	1503
Tucson	171	6.1	2418	86.9	15	0.5	3	0.1	97	3.5	78	2.8	2782
U.C. Davis	113	5.0	2037	89.8	62	2.7	4	0.2	33	1.5	20	0.9	2269
Worcester	86	3.8	2084	93.1	48	2.1	1	0.0	15	0.7	5	0.2	2239
Total	3909	4.2	84025	89.7	2141	2.3	226	0.2	1690	1.8	1685	1.8	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. Laboratory Studies

7.1 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.

7.2 Status of Analyses

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 CT 6% subsample core analytes for baseline, Year 1, and Year 3 samples. Analysis of Year 6 bloods began in September 2002 and is ongoing. See *Table 7.1* 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.

DNA Extraction

DNA extraction for WHI is done by BioServe Biotechnologies, Laurel, MD. For each buffy coat sample, BioServe prepared up to four daughter aliquots containing 3 μg DNA each and divides the remaining DNA into parent aliquots containing up to 150 μg DNA each, depending on the quantity of DNA extracted. In September 2003, the Executive Committee approved a reduction in the standard amount of DNA available in the daughter aliquots from 3 μg to 1 μg. This change was made due to advancements in technology which have made it possible to use smaller amounts of DNA for genetic studies and a continuing commitment to conserve the precious resource of WHI biologic samples. The concentration of DNA remains the same at 50 ng/μl, with the daughter aliquots containing 20 μl rather than 60 μl sample. Ancillary studies approved before October 2003 for 3 μg DNA will be asked if they require the full 3 μg DNA or if they can reduce the sample to 1 μg. Those studies requiring 3-6 μg DNA will receive the requested amount.

To date, BioServe has completed the DNA extraction of over 4,600 samples, including all of the samples for the CVD Biomarker Case Control Study of CHD, Stroke, and VTE in the HT Clinical Trial and for AS #83 (Paul Ridker, "Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study). Extraction for AS #132 (Simon Liu, "A Prospective Study of Genetic and Biochemical Predictors of Type 2

Diabetes Mellitus") began in January 2003 and is ongoing, and extraction for AS # 108 (Henry Lin, "Gene-environment Effects and Colorectal Cancer") started in July 2003.

CVD Biomarker Case-Control Study of CHD, Stroke, and VTE in the HT Clinical Trial

This study is divided into two phases, with phase I including all locally adjudicated cases of CHD, stroke, and VTE occurring within two years of randomization and phase II including similar types of cases occurring more than two years after randomization. The University of Leiden was contracted to perform the DNA testing for the study, MRL to perform the lipid analyses, and the University of Vermont to perform the thrombosis assays. Results from 15 of the 20 assays have been received. Assay of APC-resistance is pending development of new test procedures and results of the remaining four second priority assays is pending review of the data received to date. This summer, glucose and insulin were added to the list of assays, and the Steering Committee approved adding eight additional polymorphisms. The CCC issued an RFP for laboratories to perform the DNA assays, and the selection of the DNA laboratory is expected to be made by the end of the year, with completion of assays expected in 2004. *Table 7.1* lists all the assays for this study and *Table 7.2* shows the number completed assays for the Estrogen-plus-Progestin and the E-alone cases and controls

Hormones

Esoterix (Calabasas Hills, CA; formerly Endocrine Sciences) has 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 7.1* for a list of the analytes. Final results were received in March 2003 and analyses of the data are on-going.

This summer the Laboratory Working Group recommended that the CCC identify a hormone laboratory with an estradiol assay that uses 0.5 ml sample or less. Evan Stein at MRL has agreed to provide quality control samples for the CCC to send to competing labs as part of the selection process. An RFP was issued in August and submitted proposals will be reviewed in November.

Ancillary Studies

Currently, 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. Three ancillary studies were reviewed for the Spring 2003 OS blood competition and six additional ancillary studies requesting blood specimens were reviewed for Fall 2003 OS blood competition. Through August 31, 2003, WHI has approved 22 ancillary studies using WHI blood specimens, with 15 funded, 4 pending funding, and 3 not yet submitted. *Table 7.3* gives a summary of the volume of OS blood samples committed to OS ancillary studies by disease type as of August 30, 2003. 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.

Analyses of blood samples for ancillary studies greatly increased over the last six months and are scheduled to increase further over the next year. Blood analyses for AS #105 (PI - Julie Mares-Perlman, "Carotenoids in Age-Related Eye Disease") began in December 2002, and is on going. Sample selection and laboratory testing of specimens for AS #129 (PI - Howard Strickler, "Association of Diabetes and Insulin-like Growth Factor-I with Risks of Colorectal, Breast, and Endometrial Cancers") began in March and completion of blood analyses is expected before the end of the year. In the last six months analyses also started for AS #132

(Simon Liu) and AS #134 (Francesmary Modugno, "Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer"). *Table 7.3* lists the approved ancillary studies by disease type and also lists the corresponding blood and DNA assays. *Table 9.2 – Ancillary Studies* lists additional key information about ancillary studies, including sample size and funding dates.

Table 7.1

Summary of WHI Blood Studies

Disease[1]	WHI or AS #	Title	Study PI	Analytes
CT Studies				
-	CT	Core analytes (6% at baseline, Y1, Y3, Y6, Y9)	-	Alpha-carotene, beta-carotene, alpha-tocopherol, gama-tocopherol, beta-cryptoxanthine, lutein+zeaxanthin, lycopene, retinol, glucose, insulin, FVII Ag, FVIIc, fibrinogen, cholesterol, triglyceride, HDL, T17HDL-2, HDL-3, LDL, Lp(a)
-	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)	-	Albumin, androstenedione, bioavailable estradiol, DHEA, DHES, DHT, estradiol, estrone, estrone-sulfate, progesterone, prolactin, SHBG, testosterone
-	CaD	Vitamin D (460 at Y3)	-	25-hydroxy vitamin D_3
CHD, Stroke, VTE	HT	CVD Biomarkers (400 CHD, 270 stroke, 222 VTE baseline and Y1)	-	APC resistance, ATIII, CRP, D-dimer, E-selectin, PAI-1 Ag, protein C, protein S total, protein S free, F1+2, FVII Ag, FVIIIc, FIXc, FXIc, fibrinogen, PAP, MMP-9, TAFI, IL-1 beta, TFB1, TGF-beta, glucose, insulin, cholesterol, HDL, triglyceride, LDL, LDL particle size (12 measures), Lp(a), homocysteine, vWF. **DNA:** FXII val34leu, FV-HR2, FV-Leiden, MTHFR, PT19911, PT20210, PAI-1, MTHFR, ERα-PvuII4, ERα-1989/G, ER β-1730A/G, ER β-CArepeats, GPIβα-Kob,a, GPIβα-VNTR, GPIIIα-P1A1-A2, Integrin α2-807C/T
OS Ancillary Studies				
CHD	83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	tPA, PAI-1, honocysteine, D-dimer, C-RP, IL-6, sICAM-1, F1+2; **DNA:** Polymorphisms associated with the markers including Factor V Leiden
CHD	110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	Free and total testosterone, Free and total estradiol, SHBG, DHES
CHD	137	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	**DNA:** GPIIIa PI (A1),(A2), GPIbα thr/met145, GPIbα VNTR B/C, Integrin α2 807 T/C, ER β CA dinucleotide repeat, ER β 846 G→A, ER β 1082 G→A, ER β 1730 A→G

Disease[1]	WHI or AS #	Title	Study PI	Analytes
CHD	**164**	The IGF System and Coronary Heart Disease[2]	Robert Kaplan	Total IGF-I, IGFBP-3
CHD	**165**	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke[1,2]	Katherine Hartmann	TSH, Free T4, TPO Ab
Stroke	**126**	Hormones and Biomarkers Predicting Stroke in Women	Sylvia Wassertheil-Smoller	CRP, IL-6, TNF alpha, VCAM-1, E-selectin, MMP-9, F1+2, PAI-1, t-PA, PAP, D-dimer, APC resistance, vWF, FVII antigen, FVII activity, fibrinogen, TC, triglycerides, HDL , Lp(a), glucose, insulin, homocysteine
Stroke	**165**	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke[1,2]	Katherine Hartmann	TSH, Free T4, TPO Ab
Hypertension	**133**	Biochemical and Genetic Markers of Hypertension in White and Black Women[2]	Howard Sesso	CRP, sICAM-1, IL-6, TNF-α, and IL-1β, AGT, ACE. **DNA:**, AT1R, α-adducin genes
Type II Diabetes Mellitus	**132**	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	TNF-R2, IL-6, CRP, ICAM-1, VCAM-1, E-selectin, insulin, glucose. **DNA:** PPAR-g2Pro12Ala, TNF alpha G308A, E-selectin ser128Arg, UCP2, CAPN10, AP2, NOS3
Osteoporosis (hip fracture)	**90**	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	Total and bioavailable estradiol, SHBG, IGF-1, Vit K. **DNA:** VDR FOKI, Coll A1 Sp1, ApoE4, TGF-beta, Leu10pro
Breast Cancer	**129** [3]	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	Glucose, insulin, IGF-1, IGF free, IGFBP-3, estradiol
Breast Cancer	**134**	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	2-OH estrone, 16a-OH estrone
Breast Cancer	**149**	Molecular Epidemiology and Prevention of Breast Cancer	Jennifer Hu	Fatty acid profile, lipid peroxidation. **DNA:** oxidative DNA damage, GSTM1/P1/T1 genotypes, DNA repair genes
Breast Cancer	**152** [3]	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA:** genes for IGF-1, IGF BP-3, insulin, insulin receptor substrate 1
Breast Cancer	**155**	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk[2]	Tom Rohan	Alpha-carotene, beta-carotene, cryptoxanthin, lutein, lyocopene+zeaxanthin, retinol, TGFB-1. **DNA:** polymorphisms of TGFB-1, TGFB receptor type I,II,III
Breast Cancer	**167**	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer[2]	Steve Cummings	SHBG, total estradiol, total testosterone

Disease[1]	WHI or AS #	Title	Study PI	Analytes
Colorectal Cancer	**108.1**	Gene-environment effects and colorectal cancer	Henry Lin	**DNA:** GSTM1 and GSTT1 null genotypes; PTGS2/Cox-2 Val511Ala mutation
Colorectal Cancer	**128**	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study[2]	Tom Weber	**DNA**: hMSH2, hMLH1, MSH7
Colorectal Cancer	**129** [3]	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	Glucose, insulin, IGF-1, IGFBP-3, estradiol
Colorectal Cancer	**152** [3]	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: genes for IGF-1, IGF BP-3, insulin, insulin receptor substrate 1
Endometrial Cancer	**128**	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study[2]	Tom Weber	**DNA**: hMSH2, hMLH1, MSH7
Endometrial Cancer	**129** [3]	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	Glucose, insulin, IGF-1, IGFBP-3, estradiol
Endometrial Cancer	**152** [3]	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: genes for IGF-1, IGF BP-3, insulin, insulin receptor substrate 1
Leukemia	**148**	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women[2]	Harvey Preisler	**DNA:** Clonality of hemoporesis, N-ras mutation, methylation of p15 gene
Ovarian Cancer	**97**	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	CA-125, M-CSF, OVX1
Ovarian Cancer	**121**	Hyperinsulinemia and Ovarian Cancer	Francesmary Modugno	Insulin, glucose, IGF-I, IGFBP-I, IGFBP-3
Ovarian Cancer	**128**	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study[2]	Tom Weber	**DNA**: hMSH2, hMLH1, MSH7

Disease[1]	WHI or AS #	Title	Study PI	Analytes
Pancreatic Cancer	**146**	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	B12, C-peptide, CYP1A1, folate, GST, homocysteine, IGF-I, IGF-II, IGFBP-1, IGFBP-3, insulin. **DNA:** NAT1, NAT2, MTHFR, PLP
Eye disease	**105**	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Alpha-carotene, beta-carotene, 9-cis-beta-carotene,13-cis-beta-carotene, alpha-tocopherol, cryptoxanthine, gama-tocopherol, lutein, lycopene, cis-lycopene, retinol, retinyl palmitatem, zeaxanthin, cholesterol, triglyceride

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

[2] Pending funding.

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

Table 7.2
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=156)	Baseline (N=229)	Year 1 (N=162)	Baseline (N=145)	Year 1 (N=104)	Baseline (N=145)	Year 1 (N=112)	Baseline (N=152)	Year 1 (N=87)	Baseline (N=152)	Year 1 (N=96)	Baseline (N=512)	Year 1 (N=359)
Inflamation														
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
IL6	220	148	224	154	140	96	143	109	-	-	146	90	500	342
ILB-1[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
MMP9	229	154	228	156	145	103	145	111	-	-	152	92	512	349
TGFB[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Thrombosis														
Antithrombin III	-	-	222	149	-	-	140	104	149	85	148	86	497	335
APC Resistance[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
D-dimer	226	153	227	155	142	101	145	110	150	86	152	90	511	344
TGFB[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Factor VIII	226	153	228	155	142	101	144	110	151	86	152	91	511	345
Factor IX Conc	-	-	226	-	-	-	144	-	150	-	151	-	508	-
Factor XI Conc[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
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
Other Analytes														
Glucose[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Homocysteine	228	153	228	155	143	101	145	109	152	86	151	92	511	345
Insulin[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
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
Polymorphisms														
Factor V Leiden	227		228		144		143		146		149		507	
Factor V-HR2	227		228		144		143		146		149		507	
MTHF	227		228		144		143		146		149		507	
PAI-1	227		228		144		143		146		149		507	
Prothrombin 20210	227		228		144		143		146		149		507	
Prothrombin 19911	227		228		144		143		146		149		507	
Factor XIII val34leu	227		228		144		143		146		149		507	
ER α - PvuII[6]	*		*		*		*		*		*		*	
ER α - 1989 T/G[6]	*		*		*		*		*		*		*	
ER β - 1730 A/G[6]	*		*		*		*		*		*		*	
ER β - CA repeats[6]	*		*		*		*		*		*		*	
GPIβα - Kob,a[6]	*		*		*		*		*		*		*	
GPIβα - VNTR[6]	*		*		*		*		*		*		*	
GPIIIα - P1(A1),(A2	*		*		*		*		*		*		*	
Integrin α2- 807 C/T	*		*		*		*		*		*		*	

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

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

[3] Assays not done, pending analyses of data received to date.

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

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

[6] Assays added in summer 2003, to be completed in 2004 after DNA lab is selected.

Table 7.2 (continued)
Number of Assays Completed in CVD Biomarker Study: E-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=116)	Baseline (N=173)	Year 1 (N=124)	Baseline (N=124)	Year 1 (N=74)	Baseline (N=127)	Year 1 (N=86)	Baseline (N=71)	Year 1 (N=49)	Baseline (N=71)	Year 1 (N=49)	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
ILB-1[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
MMP9	173	116	173	123	126	84	127	86	-	-	71	49	365	253
TGFB[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Thrombosis														
Antithrombin III	-	-	170	121	-	-	117	80	68	46	69	49	351	247
APC Resistance[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
D-dimer	172	115	172	123	126	83	126	86	70	47	71	49	364	253
TGFB[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Factor VIII	173	115	173	123	127	83	126	86	71	47	71	49	364	253
Factor IX Conc	-	-	172	-	-	-	125	-	71	-	70	-	361	-
Factor XI Conc[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
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
Other Analytes														
Glucose[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Homocysteine	173	115	173	124	126	83	127	85	71	47	71	49	365	253
Insulin[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
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
Polymorphisms														
Factor V Leiden	172		172		122		126		70		67		359	
Factor V-HR2	172		172		122		127		70		67		359	
MTHF	172		172		122		128		70		67		359	
PAI-1	172		172		122		129		70		67		359	
Prothrombin 20210	172		172		122		130		70		67		359	
Prothrombin 19911	172		172		122		131		70		67		359	
Factor XIII val34leu	172		172		128		132		70		67		359	
ER α - PvuII[6]	*		*		*		*		*		*		*	
ER α - 1989 T/G[6]	*		*		*		*		*		*		*	
ER β - 1730 A/G[6]	*		*		*		*		*		*		*	
ER β - CA repeats[6]	*		*		*		*		*		*		*	
GPIβα - Kob,a[6]	*		*		*		*		*		*		*	
GPIβα - VNTR[6]	*		*		*		*		*		*		*	
GPIIIα - P1(A1),(A2	*		*		*		*		*		*		*	
Integrin α2- 807 C/T	*		*		*		*		*		*		*	

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

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

[3] Assays not done, pending analyses of data received to date.

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

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

[6] Assays added in summer 2003, to be completed in 2004 after DNA lab is selected.

Table 7.3
OS Blood Committed to Ancillary Studies (AS)

Disease[1]	Cases reported as of 8-03	AS #	Cases committed[2]	Volume Committed (Baseline/Year 3)			
				Serum (ml)	Citrate Plasma (ml)	EDTA Plasma (ml)	DNA (μg)
CHD	1,659	83	650		1.0	0.5	3
		110	385	1.8[3]			
		137	1,060				3
		164	350			0.3	
		165	800	0.25			
Stroke	1,351	126	1,100		1.5	1.5	
		165	750	0.25			
Hypertension	17,180	133	800			0.8	3
Type II Diabetes	3,884	132	1,800			0.75	3
Hip Fracture	702	90	400	1.5			3
Breast Cancer	3,166	129	900[4]	0.25			
		134	200	0.3			
		149	800	0.2			3
		152	900[4]				3
		155	3,500	0.3			3
		167	400			1.0	
Colorectal Cancer	656	108	800				6
		128	684				6
		129	500[4]	0.25			
		152	500[4]				3
Endometrial Cancer	422	128	591				6
		129	300[4]	0.25			
		152	300[4]				3
Leukemia	128	148	59				3
Ovarian Cancer	267	97	264 baseline, 132 Yr 3	1.0 baseline, 1.0 Yr 3			
		121	200	0.5			
		128	282				6
Pancreatic Cancer	130	146	106			0.65	3
Eye Disease	See note 5	105	1,700	1.1			

[1] Some ancillary studies include cases from more than one disease
[2] Not all volume committed to all cases
[3] No more baseline sample available for selected cases
[4] AS 129 and AS 152 share cases and controls
[5] Determined by local ancillary study screening

8. Clinical Center Performance Monitoring

8.1 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.

8.2 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; Gerardo Heiss, Chapel Hill Clinical Center PI; Betty Caan, Oakland Clinical Center PI, Michelle Naughton, Steve Rapp, Sara Wilcox, CFC; and Barbara 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; Jacques Rossouw and Shari Ludlum, Project Office; and Charles Kooperberg, Bernedine Lund, and Lori Proulx-Burns, CCC. Both PMC groups discussed the option of recombining the two groups into one PMC, but it was felt this consolidation was somewhat premature. The issue will be discussed again as the CCs near close-out.

Since March 2003, the A&R PMC has streamlined its review of CCs to help CCs better focus on study priorities before closeout. In May, after approval from the Executive Committee, the A&R PMC sent a memo to the Steering Committee describing the changes in the review process. These changes included: 1) a PMC A&R subcommittee would review all CCs on a quarterly basis, using the latest quarterly database reports; 2) the reviews would focus on study wide A&R priorities (i.e., stop follow-up, lost-to-follow-up, absolutely no follow-up, undeliverable addresses, E-Alone and CaD study pill collections, and task completion rates for *Form 33 – Medical History Update*, *Form 60 – FFQ*, *Form 10/17 – HT/CaD Management and Safety*, and *Form 85 – Mammogram*); 3) lower performing CCs would receive targeted reviews and offers of A&R PMC assistance; and 4) higher performing CCs would receive a cursory review. The subcommittee also developed a summary spreadsheet to assist in the quarterly reviews of CCs.

In July, the A&R PMC held conference calls with four CCs. While it was noted that most CCs had already implemented changes to address problems areas discussed on the calls, CCs and the committee acknowledged that the calls were useful. The calls helped disseminate information to a broader range of CC staff and helped some CCs address their issues promptly. For future conference calls with CCs, the committee plans to query CCs before scheduling the calls to determine what actions the CCs have taken to better address issues specific to that CC.

Since March 1, the O-PMC held four 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.

During the same six-month period, the O-PMC also made changes in its review of CCs. In the letters to CCs, specific goals were listed for CCs. On its March 2003 conference call, the O-PMC agreed to reduce the number of committee calls to allow time to increase the number of targeted calls to CCs to 1-2 per month. During the same time, the committee held six targeted conference calls with CCs to discuss issues with outcomes processing in more detail and to provide direction and interim goals for improving performance. CCC outcomes staff also conducted outcomes-focused visits to two CCs following previous targeted conference calls with the CCs. In August, the CCC began plans to conduct up to three week-long visits to one CC to assist CC staff in decreasing a substantial backlog of outcomes cases. Additional targeted calls with two CCs with largest backlog of cases are being scheduled. Plans over the next six months include having CCC QA Liaisons visit 3-4 CCs having particular difficulty in processing outcomes efficiently.

The PMC report showing data as of August 31, 2003 is in *Tables 8.1-8.5.* The CCs also receive these tables quarterly.

Table 8.1
Performance Monitoring Committee Report
Data as of 8/31/03
DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Jul 02 - Aug 03[3]		Dec 02 - May 03		Cum Aug 03	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	12.7	1	10.8	1	85.8	3	8.1	2
Oakland	11.4	1	9.5	1	98.3	1	5.4	1
Iowa City	10.7	1	8.6	1	97.9	1	5.8	1
Madison	10.7	1	8.9	1	92.9	1	4.5	1
Columbus	10.6	1	9.4	1	93.8	1	7.5	2
Stanford	10.5	1	9.1	1	94.5	1	7.3	2
Milwaukee	10.4	1	8.5	2	96.1	1	5.9	1
Pittsburgh	10.3	1	8.0	2	90.9	2	5.9	1
Seattle	10.2	1	8.3	2	90.1	2	10.2	3
Minneapolis	10.2	1	8.9	1	91.0	2	7.5	2
GWU-DC	10.1	2	9.8	1	94.3	1	6.5	1
Irvine	9.7	2	8.6	1	90.5	2	7.9	2
Chicago	9.6	2	8.5	2	87.7	3	9.5	3
Portland	9.3	2	8.5	2	85.2	3	9.9	3
Worcester	9.1	2	8.5	2	95.0	1	6.2	1
Gainesville	9.1	2	7.7	2	90.7	2	6.8	1
Chapel Hill	9.0	2	8.1	2	91.8	2	5.8	1
Torrance	8.9	2	6.5	3	77.3	4	12.3	4
UC Davis	8.8	2	6.3	3	83.3	4	10.4	3
LA	8.6	2	6.5	3	91.6	2	9.9	3
Brigham	8.6	3	7.2	2	90.8	2	7.9	2
Pawtucket	8.5	3	7.0	3	91.4	2	8.7	2
Tucson	8.5	3	7.1	3	89.5	3	12.4	4
Buffalo	8.4	3	6.6	3	93.0	1	8.5	2
Memphis	8.3	3	6.2	3	90.0	2	11.7	3
Stony Brook	8.3	3	6.9	3	84.2	3	8.3	2
Chi-Rush	8.2	3	8.6	1	88.0	3	14.4	4
Bowman	8.1	3	6.5	3	83.3	4	12.0	4
Houston	8.1	3	6.7	3	89.2	3	10.9	3
Atlanta	8.1	3	7.4	2	80.0	4	7.0	1
Newark	8.0	4	5.6	4	80.9	4	11.6	3
Cincinnati	7.7	4	6.0	4	95.5	1	8.9	2
Honolulu	7.5	4	4.0	4	83.8	3	11.8	4
LaJolla	7.4	4	5.5	4	85.9	3	14.1	4
NYC	7.4	4	5.4	4	84.3	3	10.8	3
Detroit	7.0	4	6.0	4	80.4	4	14.2	4
Birmingham	6.6	4	5.7	4	83.3	4	10.9	3
San Antonio	6.0	4	5.3	4	82.1	4	14.1	4
MedStar	5.5	4	3.9	4	79.3	4	12.7	4
Miami	4.7	4	2.4	4	80.5	4	22.0	4
CC Average	**8.8**		**7.2**		**88.3**		**9.6**	
Ave F/U 6.6 yr	Design Assumption 11.6				Goal ≥ 90%		Design Assumption 18.2	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)
[2] Based on FFQs collected after randomization through AV8.
[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 8.2
Performance Monitoring Committee Report
Data as of 8/31/03
HT

	E-Alone Adherence Summary ≥ 80%				Task Completeness Dec 02 - May 03				% Stopped[5]	
	Average[1]		Jul 02 - Aug 03		Form 10[3]		Form 85[4]		Cum Aug 03	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	75.5	1	66.9	1	98.1	1	92.1	1	14.5	1
Iowa City	66.4	1	55.3	1	97.4	2	94.8	1	16.9	1
Pittsburgh	65.8	1	52.3	1	96.0	3	92.0	1	26.2	3
Minneapolis	64.3	1	56.9	1	97.4	2	90.9	2	16.4	1
Cincinnati	63.4	1	55.6	1	98.6	1	90.8	2	25.7	2
Stanford	61.8	1	54.8	1	97.0	2	83.9	3	18.8	1
LA	61.3	1	47.8	2	91.4	4	91.2	2	19.7	1
Portland	60.5	1	52.8	1	97.2	2	82.9	3	20.9	2
Nevada	60.2	1	54.3	1	98.8	1	87.7	2	26.0	3
Milwaukee	59.1	1	55.4	1	99.1	1	88.5	2	19.2	1
Brigham	57.4	2	53.4	1	99.6	1	89.6	2	16.6	1
Columbus	57.1	2	48.4	2	97.0	2	90.7	2	23.4	2
Chapel Hill	56.8	2	49.6	2	98.3	1	92.6	1	17.5	1
Pawtucket	56.1	2	49.4	2	98.5	1	93.7	1	26.4	3
Worcester	55.7	2	47.6	2	98.1	1	91.8	1	20.0	1
Gainesville	54.8	2	43.5	2	96.9	3	92.0	1	28.2	3
Honolulu	53.5	2	43.3	3	94.7	4	88.9	2	20.3	2
Birmingham	53.5	2	43.6	2	92.1	4	81.9	4	28.9	4
Chicago	52.7	2	49.2	2	99.2	1	91.9	1	23.1	2
Madison	51.3	2	41.4	3	97.3	2	93.5	1	22.9	2
GWU-DC	50.7	3	39.7	4	90.3	4	79.9	4	15.3	1
UC Davis	50.5	3	40.5	4	95.3	3	87.3	3	27.1	3
Seattle	50.5	3	43.8	2	94.9	3	70.3	4	27.3	3
Buffalo	49.6	3	41.4	3	98.3	1	91.1	2	26.0	3
Stony Brook	49.6	3	36.6	4	96.9	3	92.5	1	20.1	2
Chi-Rush	48.8	3	46.5	2	95.6	3	86.2	3	30.4	4
Bowman	48.5	3	40.8	3	97.2	2	83.8	3	26.8	3
Newark	48.0	3	42.1	3	93.2	4	83.1	3	21.4	2
Irvine	47.3	3	40.6	3	96.8	3	76.0	4	25.9	2
LaJolla	46.4	3	28.3	4	92.3	4	73.3	4	28.3	3
Torrance	45.8	4	43.4	3	88.9	4	78.0	4	25.9	3
Memphis	45.0	4	41.6	3	97.2	2	84.6	3	33.2	4
NYC	44.5	4	38.9	4	95.6	3	78.2	4	22.4	2
Atlanta	44.2	4	42.4	3	97.6	2	89.5	2	30.9	4
Tucson	43.6	4	40.4	4	96.8	3	82.6	3	33.7	4
San Antonio	43.1	4	40.8	3	96.1	3	83.9	3	31.8	4
Detroit	40.1	4	28.0	4	82.6	4	71.7	4	31.1	4
MedStar	35.1	4	32.0	4	97.7	2	87.0	3	30.5	4
Houston	31.1	4	25.1	4	89.7	4	71.4	4	36.4	4
Miami	26.0	4	21.4	4	91.9	4	74.8	4	36.0	4
CC Average	**52.2**		**44.8**		**96.1**		**86.2**		**24.5**	
Ave F/U 6.4 yr	-		-		Goal ≥ 90%		Goal ≥ 90%		Design Assump. 32.5	

[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 10 - HRT Management and Safety* is -3/+3 months from target date

[4] From *WHIP 1445-Task Completeness*, complete if mammogram date on *Form 85 - Mammogram* date is -12/+6 months from AV target date

[5] From *WHIP CCC750-HRT Intervention & F/U Status*; includes E-Alone stopped intervention (excludes E-plus-P stop intervention), stopped F/U, lost-to-F/U, and deaths as percent of all HT participants

Table 8.3
Performance Monitoring Committee Report
Data as of 8/31/03
CaD

	Adherence Summary ≥ 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Sep 02 - Aug 03		Dec 02 - May 03		Cum Aug 03	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.5	1	79.7	1	98.3	2	11.8	1
Iowa City	70.9	1	68.3	1	97.8	2	19.2	1
Stanford	70.8	1	71.5	1	97.9	2	23.4	2
Minneapolis	68.6	1	66.9	1	96.9	3	20.6	1
Nevada	67.1	1	68.7	1	99.5	1	22.1	1
Columbus	65.1	1	62.2	2	98.6	1	24.0	2
Chapel Hill	64.5	1	67.4	1	99.2	1	13.9	1
Gainesville	63.5	1	63.4	1	99.1	1	29.3	3
Portland	62.6	1	62.8	1	94.4	4	26.4	2
Chi-Rush	61.8	1	59.5	2	96.4	3	31.4	4
Milwaukee	61.7	2	62.1	2	99.4	1	21.8	1
Pittsburgh	61.2	2	61.4	2	96.6	3	30.0	3
Brigham	61.2	2	60.0	2	98.5	2	25.2	2
Pawtucket	60.8	2	62.3	1	99.2	1	22.2	1
Worcester	59.0	2	60.5	2	98.9	1	18.1	1
Cincinnati	58.7	2	64.4	1	98.8	1	29.3	3
Honolulu	58.2	2	56.6	3	96.7	3	32.4	4
Madison	58.0	2	57.8	3	97.5	3	22.3	1
Torrance	56.3	2	56.2	3	92.3	4	29.8	3
LA	56.2	2	54.9	3	95.5	4	26.9	2
Buffalo	56.1	3	61.9	2	99.4	1	21.9	1
GWU-DC	56.0	3	53.0	3	96.3	3	26.8	2
UC Davis	55.9	3	58.8	2	95.3	4	28.3	2
Birmingham	55.8	3	60.2	2	95.8	4	23.9	2
Bowman	55.4	3	57.9	3	97.0	3	29.1	3
Seattle	54.3	3	58.1	3	95.4	4	30.1	3
Stony Brook	54.2	3	51.7	4	98.4	2	32.7	4
Atlanta	52.8	3	58.4	2	98.5	2	27.0	2
Tucson	52.7	3	56.6	3	96.7	3	35.8	4
Chicago	52.4	3	54.4	3	98.8	1	32.2	4
San Antonio	51.7	4	53.9	3	98.2	2	30.8	3
LaJolla	50.3	4	46.8	4	95.9	3	29.5	3
Irvine	49.2	4	47.7	4	98.2	2	30.1	3
Newark	48.6	4	50.2	4	92.7	4	29.1	3
NYC	48.6	4	51.1	4	97.4	3	32.4	4
Memphis	48.5	4	50.5	4	98.3	2	38.8	4
Detroit	44.8	4	44.2	4	83.7	4	35.3	4
Houston	44.6	4	42.8	4	90.5	4	35.1	4
MedStar	44.0	4	48.3	4	98.4	2	25.8	2
Miami	32.4	4	37.7	4	92.6	4	46.4	4
CC Average	**57.4**		**58.2**		**96.9**		**27.1**	
Ave F/U 5.5 yr	-		-		Goal ≥ 90%		Design Assump. 26.4	

[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

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

Table 8.4
Performance Monitoring Committee Report
Data as of 8/31/03
OS

	% Stopped[1]	
	Cum Aug 03	
	%	Quartile
Chapel Hill	4.4	1
Brigham	4.5	1
Columbus	4.5	1
Stony Brook	4.6	1
GWU-DC	4.7	1
Atlanta	4.7	1
Worcester	4.7	1
Madison	5.0	1
Pawtucket	5.5	1
LA	5.7	1
Iowa City	5.8	2
Oakland	6.4	2
Minneapolis	6.5	2
Stanford	6.7	2
Newark	7.1	2
Buffalo	7.2	2
Bowman	7.2	2
UC Davis	7.3	2
Milwaukee	7.4	2
Gainesville	7.7	2
MedStar	7.8	3
Portland	7.8	3
Chicago	7.9	3
Nevada	7.9	3
Irvine	8.0	3
Birmingham	8.7	3
Cincinnati	9.2	3
Torrance	9.6	3
NYC	9.7	3
Houston	9.8	3
Pittsburgh	10.0	4
Seattle	10.1	4
Memphis	10.1	4
Detroit	10.3	4
San Antonio	10.4	4
Chi-Rush	10.8	4
Honolulu	10.9	4
LaJolla	10.9	4
Tucson	12.5	4
Miami	19.4	4
CC Average	**7.8**	
Ave F/U 6.0 yr	-	

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

Table 8.5
Performance Monitoring Committee Report
Data as of 8/31/03
OC

	Task Completeness						Outcomes Processing Sep 02 - Aug 03							
	CT Form 33[1] Dec 02 - May 03		OS Form 33[2] May 02 - Oct 02		Form 33D[3] Sept 02 – Aug 03		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
Chapel Hill	97.5	1	98.7	1	97.7	2	97.3	1	97.0	1	0.0	1	97.9	1
Buffalo	97.2	1	97.5	1	99.5	1	92.9	2	99.3	1	33.0	4	88.7	1
Nevada	97.0	1	98.3	1	96.2	3	92.0	2	83.5	3	13.0	1	89.3	1
Madison	96.9	1	98.4	1	94.2	3	92.3	2	60.4	4	12.2	1	88.5	2
Worcester	96.9	1	98.9	1	99.0	1	95.1	1	85.8	3	13.7	1	90.3	1
Brigham	96.8	1	94.2	2	98.7	1	92.7	2	73.0	4	9.2	1	82.1	3
Iowa City	96.5	1	96.6	2	93.2	4	92.1	2	78.4	3	26.4	3	80.0	3
Oakland	96.4	1	98.0	1	95.6	3	94.6	1	75.0	4	30.7	4	80.2	3
Milwaukee	96.2	1	94.7	2	93.5	4	95.2	1	96.1	2	12.5	1	82.4	2
Columbus	95.9	1	97.6	1	99.3	1	93.9	1	58.0	4	24.7	3	85.0	2
Stony Brook	95.8	2	98.0	1	97.9	2	91.9	3	92.3	2	20.5	2	84.6	2
Minneapolis	95.6	2	95.0	2	93.1	4	97.0	1	92.6	2	29.0	3	92.9	1
Atlanta	95.6	2	97.8	1	96.5	3	93.1	2	79.6	3	36.0	4	84.4	2
Pittsburgh	95.2	2	92.8	3	99.5	1	88.8	3	100.0	1	15.5	2	89.0	1
Stanford	95.2	2	96.1	2	99.0	1	93.4	1	82.8	3	26.7	3	82.2	2
Gainesville	94.9	2	94.1	2	98.5	2	92.6	2	99.7	1	16.0	2	91.3	1
Pawtucket	94.8	2	93.4	3	94.0	4	92.0	2	58.7	4	21.5	2	82.0	3
GWU-DC	94.7	2	97.9	1	92.6	4	84.7	4	100.0	1	28.8	3	80.3	3
Memphis	94.4	2	88.4	4	94.7	3	93.7	1	99.6	1	8.5	1	89.9	1
Cincinnati	94.1	2	92.8	3	99.8	1	99.4	1	100.0	1	7.6	1	97.2	1
Birmingham	94.0	3	92.0	3	98.3	2	88.2	3	97.4	1	32.2	4	78.5	3
Chicago	93.9	3	94.2	2	96.8	2	84.8	3	99.2	1	25.3	3	81.9	3
Irvine	92.6	3	94.1	2	95.7	3	88.9	3	95.8	2	21.7	2	78.4	3
MedStar	92.5	3	91.4	3	97.5	2	88.0	3	92.3	2	23.0	2	81.0	3
LA	92.2	3	96.8	2	95.5	3	89.0	3	87.9	3	21.0	2	52.3	4
Bowman	91.9	3	92.6	3	99.0	1	73.8	4	58.8	4	20.1	2	46.1	4
UC Davis	91.9	3	95.6	2	95.9	3	74.2	4	100.0	1	33.8	4	71.5	4
Seattle	91.5	3	89.4	4	99.1	1	93.3	1	89.2	3	14.1	1	83.3	2
Portland	91.2	3	92.9	3	96.6	2	73.4	4	86.9	3	41.3	4	68.8	4
Tucson	90.9	3	92.4	3	98.1	2	91.2	3	95.4	2	23.1	3	87.4	2
Chi-Rush	90.9	4	92.2	3	99.0	1	91.4	3	96.9	2	39.4	4	88.7	1
NYC	90.8	4	89.2	4	94.5	3	78.6	4	89.8	3	30.3	4	58.1	4
Newark	89.8	4	89.6	4	94.3	3	83.7	4	58.5	4	24.4	3	75.9	4
Honolulu	89.6	4	88.0	4	92.9	4	92.9	2	96.8	2	17.1	2	85.4	2
LaJolla	89.5	4	90.8	4	91.9	4	66.7	4	69.2	4	43.3	4	46.0	4
San Antonio	89.4	4	90.3	4	90.7	4	92.7	2	83.9	3	15.1	1	90.2	1
Houston	86.7	4	93.7	3	94.0	4	70.5	4	68.4	4	56.0	4	33.9	4
Detroit	85.0	4	86.9	4	96.8	2	73.9	4	94.3	2	30.1	3	72.7	4
Torrance	82.5	4	87.4	4	81.0	4	91.8	3	95.0	2	16.1	2	78.3	3
Miami	82.3	4	79.9	4	97.2	2	81.5	4	53.0	4	25.3	3	57.8	4
CC Ave	**93.1**		**93.6**		**96.1**		**88.9**		**85.6**		**25.1**		**79.7**	
Goals	≥ 95.2%		≥ 95.5%		≥ 96.4%		≥ 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

9. 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 9.1 – Publications presents current and proposed publications that have been approved by the Publications and Presentations Committee.

Table 9.2 – Ancillary Studies lists all ancillary study proposals received by the Design and Analysis Committee along with some key features of the studies and their current status.

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
	Outcomes ascertainment and adjudication methods in the Women's Health Initiative	Gen	**Curb**, McTiernan, Heckbert, Kooperberg, Stanford, Nevitt, Johnson, Proulx-Burns, Pastore L, Criqui, Daugherty.	11	Ann Epidemiol. 2003 Oct;13(9S):S122-S128.
	The Women's Health Initiative Observational Study: Baseline Characteristics of Participants and reliability of Baseline measures	Gen	**Langer**, White, Lewis, Kotchen, Hendrix, Trevisan.	11	Ann Epidemiol. 2003 Oct;13(9S):S107-S121.
	The Women's Health Initiative Calcium-Vitamin D trial: Overview and Baseline Characteristics of Participants	Gen	**Jackson**, LaCroix, Cauley, McGowan.	11	Ann Epidemiol. 2003 Oct;13(9S):S98-S106.
	The Women's Health Initiative Dietary Modification trial: Overview and Baseline Characteristics of Participants	Gen	**Ritenbaugh**, Patterson, Chlebowski, Caan, Fels-Tinker, Howard, Ockene.	11	Ann Epidemiol. 2003 Oct;13(9S):S87-S97.
	The Women's Health Initiative Postmenopausal Hormone Trials: Overview and Baseline Characteristics of Participants	Gen	**Stefanick**, Cochrane, Hsia, Barad, Liu, Johnson.	11	Ann Epidemiol. 2003 Oct;13(9S):S78-S86.
	The Women's Health Initiative Recruitment Methods and Results	Gen	**Hays**, Hunt, Hubbell, Anderson GL, Limacher, Allen, Rossouw.	11	Ann Epidemiol. 2003 Oct;13(9S):S18-S77.
	Implementation of the Women's Health Initiative Study Design	Gen	**Anderson GL**, Manson, Wallace, Lund, Hall, Davis, Shumaker, Wang, Stein, Prentice.	11	Ann Epidemiol. 2003 Oct;13(9S):S5-S17.
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

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	In press, Archives of Internal Medicine
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
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)
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

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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
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
60	WHIMS: a Trial of the Effect of Estrogen Therapy in Preventing and Slowing the Progression of Dementia	WHIMS	**Shumaker**, Bowen	11	Controlled Clinical Trials 19:604-621
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, Vigorous Exercise, and Incidence of Cardiovascular Disease in an Ethnically Diverse Cohort of Women	OS	**Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	11	N Engl J Med, Vol. 347, No. 10
67	Yogurt Consumption is Associated with Healthy Behaviors in Post-Menopausal Women	OS	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	11	Clinical Journal of Women's Health
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
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.

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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
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
93	Fat Intake in Husbands of Women in the Dietary Modification Component of the Women's Health Initiative	Gen	**Shikany**	11	Nutr Res, 2002;22:577-86
98	Antioxidant Use in the Women's Health Initiative Participants	Gen	**Shikany**, Patterson, Agurs-Collins, Anderson	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
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.
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 and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	CT	**Nelson**, Hendrix	11	J Bone Miner Res 2000; 15(10):1992-1997

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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
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
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
132	Second Malignancy and Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	Gen	**Rosenberg**, Greenland, Khandekar, Ascensao, Lopez	11	In press, Cancer
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	In press, JADA
138	Baseline Experience with the Modified Mini-Mental State Exam: The Women's Health Initiative Memory Study	WHIMS	**Rapp**, Espeland, Hogan, Jones, Dugan	11	In press: Aging and Mental Health
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 African-American and White Women	OS	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Hsia, Klouj	11	Am Heart J, 2003; 145 : 724-9
145	Breast Cancer and Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Prospective Results from the Women's Health Initiative	OS	**Harris**, Chlebowski, Jackson, Frid, Ascensao, Anderson, Sparks, Rodabough, White, McTiernan	11	Cancer Research 63, 6096-6101
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, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, Van Horn, Rodabough	11	JADA, April 2003, Vol 103, Number 4, p. 454-459
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	In press, Am J Epidemiology

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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.
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	In press, Amer Journal of OB/GYN
189	Dietary Adherence in the WHI Dietary Modification Trial	CT	**Patterson**, Prentice, Tinker, Perri, Parker, Mossavar-Rahmani, Rosal, Van Horn, Caan	11	In press, JADA
198	Aspects of the Management and Coordination of The Women's Health Initiative	Gen	**Cochrane**, Lund, Anderson S, 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.
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 the Women's Health Initiative	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
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.
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

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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.
224	Estimation of Dependence Between Paired Correlated Failure Times in the Presence of Covariate Measurement Error	OS	**Gorfine**, Hsu, Prentice	11	Journal of the Royal Statistical Society B. 65:633-661, 2002.
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
235	Hormone Replacement Therapy and Risk of Cardiovascular Disease	CT	**Kuller**	11	Arterioscler Thromb Vasc Biol. 2003;23: 11-16
240	Risks and benefits of estrogen plus 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	In press, Seminars in Oncology
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.
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	
61	WHI Halfway Paper (100K Paper)	Gen	**Langer**, Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	10	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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, Cochrane	10	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	Gen	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	10	
129	Thrombotic Markers for Coronary Heart Disease in Women	OS	**Pradhan**, LaCroix, Trevisan, Lewis, Langer, Hsia, Oberman, Kotchen, Ridker	10	
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	OS	**Margolis**, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	10	Submitted to JAMA
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	10	In press, Menopause
197	Predictors of Angina vs Myocardial Infarction: Prospective Analysis from the Women's Health Initiative	OS	**Hsia**, Rossouw, Brunner, LaCroix, Wallace	10	Submitted, Circulation
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	10	Submitted, Diabetes Care
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	10	Submitted, NEJM
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 J Clin Epidemiol
282	Improving Dietary Self-Monitoring and Adherence with Hand-Held Computers: A Pilot Study	CT	**Glanz**	10	Submitted, American Journal of Preventive Medicine
290	Abnormal Mammograms and Ultra Low Estrogen	CT	**Chlebowski**	10	Editorial, In press
294	Weighted Estimators for Proportional Hazards Regression with Missing Covariates	OS	**Qi**, Wang, Prentice	10	Submitted to JASA
16	Caloric Requirements and Dietary Self-report	Gen	**Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	9	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
25	Hormone Replacement Therapy and the QT Interval	CT	**Kadish**, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz	9	
26	Special Populations Recruitment for the WHI: Success and Limitations	Gen	**Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	9	
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	Determinants of Fasting Hyperinsulinemia	Gen	**Manson**, LaCroix, Haan, Rodrigues, Wagenknecht, Johnson, Allen, Hendrix	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	
102	Cardiovascular Outcomes Related to Anti-Hypertensive Drug Therapy in Older Women: The Women's Health Initiative Observational Study	OS	**Wassertheil-Smoller**, Psaty, Greenland, Margolis, Oberman, Kotchen, Mouton, Hilkert, Black, Anderson, Trevisan, Aragaki	9	
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	CT	**Johnson**, Williams, Fouad	9	
109	NCI Monograph: Approaches to Research Trials Recruitment in Hispanic Communities: Review and Recommendations	Gen	**Larkey**	9	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	OS	**Bowen**, Green, Vizenor, Vu, Kreuter, Rolls	9	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	CT	**Kearney**, Rosal, Ockene, Churchill	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	
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	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
220	The Women's Health Initiative: A Glimpse Behind the Scenes	CT	**Furniss**	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	
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	Gen	**Pastore**, Carter, Hulka, Wells	8	
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	Gen	**Howard**, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetselaar	8	
156	Incidence of Systemic Lupus Erythematosus in the Women's Health Initiative	OS	**Assaf**, Cyr, Crowley, Coccio	8	
186	Physical Activity and Diabetes Risk in Postmenopausal White, Black, Hispanic, and Asian Women: The WHI	Gen	**Hsia**, Howard, Limacher, Oberman, Safford, Allen, Torrens, Lawson	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	
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	8	
217	Associations with Gun-related Threats and Household Fear in Postmenopausal Women	OS	**Mouton**, Tan, del Aguila	8	
222	Venous Thromboembolism in the Estrogen plus Progestin Trial of the Women's Health Initiative	CT	**Cushman**, Prentice, Kuller, Sidney, Stafford, Psaty, Rodabough, Rosendaal	8	
228	Past Hysterectomy as a Risk Factor for Hypertension in the Women's Health Initiative Observational Study Participants	OS	**Barad**	8	
248	Progression of Coronary Calcification in Postmenopausal Women	OS	**Hsia**, Klouj, Prasad, Burt, Adams-Campbell, Howard	8	
271	Factors associated with treatment initiation after screening and diagnosis of osteoporosis	CT	**Brennan**, Wactawski-Wende, Crespi, Dmochowski	8	
29	Effects of Diet Intervention on Motivation to make other Health Related Changes	CT	**Langer**, Lo	7	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
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	
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	
31	Comparisons between Never Smokers, Former Smokers, and Current Smokers in the WHI	OS	**Ockene**, Bowen, Brunner, Robbins, Shikany	6	
36	Prevalence of Silent MI	CT	**Sagar**, Kotchen, Wong, Graettinger, Burke, Van Vorhees, McIntosh	6	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	Gen	**Agurs-Collins**, Dolan, Pasaro, Howard	6	
78	Association Between Antioxidants and BMD in an Ethnically Diverse Population of Older Women	Gen	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	6	
144	Hysterectomy and Risk of CVD	OS	**Howard**, Assaf, Cochrane, Kuller, Lasser, Manson, Stefanick, Trevisan, Van Horn	6	
163	Racial/Ethnic Differences in Breast Cancer Incidence Rates	OS	**Chlebowski**, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan	6	
52	Nutrient Intake of Women with Diabetes in the WHI Observational Study Cohort	Gen	**Tinker**, Gans, Lee, Smith, West, Snetselaar, Caggiula	5	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	OS	**Paskett**, Sherman, Andersen, Hays, McDonald, Naughton	5	
87	Incidence and Correlates of Hip and Knee Replacement in the WHI	Gen	**Wallace**, Chang, Nevitt, LaCroix, Kaplan, Sturm	5	
92	Comparison of Self-report, Discharge Diagnosis, and Adjudication of Cardiovascular Events in the WHI	Gen	**Heckbert**, Hsia, Kooperberg, McTiernan, Curb, Barbour, Gaziano, Safford, Psaty, Frishman	5	
106	Utility of Body Mass Index (BMI) as a Proxy for Obesity Among White, Black, Asian, Native American and Hispanic Post-menopausal Women	Gen	**Going**, Chen, Tinker, St. Jeor, Lewis	5	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	OS	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	5	

Table 9.1

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	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	
154	Does Acidogenic Diet Contribute to the Incidence of Hip Fracture?	OS	**Barzel**, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	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	
190	Predictors of LVH	CT	**Oberman**, Ko, Lasser, LaCroix, Wylie	5	
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	5	
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, Allen, Kotchen	5	
277	Peripheral arterial disease in the randomized E+P trial	CT	**Hsia**, Kotchen, Bonds, Allison, Phillips, Masaki, Langer, Resnick, Caralis	5	
20	Demographic, menstrual, and reproductive correlates of endogenous sex hormone concentrations in the WHI	CT	**McTiernan**, Chen, Rohan, Modugno, Hendrix	4	
124	Relationships Between Nutritional Intake and Measures of Cognition	WHIMS	**Espeland**, Bowen, Haan, Brunner, Snetselaar, Dunn	4	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
178	Three Year Change in BMD	OS	**Lewis**, Robbins, LaCroix, Chen, Wactawski-Wende, Nevitt, Jackson, Cauley	4	
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	4	
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	4	
182	The Effect of Moderate Alcohol Consumption on the Incidence of Ovarian Cancer	OS	**Assaf**, Coccio, Anderson, Caan, Kaunitz, DeSantis, Duffy, Burkholder	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	
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	4	
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	4	
195	Predictors of Calcium/Vitamin D Supplementation Adherence in the Women's Health Initiative	CT	**Brunner**, Cauley, Snetselaar, Jackson, Cochrane, Granek, Wactawski-Wende	4	
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	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	
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	4	
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	4	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
249	Estrogen Plus Progestin Use and Urinary Incontinence in WHI Women	CT	**Hendrix**, Handa	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**	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	
259	Alcohol, Caffeine and ARM in the WHISE Study	CT	**Klein**, Seddon, Klein, Johnson, Tomany, Hyman, Musch, Johnson	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	
273	Evaluating Estrogen Therapy for Chronic Disease Prevention: Principal results from the Women's Health Initiative Randomized Controlled Trial	CT	**The Writing Group for the WHI Investigators**	4	
274	Association Between Self-Reported Alcohol Intake and Changes in Cognition: Results from the Women's Health Initiative Memory Study (WHIMS)	CT	**Espeland**, Langer, Stefanick, Gu	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	4	
280	Diet, physical activity, energy balance and endogenous sex hormone concentrations in the WHI	CT	**McTiernan**	4	
18	The Relationship of Dietary Phytoestrogens to Menopausal Symptoms and Major Morbidity in Postmenopausal Women	CT	**Assaf**, Cyr, Coccio, Hixson	3	
45	Socio-demographic Determinants of Folic Acid Intake	Gen	**Beresford**, Kritchevsky, Vitolins, Wodarski	3	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
54	Current Treatment Patterns in Women with Hypercholesterolemia	Gen	**Manson**, Freed, Chae	3	
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	
118	Association Between Depressive Symptomatology and Physical Activity in Post-menopausal Women	Gen	**Ockene**, Rosal, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson	3	
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	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	
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	3	
188	Electrocardiographic Repolarization Phenotypes and Mortality Risk in Postmenopausal Women	CT	**Rautaharju**, LaCroix, Kooperberg	3	
200	Repression of Negative Emotion and Ambivalence about Negative Emotion: Associations with Psychosocial and Health-related Outcomes in the Women's Health Initiative	Gen	**Michael**, Perrin, O'Connor, Wisdom, Ritenbaugh, Bowen, Brzyski, Cochrane	3	
201	Normal Electrocardiographic Patterns in Older Adult Women. Depolarization and Repolarization Phenotypes	Gen	**Rautaharju**, Prineas, Hsia, Kadish, Lund	3	
206	Are Postmenopausal Survivors of Breast Cancer at an Increased Risk for Osteoporosis?	Gen	**Chen**, Barad, Ritenbaugh, Gass, Lopez, LeBoff, Bassford, Maricic	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	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
218	The Relationship of Physical and Verbal Abuse with Mental and Emotional Health in Postmenopausal Women	OS	**Mouton**, Rodabough, Cochrane, Brzyski, Rovi, Talamantes, Burge, Katerndahl	3	
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	3	
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	3	
272	Estrogen Plus Progestin therapy, medications, and the development of gallstone disease in women in the WHI CT.	CT	**Wallace**, LaCroix, Limacher, Greenland	3	
284	The Effect of E+P on Bone Mineral Density	CT	**Jackson**, Cauley, Chen, LaCroix, Phillips, Robbins, Rodrigues, Tylavsky, Wactawski-Wende	3	
287	Prior menopausal Hormone Therapy and Breast Cancer Risk in the WHI Trial of E+P Therapy	CT	**Anderson**, Chlebowski	3	
289	Occurrence of Second Malignancy following Nonmelanoma Skin Cancer: A Prospective OS from the WHI.	OS	**Rosenberg**, Greenland, Khandekar	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 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
181	Estradiol, Cytokines and Bone Turnover: Effects on Hip Fracture	Jane Cauley	Lew Kuller	under review	none	OS	400/400	yes	2004-2008	not yet submitted
180	Macrovascular Complications of Diabetes in Postmenopausal Women	Rongling Li	Karen Johnson	under review	none	OS	3164 cases	yes	12/04-11/08	not yet submitted
179	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women	Andrea LaCroix	Andrea LaCroix	under review	none	OS	1200/600	yes	01/05-12/07	not yet submitted
178	Mammographic Density and Invasive Breast Cancer	Etta Pisano	Gerardo Heiss	yes	all	HRT	317/951	no	NA	pending - submitted
177	Relative Risk Differences Between FFQs and Food Records	Amy Subar	Ruth Patterson	yes	all to be invited	DM	600/1200	no	9/03-9/04	funded
176	Long Term Breast and Colorectal Cancer Survivors in the OS	Yasmin Rahmani	S. Wassertheil-Smoller	not approved	10 - not specified	OS	2464/2033	no	2004-2007	dropped
175	Physical Function Determinants in Minority Women	J. Skye Nicholas	Tamsen Bassford	yes	none	OS	100/100	no	08/03-08/06	not yet submitted
174	Proinflammatory Markers and Colorectal Cancer	Gloria Ho	Sylvia Smoller	not approved		OS	500/900	yes	7/1/04-6/30/08	dropped
173	Relationship of Biomarkers and Genetic Markers to Risk of Congestive Heart Failure	Claudia Chae	JoAnn Manson	not approved	none	OS	656 cases/1312 controls for genetic study; 656 for biomarkers	yes	7/1/04-7/1/08	dropped
171	Analysis of Heart Rate Variability from Ultra-short Records: The WHI Study	Yvonne L. Michaels	Cheryl Ritenbaugh	yes	none	DM and HRT	76	no	1/03-6/03	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
170	WHI Nutrition and Diabetes Study (WHINDS)	Karen Margolis	Karen Margolis	yes	all invited to participate	DM	14000 cases/14000 controls	no	1/1/04-12/31/06	dropped
169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Robert Kaplan	S. Wassertheil-Smoller	under review (re-submitted)	none	OS	250/250	yes	12/03-11/05	not yet submitted
167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Steve Cummings	Steve Cummings	yes	none	OS	400	yes	6/04-12/05	not yet submitted
165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	Gerardo Heiss	yes	none	OS	1500/3200	yes	01/04-02/06	pending - submitted
164	The IGF System and Coronary Heart Disease	Robert Kaplan	S. Wassertheil-Smoller	yes	none	OS	350/350	yes	1/1/04-12/31/07	pending - submitted;
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Jennifer Hays	Jennifer Hays	yes	none	CT & OS	405	no	1/03-12/04	pending - submitted
162	Interactive Telephone Strategy to Maintain Diet Change	Shirley Beresford	Shirley Beresford	tabled	none	CT	310	no	7/1/03-6/30/08	not yet submitted
161	Bone Mass Response to Termination of Estrogen + Progestin	Jane Cauley	Lew Kuller	yes	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	yes	none	CT	250	no	7/02-8/02	funded
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Charles Mouton	Robert Schenken	yes	none	OS	217/217	no	10/02-9/05	pending - submitted

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Tom Rohan	S. Wassertheil-Smoller	yes	none	OS	3500/3500	yes	4/03-3/06	not yet submitted
153	Longitudinal Changes in Hip Geometry and Lower Limb Skeletal Muscle among Aging Women	Zhao Chen	Tamsen Bassford	yes	none	All BMD women	all BMD women	no	07/03-06/08	funded
152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	S. Wassertheil-Smoller	yes	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	yes	none	OS	all OS women	no	5/02-4/04	funded
149	Gene-Environment Interactions & Human Breast Cancer Risk	Jennifer Hu	Electra Paskett	yes	none	OS	800/800	yes	1/03-12/04	not funded
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Priesler	Henry Black	yes	none	OS	59/177	yes	4/03-3/05	not yet submitted
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson	yes	none	OS	106/318	yes	03/03-02/04	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	yes	none	OS	80	no	04/01-06/01	funded
140	Environmental Epidemiology of Arrhythmogenesis in WHI	Eric Whitsel	Gerardo Heiss	yes	none	CT	all CT women	no	04/03-09/07	funded
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Greg Burke	yes	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	yes	none	OS	1060/2120	yes	10/03-09/07	funded
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	yes	none	HRT	400	no	7/01-6/06	funded
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Frances-mary Modugno	Lew Kuller	yes	none	OS	200/200	yes	6/1/02-5/31/04	funded
133	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso	JoAnn Manson	yes	none	OS	800/800	yes	12/03-11/07	pending - submitted
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	JoAnn Manson	yes	none	OS	1800/2700	yes	7/02-6/07	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
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	yes	all	DM, HRT	3000	no	7/01-06/06	funded
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	yes	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	yes	none	OS	1500/1500	yes	07/03-06/07	pending - submitted
127	Impact of Risk Perception on Preventive Health Behaviors, Process of Care and Outcomes Among a Diverse Cohort of Women at High Risk of Ischemic Heart Disease	Janice Barnhart	S. Wassertheil-Smoller	yes	none	OS	350	no	4/1/2002-3/31/2006	funded
126	Molecular and Genetic Determinants of Stroke in the Women's Health Initiative Observational Study	Sylvia Smoller	S. Wassertheil-Smoller	yes	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	yes	none	DM	90-150	no	6/00-12/00	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	yes	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Frances-Mary Modugno	Lew Kuller	yes	none	OS	200/200	yes	9/1/02-08/01/04	funded
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	28,29	OS	4000	no	12/00-11/04	dropped
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Christine L. Coy	Allan Hubbell	yes	none	DM	191	no	12/1999-4/2000	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	yes	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	yes	none	OS	1000	no	8/1/99 - 7/31/02	funded
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	JoAnn Manson	yes	none	OS	385/385	yes	8/1/00 - 7/31/03	funded
108.2	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski Harbor UCLA	yes	none	OS	750/750	yes	1/03-12/03	not yet submitted
108.1	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski Harbor UCLA	yes	none	OS	50/150	yes	01/03-12/03	funded
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	yes	21,66,56	OS	2880	yes	5/1/00 - 4/30/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	yes	none	OS	150	no	7/1/99 - 6/30/02	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Popu-lation	Sample Size (Cases/Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker	Sally Shumaker	yes	not specified	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	yes	none	OS	120	no	10/98 - 9/98	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes		OS	775	no	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski	yes	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	yes	none	OS	1000	no	4/2002-4/2006	funded
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	Garnet Anderson	yes	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	yes	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer	yes	not specified	OS	725	no	3/11/98 - 6/30/99	funded
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard	Barbara Howard	tabled	all	CT	all HRT, DM	no	N/A	tabled
90	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	Steve Cummings	yes	none	OS	400/400	yes	4/03-3/06	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
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	yes	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	Philip Greenland	yes	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	yes	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	yes	none	OS	200	no	7/1/97 - 6/30/01	funded
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad	Al Oberman	yes	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	yes	none	DM	28	no	9/1/97 - 8/13/98	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	yes	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	yes	none	DM	50	no	7/1/97 - 9/30/97	funded
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	yes	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	yes	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	yes	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	yes	51	OS	782	no	1/1/97 - 12/31/05	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease in Postmenopausal Women	Marjita Zakarija	Mary Jo O'Sullivan	yes	51	OS	1040	no	ongoing	funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	all	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines	Gerardo Heiss	yes	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	yes	30	HRT	3300	no	1/99 - 1/07	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Mary Haan	John Robbins	yes	none	HRT	110	no	on-going	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	yes	none	DM Partners		no	12/1/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	yes	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	yes	none	DM	260	no	9/1/96 - 8/31/98	funded
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	yes	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	yes	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	yes	none	DM	150	no	5/1/96 - 4/30/97	funded
40	Ethnic and age differences in use of Mammography	S. Wasserthei l-Smoller	S. Wassertheil -Smoller	yes	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Sally Shumaker	Sally Shumaker	yes	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	yes	all	HRT	NA	no	1/98 - 12/02	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	yes	none	HRT	330	no	12/1/96 - 12/31/02	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases/Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	yes	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	yes	none	OS	300	no	N/A	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	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	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	yes	none	OS	1000	no	10/25/94- 10/24/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	none	OS	1300	no	9/16/96 - 09/15/01	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	yes	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	yes	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	yes	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	Al Oberman	yes	none	OS	650	no	6/1/95 - 5/31/04	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	yes	none	DM	160	no	4/1/95 - 9/30/96	funded