Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
September 1, 2001 to February 28, 2002

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

June 27, 2002

WHI Semi-Annual Progress Report

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Executive Summary

This report, summarizing data accumulated through February 28, 2002, presents the current status of the three clinical trial components and the observational study (OS) of the Women's Health Initiative (WHI). The primary areas for this report are adherence to the interventions, completeness of follow-up, and safety and event rate comparisons for these three clinical trial components.

The Hormone Replacement Therapy (HRT) trial randomized 27,347 women, including nearly 40% who had previously had a hysterectomy. The average follow-up on these women is approximately 5 years. Drop-out rates have been generally stable but somewhat higher than design assumptions. "Drop-in" rates are also larger than projected. Analyses of intermediate effects, including blood biomarker analyses and bone density are provided by race/ethnicity. Vital status is known within the last 18 months for all but 1,010 women (3.7%). 2.7% of HRT participants are deceased. We lack recent follow-up on another 45 (0.2%). The current event rates for CHD, breast cancer, colorectal cancer and hip fractures are 70%, 80%, 80%, and 40% respectively, of projected control group rates. Event rates by uterus status, age and race/ethnicity are provided. Updates are also provided for the ancillary study in HRT women looking at cognitive function (WHIMS) and eye disease (WHISE).

The Dietary Modification (DM) component randomized 48,836 women. Intervention adherence is monitored by the difference between the Intervention and Control arms in the 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 7.6% at AV-7. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing to 0.25% per year though adequate power can be maintained as long as this difference remains at or above 10%. Overall, 81% of DM Intervention participants have the reduced fat gram goals. 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-half serving at AV-7. Currently 3.6% of the DM participants are lost-to-follow-up or have stopped follow-up and 2.3% of participants are deceased. The average follow-up time for DM women is approximately 5.2 years. The current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 105%, 75%, 60%, respectively, of what was assumed in the study design. Event rate comparisons by age and race/ethnicity are presented for all monitored outcomes.

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 56% – 65%, though still lower than desirable. Follow-up rates for CaD participants are better than for the other CT components; as only 1.8% of participants are lost-to-follow-up or have stopped follow-up, and 1.9% 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. Distributions of intermediate outcomes (blood results, bone mineral density measures, and blood pressures) are presented by race/ethnicity. With just over 4 years of average follow-up, the current rates of hip fractures, invasive breast cancer, and colorectal cancer are approximately 40%, 110%, and 80%, respectively,

of what was assumed in the study design. Event rates by age and race/ethnicity are presented for all monitored outcomes.

Observational Study recruitment ended with 93,676 women enrolled. Follow-up rates suggest strong retention overall as only 3.2% are considered lost to follow-up or have stopped follow-up, and about 0.2% have not provided recent outcomes data. Responses to mailings are generally high (>93%). Approximately 83% of the 3-year clinic visits due have been conducted, as judged by task completeness. Event rates by age, race/ethnicity and follow-up time (pre- vs. post-year 3 visit) are presented for all adjudicated outcomes.

Additional information on the timeliness and quality of outcomes ascertainment is provided. Clinical center performance monitoring is summarized and a tabulation of ancillary studies and clinical center participation in these studies is also provided.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) through February 28, 2002. Topics include intervention adherence, follow-up, safety, outcomes, study power, 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, major milestones, emphases, and efforts have included:

- Completion of the process to update HRT trial participants regarding the continuing elevation in the risk of cardiovascular disease.
- Continuing efforts to examine CVD biomarkers in the HRT trial.
- Completion of the "Targeted Message Campaign," an initiative to support the DM Intervention.
- Final planning for the next DM intervention initiative referred to as the Personalized Evaluation of Fat Intake (PEFI) for implementation in mid 2002.
- Change in central adjudication plans, requiring central adjudication of all key cardiovascular endpoints in the HRT.
- Change in final reporting plans for the CT to use centrally-defined outcomes for the primary reporting of the primary outcome of each trial.
- Development and submission of a concept proposal for continuing follow-up of all WHI participants through the year 2010.

All reports summarize Clinical Center (CC) data provided to the CCC by February 28, 2002. 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*).

Clinical Center locations and Principal Investigators (PI) are listed in Table 1.1. We wish to acknowledge some changes in the leadership of these centers. Dr. Greg Burke is again the PI for the Bowman-Gray CC, replacing Dr. Electra Paskett who has moved to Columbus.

Table 1.1
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
ATLANTA	Emory University Atlanta (Decatur), Georgia	Larry Phillips, MD
BIRMING	University of Alabama at Birmingham Birmingham, Alabama	Cora Lewis, MD MSPH
BOWMAN	Bowman Gray School of Medicine Winston-Salem (Greensboro), North Carolina	Gregory Burke, MD MS
BRIGHAM	Brigham and Women's Hospital Boston (Chestnut Hill), Massachusetts	Joann Manson, MD DrPH
BUFFALO	State University of New York, Buffalo Buffalo, New York	Maurizio Trevisan, MD MS
CHAPHILL	University of North Carolina at Chapel Hill Chapel Hill, North Carolina	Gerardo Heiss, MD MPH
CHICAGO	Northwestern University Chicago and Evanston, Illinois	Linda Van Horn, PhD RD
CHI-RUSH	Rush Presbyterian- St. Luke's Medical Center Chicago, Illinois	Henry Black, MD
CINCINNA	University of Cincinnati Cincinnati, Ohio	Marjorie Gass, MD
COLUMBUS	Ohio State University Columbus, Ohio	Rebecca Jackson, MD
DETROIT	Wayne State University Detroit, Michigan	Susan Hendrix, DO
GAINESVI	University of Florida Gainesville and Jacksonville, Florida	Marian Limacher, MD
GWU-DC	George Washington University Washington, DC	Judith Hsia, MD
HONOLULU	University of Hawaii Honolulu, Hawaii	David Curb, MD
HOUSTON	Baylor College of Medicine Houston, Texas	Jennifer Hays, PhD
IOWACITY	University of Iowa Iowa City and Bettendorf, Iowa	Robert Wallace, MD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
IRVINE	University of California, Irvine Irvine, California	Allan Hubbell, MD
LA	University of California, Los Angeles Los Angeles, California	Howard Judd, MD
LAJOLLA	University of California, San Diego La Jolla and Chula Vista, California	Robert Langer, MD MPH
MADISON	University of Wisconsin Madison, Wisconsin	Catherine Allen, PhD
MEDLAN	Medlantic Research Institute Washington, D.C.	Barbara Howard, PhD
MEMPHIS	University of Tennessee Memphis, Tennessee	Karen Johnson, MD
MIAMI	University of Miami Miami, Florida	Mary-Jo O'Sullivan, MD
MILWAUKE	Medical College of Wisconsin Milwaukee, Wisconsin	Jane Morley Kotchen MD MPH
MINNEAPO	University of Minnesota Minneapolis, Minnesota	Karen Margolis, MD
NEVADA	University of Nevada Reno, Nevada	Robert Brunner, PhD
NEWARK	University of Medicine and Dentistry Newark, New Jersey	Norman Lasser, MD PhD
NY-CITY	Albert Einstein College of Medicine Bronx, New York	Sylvia Wassertheil-Smoller, PhD
OAKLAND	Kaiser Foundation Research Institute Oakland, California	Bette Caan, PhD
PAWTUCK	Memorial Hospital of Rhode Island Pawtucket, Rhode Island	Annlouise Assaf, PhD
PITTSBUR	University of Pittsburgh Pittsburgh, Pennsylvania	Lewis Kuller, MD DrPH
PORTLAND	Kaiser Foundation Research Institute Portland, Oregon	Cheryl Ritenbaugh, PhD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
SANANTON	University of Texas San Antonio, Texas	Robert Schenken, MD
SEATTLE	Fred Hutchinson Cancer Research Center Seattle, Washington	Shirley Beresford, PhD
STANFORD	Stanford University San Jose, California	Marcia Stefanick, PhD
STONYBRK	Research Foundation of SUNY, Stony Brook Stony Brook, NY	Dorothy Lane, MD MPH
TORRANCE	University of California, Los Angeles Torrance, California	Rowan Chlebowski, MD PhD
TUCSON	University of Arizona Tucson and Phoenix, Arizona	Tamsen Bassford, MD
UCDAVIS	University of California, Davis Sacramento, California	John Robbins, MD
WORCESTR	University of Massachusetts Worcester, Massachusetts	Judith Ockene, PhD

2. HRT Component

2.1 Recruitment

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 either unopposed estrogen (ERT) or placebo in equal proportions. The remaining 16,608 women with an intact uterus were randomized to combined estrogen/progestin (PERT) or its placebo, again in equal proportions for most of the recruitment period. *Table 2.1* documents the age and racial/ethnic distribution of this population.

2.2 Adherence

Adherence to 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* gives descriptive data on all women who are considered due for each contact by treatment arm. For visits that were complete in the last report, only summaries across arms are provided. At this point, all 27,347 women have passed their 3 year visit window (AV-3), 24,776 (91%) have passed AV-4, 15,909 (58%) have passed AV-5, 7,666 (28%) have passed the AV-6 window and only 2,858 women (10%) have been in the study more than seven years. Thus, most women are in their fifth or sixth year of participation. The rate of stopping pills during these intervals is in the range of 4% to 6% per year.

The calculations for several columns of this report have changed since our last version. Previously, women who stopped and restarted study pills were counted as stopped. In the current version, all women are classified according to their current status. This has had a negligible change on the observed fraction of women stopping intervention. Also in our earlier approach, women who returned their bottles outside of a protocol-required contact were excluded from the pill collection, medication rate and adherence summary calculations for the interval in question. In the current report, these "outside of protocol" adherence reports are included in the summary. This modification increases the reported number of women with pill collections and therefore the women with non-zero adherence. The end result is that the adherence summary is increased, generally by 0-2%. This change has been applied to all data in this table so it is internally consistent but comparisons to previous reports are not directly applicable.

The adherence summary in the final column in the last five annual visits (AV-3 to AV-7) are 65%, 61%, 57%, 54%, and 52%, which after accounting for the change noted above, is unchanged in the last 6 months. There is some continuing evidence of better adherence in women with a uterus.

Figure 2.1 presents the secular trends in adherence rates for each visit type for the entire HRT cohort and by hysterectomy status. The change in the methodology for calculating adherence has not been applied retrospectively to the results at previous reporting intervals. The increase between the last reporting value and the current is likely to be an artifact of this change.

Drop-out and drop-in rates are presented in *Table 2.3* 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. The results for AV-3 through AV-7 suggest decreasing rate of stopping pills over time that are approximately offset by increasing death/lost to follow-up rates, giving an overall rather stable drop-out rate in the range of 7.5%-8%. At AV-5,

where the estimates should be stable with 58% of results available, 36.8% of women without a uterus and 34% women with a uterus had dropped out, as compared to a projected 28.5%. The cumulative rates at AV-7, though less reliable, are 46% and 44% respectively, as compared to the design projection of 36.7%. Overall, 42% of HRT women have stopped their study pills at some point (45% and 40% for without and with a uterus, respectively) but 60.7% were active at their last contact (59.5% and 61.7%).

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. Among women with a hysterectomy, the observed (design) cumulative rates are 2.9% (1.5%) at AV-1, 7.0% (4.4%) at AV-3, and 10.7% (8.7%) at AV-6, notably larger than expected. In women with a uterus, the corresponding "drop-in" rates were 2.1%, 5.6%, and 8.4%, which is also somewhat greater than planned.

Reasons for stopping study hormones are presented in *Table 2.4*. In these data, women may report multiple reasons. Most of the specific reasons are cited infrequently, with the exception of two health issues: Advised not to participate by health care provider (14%) and study conflicts with other health issues (11.5%-13.4%). We note that 8.2% of women with a uterus listed vaginal bleeding as a reason for stopping. In women with a hysterectomy, 4.1% stopped to take active HRT and 6.1% indicated that they would not be taking any HRT. Among women with a uterus, 2.8% stopped to take active HRT and 6.7% will not take any HRT. At most 1% of women in either stratum stopped to take SERMS or other hormone medications. *Table 2.5* displays reasons for stopping by age in women without and with a uterus. A similar breakdown by race/ethnicity is provided in *Table 2.6*.

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 bleeding and breast changes. Reports of bleeding and breast changes by contact type and treatment arms are shown in *Tables 2.7* and *2.8*, respectively. Reports of bleeding in women with a uterus reached a high of nearly 30% at 6 months (SAV-1), declining to approximately 5% after AV-5. Reports of breast changes peaked at 6 weeks after randomization and have declined to less than 2% in both strata.

2.4 Safety Monitoring

Table 2.9 presents results of endometrial aspirations by time since randomization. As routine post-randomization biopsies are required of only a small sample (6%) of women at AV-3, AV-6, and AV-9, the vast majority of these tests represent non-routine aspirations performed in response to bleeding problems. Among 5,251 total biopsies, 125 (2.4%) yielded an abnormal result: 71 cystic, 16 adenomatous, 27 atypia, and 11 cancer.

2.5 Laboratory Studies

Tables 2.10 and 2.11 present the results of blood specimen analyses from a small (8.6%) cohort of HRT women selected randomly at baseline for these prospective analyses. These results are essentially the same as our last report and are shown here only for completeness. The subsample analyzed incorporated over-sampling of minorities. The results in *Table 2.10* are weighted to reflect the overall WHI-CT distribution of race/ethnicity. In *Table 2.11*, similar results are provided for each racial/ethnic group, though some groups have rather small sample sizes.

2.6 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 2.12* 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. The pattern of treatment effects is similar in both hysterectomy strata. *Table 2.13* presents BMD data for Black/African American, Hispanic/Latino, and White women participating in the HRT component at these three centers.

2.7 Vital Status

Table 2.14 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 5 – Outcomes*. 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, 3.7% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 2.7% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or dead. Currently, the average follow-up for HRT participants is about 5.0 years, suggesting that approximately 14.1% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions. Follow-up in women with a uterus is slightly better than in women who have had a hysterectomy.

2.8 Outcomes

Table 2.15 contains counts of the number of locally verified major WHI outcomes for HRT participants by age and race/ethnicity. 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 4% 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 70% of the expected number of CHD events, 80% of the expected number of breast cancers, 80% of the expected number of colorectal cancers, and about 40% of the expected number of hip fractures.

We 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 6 and strokes for which the Glasgow classification was not yet complete.

Table 2.16 compares the rates of the same locally 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 2.17 compares the stroke diagnosis for HRT participants with and without a uterus. The distribution of the subtype of stroke appears to be similar for the women with and without a uterus.

Table 2.18 compares the Glasgow scale for strokes among HRT participants. 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 2.19 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 numbers in this table should be taken as an upper bound on the number of events that have occurred in HRT participants.

2.9 WHI Memory Study – WHIMS

The WHI Memory Study is an ancillary study in the HRT component, funded by Wyeth Ayerst through a grant to Dr. Sally Shumaker, Wake Forest University. The aim of this study is to determine whether hormone replacement therapy reduces the incidence of dementia in women over 65 years of age. 7,526 women were enrolled in the 39 participating centers, representing approximately 61% of the age eligible cohort and 28% of the entire HRT study cohort. Baseline characteristics of WHIMS participants are shown in *Table 2.20* by hysterectomy strata.

HRT women over 65 years of age are to be administered the Modified Mini-Mental Status instrument (*Form 39—Cognitive Function*) at baseline and years 1, 3, 6, and 9 of follow-up as part of WHI. The WHIMS protocol asks that the same instrument be administered to WHIMS participants in the intervening years. *Table 2.21* presents the 25th and 50th percentile of the distribution of *F39* scores in the entire HRT cohort and the subset participating in WHIMS by treatment arm and visit type. Percentile scores are reported as the scores for this population are highly skewed. These data suggest that participants who enrolled in WHIMS have slightly better *F39* cognitive function scores than those who declined to participate.

Women who score below an education-adjusted threshold are referred for an intensive cognitive and

neurological evaluation (Phase II/III). The results of these tests are used to classify participants into four categories: probable dementia (PD); minor cognitive impairment (MCI); no dementia (ND); or refused the Phase II/III exam (REF). *Table 2.22* describes this cascade of events by hysterectomy strata.

2.10 WHI Site Examination Study (WHI-SE)

The WHI-SE is an ancillary study in the HRT component, sponsored by Wyeth Ayerst through a grant to Dr. Mary Haan, University of Michigan. The aim of this study is to evaluate whether postmenopausal hormone replacement therapy can prevent age-related macular degeneration (ARM), or slow the progression of this disease in women who already have ARM, and/or reduces the risk of late forms of age-related maculopathy, including geographic atrophy, retinal pigment epithelial detachments and choroidal neovascular membranes. HRT participants are eligible if they are 65 years or older, read and speak English or Spanish, consent to study procedures including two eye exams with fundus photography, and have at least one eye that could be dilated for the retinal fundus photography. Women are excluded if they have allergies or other known contraindications for administering eye drops or cannot be subjected to retinal fundus photography. Recruitment began in May 2000 with a target sample size of 4,500. Currently 3,742 women have been enrolled in the 19 participating centers representing approximately 19.35% of the age eligible cohort and 13.7% of the entire HRT study. Baseline characteristics of WHI-SE participants are shown in *Table 2.23* by hysterectomy strata.

Follow-up consists of an annual questionnaire sent to participants to assess development or worsening of vision problems. Follow-up eye exams, photos, and repeated questionnaires will occur during 2004-2005.

Table 2.24 presents the prevalence of various diagnoses of eye conditions at the time of entry into WHI-SE by hysterectomy strata. Note this entry time is generally at least 2 years after randomization to HRT.

2.11 Issues

The primary issues of concern in the HRT trial continue to be around adherence and the notification to participants of the early adverse effects. The notification has taken place to all HRT participants in the form of a letter and brochure ("HRT Update"). This process has been completed with 23,306 women having returned postcards or indicated directly to clinic staff that they had received the materials. Of the remaining 4,041, 37% of non-respondents are deceased, lost-to-follow-up or stopped follow-up. The participants seem to have accepted this information without alarm. Though there have been anecdotal reports of women dropping out after receiving this information, the data available to us at this point provide no evidence of important changes to participation or adherence to medications. Clinical center investigators and staff have worked diligently to help women understand the need to continue their active participation, even in the face of discouraging news.

Methods to maintain and improve adherence continue to be discussed by study investigators. The current adherence rates are well above that expected from community-based estimates of hormone use but the study design projected even better rates. Continued efforts are needed to monitor and understand women's acceptance or refusal of long-term hormones. Creative approaches to motivate study participants with low impact to the clinical centers would be most welcome.

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

Data as of: February 28, 2002

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3425	125%	13%	10
55-59	5408	99%	20%	20
60-69	12364	100%	45%	45
70-79	6150	90%	22%	25
Without Uterus	**10,739**			
50-54	1396	113%	13%	10
55-59	1916	78%	18%	20
60-69	4852	88%	45%	45
70-79	2575	84%	24%	25
With Uterus	**16,608**			
50-54	2029	135%	12%	10
55-59	3492	116%	21%	20
60-69	7512	111%	45%	45
70-79	3575	95%	22%	25
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2738		10%	
Hispanic	1537		6%	
White	22030		81%	
Unknown	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1616		15%	
Hispanic	651		6%	
White	8084		75%	
Unknown	149		1%	
With Uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1122		7%	
Hispanic	886		5%	
White	13946		84%	
Unknown	236		1%	

Table 2.2
HRT Adherence Summary

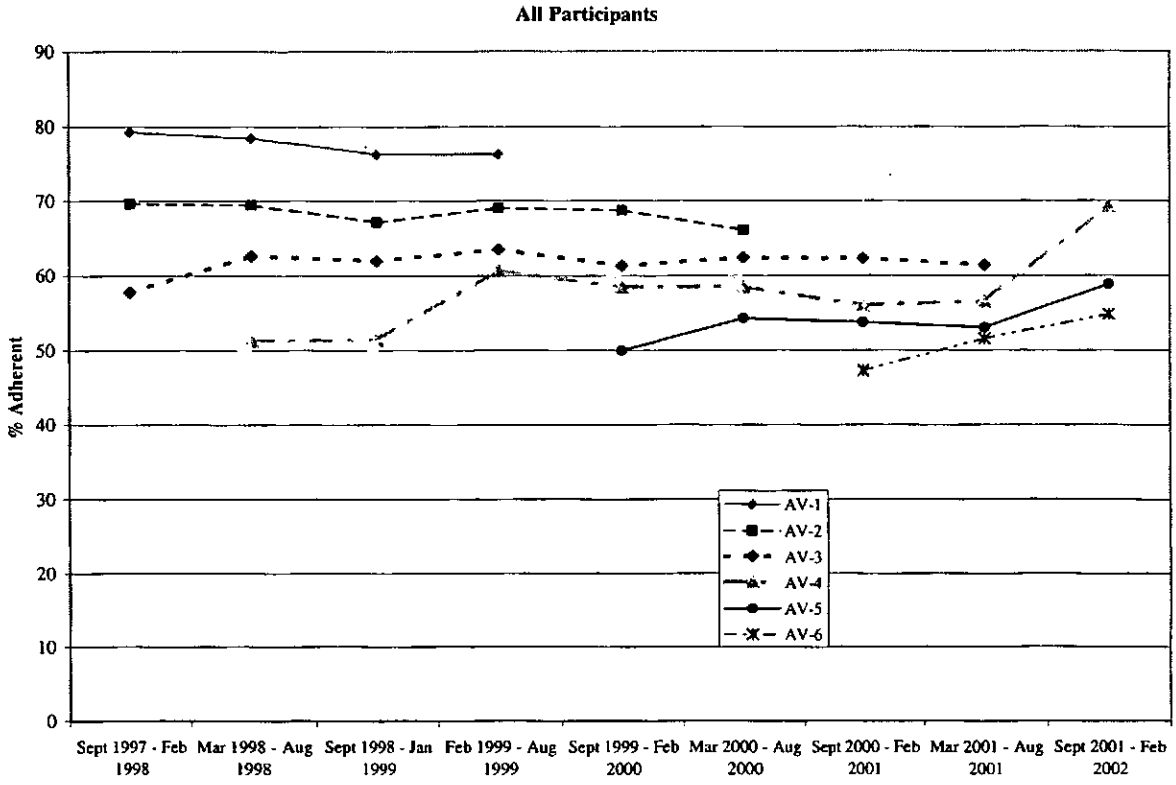
Data as of: February 28, 2002

Contact	Due N	Conducted N	Conducted %	Conducted in Window N	Conducted in Window %	Stopped HRT during interval N	Stopped HRT during interval %	Missed Pill Collection N	Missed Pill Collection %	Total with Collections N	Total with Collections %	Medication Rate[1] <50% N	Medication Rate[1] <50% %	Medication Rate[1] 50%-80% N	Medication Rate[1] 50%-80% %	Medication Rate[1] 80% + N	Medication Rate[1] 80% + %	Adherence Summary[2] %
Semi-Annual Visit-1	27347	26710	98	22785	83	1031	4	219	1	26764	99	1744	7	2189	8	22831	85	85
Annual Visit-1	27347	26503	97	21882	80	1178	4	340	1	25573	99	2136	8	2559	10	20878	82	78
Annual Visit-2	27347	25897	95	20508	75	2332	9	493	2	24155	98	2278	9	2703	11	19174	79	71
Without Uterus	10739	10062	94	7944	74	1013	10	222	2	9580	98	951	10	1185	12	7444	78	70
With Uterus	16608	15835	95	12564	76	1319	8	271	2	14575	98	1327	9	1518	10	11730	80	73
Annual Visit –3	27347	25775	94	19120	70	1870	7	524	2	21696	98	2003	9	2355	11	17338	80	65
Without Uterus	10739	10031	93	7445	69	817	8	247	3	8492	97	807	10	1045	12	6640	78	63
With Uterus	16608	15744	95	11675	70	1053	7	277	2	13204	98	1196	9	1310	10	10698	81	66
Annual Visit –4	24776	22944	93	16175	65	1446	6	458	2	17928	98	1393	8	1986	11	14549	81	61
Without Uterus	9742	8883	91	6250	64	595	6	202	3	6958	97	544	8	846	12	5568	80	58
With Uterus	15034	14061	94	9925	66	851	6	256	2	10970	98	849	8	1140	10	8981	82	62
Annual Visit –5	15898	14491	91	9995	63	834	5	270	2	10606	98	813	8	1176	11	8617	81	57
Without Uterus	6303	5668	90	3894	62	343	6	119	3	4150	97	334	8	517	12	3299	79	54
With Uterus	9595	8823	92	6101	64	491	5	151	2	6456	98	479	7	659	10	5318	82	59
Annual Visit –6	7666	6981	91	4585	60	337	5	141	3	4685	97	318	7	482	10	3885	83	54
Without Uterus	3073	2778	90	1823	59	140	5	57	3	1885	97	129	7	202	11	1554	82	52
With Uterus	4593	4203	92	2762	60	197	5	84	3	2800	97	189	7	280	10	2331	83	56
Annual Visit –7	2858	2535	89	1587	56	96	4	39	2	1537	98	95	6	174	11	1268	82	52
Without Uterus	1203	1041	87	648	54	44	4	12	2	699	98	48	7	77	11	574	82	50
With Uterus	1655	1494	90	939	57	52	4	27	3	838	97	47	6	97	12	694	83	54

[1] Medication rate calculated as number of pills taken divided by number of days since bottle(s) were dispensed.
[2] 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]

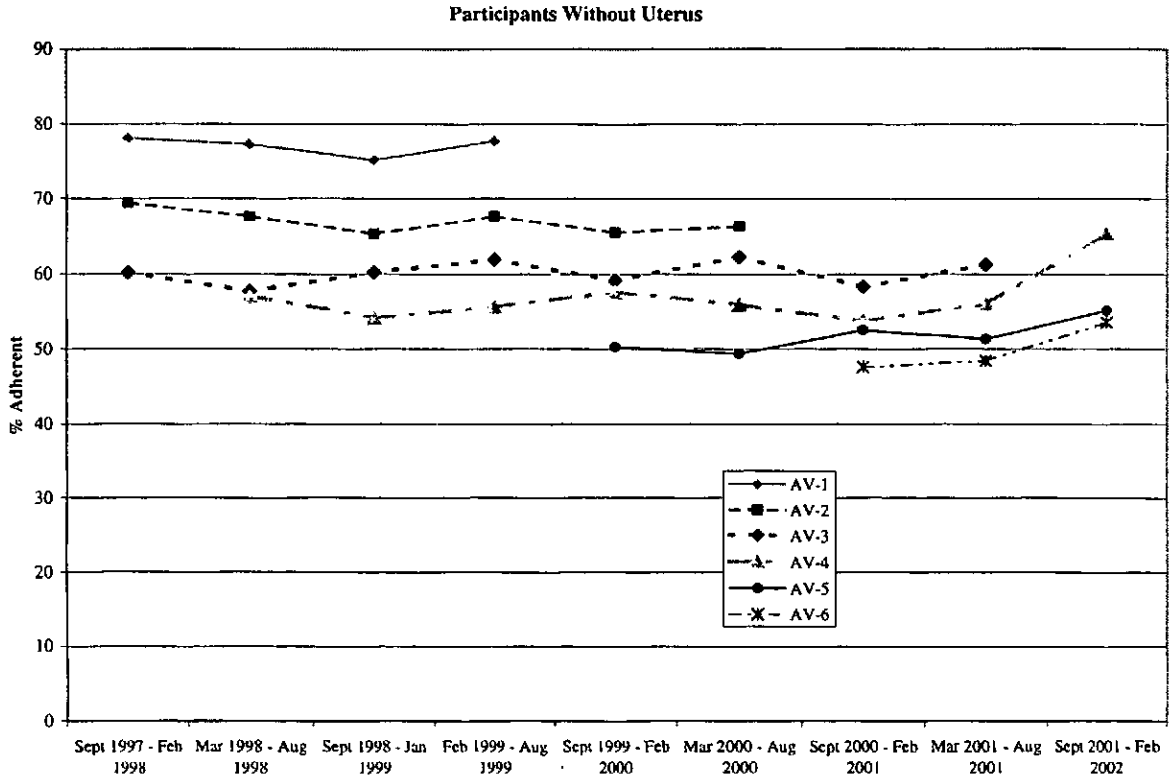
Data as of February 28, 2002

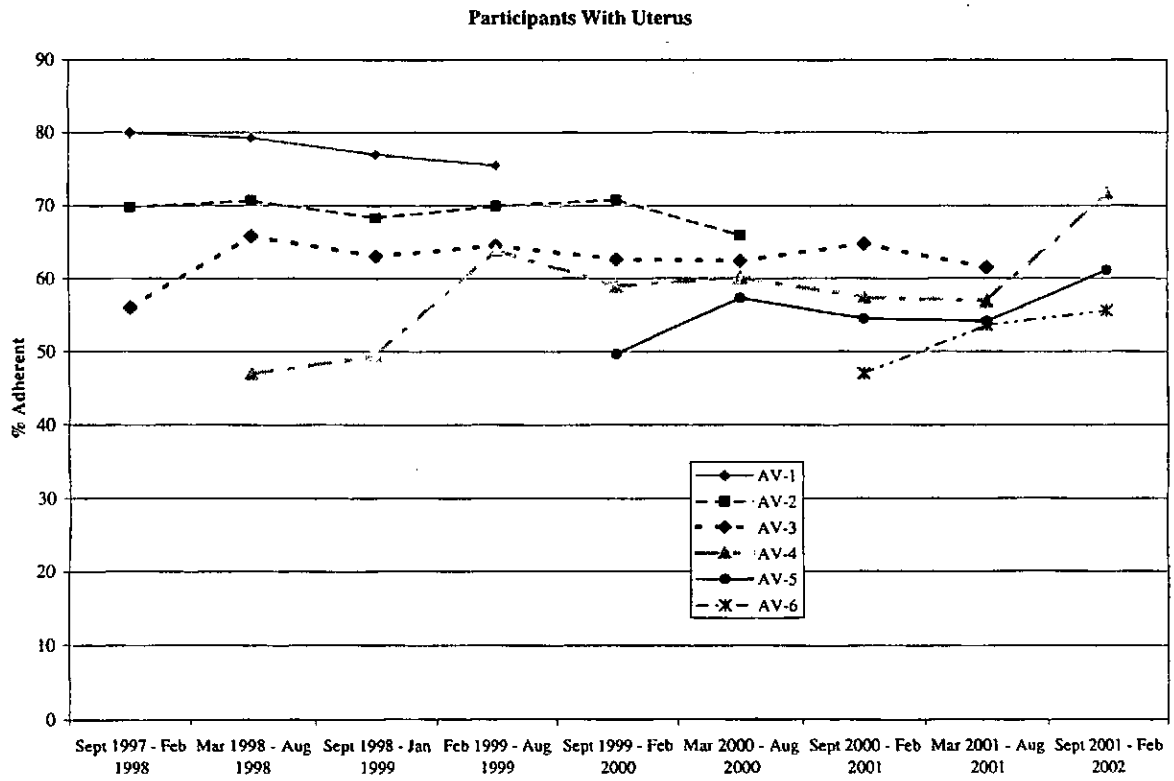


[1] Adherence calculations changed as of the September 2001 – February 2002 interval.

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

Data as of February 28, 2002





[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

Data as of: February 28, 2002

	Design		Without Uterus				With Uterus			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]										
AV-1	8.8	8.8	7.9	0.4	8.3	8.3	8.1	0.4	8.5	8.5
AV-2	5.9	14.2	9.5	1.0	10.5	17.9	8.2	0.8	9.0	16.7
AV-3	5.9	19.2	7.7	1.4	9.1	25.4	6.5	1.1	7.6	23.0
AV-4	5.9	24.0	6.2	1.9	8.1	31.5	5.9	1.6	7.5	28.8
AV-5	5.9	28.5	5.6	2.2	7.8	36.8	5.4	1.9	7.3	34.0
AV-6	5.9	32.7	4.7	3.0	7.7	41.7	4.7	3.1	7.8	39.2
AV-7	5.9	36.7	3.8	3.6	7.4	46.0	4.1	3.9	8.0	44.0
Drop-Ins[6]										
AV-1	1.5	1.5			2.9	2.9			2.1	2.1
AV-3	2.9	4.4			4.2	7.0			3.6	5.6
AV-6	4.4	8.7			4.0	10.7			3.0	8.4

[1] Estimated rate of stopping hormones in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] Combined rate of stopping and death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping and death or lost to follow-up.
[5] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.
[6] 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]

Data as of February 28, 2002

Reasons[2]	Without Uterus (N = 4369)		With Uterus (N =6214)	
Personal/family				
Demands of work	80	1.8%	108	1.7%
Family illness, emergency or other family demands[3]	187	4.3%	223	3.6%
Financial problems	9	0.2%	6	0.1%
Lack of cooperation/support from family/friends[4]	41	0.9%	64	1.0%
Living in nursing home	8	0.2%	16	0.3%
Issues of interest in study[5]	94	2.2%	123	2.0%
Travel				
Too far to CC	156	3.6%	178	2.9%
Moved out of area or refuses to be followed to another CC	31	0.7%	38	0.6%
Other travel issues[6]	96	2.2%	75	1.2%
Visits & Procedures				
Doesn't like visits, calls	53	1.2%	38	0.6%
Mammogram Issues[7]	24	0.5%	37	0.6%
Doesn't like gynecologic procedures	11	0.3%	47	0.8%
Doesn't like required forms or safety procedures[8]	75	1.7%	96	1.5%
Problems with other procedures[9]	9	0.2%	21	0.3%
Worried about health effects of medical tests/procedures	17	0.4%	24	0.4%
Wants test results[10]	1	<0.1%	2	<0.1%
Problems with CC[11]	28	0.6%	46	0.7%

(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]

Data as of February 28, 2002

Reasons[2]	Without Uterus (N = 4369)		With Uterus (N =6214)	
Symptoms				
Vaginal Bleeding	6	0.1%	508	8.2%
Breast Symptoms[3]	174	4.0%	269	4.3%
Vaginal Changes	16	0.4%	12	0.2%
Hot flashes/night sweats	30	0.7%	9	0.1%
Other[4]	1035	23.7%	1479	23.8%
Health Conditions				
Breast Cancer	64	1.5%	144	2.3%
Complex or atypical hyperplasia	0	0.0%	6	0.1%
Endometrial cancer	2	<0.1%	21	0.3%
Venous thromboembolism[5]	39	0.9%	82	1.3%
High triglycerides (> 1000 mg/dL)	3	0.1%	5	0.1%
Malignant melanoma	7	0.2%	23	0.4%
Gallbladder disease	4	0.1%	7	0.1%
Heart Attack	45	1.0%	36	0.6%
Stroke	64	1.5%	93	1.5%
Meningioma	3	0.1%	1	<0.1%
Depression	12	0.3%	14	0.2%
Cholesterol (high or concern about levels)	7	0.2%	1	<0.1%
Osteoporosis	34	0.8%	38	0.6%
Cognitive/memory changes	15	0.3%	35	0.6%
Other[6]	431	9.9%	636	10.2%

(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]

Data as of February 28, 2002

Reasons[2]	Without Uterus (N = 4369)		With Uterus (N =6214)	
Intervention				
Doesn't like randomized nature of intervention	85	1.9%	129	2.1%
Expected some benefit from intervention	39	0.9%	39	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	3	0.1%	8	0.1%
Takes too many pills	25	0.6%	27	0.4%
Other pill issues[3]	127	2.9%	152	2.4%
CaD Issues[4]	25	0.6%	29	0.5%
DM Issues[5]	5	0.1%	10	0.2%
Taking active HRT[6]	177	4.1%	174	2.8%
Will not be on any HRT[7]	268	6.1%	417	6.7%
Taking SERMs or other hormone medications[8]	40	0.9%	65	1.0%
Other Health Issues				
Worried about cost if adverse effects occur	11	0.3%	8	0.1%
Expected more health care	13	0.3%	15	0.2%
Advised not to participate by health care provider[9]	620	14.2%	825	13.3%
Study conflicts with other health issues[10]	586	13.4%	715	11.5%
Other				
Other reasons not listed above	935	21.4%	1240	20.0%
Refuses to give a reason	71	1.6%	85	1.4%

[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 by Age at Screening[1]: HRT Participants

Data as of February 28, 2002

			Age at Screening							
	All (N = 10,739)		50 – 54 (N = 1,396)		55 –59 (N = 1,916)		60 –69 (N = 4,852)		70 –79 (N = 2,575)	
Without Uterus	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	4369	40.7%	584	41.8%	753	39.3%	1900	39.2%	1132	44.0%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	187	4.3%	25	4.3%	35	4.6%	86	4.5%	41	3.6%
Vaginal bleeding	6	0.1%	2	0.3%	2	0.3%	1	0.1%	1	0.1%
Breast symptoms[6]	174	4.0%	13	2.2%	22	2.9%	68	3.6%	71	6.3%
Taking active HRT[7]	177	4.1%	26	4.5%	40	5.3%	74	3.9%	37	3.3%
Will not be on any HRT[8]	268	6.1%	22	3.8%	32	4.2%	127	6.7%	87	7.7%
Advised not to participate by health care provider[9]	620	14.2%	86	14.7%	101	13.4%	264	13.9%	169	14.9%
Study conflicts with other health issues[10]	586	13.4%	83	14.2%	95	12.6%	259	13.6%	149	13.2%
	(N = 16,608)		(N = 2,029)		(N = 3,492)		(N = 7,512)		(N = 3,575)	
With Uterus	N	%[11]	N	%[11]	N	%[11]	N	%[11]	N	%[11]
Women Stopping HRT	6214	37.4%	739	36.4%	1206	34.5%	2746	36.6%	1523	42.6%
REASONS FOR STOPPING[3]	N	%[12]	N	%[12]	N	%[12]	N	%[12]	N	%[12]
Family illness, emergency, or other family demands[5]	223	3.6%	19	2.6%	42	3.5%	106	3.9%	56	3.7%
Vaginal bleeding	508	8.2%	37	5.0%	72	6.0%	254	9.2%	145	9.5%
Breast symptoms[6]	269	4.3%	12	1.6%	38	3.2%	122	4.4%	97	6.4%
Taking active HRT[7]	174	2.8%	20	2.7%	40	3.3%	80	2.9%	34	2.2%
Will not be on any HRT[8]	417	6.7%	32	4.3%	75	6.2%	200	7.3%	110	7.2%
Advised not to participate by health care provider[9]	825	13.3%	104	14.1%	157	13.0%	381	13.9%	183	12.0%
Study conflicts with other health issues[10]	715	11.5%	87	11.8%	150	12.4%	309	11.3%	169	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 category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same age 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".
[11] Percentages are of HRT participants with uterus in the same age category.
[12] Percentages are of HRT participants with uterus in the same age category who stopped HRT.

Table 2.6
Reasons for Stopping HRT by Race/Ethnicity[1]: HRT Participants

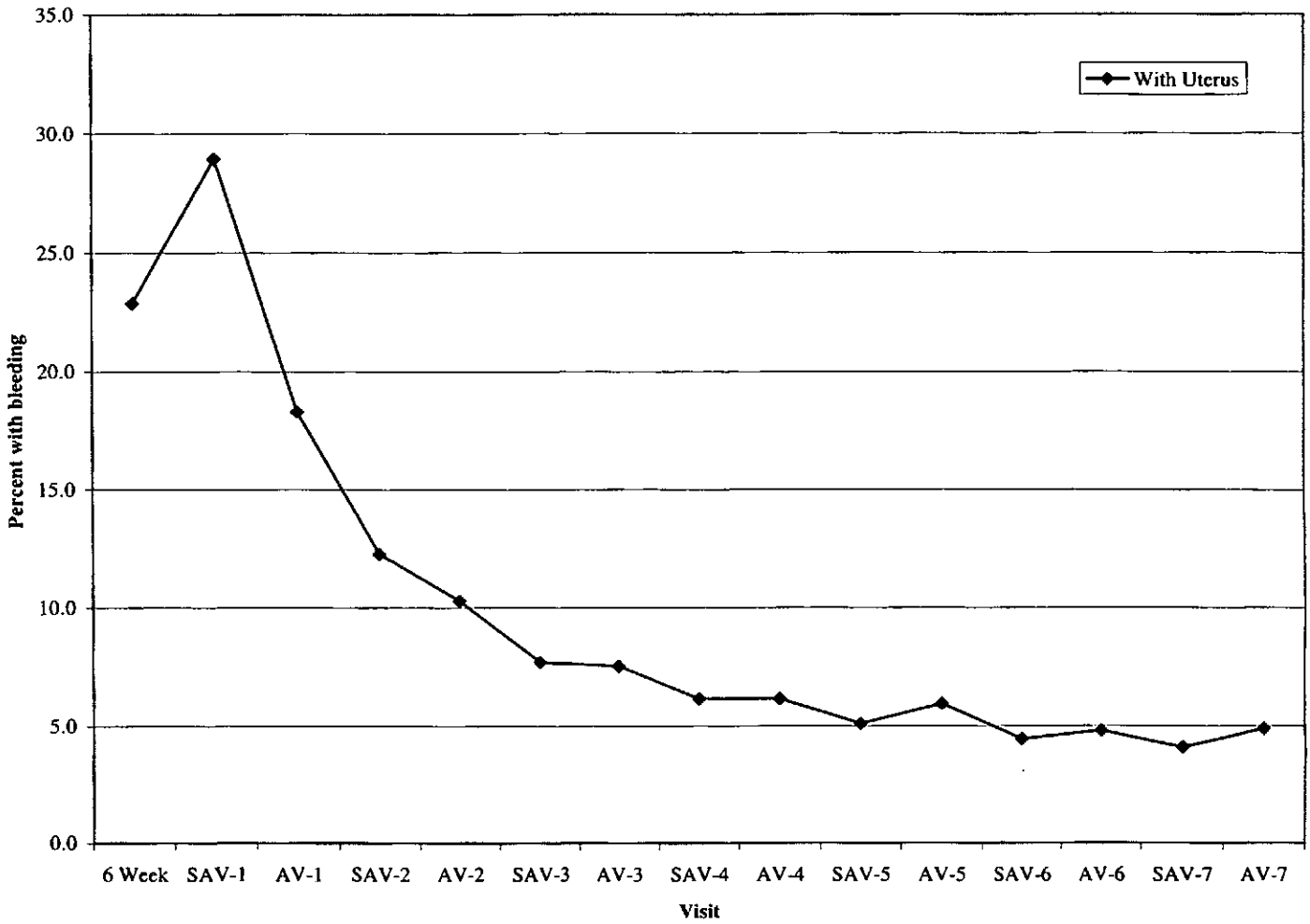
Data as of February 28, 2002

	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)	
Without Uterus	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	28	37.3%	56	34.1%	69	42.9%	311	47.8%	322	39.9%	59	39.6%
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	3.6%	2	3.6%	41	5.9%	22	7.1%	118	3.7%	3	5.1%
Vaginal bleeding	0	0.0%	0	0.0%	2	0.3%	1	0.3%	3	0.1%	0	0.0%
Breast symptoms[6]	1	3.6%	2	3.6%	25	3.6%	13	4.2%	131	4.1%	2	3.4%
Taking active HRT[7]	0	0.0%	0	0.0%	20	2.9%	10	3.2%	144	4.5%	3	5.1%
Will not be on any HRT[8]	1	3.6%	2	3.6%	42	6.1%	14	4.5%	205	6.4%	4	6.8%
Advised not to participate by health care provider[9]	5	17.9%	10	17.9%	69	10.0%	36	11.6%	491	15.2%	9	15.3%
Study conflicts with other health issues[10]	5	17.9%	11	19.6%	67	9.7%	29	9.3%	466	14.5%	8	13.6%
	(N = 55)		(N = 363)		(N = 1,122)		(N = 886)		(N = 13,946)		(N = 236)	
With Uterus	N	%[11]	N	%[11]	N	%[11]	N	%[11]	N	%[11]	N	%[11]
Women Stopping HRT	24	43.6%	11	32.2%	47	42.7%	370	41.8%	512	36.7%	99	41.9%
REASONS FOR STOPPING[3]	N	%[12]	N	%[12]	N	%[12]	N	%[12]	N	%[12]	N	%[12]
Family illness, emergency, or other family demands[5]	0	0.0%	2	1.7%	29	6.1%	13	3.5%	171	3.3%	8	8.1%
Vaginal bleeding	2	8.3%	7	6.0%	49	10.2%	25	6.8%	415	8.1%	10	10.1%
Breast symptoms[6]	1	4.2%	2	1.7%	18	3.8%	16	4.3%	228	4.4%	4	4.0%
Taking active HRT[7]	3	12.5%	5	4.3%	12	2.5%	6	1.6%	147	2.9%	1	1.0%
Will not be on any HRT[8]	0	0.0%	12	10.3%	35	7.3%	23	6.2%	339	6.6%	8	8.1%
Advised not to participate by health care provider[9]	0	0.0%	21	17.9%	52	10.9%	39	10.5%	705	13.8%	8	8.1%
Study conflicts with other health issues[10]	1	4.2%	17	14.5%	41	8.6%	25	6.8%	624	12.2%	7	7.1%

[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 race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same 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".
[11] Percentages are of HRT participants with uterus in the same race/ethnicity category.
[12] Percentages are of HRT participants with uterus in the same race/ethnicity category who stopped HRT.

Table 2.7
Reports of Bleeding

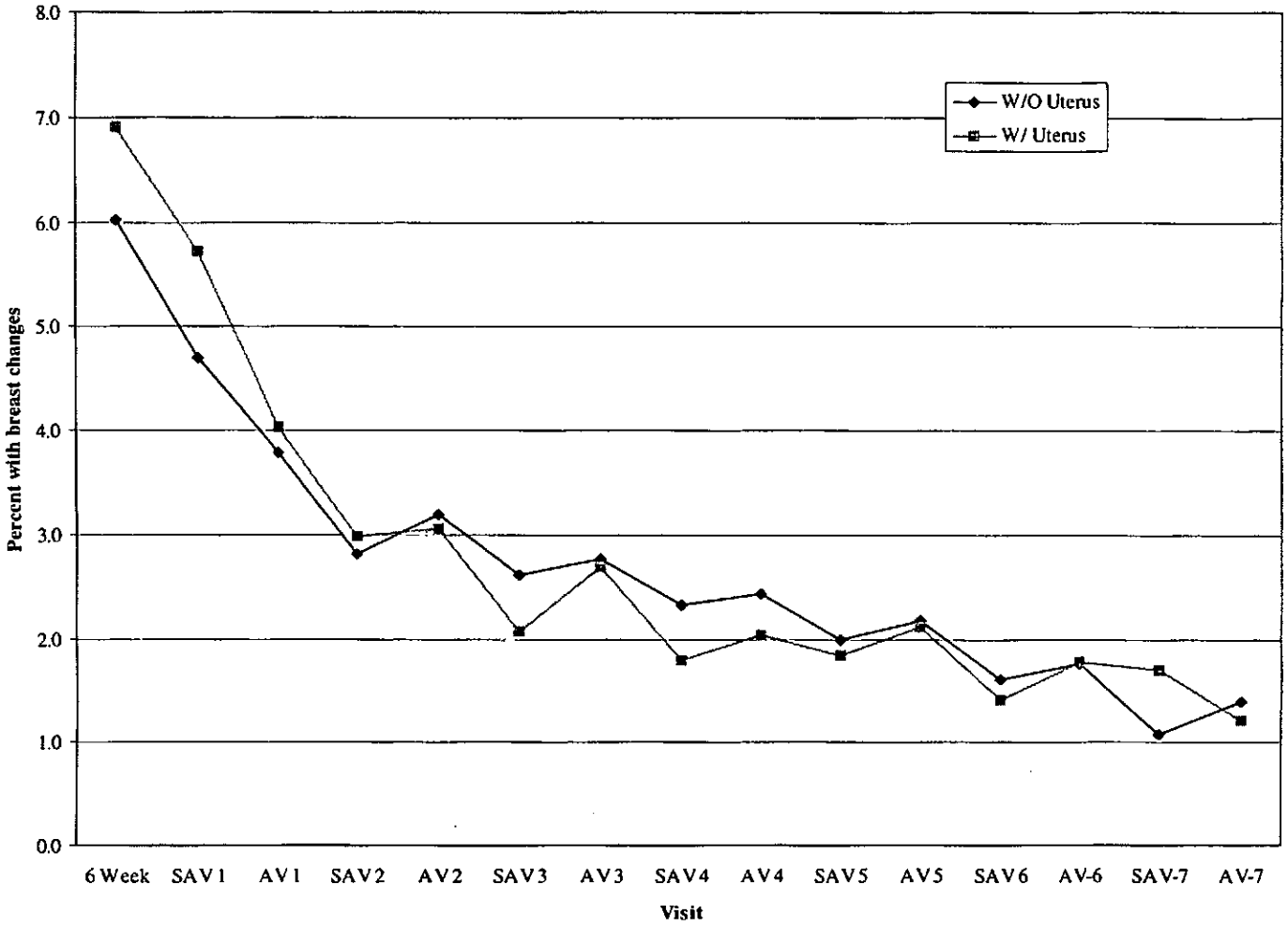
Data as of: February 28, 2002



Contact	With Uterus	
Semi-Annual Visit 3 – Number with Bleeding	1194	(7.7%)
Annual Visit 3 – Number with Bleeding	1186	(7.5%)
Semi-Annual Visit 4 – Number with Bleeding	947	(6.1%)
Annual Visit 4 – Number with Bleeding	865	(6.2%)
Semi-Annual Visit 5 – Number with Bleeding	591	(5.1%)
Annual Visit 5 – Number with Bleeding	524	(5.9%)
Semi-Annual Visit 6 – Number with Bleeding	272	(4.5%)
Annual Visit 6 – Number with Bleeding	202	(4.8%)
Semi-Annual Visit 7 – Number with Bleeding	104	(4.1%)
Annual Visit 7 – Number with Bleeding	73	(4.9%)

Table 2.8
Reports of Breast Changes

Data as of: February 28, 2002



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	220	(2.6%)	275	(2.1%)
Annual Visit 3 – Number with Breast Changes	229	(2.8%)	355	(2.7%)
Semi-Annual Visit 4 – Number with Breast Changes	180	(2.3%)	223	(1.8%)
Annual Visit 4 – Number with Breast Changes	168	(2.4%)	229	(2.0%)
Semi-Annual Visit 5 – Number with Breast Changes	113	(2.0%)	166	(1.8%)
Annual Visit 5 – Number with Breast Changes	93	(2.2%)	144	(2.1%)
Semi-Annual Visit 6 – Number with Breast Changes	47	(1.6%)	66	(1.4%)
Annual Visit 6 – Number with Breast Changes	35	(1.8%)	55	(1.8%)
Semi-Annual Visit 7 – Number with Breast Changes	13	(1.1%)	32	(1.7%)
Annual Visit 7 – Number with Breast Changes	10	(1.4%)	13	(1.2%)

Table 2.9
Endometrial Aspiration Results

Data as of: February 28, 2002

Months since randomized	N of aspirations[2,3]	Number with Abnormal Results[1]				
		Cystic	Adenomatous	Atypia	Cancer	Total[4]
0-6	103	5	1	1	-	2
6-12	726	11	2	4	-	6
12-18	731	13	3	3	3	9
18-24	532	15	4	3	-	7
24-30	412	3	-	1	-	1
30-36	705	2	-	4	3	7
36-42	687	3	2	3	1	6
42-48	338	5	1	2	-	3
48-54	290	2	-	1	-	1
54-60	231	5	1	-	-	1
60-66	161	1	-	2	2	4
66-72	142	1	1	-	1	2
72-78	142	4	1	2	-	3
78-84	27	-	-	1	1	2
84-90	21	1	-	-	-	-
90-96	3	-	-	-	-	-
Total	5251	71	16	27	11	54

[1] Abnormal results are based on local readings with the following groupings defined as follows:
Cystic is cystic hyperplasia without atypia
Adenomatous is adenomatous hyperplasia without atypia
Atypia is atypia or cystic or adenomatous hyperplasia with atypia

[2] All endometrial aspirations after first adenomatous or worse result removed. If participants had more than one endometrial aspiration within a 30-day period, the latest was used. Please note that routine aspirations for the Endometrial Aspiration subsample are included in this table.

[3] ERT-TO-PERT removed.

[4] Row totals combine adenomatous, atypias and cancer categories

Table 2.10
Blood Specimen Analysis: HRT Participants

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	1163	0.07	0.07	1468	0.09	0.08
AV-1	1022	0.07	0.06	1365	0.08	0.08
AV-1 – Baseline	1000	-0.01	0.06	1332	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	1162	0.29	0.27	1468	0.34	0.33
AV-1	1021	0.26	0.25	1366	0.31	0.30
AV-1 – Baseline	999	-0.03	0.22	1333	-0.04	0.21
Alpha-tocopherol (µg/ml)						
Baseline	1163	16.09	7.04	1468	16.31	7.70
AV-1	1022	17.70	8.91	1366	16.81	7.42
AV-1 – Baseline	1000	1.63	6.25	1333	0.51	5.73
Gamma-tocopherol (µg/ml)						
Baseline	1163	2.48	1.65	1468	2.24	1.40
AV-1	1022	2.22	1.84	1366	1.84	1.24
AV-1 – Baseline	1000	-0.30	1.13	1333	-0.37	0.93
Beta-Cryptoxanthine (µg/ml)						
Baseline	1163	0.08	0.08	1468	0.09	0.10
AV-1	1022	0.08	0.07	1365	0.09	0.09
AV-1 - Baseline	1000	-0.00	0.06	1332	-0.01	0.07
Lycopene (µg/ml)						
Baseline	1163	0.40	0.20	1468	0.41	0.20
AV-1	1022	0.39	0.19	1366	0.40	0.19
AV-1 - Baseline	1000	-0.01	0.17	1333	-0.01	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	1163	0.20	0.10	1468	0.21	0.09
AV-1	1022	0.20	0.10	1366	0.21	0.10
AV-1 - Baseline	1000	0.00	0.07	1333	0.00	0.06
Retinol (µg/ml)						
Baseline	1163	0.60	0.15	1468	0.60	0.15
AV-1	1022	0.63	0.16	1366	0.61	0.15
AV-1 - Baseline	1000	0.03	0.11	1333	0.01	0.10

(continues)

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

Table 2.10 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	1121	128.49	28.82	1415	123.49	28.32
AV-1	973	139.42	35.19	1319	129.64	31.02
AV-1 – Baseline	927	10.40	25.42	1248	5.94	22.53
Factor VII C (%)[2]						
Baseline	1101	129.99	28.24	1396	125.15	27.13
AV-1	961	136.32	31.68	1308	124.89	27.96
AV-1 – Baseline	899	6.23	23.93	1220	-0.58	21.84
Fibrinogen (mg/dl)						
Baseline	1118	312.18	63.50	1413	306.41	59.37
AV-1	971	301.34	61.46	1316	299.11	59.45
AV-1 – Baseline	923	-11.50	52.68	1243	-7.95	53.17
Hormones / Other						
Glucose (mg/dl)						
Baseline	1160	105.16	35.35	1466	100.47	26.73
AV-1	1020	102.91	31.69	1362	98.72	24.59
AV-1 – Baseline	995	-2.76	21.30	1326	-1.94	17.24
Insulin (µIU/ml)						
Baseline	1139	12.88	10.62	1421	11.42	6.86
AV-1	1004	12.16	8.14	1317	11.37	7.18
AV-1 – Baseline	964	-0.74	5.98	1264	-0.09	5.56

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.10 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	1163	162.97	99.73	1469	146.01	74.89
AV-1	1020	176.31	132.80	1365	149.20	74.99
AV-1 – Baseline	997	13.67	73.57	1332	3.01	55.53
Total Cholesterol (mg/dl)						
Baseline	1163	229.63	41.21	1469	224.84	36.85
AV-1	1020	223.25	40.59	1365	215.84	35.23
AV-1 – Baseline	997	-6.04	29.85	1332	-8.79	28.18
LDL-C (mg/dl)						
Baseline	1139	142.06	36.82	1444	138.73	32.93
AV-1	998	128.48	35.85	1340	127.13	32.49
AV-1 – Baseline	966	-13.26	27.27	1298	-11.34	25.66
HDL-C (mg/dl)						
Baseline	1157	55.59	14.52	1464	56.92	14.38
AV-1	1018	59.92	16.83	1365	59.13	14.89
AV-1 – Baseline	993	4.11	9.36	1327	2.29	8.16
HDL-2 (mg/dl)						
Baseline	1133	16.92	7.52	1423	17.72	7.57
AV-1	995	19.35	8.80	1332	19.05	8.12
AV-1 – Baseline	952	2.05	5.05	1263	1.20	4.67
HDL-3 (mg/dl)						
Baseline	1134	38.75	8.41	1423	39.14	8.11
AV-1	997	40.86	9.49	1333	40.11	8.18
AV-1 – Baseline	954	2.10	5.77	1264	1.03	5.21
Lp(a) (mg/dl)						
Baseline	1141	26.81	26.19	1449	27.34	27.77
AV-1	1005	25.40	27.00	1351	25.25	27.27
AV-1 – Baseline	970	-1.12	10.84	1303	-2.01	10.88

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

Table 2.11
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	32	0.06	0.04	30	0.05	0.04
AV-1	27	0.07	0.08	25	0.05	0.03
AV-1 - Baseline	27	0.01	0.06	24	-0.01	0.03
Beta-Carotene (µg/ml)						
Baseline	32	0.33	0.38	30	0.25	0.20
AV-1	27	0.34	0.39	25	0.30	0.32
AV-1 – Baseline	27	-0.02	0.24	24	0.03	0.17
Alpha-tocopherol (µg/ml)						
Baseline	32	18.70	9.89	30	13.04	4.96
AV-1	27	19.18	10.00	25	14.86	8.17
AV-1 – Baseline	27	1.33	6.21	24	2.08	8.17
Gamma-tocopherol (µg/ml)						
Baseline	32	2.47	1.64	30	3.06	1.80
AV-1	27	2.64	2.73	25	2.34	0.99
AV-1 – Baseline	27	0.04	1.81	24	-0.76	1.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	32	0.09	0.11	30	0.06	0.03
AV-1	27	0.08	0.06	25	0.07	0.05
AV-1 - Baseline	27	-0.01	0.10	24	0.01	0.04
Lycopene (µg/ml)						
Baseline	32	0.37	0.22	30	0.39	0.16
AV-1	27	0.40	0.21	25	0.42	0.18
AV-1 - Baseline	27	0.03	0.21	24	0.05	0.16
Lutein and Zeaxanthin (µg/ml)						
Baseline	32	0.21	0.10	30	0.18	0.09
AV-1	27	0.25	0.15	25	0.18	0.09
AV-1 - Baseline	27	0.03	0.09	24	-0.00	0.05
Retinol (µg/ml)						
Baseline	32	0.62	0.20	30	0.52	0.12
AV-1	27	0.65	0.19	25	0.55	0.16
AV-1 – Baseline	27	0.05	0.07	24	0.03	0.09

(continues)

Table 2.11 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	30	144.43	37.09	27	118.30	32.15
AV-1	26	154.77	44.02	25	126.84	35.71
AV-1 – Baseline	24	13.08	28.42	21	1.95	20.69
Factor VII C (%)[1]						
Baseline	30	141.67	30.83	27	117.67	33.09
AV-1	25	141.24	30.15	25	126.44	32.24
AV-1 – Baseline	23	6.70	16.45	21	3.90	23.09
Fibrinogen (mg/dl)						
Baseline	30	325.93	67.56	27	312.41	79.21
AV-1	26	315.69	83.44	25	307.40	76.47
AV-1 – Baseline	24	-9.04	75.45	21	-13.33	52.01
Hormones / Other						
Glucose (mg/dl)						
Baseline	32	112.22	42.33	30	116.17	51.66
AV-1	27	112.30	42.55	25	113.44	60.34
AV-1 – Baseline	27	-3.59	41.95	24	0.67	28.55
Insulin (μIU/ml)						
Baseline	32	13.63	8.05	30	12.61	8.81
AV-1	27	13.22	7.68	24	12.52	7.35
AV-1 – Baseline	27	-0.86	3.72	23	-0.26	2.88

(continues)

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

Table 2.11 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	31	186.87	107.13	30	154.20	84.64
AV-1	27	214.63	159.36	25	161.12	100.16
AV-1 – Baseline	26	35.85	98.82	24	10.88	56.74
Total Cholesterol (mg/dl)						
Baseline	31	239.94	46.31	30	218.70	42.32
AV-1	27	230.78	47.19	25	208.32	41.70
AV-1 – Baseline	26	-4.23	27.84	24	-2.83	19.24
LDL-C (mg/dl)						
Baseline	28	143.11	28.19	30	133.93	38.98
AV-1	23	125.13	38.01	24	122.21	39.54
AV-1 – Baseline	22	-15.77	25.61	23	-7.04	20.73
HDL-C (mg/dl)						
Baseline	31	54.71	13.06	30	53.90	14.50
AV-1	27	59.44	15.82	25	56.28	13.48
AV-1 – Baseline	26	5.04	7.68	24	2.67	7.85
HDL-2 (mg/dl)						
Baseline	31	16.55	5.86	30	16.27	6.51
AV-1	26	19.42	7.17	25	16.76	5.80
AV-1 – Baseline	25	2.68	3.67	24	0.50	4.31
HDL-3 (mg/dl)						
Baseline	32	38.06	7.75	30	37.63	8.72
AV-1	26	40.69	9.38	25	39.52	9.30
AV-1 – Baseline	26	2.69	4.87	24	2.17	4.50
Lp(a) (mg/dl)						
Baseline	31	35.90	39.11	30	21.83	32.28
AV-1	26	32.08	43.78	25	14.32	15.48
AV-1 – Baseline	26	-0.50	14.62	24	-2.00	5.50

Table 2.11 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	50	0.12	0.10	124	0.12	0.07
AV-1	45	0.09	0.07	115	0.11	0.08
AV-1 - Baseline	45	-0.04	0.09	113	-0.01	0.07
Beta-Carotene (µg/ml)						
Baseline	50	0.57	0.53	124	0.54	0.37
AV-1	45	0.40	0.33	115	0.44	0.27
AV-1 – Baseline	45	-0.13	0.30	113	-0.10	0.30
Alpha-tocopherol (µg/ml)						
Baseline	50	20.49	8.12	124	18.62	8.88
AV-1	45	21.30	8.68	115	19.55	10.14
AV-1 – Baseline	45	0.90	5.79	113	0.69	6.09
Gamma-tocopherol (µg/ml)						
Baseline	50	1.67	1.24	124	1.55	1.06
AV-1	45	1.36	1.15	115	1.26	0.99
AV-1 – Baseline	45	-0.27	0.71	113	-0.26	0.76
Beta-Cryptoxanthine (µg/ml)						
Baseline	50	0.16	0.14	124	0.24	0.37
AV-1	45	0.17	0.19	115	0.23	0.34
AV-1 - Baseline	45	0.01	0.14	113	-0.02	0.25
Lycopene (µg/ml)						
Baseline	50	0.42	0.25	124	0.40	0.21
AV-1	45	0.35	0.19	115	0.36	0.19
AV-1 - Baseline	45	-0.06	0.19	113	-0.04	0.19
Lutein and Zeaxanthin (µg/ml)						
Baseline	50	0.30	0.14	124	0.29	0.11
AV-1	45	0.28	0.13	115	0.28	0.12
AV-1 - Baseline	45	-0.03	0.08	113	-0.01	0.09
Retinol (µg/ml)						
Baseline	50	0.62	0.13	124	0.60	0.15
AV-1	45	0.65	0.15	115	0.61	0.18
AV-1 - Baseline	45	0.03	0.11	113	0.01	0.11

(continues)

Table 2.11 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	47	127.23	23.78	122	122.39	27.53
AV-1	43	143.30	41.46	111	127.50	26.93
AV-1 – Baseline	41	18.83	33.34	108	3.82	21.88
Factor VII C (%)[1]						
Baseline	47	126.96	24.75	122	124.72	24.52
AV-1	43	134.42	24.89	111	123.19	27.23
AV-1 – Baseline	41	9.29	19.47	108	-1.48	16.86
Fibrinogen (mg/dl)						
Baseline	47	290.96	62.19	122	298.55	57.06
AV-1	43	286.44	65.15	111	286.46	54.74
AV-1 – Baseline	41	-5.37	57.30	108	-13.99	49.10
Hormones / Other						
Glucose (mg/dl)						
Baseline	50	105.40	28.34	124	101.58	24.24
AV-1	45	105.78	36.28	115	100.99	22.78
AV-1 – Baseline	45	-0.58	12.59	113	-0.92	12.16
Insulin (μIU/ml)						
Baseline	49	12.06	8.12	116	10.70	7.71
AV-1	44	11.75	9.46	109	10.05	7.03
AV-1 – Baseline	43	-0.88	5.54	107	-0.43	5.33

(continues)

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

Table 2.11 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	50	176.18	84.55	124	146.48	71.67
AV-1	45	197.38	102.02	114	160.58	102.70
AV-1 – Baseline	45	19.93	79.99	112	12.00	80.72
Total Cholesterol (mg/dl)						
Baseline	50	231.80	32.71	124	222.26	33.71
AV-1	45	219.98	33.82	114	211.69	32.20
AV-1 – Baseline	45	-14.82	21.84	112	-10.92	26.78
LDL-C (mg/dl)						
Baseline	48	138.19	30.66	123	132.40	30.46
AV-1	44	118.75	35.98	111	120.50	29.88
AV-1 – Baseline	42	-22.83	28.41	109	-12.96	27.33
HDL-C (mg/dl)						
Baseline	50	58.50	17.42	124	59.96	16.19
AV-1	45	63.56	18.58	114	60.40	15.75
AV-1 – Baseline	45	3.76	8.35	112	0.88	8.49
HDL-2 (mg/dl)						
Baseline	49	17.73	9.38	123	18.96	8.87
AV-1	44	20.20	9.85	111	20.06	8.55
AV-1 – Baseline	43	1.51	6.54	109	1.32	4.52
HDL-3 (mg/dl)						
Baseline	49	40.43	9.13	123	40.78	8.42
AV-1	44	43.39	11.30	112	40.27	7.98
AV-1 – Baseline	43	1.95	5.88	110	-0.39	5.94
Lp(a) (mg/dl)						
Baseline	50	20.74	14.22	122	19.81	18.78
AV-1	45	16.62	14.70	114	17.31	17.67
AV-1 – Baseline	45	-4.73	7.81	111	-3.04	12.22

Table 2.11 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	395	0.07	0.08	282	0.06	0.06
AV-1	343	0.06	0.08	262	0.06	0.07
AV-1 - Baseline	334	-0.00	0.06	257	-0.00	0.05
Beta-Carotene (µg/ml)						
Baseline	394	0.36	0.38	282	0.30	0.25
AV-1	342	0.35	0.37	263	0.29	0.26
AV-1 – Baseline	333	-0.01	0.21	258	-0.02	0.19
Alpha-tocopherol (µg/ml)						
Baseline	395	14.36	6.52	282	14.39	6.35
AV-1	343	14.37	5.40	263	14.66	6.56
AV-1 – Baseline	334	0.12	5.07	258	0.06	5.05
Gamma-tocopherol (µg/ml)						
Baseline	395	2.50	1.38	282	2.53	1.42
AV-1	343	2.33	1.38	263	2.29	1.31
AV-1 – Baseline	334	-0.17	0.91	258	-0.21	0.94
Beta-Cryptoxanthine (µg/ml)						
Baseline	395	0.09	0.06	282	0.09	0.07
AV-1	343	0.09	0.07	263	0.09	0.06
AV-1 - Baseline	334	0.00	0.06	258	-0.00	0.06
Lycopene (µg/ml)						
Baseline	395	0.39	0.21	282	0.40	0.21
AV-1	343	0.38	0.21	263	0.38	0.21
AV-1 - Baseline	334	-0.00	0.18	258	-0.02	0.19
Lutein and Zeaxanthin (µg/ml)						
Baseline	395	0.24	0.12	282	0.23	0.11
AV-1	343	0.25	0.12	263	0.24	0.11
AV-1 - Baseline	334	0.00	0.08	258	0.01	0.08
Retinol (µg/ml)						
Baseline	395	0.56	0.16	282	0.56	0.16
AV-1	343	0.57	0.15	263	0.57	0.15
AV-1 - Baseline	334	0.01	0.10	258	0.01	0.08

(continues)

Table 2.11 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	383	113.26	22.95	268	113.54	26.49
AV-1	334	119.15	28.31	254	118.29	30.43
AV-1 – Baseline	317	5.64	20.62	239	4.70	18.58
Factor VII C (%)[1]						
Baseline	373	117.99	28.00	262	116.98	29.20
AV-1	330	119.30	27.11	253	115.93	27.30
AV-1 – Baseline	303	1.76	19.50	232	-1.88	20.49
Fibrinogen (mg/dl)						
Baseline	382	328.07	66.21	268	318.81	65.87
AV-1	333	323.92	66.78	254	314.64	64.60
AV-1 – Baseline	316	-2.01	52.20	239	-4.26	47.77
Hormones / Other						
Glucose (mg/dl)						
Baseline	394	111.38	42.90	283	106.94	38.02
AV-1	343	108.62	40.78	261	109.82	41.39
AV-1 – Baseline	333	-1.14	36.72	256	0.63	26.09
Insulin (μIU/ml)						
Baseline	386	15.99	25.09	279	13.16	8.24
AV-1	341	14.38	13.52	261	13.18	7.77
AV-1 – Baseline	324	-0.86	8.40	253	-0.14	6.24

(continues)

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

Table 2.11 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	395	119.97	54.59	283	118.84	60.74
AV-1	343	122.01	50.37	263	119.79	59.57
AV-1 – Baseline	334	4.30	38.53	258	-2.10	39.83
Total Cholesterol (mg/dl)						
Baseline	395	224.05	42.33	283	221.35	41.99
AV-1	343	220.02	41.01	263	214.95	38.34
AV-1 – Baseline	334	-4.89	29.09	258	-6.82	24.91
LDL-C (mg/dl)						
Baseline	394	143.33	40.35	281	140.54	38.87
AV-1	343	134.12	39.02	260	132.36	37.67
AV-1 – Baseline	334	-9.86	27.40	255	-8.78	22.85
HDL-C (mg/dl)						
Baseline	394	56.73	13.77	282	56.71	13.47
AV-1	343	61.44	15.73	263	59.24	14.51
AV-1 – Baseline	334	4.08	9.64	257	2.60	8.37
HDL-2 (mg/dl)						
Baseline	392	17.52	7.15	276	17.12	7.17
AV-1	341	20.25	8.62	261	18.81	8.19
AV-1 – Baseline	330	2.25	5.46	250	1.58	5.16
HDL-3 (mg/dl)						
Baseline	392	39.20	8.14	276	39.55	7.49
AV-1	343	41.26	9.00	261	40.23	7.78
AV-1 – Baseline	331	1.80	5.81	250	0.74	4.84
Lp(a) (mg/dl)						
Baseline	388	40.45	31.50	277	38.83	28.83
AV-1	341	38.48	31.37	262	37.15	27.76
AV-1 – Baseline	327	-1.15	13.04	252	-2.08	10.95

Table 2.11 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	177	0.09	0.11	222	0.10	0.09
AV-1	148	0.08	0.06	185	0.09	0.07
AV-1 - Baseline	144	-0.02	0.11	183	-0.01	0.08
Beta-Carotene (µg/ml)						
Baseline	177	0.32	0.49	222	0.32	0.31
AV-1	148	0.27	0.26	185	0.28	0.23
AV-1 – Baseline	144	-0.07	0.38	183	-0.05	0.25
Alpha-tocopherol (µg/ml)						
Baseline	177	15.52	7.30	222	15.78	6.81
AV-1	148	16.91	7.56	185	16.56	7.41
AV-1 – Baseline	144	1.42	6.23	183	0.76	5.12
Gamma-tocopherol (µg/ml)						
Baseline	177	2.29	1.37	222	2.23	1.37
AV-1	148	2.12	1.44	185	1.96	1.33
AV-1 – Baseline	144	-0.22	0.98	183	-0.28	0.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	177	0.12	0.17	222	0.12	0.11
AV-1	148	0.11	0.11	185	0.12	0.11
AV-1 - Baseline	144	-0.02	0.15	183	-0.01	0.09
Lycopene (µg/ml)						
Baseline	177	0.40	0.19	222	0.45	0.21
AV-1	148	0.38	0.18	185	0.40	0.19
AV-1 - Baseline	144	-0.03	0.15	183	-0.05	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	177	0.19	0.09	222	0.22	0.10
AV-1	148	0.20	0.09	185	0.22	0.11
AV-1 - Baseline	144	0.00	0.06	183	-0.01	0.08
Retinol (µg/ml)						
Baseline	177	0.53	0.13	222	0.56	0.14
AV-1	148	0.55	0.13	185	0.56	0.15
AV-1 - Baseline	144	0.02	0.08	183	-0.00	0.09

(continues)

Table 2.11 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	170	122.91	25.34	209	124.94	27.93
AV-1	134	128.32	26.46	179	129.13	28.73
AV-1 – Baseline	124	9.34	24.44	168	4.43	22.81
Factor VII C (%)[1]						
Baseline	164	126.37	29.10	202	124.85	27.65
AV-1	131	126.92	24.66	174	123.49	26.08
AV-1 – Baseline	118	3.15	26.69	158	-0.80	19.87
Fibrinogen (mg/dl)						
Baseline	170	318.05	66.36	209	316.09	63.72
AV-1	134	311.28	60.61	178	315.65	61.87
AV-1 – Baseline	124	-5.34	54.42	167	-6.71	52.31
Hormones / Other						
Glucose (mg/dl)						
Baseline	176	104.09	30.87	222	106.05	35.26
AV-1	148	106.64	36.96	185	104.92	30.63
AV-1 – Baseline	142	2.91	23.64	183	-1.09	17.83
Insulin (µIU/ml)						
Baseline	174	14.00	8.69	220	13.60	7.88
AV-1	146	13.73	9.11	182	13.21	6.62
AV-1 – Baseline	140	-0.39	6.26	180	-0.41	6.00

(continues)

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

Table 2.11 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	178	162.16	67.43	222	166.98	86.24
AV-1	148	169.21	67.99	185	181.77	123.47
AV-1 – Baseline	144	8.65	51.64	183	14.21	94.14
Total Cholesterol (mg/dl)						
Baseline	178	219.26	37.88	222	224.51	37.44
AV-1	148	212.66	34.96	185	215.15	35.35
AV-1 – Baseline	144	-6.39	27.28	183	-11.76	23.84
LDL-C (mg/dl)						
Baseline	176	132.35	32.60	216	137.42	35.02
AV-1	147	122.43	31.51	178	127.15	33.73
AV-1 – Baseline	141	-9.70	26.16	174	-14.01	24.32
HDL-C (mg/dl)						
Baseline	177	54.01	12.96	222	53.64	14.08
AV-1	148	56.93	14.89	185	53.79	13.04
AV-1 – Baseline	143	2.54	9.43	183	0.64	7.14
HDL-2 (mg/dl)						
Baseline	177	15.97	6.45	218	15.61	6.68
AV-1	147	17.88	7.89	185	16.59	6.73
AV-1 – Baseline	142	1.36	5.25	180	0.89	4.43
HDL-3 (mg/dl)						
Baseline	177	38.03	7.75	218	37.58	7.65
AV-1	147	39.03	8.12	185	37.19	7.57
AV-1 – Baseline	142	1.18	5.43	180	-0.31	4.77
Lp(a) (mg/dl)						
Baseline	175	17.59	17.80	222	21.97	22.40
AV-1	145	16.40	17.78	184	19.75	20.96
AV-1 – Baseline	140	-0.73	7.22	182	-1.79	10.78

Table 2.11 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	484	0.07	0.06	777	0.09	0.08
AV-1	436	0.06	0.05	749	0.08	0.08
AV-1 - Baseline	427	-0.01	0.05	727	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	484	0.27	0.22	777	0.34	0.34
AV-1	436	0.24	0.22	749	0.31	0.31
AV-1 – Baseline	427	-0.02	0.20	727	-0.04	0.21
Alpha-tocopherol (µg/ml)						
Baseline	484	16.18	6.94	777	16.52	7.83
AV-1	436	18.04	9.19	749	17.02	7.36
AV-1 – Baseline	427	1.86	6.39	727	0.54	5.80
Gamma-tocopherol (µg/ml)						
Baseline	484	2.51	1.70	777	2.22	1.40
AV-1	436	2.23	1.91	749	1.80	1.21
AV-1 – Baseline	427	-0.32	1.15	727	-0.40	0.92
Beta-Cryptoxanthine (µg/ml)						
Baseline	484	0.08	0.07	777	0.09	0.07
AV-1	436	0.07	0.06	748	0.08	0.07
AV-1 - Baseline	427	-0.00	0.04	726	-0.01	0.06
Lycopene (µg/ml)						
Baseline	484	0.40	0.20	777	0.41	0.19
AV-1	436	0.39	0.19	749	0.40	0.19
AV-1 - Baseline	427	-0.01	0.17	727	-0.01	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	484	0.19	0.09	777	0.20	0.09
AV-1	436	0.20	0.09	749	0.21	0.09
AV-1 - Baseline	427	0.00	0.06	727	0.00	0.06
Retinol (µg/ml)						
Baseline	484	0.61	0.14	777	0.61	0.15
AV-1	436	0.64	0.15	749	0.62	0.14
AV-1 - Baseline	427	0.03	0.11	727	0.01	0.10

(continues)

Table 2.11 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	466	130.54	29.03	756	124.77	28.36
AV-1	413	142.32	35.17	722	131.18	31.03
AV-1 – Baseline	398	10.84	25.67	684	6.25	23.04
Factor VII C (%)[1]						
Baseline	463	131.66	27.89	750	126.27	26.73
AV-1	409	139.00	32.05	717	126.12	27.93
AV-1 – Baseline	392	6.86	24.44	673	-0.44	22.25
Fibrinogen (mg/dl)						
Baseline	464	310.11	62.68	754	304.41	57.78
AV-1	412	298.22	59.62	720	296.60	58.17
AV-1 – Baseline	395	-13.02	52.01	680	-8.11	53.98
Hormones / Other						
Glucose (mg/dl)						
Baseline	483	104.40	34.60	773	99.20	23.96
AV-1	434	101.79	29.67	747	96.81	20.23
AV-1 – Baseline	425	-3.37	18.03	721	-2.36	15.78
Insulin (µIU/ml)						
Baseline	473	12.47	7.13	742	11.11	6.52
AV-1	423	11.81	7.05	712	11.09	7.10
AV-1 – Baseline	407	-0.75	5.63	672	-0.06	5.49

(continues)

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

Table 2.11 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	484	167.85	104.44	776	148.16	75.10
AV-1	434	182.58	141.40	749	150.63	70.86
AV-1 – Baseline	425	14.68	77.27	726	2.72	53.47
Total Cholesterol (mg/dl)						
Baseline	484	230.56	41.19	776	225.46	36.16
AV-1	434	224.01	40.78	749	216.14	34.82
AV-1 – Baseline	425	-6.00	30.26	726	-8.92	28.82
LDL-C (mg/dl)						
Baseline	469	142.35	36.70	760	138.85	31.99
AV-1	418	128.17	35.47	738	126.68	31.58
AV-1 – Baseline	405	-13.65	27.27	708	-11.57	25.97
HDL-C (mg/dl)						
Baseline	480	55.47	14.64	772	57.06	14.40
AV-1	432	59.82	17.04	749	59.41	14.94
AV-1 – Baseline	422	4.19	9.38	722	2.40	8.18
HDL-2 (mg/dl)						
Baseline	459	16.89	7.60	743	17.89	7.59
AV-1	415	19.30	8.87	721	19.21	8.14
AV-1 – Baseline	390	2.06	4.96	672	1.17	4.63
HDL-3 (mg/dl)						
Baseline	459	38.70	8.48	743	39.14	8.18
AV-1	415	40.84	9.58	721	40.26	8.24
AV-1 – Baseline	390	2.17	5.79	672	1.19	5.26
Lp(a) (mg/dl)						
Baseline	472	25.65	25.24	764	26.46	27.75
AV-1	426	24.39	26.22	737	24.41	27.46
AV-1 – Baseline	410	-1.06	10.74	705	-1.96	10.81

Table 2.11 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	25	0.10	0.05	33	0.11	0.13
AV-1	23	0.10	0.09	29	0.09	0.10
AV-1 - Baseline	23	0.00	0.07	28	-0.03	0.05
Beta-Carotene (µg/ml)						
Baseline	25	0.35	0.32	33	0.42	0.45
AV-1	23	0.35	0.25	29	0.35	0.31
AV-1 – Baseline	23	-0.03	0.16	28	-0.07	0.29
Alpha-tocopherol (µg/ml)						
Baseline	25	17.48	8.26	33	16.71	7.64
AV-1	23	18.94	11.06	29	17.21	6.22
AV-1 – Baseline	23	0.97	5.11	28	0.09	5.64
Gamma-tocopherol (µg/ml)						
Baseline	25	2.19	1.14	33	1.90	1.08
AV-1	23	2.00	0.87	29	1.73	1.06
AV-1 – Baseline	23	-0.14	0.99	28	-0.08	0.70
Beta-Cryptoxanthine (µg/ml)						
Baseline	25	0.09	0.08	33	0.11	0.12
AV-1	23	0.11	0.07	29	0.08	0.06
AV-1 - Baseline	23	0.01	0.05	28	-0.02	0.08
Lycopene (µg/ml)						
Baseline	25	0.48	0.21	33	0.36	0.21
AV-1	23	0.44	0.23	29	0.33	0.22
AV-1 - Baseline	23	-0.06	0.24	28	-0.00	0.16
Lutein and Zeaxanthin (µg/ml)						
Baseline	25	0.20	0.10	33	0.20	0.14
AV-1	23	0.20	0.11	29	0.22	0.12
AV-1 - Baseline	23	-0.01	0.07	28	0.01	0.10
Retinol (µg/ml)						
Baseline	25	0.59	0.14	33	0.58	0.13
AV-1	23	0.64	0.19	29	0.60	0.13
AV-1 - Baseline	23	0.06	0.13	28	0.00	0.12

(continues)

Table 2.11 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	25	124.88	22.36	33	120.91	21.99
AV-1	23	133.00	26.98	28	130.21	27.60
AV-1 – Baseline	23	8.43	26.66	28	8.82	16.06
Factor VII C (%)[1]						
Baseline	24	123.79	22.90	33	123.64	21.38
AV-1	23	130.57	20.25	28	127.11	27.36
AV-1 – Baseline	22	7.41	19.63	28	3.71	18.73
Fibrinogen (mg/dl)						
Baseline	25	317.08	55.39	33	324.70	71.74
AV-1	23	294.04	64.72	28	307.32	59.63
AV-1 – Baseline	23	-24.48	53.87	28	-23.04	51.03
Hormones / Other						
Glucose (mg/dl)						
Baseline	25	98.32	19.88	34	100.62	26.89
AV-1	23	103.04	28.07	29	99.59	19.11
AV-1 – Baseline	23	4.17	14.54	29	-2.83	14.46
Insulin (μIU/ml)						
Baseline	25	10.15	6.58	34	10.24	4.97
AV-1	23	10.90	7.41	29	10.97	6.59
AV-1 – Baseline	23	0.61	6.25	29	0.11	3.45

(continues)

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

Table 2.11 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	25	155.40	89.00	34	157.29	73.88
AV-1	23	168.13	68.18	29	161.72	75.02
AV-1 – Baseline	23	11.57	62.43	29	2.21	38.74
Total Cholesterol (mg/dl)						
Baseline	25	238.76	41.89	34	221.15	35.46
AV-1	23	236.48	36.92	29	220.34	38.73
AV-1 – Baseline	23	-4.96	28.61	29	-1.17	29.84
LDL-C (mg/dl)						
Baseline	24	152.25	37.79	34	135.24	33.35
AV-1	23	143.65	35.75	29	132.62	41.10
AV-1 – Baseline	22	-10.27	23.25	29	-2.62	29.46
HDL-C (mg/dl)						
Baseline	25	55.32	12.58	34	54.47	14.86
AV-1	23	59.17	13.34	29	55.31	15.06
AV-1 – Baseline	23	4.61	7.45	29	0.93	4.78
HDL-2 (mg/dl)						
Baseline	25	16.48	6.76	33	16.03	8.12
AV-1	22	18.73	7.25	29	17.00	9.21
AV-1 – Baseline	22	1.91	5.08	28	0.57	4.14
HDL-3 (mg/dl)						
Baseline	25	38.84	7.11	33	38.00	7.80
AV-1	22	41.50	6.84	29	38.31	7.28
AV-1 – Baseline	22	3.00	4.86	28	0.18	3.38
Lp(a) (mg/dl)						
Baseline	25	20.64	22.31	34	27.41	25.20
AV-1	22	20.23	23.22	29	23.00	19.88
AV-1 – Baseline	22	-0.55	3.20	29	-3.55	15.82

Table 2.12
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: February 28, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline	930	1.01	0.11	1017	0.99	0.10
AV1	838	1.01	0.11	926	1.00	0.10
AV3	766	1.03	0.12	854	1.02	0.10
AV6	359	1.03	0.12	385	1.02	0.11
AV1 % Change from baseline BMD[2]	833	0.41	2.79	921	0.26	2.35
AV3 % Change from baseline BMD[3]	761	2.08	4.28	846	1.97	3.79
AV6 % Change from baseline BMD[4]	356	2.27	5.21	379	2.65	5.19
Spine Scan						
Baseline	905	0.97	0.16	991	0.95	0.16
AV1	817	0.99	0.16	896	0.97	0.16
AV3	752	1.00	0.17	834	0.99	0.17
AV6	355	1.01	0.17	376	0.99	0.17
AV1 % Change from baseline BMD[2]	813	1.91	4.55	892	2.06	4.34
AV3 % Change from baseline BMD[3]	748	3.53	6.17	828	4.09	6.05
AV6 % Change from baseline BMD[4]	352	4.33	7.77	374	5.21	7.77
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	774	0.88	0.15	860	0.86	0.14
AV6	365	0.88	0.14	394	0.86	0.13
AV1 % Change from baseline BMD[2]	838	0.72	3.31	925	0.63	3.17
AV3 % Change from baseline BMD[3]	768	2.22	4.86	854	2.17	4.78
AV6 % Change from baseline BMD[4]	362	0.81	5.67	388	1.53	5.73

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 2.13
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of: February 28, 2002

	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	97	1.08	0.11	65	1.03	0.10	61	1.02	0.11	679	0.99	0.10	837	0.98	0.09
AV1	153	1.07	0.11	86	1.08	0.11	43	1.04	0.10	50	1.03	0.10	631	0.99	0.10	773	0.99	0.09
AV3	150	1.09	0.11	87	1.10	0.12	50	1.05	0.12	45	1.06	0.11	558	1.01	0.11	705	1.00	0.10
AV6	76	1.08	0.11	42	1.09	0.11	24	1.10	0.12	17	1.11	0.15	254	1.01	0.11	319	1.01	0.10
AV1 % Change from baseline BMD[2]	153	0.75	2.95	86	0.91	2.86	43	-0.16	2.33	49	-0.07	2.42	626	0.37	2.76	769	0.21	2.28
AV3 % Change from baseline BMD[3]	150	2.06	3.45	87	2.15	3.18	50	1.61	4.61	44	3.15	5.43	553	2.13	4.46	698	1.85	3.74
AV6 % Change from baseline BMD[4]	76	0.46	3.93	42	0.39	4.27	24	5.65	6.57	17	6.36	4.29	251	2.48	5.20	313	2.78	5.26
Spine Scan																		
Baseline	171	1.04	0.15	97	1.08	0.19	64	0.96	0.13	61	0.92	0.14	658	0.95	0.16	811	0.93	0.15
AV1	150	1.05	0.16	86	1.09	0.19	43	0.97	0.11	49	0.95	0.15	613	0.97	0.16	744	0.96	0.16
AV3	147	1.07	0.17	87	1.11	0.20	50	0.95	0.12	45	0.94	0.14	547	0.98	0.17	685	0.97	0.16
AV6	73	1.08	0.17	41	1.12	0.20	24	0.99	0.15	16	0.99	0.19	253	0.99	0.16	312	0.97	0.16
AV1 % Change from baseline BMD[2]	150	1.92	4.39	85	1.73	4.84	43	-0.39	4.16	49	1.71	6.86	609	2.10	4.58	741	2.12	4.09
AV3 % Change from baseline BMD[3]	147	3.43	6.16	86	3.10	6.38	50	-0.05	5.37	44	2.97	7.06	543	3.91	6.11	681	4.28	5.93
AV6 % Change from baseline BMD[4]	73	3.84	7.12	40	2.64	8.01	24	1.32	8.21	16	5.17	9.10	250	4.83	7.91	311	5.53	7.66
Hip Scan																		
Baseline	174	0.96	0.13	98	0.97	0.15	65	0.87	0.11	61	0.84	0.13	683	0.83	0.13	843	0.82	0.12
AV1	153	0.97	0.13	86	0.97	0.14	43	0.87	0.11	50	0.85	0.12	634	0.83	0.13	775	0.83	0.12
AV3	150	0.98	0.14	87	0.99	0.15	50	0.89	0.13	45	0.88	0.13	566	0.85	0.14	711	0.84	0.13
AV6	77	0.95	0.14	43	0.96	0.13	24	0.91	0.15	17	0.86	0.11	259	0.85	0.13	327	0.84	0.12
AV1 % Change from baseline BMD[2]	153	1.16	2.97	86	1.14	3.43	43	0.31	3.62	49	1.09	3.47	631	0.65	3.37	773	0.54	3.13
AV3 % Change from baseline BMD[3]	150	1.87	3.91	87	1.38	3.94	50	2.74	5.32	44	4.51	5.97	560	2.26	5.03	706	2.08	4.77
AV6 % Change from baseline BMD[4]	77	-1.73	5.35	42	-2.20	5.31	24	2.97	7.07	17	4.18	7.23	256	1.41	5.39	322	1.91	5.52

[1] Measured in (g/cm2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 2.14
Lost-to-Follow-up and Vital Status: HRT Participants by Hysterectomy Status

Data as of: February 28, 2002

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	335	3.1	417	2.5	752	2.7
Alive: Current Participation[1]	9689	90.2	15283	92.0	24972	91.3
Alive: Recent Participation[2]	247	2.3	321	1.9	568	2.1
Alive: Past/Unknown Participation[3]	23	0.2	22	0.1	45	0.2
Stopped Follow-Up[4]	239	2.2	327	2.0	566	2.1
Lost to Follow-Up[5]	206	1.9	238	1.4	444	1.6

[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 2.15

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

Data as of: February 28, 2002

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3425		5408		12364		6150	
Mean follow-up (months)	59.7		64.8		61.7		58.7		57.0	
Cardiovascular										
CHD[1]	499	(0.37%)	30	(0.16%)	41	(0.15%)	222	(0.37%)	206	(0.71%)
CHD death[2]	118	(0.09%)	7	(0.04%)	11	(0.04%)	44	(0.07%)	56	(0.19%)
Total MI[3]	420	(0.31%)	25	(0.14%)	32	(0.12%)	189	(0.31%)	174	(0.60%)
Clinical MI	406	(0.30%)	24	(0.13%)	32	(0.12%)	181	(0.30%)	169	(0.58%)
Evolving Q-wave MI[4]	14	(0.01%)	1	(0.01%)	0	(0.00%)	8	(0.01%)	5	(0.02%)
Possible evolving Q-wave MI[4]	83	(0.06%)	9	(0.05%)	9	(0.03%)	31	(0.05%)	34	(0.12%)
Angina	723	(0.53%)	28	(0.15%)	89	(0.32%)	334	(0.55%)	272	(0.93%)
CABG/PTCA	675	(0.50%)	27	(0.15%)	76	(0.27%)	320	(0.53%)	252	(0.86%)
Carotid artery disease	139	(0.10%)	0	(0.00%)	15	(0.05%)	72	(0.12%)	52	(0.18%)
Congestive heart failure	388	(0.29%)	18	(0.10%)	43	(0.15%)	157	(0.26%)	170	(0.58%)
Stroke	393	(0.29%)	11	(0.06%)	41	(0.15%)	172	(0.28%)	169	(0.58%)
Non-disabling stroke	233	(0.17%)	9	(0.05%)	26	(0.09%)	107	(0.18%)	91	(0.31%)
Fatal/disabling stroke	96	(0.07%)	1	(0.01%)	6	(0.02%)	37	(0.06%)	52	(0.18%)
Unknown status from stroke	64	(0.05%)	1	(0.01%)	9	(0.03%)	28	(0.05%)	26	(0.09%)
PVD	111	(0.08%)	6	(0.03%)	10	(0.04%)	55	(0.09%)	40	(0.14%)
DVT	233	(0.17%)	13	(0.07%)	32	(0.12%)	104	(0.17%)	84	(0.29%)
Pulmonary embolism	140	(0.10%)	6	(0.03%)	21	(0.08%)	64	(0.11%)	49	(0.17%)
CHD[1]/Possible evolving Q-wave MI	578	(0.42%)	39	(0.21%)	50	(0.18%)	251	(0.41%)	238	(0.81%)
Coronary disease[5]	1506	(1.11%)	79	(0.43%)	169	(0.61%)	677	(1.12%)	581	(1.99%)
DVT/PE	307	(0.23%)	15	(0.08%)	42	(0.15%)	145	(0.24%)	105	(0.36%)
Total cardiovascular disease	2266	(1.67%)	109	(0.59%)	254	(0.91%)	1046	(1.73%)	857	(2.93%)
Cancer										
Breast cancer[6]	519	(0.38%)	48	(0.26%)	86	(0.31%)	257	(0.42%)	128	(0.44%)
Invasive breast cancer	412	(0.30%)	37	(0.20%)	70	(0.25%)	200	(0.33%)	105	(0.36%)
Non-invasive breast cancer	112	(0.08%)	11	(0.06%)	17	(0.06%)	61	(0.10%)	23	(0.08%)
Ovarian cancer	51	(0.04%)	1	(0.01%)	7	(0.03%)	32	(0.05%)	11	(0.04%)
Endometrial cancer[7]	46	(0.06%)	1	(0.01%)	8	(0.04%)	23	(0.06%)	14	(0.08%)
Colorectal cancer	197	(0.14%)	9	(0.05%)	20	(0.07%)	98	(0.16%)	70	(0.24%)
Other cancer[8]	668	(0.49%)	50	(0.27%)	94	(0.34%)	310	(0.51%)	214	(0.73%)
Total cancer	1439	(1.06%)	109	(0.59%)	210	(0.76%)	697	(1.15%)	423	(1.45%)
Fractures										
Hip fracture	161	(0.12%)	3	(0.02%)	4	(0.01%)	53	(0.09%)	101	(0.35%)
Vertebral fracture	159	(0.12%)	6	(0.03%)	17	(0.06%)	63	(0.10%)	73	(0.25%)
Other fracture[8]	2027	(1.49%)	229	(1.24%)	317	(1.14%)	962	(1.59%)	519	(1.78%)
Total fracture	2269	(1.67%)	236	(1.28%)	333	(1.20%)	1046	(1.73%)	654	(2.24%)
Deaths										
Cardiovascular deaths	224	(0.16%)	9	(0.05%)	20	(0.07%)	88	(0.15%)	107	(0.37%)
Cancer deaths	309	(0.23%)	15	(0.08%)	28	(0.10%)	149	(0.25%)	117	(0.40%)
Other known cause	106	(0.08%)	8	(0.04%)	14	(0.05%)	39	(0.06%)	45	(0.15%)
Unknown cause	50	(0.04%)	5	(0.03%)	6	(0.02%)	18	(0.03%)	21	(0.07%)
Not yet adjudicated	63	(0.05%)	4	(0.02%)	7	(0.03%)	27	(0.04%)	25	(0.09%)
Total death	752	(0.55%)	41	(0.22%)	75	(0.27%)	321	(0.53%)	315	(1.08%)

[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] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] 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 2.15 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Replacement Therapy

Data as of: February 28, 2002

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)	58.0		55.9		59.2		56.7		60.1		55.9	
Cardiovascular												
CHD[1]	3	(0.48%)	6	(0.24%)	48	(0.36%)	16	(0.22%)	415	(0.38%)	11	(0.61%)
CHD death[2]	1	(0.16%)	3	(0.12%)	21	(0.16%)	4	(0.06%)	87	(0.08%)	2	(0.11%)
Total MI[3]	2	(0.32%)	5	(0.20%)	34	(0.25%)	13	(0.18%)	356	(0.32%)	10	(0.56%)
Clinical MI	2	(0.32%)	5	(0.20%)	33	(0.24%)	13	(0.18%)	344	(0.31%)	9	(0.50%)
Evolving Q-wave MI[4]	0	(0.00%)	0	(0.00%)	1	(0.01%)	0	(0.00%)	12	(0.01%)	1	(0.06%)
Possible evolving Q-wave MI[4]	0	(0.00%)	1	(0.04%)	9	(0.07%)	4	(0.06%)	68	(0.06%)	1	(0.06%)
Angina	4	(0.64%)	11	(0.45%)	73	(0.54%)	31	(0.43%)	597	(0.54%)	7	(0.39%)
CABG/PTCA	4	(0.64%)	6	(0.24%)	57	(0.42%)	27	(0.37%)	572	(0.52%)	9	(0.50%)
Carotid artery disease	1	(0.16%)	1	(0.04%)	6	(0.04%)	0	(0.00%)	131	(0.12%)	0	(0.00%)
Congestive heart failure	3	(0.48%)	5	(0.20%)	57	(0.42%)	11	(0.15%)	308	(0.28%)	4	(0.22%)
Stroke	3	(0.48%)	8	(0.33%)	49	(0.36%)	10	(0.14%)	318	(0.29%)	5	(0.28%)
Non-disabling stroke	2	(0.32%)	6	(0.24%)	27	(0.20%)	8	(0.11%)	187	(0.17%)	3	(0.17%)
Fatal/disabling stroke	1	(0.16%)	1	(0.04%)	13	(0.10%)	1	(0.01%)	79	(0.07%)	1	(0.06%)
Unknown status from stroke	0	(0.00%)	1	(0.04%)	9	(0.07%)	1	(0.01%)	52	(0.05%)	1	(0.06%)
PVD	1	(0.16%)	0	(0.00%)	11	(0.08%)	2	(0.03%)	97	(0.09%)	0	(0.00%)
DVT	1	(0.16%)	1	(0.04%)	20	(0.15%)	4	(0.06%)	207	(0.19%)	0	(0.00%)
Pulmonary embolism	3	(0.48%)	1	(0.04%)	11	(0.08%)	1	(0.01%)	124	(0.11%)	0	(0.00%)
CHD[1]/Possible evolving Q-wave MI	3	(0.48%)	7	(0.29%)	56	(0.41%)	20	(0.28%)	480	(0.43%)	12	(0.67%)
Coronary disease[5]	8	(1.27%)	19	(0.77%)	167	(1.24%)	60	(0.83%)	1231	(1.12%)	21	(1.17%)
DVT/PE	4	(0.64%)	1	(0.04%)	25	(0.19%)	4	(0.06%)	273	(0.25%)	0	(0.00%)
Total cardiovascular disease	14	(2.23%)	28	(1.14%)	241	(1.79%)	73	(1.01%)	1884	(1.71%)	26	(1.45%)
Cancer												
Breast cancer[6]	0	(0.00%)	10	(0.41%)	43	(0.32%)	18	(0.25%)	446	(0.40%)	2	(0.11%)
Invasive breast cancer	0	(0.00%)	8	(0.33%)	34	(0.25%)	12	(0.17%)	356	(0.32%)	2	(0.11%)
Non-invasive breast cancer	0	(0.00%)	2	(0.08%)	10	(0.07%)	6	(0.08%)	94	(0.09%)	0	(0.00%)
Ovarian cancer	0	(0.00%)	0	(0.00%)	4	(0.03%)	0	(0.00%)	47	(0.04%)	0	(0.00%)
Endometrial cancer[7]	1	(0.38%)	0	(0.00%)	0	(0.00%)	1	(0.02%)	44	(0.06%)	0	(0.00%)
Colorectal cancer	0	(0.00%)	6	(0.24%)	20	(0.15%)	11	(0.15%)	158	(0.14%)	2	(0.11%)
Other cancer[8]	4	(0.64%)	12	(0.49%)	59	(0.44%)	23	(0.32%)	560	(0.51%)	10	(0.56%)
Total cancer	5	(0.80%)	28	(1.14%)	121	(0.90%)	51	(0.70%)	1221	(1.11%)	13	(0.73%)
Fractures												
Hip fracture	0	(0.00%)	1	(0.04%)	6	(0.04%)	3	(0.04%)	151	(0.14%)	0	(0.00%)
Vertebral fracture	0	(0.00%)	2	(0.08%)	1	(0.01%)	2	(0.03%)	152	(0.14%)	2	(0.11%)
Other fracture[8]	8	(1.27%)	27	(1.10%)	105	(0.78%)	71	(0.98%)	1796	(1.63%)	20	(1.12%)
Total fracture	8	(1.27%)	29	(1.18%)	112	(0.83%)	74	(1.02%)	2025	(1.83%)	21	(1.17%)
Deaths												
Cardiovascular deaths	1	(0.16%)	4	(0.16%)	40	(0.30%)	4	(0.06%)	172	(0.16%)	3	(0.17%)
Cancer deaths	1	(0.16%)	10	(0.41%)	29	(0.21%)	7	(0.10%)	259	(0.23%)	3	(0.17%)
Other known cause	2	(0.32%)	1	(0.04%)	11	(0.08%)	0	(0.00%)	92	(0.08%)	0	(0.00%)
Unknown cause	1	(0.16%)	0	(0.00%)	6	(0.04%)	1	(0.01%)	40	(0.04%)	2	(0.11%)
Not yet adjudicated	0	(0.00%)	2	(0.08%)	7	(0.05%)	3	(0.04%)	50	(0.05%)	1	(0.06%)
Total death	5	(0.80%)	17	(0.69%)	93	(0.69%)	15	(0.21%)	613	(0.56%)	9	(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] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] 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 2.16
Locally Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: February 28, 2002

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	59.6		59.7	
Cardiovascular				
CHD[1]	220	(0.41%)	279	(0.34%)
CHD death[2]	61	(0.11%)	57	(0.07%)
Total MI[3]	181	(0.34%)	239	(0.29%)
Clinical MI	174	(0.33%)	232	(0.28%)
Evolving Q-wave MI[4]	12	(0.02%)	16	(0.02%)
Possible evolving Q-wave MI[4]	36	(0.07%)	58	(0.07%)
Angina	389	(0.73%)	334	(0.40%)
CABG/PTCA	335	(0.63%)	340	(0.41%)
Carotid artery disease	71	(0.13%)	68	(0.08%)
Congestive heart failure	219	(0.41%)	169	(0.20%)
Stroke	193	(0.36%)	200	(0.24%)
Non-disabling stroke	116	(0.22%)	117	(0.14%)
Fatal/disabling stroke	41	(0.08%)	55	(0.07%)
Unknown status from stroke	36	(0.07%)	28	(0.03%)
PVD	54	(0.10%)	57	(0.07%)
DVT	73	(0.14%)	160	(0.19%)
Pulmonary embolism	43	(0.08%)	97	(0.12%)
CHD[1]/Possible evolving Q-wave MI	249	(0.47%)	329	(0.40%)
Coronary disease[5]	751	(1.41%)	755	(0.91%)
DVT/PE	97	(0.18%)	210	(0.25%)
Total cardiovascular disease	1078	(2.02%)	1188	(1.44%)
Cancer				
Breast cancer[6]	177	(0.33%)	342	(0.41%)
Invasive breast cancer	136	(0.25%)	276	(0.33%)
Non-invasive breast cancer	42	(0.08%)	70	(0.08%)
Ovarian cancer	17	(0.03%)	34	(0.04%)
Endometrial cancer[7]	0	N/A	46	(0.06%)
Colorectal cancer	93	(0.17%)	104	(0.13%)
Other cancer[8]	251	(0.47%)	417	(0.50%)
Total cancer	527	(0.99%)	912	(1.10%)
Fractures				
Hip fracture	58	(0.11%)	103	(0.12%)
Vertebral fracture	60	(0.11%)	99	(0.12%)
Other fracture[8]	784	(1.47%)	1240	(1.50%)
Total fracture	873	(1.64%)	1393	(1.69%)
Deaths				
Cardiovascular deaths	112	(0.21%)	112	(0.14%)
Cancer deaths	134	(0.25%)	175	(0.21%)
Other known cause	36	(0.07%)	70	(0.08%)
Unknown cause	23	(0.04%)	27	(0.03%)
Not yet adjudicated	30	(0.06%)	33	(0.04%)
Total death	335	(0.63%)	417	(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] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] 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 2.17
Frequency (%)[1] of Various Subcategories of Stroke Diagnosis: HRT Participants

Data as of: February 28, 2002

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Stroke Diagnosis				
Subarachoid hemorrhage	8	4.1%	9	4.5%
Intracerebral hemorrhage	24	12.4%	28	14.0%
Other intracranial hemorrhage	2	1.0%	2	1.0%
Occlusion of cerebral arteries with infarction	111	57.5%	115	57.5%
Acute cerebrovascular disease	35	18.1%	27	13.5%
Central nervous system complications	10	5.2%	8	4.0%
Report of cerebrovascular death only	3	1.6%	10	5.0%
Missing	0	0.0%	1	0.5%
Total	193	100%	200	100%

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

Table 2.18
Frequency (%)[1] of Disability Levels Following Stroke – Glasgow Scale: HRT Participants

Data as of: February 28, 2002

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Glasgow scale				
Good recovery	64	33.2%	63	31.5%
Moderately disabled	52	26.9%	54	27.0%
Severely disabled	17	8.8%	24	12.0%
Vegetative survival	0	0.0%	4	2.0%
Death or death within 1 month	24	12.4%	27	13.5%
Unable to categorize stroke	9	4.7%	10	5.0%
Not yet categorized	27	14.0%	18	9.0%
Total	193	100%	200	100%

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

Table 2.19
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: February 28, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3425	5408	12364	6150
Mean follow-up (months)	59.7	64.8	61.7	58.7	57.0
Hospitalizations					
Ever	9947 (7.31%)	881 (4.76%)	1564 (5.62%)	4597 (7.60%)	2905 (9.94%)
Two or more	4478 (3.29%)	350 (1.89%)	628 (2.26%)	2071 (3.42%)	1429 (4.89%)
Other					
Diabetes (treated)	1338 (1.04%)	182 (1.03%)	269 (1.02%)	607 (1.06%)	280 (1.02%)
Gallbladder disease[1]	1361 (1.20%)	179 (1.12%)	292 (1.23%)	642 (1.28%)	248 (1.05%)
Hysterectomy	431 (0.52%)	35 (0.32%)	81 (0.45%)	219 (0.59%)	96 (0.57%)
Glaucoma	1829 (1.40%)	153 (0.84%)	301 (1.11%)	877 (1.51%)	498 (1.84%)
Osteoporosis	3720 (2.88%)	245 (1.35%)	533 (1.97%)	1795 (3.13%)	1147 (4.35%)
Osteoarthritis[2]	3140 (3.77%)	382 (2.78%)	622 (3.26%)	1435 (4.01%)	701 (4.75%)
Rheumatoid arthritis	1067 (0.82%)	145 (0.81%)	237 (0.89%)	458 (0.79%)	227 (0.82%)
Intestinal polyps	2235 (1.76%)	215 (1.20%)	374 (1.41%)	1153 (2.05%)	493 (1.90%)
Lupus	169 (0.12%)	21 (0.11%)	36 (0.13%)	83 (0.14%)	29 (0.10%)
Kidney stones[2]	396 (0.37%)	43 (0.31%)	79 (0.37%)	182 (0.38%)	92 (0.40%)
Cataracts[2]	5485 (5.86%)	253 (1.84%)	722 (3.42%)	2945 (6.89%)	1565 (9.80%)
Pills for hypertension	4801 (4.97%)	510 (3.42%)	910 (4.25%)	2184 (5.21%)	1197 (6.54%)

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)	58.0	55.9	59.2	56.7	60.1	55.9
Hospitalizations						
Ever	49 (7.80%)	120 (4.89%)	1031 (7.64%)	427 (5.88%)	8202 (7.43%)	118 (6.58%)
Two or more	25 (3.98%)	46 (1.87%)	491 (3.64%)	160 (2.20%)	3714 (3.36%)	42 (2.34%)
Other						
Diabetes (treated)	9 (1.67%)	31 (1.38%)	240 (2.04%)	119 (1.78%)	920 (0.87%)	19 (1.14%)
Gallbladder disease[1]	9 (1.87%)	20 (0.89%)	122 (1.01%)	75 (1.38%)	1118 (1.22%)	17 (1.15%)
Hysterectomy	2 (0.76%)	2 (0.12%)	25 (0.46%)	16 (0.39%)	382 (0.55%)	4 (0.37%)
Glaucoma	9 (1.52%)	35 (1.48%)	235 (1.88%)	114 (1.63%)	1411 (1.33%)	25 (1.50%)
Osteoporosis	19 (3.20%)	78 (3.30%)	187 (1.44%)	174 (2.58%)	3206 (3.07%)	56 (3.30%)
Osteoarthritis[2]	18 (4.23%)	59 (3.45%)	331 (4.09%)	227 (4.55%)	2450 (3.66%)	55 (4.81%)
Rheumatoid arthritis	6 (1.08%)	21 (0.89%)	183 (1.48%)	153 (2.22%)	686 (0.65%)	18 (1.06%)
Intestinal polyps	8 (1.38%)	32 (1.42%)	220 (1.75%)	112 (1.61%)	1848 (1.80%)	15 (0.91%)
Lupus	1 (0.16%)	3 (0.12%)	23 (0.17%)	14 (0.19%)	128 (0.12%)	0 (0.00%)
Kidney stones[2]	4 (0.87%)	14 (0.72%)	38 (0.36%)	32 (0.57%)	306 (0.36%)	2 (0.14%)
Cataracts[2]	27 (6.09%)	85 (4.95%)	496 (5.32%)	289 (5.32%)	4525 (5.99%)	63 (5.07%)
Pills for hypertension	28 (6.36%)	91 (5.30%)	455 (6.83%)	284 (5.23%)	3888 (4.79%)	55 (4.73%)

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

Table 2.20
Baseline Characteristics of HRT Participants Enrolled in WHIMS

Data as of: February 28, 2002

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16608	
Eligible HRT Population	4942		7303	
Enrolled in WHIMS	2970		4556	
% Enrolled of Total HRT		27.7%		27.4%
% Enrolled of Eligible		60.1%		62.4%
WHIMS Participants	**(N = 2970)**		**(N = 4556)**	
Age at Screening				
< 70	1424	(47.9%)	2293	(50.3%)
70-74	1062	(35.8%)	1540	(33.8%)
75+	484	(16.3%)	723	(15.9%)
Education				
Missing	8	(0.3%)	16	(0.4%)
0-8 years	68	(2.3%)	68	(1.5%)
Some high school	213	(7.2%)	231	(5.1%)
High school diploma/GED	706	(23.8%)	947	(20.8%)
School after high school	1246	(42.0%)	1775	(39.0%)
College degree or higher	729	(24.5%)	1519	(33.3%)
Ethnicity				
American Indian	16	(0.5%)	10	(0.2%)
Asian/Pacific Islander	37	(1.2%)	91	(2.0%)
Black	326	(11.0%)	216	(4.7%)
Hispanic	84	(2.8%)	105	(2.3%)
White	2457	(82.7%)	4065	(89.2%)
Unknown	50	(1.7%)	69	(1.5%)
Family Income				
Missing	182	(6.1%)	274	(6.0%)
< $10,000	226	(7.6%)	197	(4.3%)
$10,000 - $19,999	649	(21.9%)	789	(17.3%)
$20,000 - $34,999	897	(30.2%)	1325	(29.1%)
$35,000 - $49,999	516	(17.4%)	931	(20.4%)
$50,000 - $74,999	324	(10.9%)	660	(14.5%)
$75,000 +	176	(5.9%)	380	(8.3%)

Table 2.21
Cognitive Function Screening Scores for HRT Participants Enrolled in WHIMS

Data as of: February 28, 2002

	HRT Participants			
	Without Uterus		With Uterus	
	N	F39 Score	N	F39 Score
Baseline				
WHIMS	2939		4514	
25th Percentile		92		94
Median		96		97
Non-WHIMS	633		888	
25th Percentile		90		92
Median		95		96
Annual Visit 1				
WHIMS	2794		4311	
25th Percentile		94		95
Median		97		97
Non-WHIMS	1055		1606	
25th Percentile		92		93
Median		95		96
Annual Visit 2				
WHIMS	2614		4111	
25th Percentile		94		95
Median		97		98
Annual Visit 3				
WHIMS	2582		4066	
25th Percentile		94		95
Median		97		98
Non-WHIMS	1669		2450	
25th Percentile		92		93
Median		96		96
Annual Visit 4				
WHIMS	1963		3042	
25th Percentile		95		96
Median		97		98
Annual Visit 5				
WHIMS	563		923	
25th Percentile		95		96
Median		98		98

Table 2.22
Incidence of Probable Dementia in HRT Participants Enrolled in WHIMS

Data as of: February 28, 2002

	Without Uterus	With Uterus	All
Baseline			
F39 Completed	2939	4514	7453
Positive Screen	17	10	27
Diagnosis[1]			
PD	2	1	3
MCI	5	3	8
ND	10	6	16
Unknown	0	0	0
AV1			
F39 Completed	2794	4311	7105
Positive Screen	79	88	167
Diagnosis[1]			
PD	7	11	18
MCI	20	23	43
ND	39	44	83
Unknown	13	10	23
Deceased	0	1	1
AV2			
F39 Completed	2614	4111	6725
Positive Screen	116	125	241
Diagnosis[1]			
PD	8	16	24
MCI	34	42	76
ND	50	53	103
Unknown	24	14	38
AV3			
F39 Completed	2582	4066	6648
Positive Screen	103	108	211
Diagnosis[1]			
PD	10	13	23
MCI	25	38	63
ND	36	24	60
Unknown	32	33	65
Deceased	0	1	1
AV4			
F39 Completed	1963	3042	5005
Positive Screen	94	72	166
Diagnosis[1]			
PD	24	23	47
MCI	15	6	21
ND	15	15	30
Unknown	40	28	68
AV5			
F39 Completed	563	923	1486
Positive Screen	28	30	58
Diagnosis[1]			
PD	6	7	13
MCI	4	3	7
ND	2	1	3
Unknown	16	19	35
Deceased	1	0	1

[1] Diagnoses: PD – Probable Dementia
MCI – Minor Cognitive Impairment
ND – No Dementia
Unknown -- Refused phase 2/3 or materials are under review

Table 2.23
Baseline Characteristics of HRT Participants Enrolled in WHI-SE

Data as of: February 28, 2002

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16608	
Eligible HRT Population	7773		11616	
Enrolled in WHI-SE	1436		2306	
% Enrolled of Total HRT		13.4%		13.9%
% Enrolled of Eligible		18.5%		19.9%
WHI-SE Participants	**(N = 1436)**		**(N = 2306)**	
Age at Screening				
< 70	967	(67.3%)	1669	(72.4%)
70-74	345	(24.0%)	477	(20.7%)
75+	124	(8.6%)	160	(6.9%)
Education				
Missing	8	(0.6%)	10	(0.4%)
0-8 years	28	(1.9%)	25	(1.1%)
Some high school	77	(5.4%)	85	(3.7%)
High school diploma/GED	359	(25.0%)	514	(22.3%)
School after high school	603	(42.0%)	835	(36.2%)
College degree or higher	361	(25.1%)	837	(36.3%)
Ethnicity				
White	1238	(86.2%)	2132	(92.5%)
Black	140	(9.7%)	95	(4.1%)
Hispanic	30	(2.1%)	46	(2.0%)
American Indian	8	(0.6%)	1	(0.0%)
Asian/Pacific Islander	6	(0.4%)	17	(0.7%)
Unknown	14	(1.0%)	15	(0.7%)
Family Income				
Missing	69	(4.8%)	131	(5.7%)
< $10,000	97	(6.8%)	82	(3.6%)
$10,000 - $19,999	296	(20.6%)	305	(13.2%)
$20,000 - $34,999	421	(29.3%)	714	(31.0%)
$35,000 - $49,999	283	(19.7%)	473	(20.5%)
$50,000 - $74,999	173	(12.0%)	377	(16.3%)
$75,000 +	97	(6.8%)	224	(9.7%)

Table 2.24
Prevalence of WHI-SE Outcomes in HRT Participants at WHI-SE Baseline Exam

Data as of: February 28, 2002

	Without Uterus (N = 1436)	With Uterus (N = 2306)	All (N = 3742)
Age-Related Maculopathy			
Left eye	206	293	499
Right eye	205	268	473
Both eyes	109	149	258
Either eye	302	412	714
Diabetic Retinopathy			
Left eye	57	39	96
Right eye	61	40	101
Both eyes	38	27	65
Either eye	80	52	132
Large C/D Ratio			
Present	78	87	165
Questionable	68	88	156
None	1281	2124	3405
Do not know/cannot grade	9	7	16
Glaucoma (self-reported)			
Yes	84	117	201
No	1266	2057	3323
Do not know	86	132	218
Intraocular pressure at eye exam			
30+	2	1	3
<30	1362	2162	3524
Do not know	72	143	215
Cataract (self-reported)			
Yes	682	956	1638
No	633	1131	1764
Do not know	121	219	340

3. DM Component

3.1 Recruitment

Age and race/ethnicity-specific DM recruitment data are presented in *Table 3.1*. The age-specific enrollment exceeded the design assumptions for ages 50-54, 55-59, and 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* and *Figure 3.1*. Studywide, the Food Frequency Questionnaire (FFQ) mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.6% at AV-7. The C-I difference is slightly larger for women who were randomized later in WHI and were given reduced fat gram goals (*Table 3.3*). This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.4*). 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. For example, missing data account for 11.5% of our sample at AV-1 and 15.2% at AV-3. The overall C-I percent energy from fat is approximately 2 to 3 percentage points lower than the design assumptions. Refer to *Sections 3.7* and *3.8* for a discussion of the impact of the C-I on study power and of the advanced adherence initiatives that are underway.

As shown in *Table 3.2* and *Figure 3.1*, for fruit and vegetable intake, the mean difference between the arms of the trial is about 1.3 more servings 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-half serving at AV-7. *Table 3.3* reports adherence among the 81% of women recruited after the fat gram goals were revised. *Table 3.4* presents adherence by race/ethnicity. Because of very sparse numbers, some of these results are highly variable.

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 3.5*). The only participant characteristics that are consistently associated with a lower C-I difference was being older than age 60-69 ($p<0.05$) or being Black compared to White ($p<0.05$). DM Participants randomized to HRT were also significantly more adherent than non-HRT participants. 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. 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 *Table 3.6*. The difference in body weight between Control and Intervention participants at AV-1 was almost 2 kg ($p<0.01$). The body weight C-I has steadily decreased and there is no statistically significant difference at AV-6 and AV-7. Participants with revised fat gram goals have maintained a C-I difference of 1.0 kg at AV-6 ($P=0.02$). From a trend perspective, these results are consistent with changes in energy intake estimated with the FFQ. The

body weight data by race/ethnicity show that American Indians on the Intervention have maintained the same mean weight for four years, while the control arm has gained 4-5 kg, producing marginally significant differences at AV-3 through AV-5.

Tables 3.7-3.8 give reasons for stopping DM categorized by general type and stratified by age and race/ethnicity. Overall, the major reasons for stopping given by participants were family responsibilities (13.0%), demands of work (11.1%), and issues of interest in the study (10.2%). 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 of issues related to interest in the study or because it was too far to the CC. Compared to the other race/ethnicity groups, Hispanic/Latina women were most likely to indicate that they were stopping intervention because of family demands, but least likely to stop intervention because 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 Blood Specimen and Bone Density Analyses

Tables 3.9-3.10 present the results of blinded blood specimen analyses from a small (4.3%) cohort of DM women selected randomly at baseline for these prospective analyses. This subsample incorporated oversampling of minorities. The results shown in *Table 3.9* are weighted to reflect the overall WHI distribution of race/ethnicity. *Table 3.10* presents analysis by race/ethnicity. Differences between baseline and AV-1 are mostly modest, with reductions of approximately 5% in LDL cholesterol and about 3% in total cholesterol for Intervention and Control women combined. There are no substantial changes in HDL-cholesterol or triglycerides in the combined groups. Blood specimen analyses are presented by race/ethnicity group and appear to be consistent with the dietary data. For example, LDL cholesterol reductions averaged 7% in Asian/Pacific Islander women and 5% in white women but are slightly lower among other groups (about 4% in Hispanic/Latinas and American Indian/Alaskan Native women and 3% in Blacks/African American). Note that baseline and AV-1 specimens were batched together for concurrent analyses by Medical Research Labs.

Tables 3.11-3.12 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 are interesting with increases in mean bone mineral density in the whole body scan as well as the spine and hip scan. An increase in BMD was not expected from this intervention. There were, generally, similar trends by race/ethnicity. Possible reasons for this observation 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 Adherence to Follow-up

Table 3.13 summarizes adherence to follow-up contacts by treatment arm and contact type. Follow-up participation has been roughly equivalent in the two arms. The acceptable adherence rates specified by the Steering Committee for collection of outcome data are 90% at AV-1, with a decline of no more than 1% per year, going no lower than 85%. WHI adherence rates are above those rates for all annual visits.

3.5 Vital Status

Table 3.14 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 5 – Outcomes*. 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 3.6% of the DM participants are lost-to-follow-up or have stopped follow-up (an increase of 0.3% compared to the Fall 2001 report), and 2.3% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for DM participants is about 5.2 years, suggesting that approximately 14.5% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.15 contains counts of the number of locally verified major WHI outcomes for DM participants by race/ethnicity and age. Approximately 4% 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 105% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, about 60% of the expected number of CHD events, and about 25% of the expected number hip fractures.

Table 3.16 contains counts of the number of self-reports for some outcomes that are not locally 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.

3.7 Power Considerations

The power under the design assumptions for adherence and overall incidence rates and values derived from the observed data through August 31, 2001 are shown in *Table 3.17*. While the observed Comparison - Intervention (C-I) differences represent a substantial achievement, they fall short of the assumptions of 13% C-I at AV-1 and subsequent decline of 0.25% per year. The lower than anticipated value of C-I at AV-1 will reduce the overall power of the study, but the size of the impact depends on the degree of adherence throughout the remaining years of follow-up. Under design assumptions, the study had 86% power for breast cancer and 90% for colorectal cancer. A second scenario assumes that the C-I starts at 11% but stays at 9% throughout the remaining follow-up. Using the final sample size and age distribution of DM participants, 8.5 years of average follow-up, and observed control rates for years 1-5 with adjustment toward design assumptions thereafter; the study is estimated to have 67% power for breast cancer and 60% power for colorectal cancer. We note that the intervention effect modeling for design considerations was based on percent of energy from fat. Other changes associated with the low fat eating pattern (e.g., increases in fruits, vegetables, and grains) would likely improve the power as these changes may have additional, complementary prevention effects.

3.8 Issues

As noted above, the C-I difference is less than the design assumptions. The WHI investigators and staff have undertaken a number of activities addressing adherence. In summer 1999, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of interviews using motivational enhancement techniques. Nutritionists targeted "medium adherers," defined as women who are attending some sessions but not meeting their fat gram goal or not self-monitoring (about 40% of intervention women). This protocol was completed on March 30, 2001. A preliminary evaluation of the IIP among intervention participants indicated that these contacts had a positive effect on adherence to fat intake goals among medium adherers. Specifically, 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 ($p<0.05$).

The second major DM initiative was called the Targeted Message Campaign (TMC). The campaign began with a 2000 Fall/Winter Kickoff Newsletter to raise awareness and excitement. Starting in January 2001, participants received a mailing introducing five themes to help them rediscover their intrinsic motivation(s) for participating in WHI. This first mailing was followed by a motivational enhancement phone call that supports participants in the process of identifying their primary motivation. Finally, 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. This campaign was completed at the end of 2001.

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 is performed using a specially designed instrument that focuses on usual fat-intake over the past 4 weeks. After scanning, computerized algorithms provide printed, individualized feedback on estimated grams of fat consumed (by foods) and food-specific behavioral change suggestions. The dietary questionnaire will be administered during summer 2002 group sessions. The written feedback will be provided and reinforced in Fall 2002 group sessions. CCs will conduct individual follow-up of group non-attenders by phone and mail.

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

Data as of: February 28, 2002

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,836**			
50-54	6961	149%	14%	10
55-59	11043	118%	23%	20
60-69	22714	108%	47%	45
70-79	8118	70%	17%	25
Race/Ethnicity	**48,836**			
American Indian	202		<1%	
Asian	1105		2%	
Black	5262		11%	
Hispanic	1845		4%	
White	39763		81%	
Unknown	659		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	19542	38.8	5.0	29294	38.8	5.0	0.0	0.0	0.83
FFQ Year 1[3]	18096	25.2	7.5	26770	36.1	6.9	10.9	0.1	<.01
FFQ Year 2[4]	5921	26.3	7.6	8660	36.3	7.0	9.9	0.1	<.01
FFQ Year 3[5]	3239	27.7	7.9	4891	37.3	7.1	9.6	0.2	<.01
FFQ Year 4[6]	4681	28.4	8.1	7357	37.6	7.1	9.2	0.1	<.01
FFQ Year 5[7]	4064	28.8	8.3	6258	37.7	7.3	9.0	0.2	<.01
FFQ Year 6[8]	2769	29.4	8.2	4220	37.5	7.1	8.2	0.2	<.01
FFQ Year 7[9]	1021	29.8	7.9	1594	37.4	6.9	7.6	0.3	<.01
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	805	21.7	7.3	1171	32.9	6.8	11.3	0.3	<.01
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	<.01
24 Hr Recall, Year 2	214	23.8	9.7	244	32.5	8.0	8.7	0.8	<.01
24 Hr Recall, Year 3	204	25.1	9.3	247	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	164	25.0	9.0	190	33.6	8.7	8.6	0.9	<.01
24 Hr Recall, Year 5	66	28.2	9.9	124	34.0	8.1	5.8	1.3	<.01
24 Hr Recall, Year 6	38	27.9	10.9	51	34.2	8.3	6.3	2.0	<.01
24 Hr Recall, Year 6 Cohort	222	26.2	8.6	373	33.2	7.7	7.0	0.7	<.01
Total Energy (kcal)									
FFQ Baseline	19542	1789.1	713.2	29294	1789.4	706.6	0.3	6.6	0.93
FFQ Year 1	18096	1474.0	534.4	26770	1584.3	641.6	110.3	5.8	<.01
FFQ Year 2	5921	1479.7	534.9	8660	1575.5	625.2	95.8	10.0	<.01
FFQ Year 3	3239	1476.3	538.3	4891	1572.0	644.3	95.7	13.7	<.01
FFQ Year 4	4681	1444.6	537.4	7357	1567.0	639.7	122.4	11.3	<.01
FFQ Year 5	4064	1471.7	541.1	6258	1566.2	640.3	94.5	12.2	<.01
FFQ Year 6	2769	1456.4	549.7	4220	1543.7	629.0	87.3	14.6	<.01
FFQ Year 7	1021	1475.2	533.8	1594	1550.2	641.5	75.1	24.1	0.05
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	204	1447.8	426.2	247	1592.1	503.5	144.3	44.5	<.01
24 Hr Recall, Year 3 Cohort	787	1432.0	391.1	1183	1589.9	489.3	157.9	20.8	<.01
24 Hr Recall, Year 4	164	1463.8	409.2	190	1547.3	472.1	83.5	47.3	0.14
24 Hr Recall, Year 5	66	1475.4	489.0	124	1611.2	530.2	135.8	78.7	0.09
24 Hr Recall, Year 6	38	1403.8	370.4	51	1588.5	515.8	184.7	98.5	0.07
24 Hr Recall, Year 6 Cohort	222	1450.7	412.7	373	1550.1	477.7	99.4	38.5	0.04

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4953 (27%) Intervention women had <=20% energy from fat at year 1.
[4] 1267 (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] 743 (16%) Intervention women had <=20% energy from fat at year 4.
[7] 589 (14%) Intervention women had <=20% energy from fat at year 5.
[8] 308 (11%) Intervention women had <=20% energy from fat at year 6.
[9] 99 (10%) Intervention women had <=20% energy from fat at year 7.

Table 3.2 (continued)
Nutrient Intake Monitoring
Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Total Fat (g)									
FFQ Baseline	19542	77.9	35.3	29294	77.8	34.7	0.0	0.3	0.87
FFQ Year 1	18096	41.5	21.8	26770	64.5	31.8	23.0	0.3	<.01
FFQ Year 2	5921	43.5	22.3	8660	64.5	31.3	21.0	0.5	<.01
FFQ Year 3	3239	45.9	23.8	4891	66.0	32.5	20.2	0.7	<.01
FFQ Year 4	4681	46.0	24.0	7357	66.4	32.4	20.4	0.6	<.01
FFQ Year 5	4064	47.6	24.7	6258	66.7	32.9	19.1	0.6	<.01
FFQ Year 6	2769	47.7	24.0	4220	65.2	31.8	17.4	0.7	<.01
FFQ Year 7	1021	49.3	25.5	1594	65.6	32.6	16.3	1.2	<.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	204	41.1	21.3	247	60.4	28.0	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	164	41.4	20.9	190	59.5	27.2	18.1	2.6	<.01
24 Hr Recall, Year 5	66	46.5	24.0	124	63.1	29.3	16.6	4.2	<.01
24 Hr Recall, Year 6	38	43.1	19.9	51	61.8	29.1	18.6	5.5	<.01
24 Hr Recall, Year 6 Cohort	222	42.7	21.2	373	58.5	25.5	15.8	2.0	<.01
Saturated Fat (g)									
FFQ Baseline	19542	27.4	13.4	29294	27.3	13.2	0.1	0.1	0.85
FFQ Year 1	18096	14.2	8.1	26770	22.5	11.9	8.4	0.1	<.01
FFQ Year 2	5921	14.8	8.2	8660	22.5	11.7	7.7	0.2	<.01
FFQ Year 3	3239	15.5	9.0	4891	22.9	12.2	7.4	0.2	<.01
FFQ Year 4	4681	15.7	8.9	7357	23.2	12.3	7.6	0.2	<.01
FFQ Year 5	4064	16.2	9.2	6258	23.4	12.5	7.2	0.2	<.01
FFQ Year 6	2769	16.2	8.7	4220	22.9	12.2	6.7	0.3	<.01
FFQ Year 7	1021	17.0	9.5	1594	23.2	12.7	6.2	0.5	<.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	204	13.4	7.7	247	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	164	13.4	8.0	190	19.8	10.4	6.5	1.0	<.01
24 Hr Recall, Year 5	66	15.0	7.6	124	21.7	10.7	6.7	1.5	<.01
24 Hr Recall, Year 6	38	13.5	5.7	51	21.5	11.8	8.0	2.1	<.01
24 Hr Recall, Year 6 Cohort	222	13.8	7.8	373	19.9	9.8	6.1	0.8	<.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

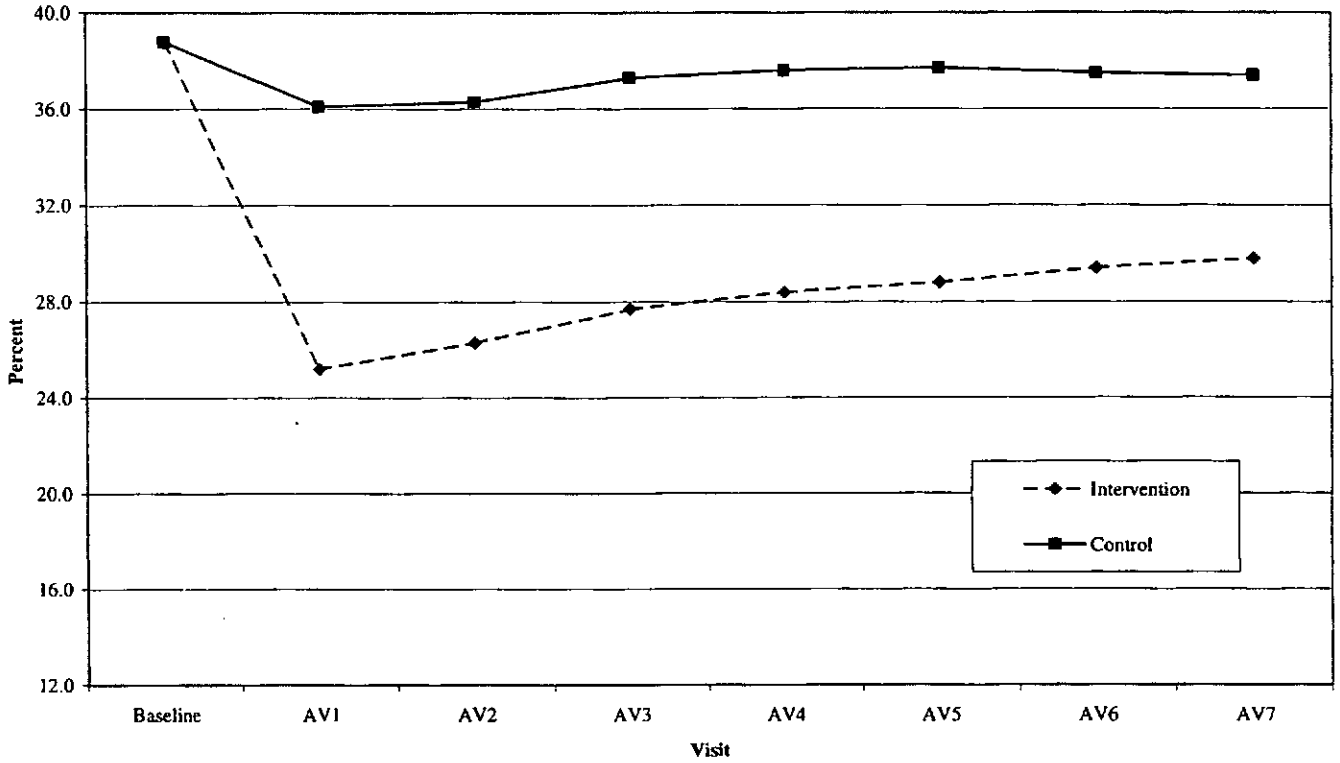
Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19542	15.3	7.6	29294	15.3	7.6	0.0	0.1	0.78
FFQ Year 1	18096	7.9	4.4	26770	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	5921	8.3	4.5	8660	12.4	6.5	4.1	0.1	<.01
FFQ Year 3	3239	8.8	4.7	4891	12.8	6.8	4.0	0.1	<.01
FFQ Year 4	4681	8.9	4.8	7357	12.8	6.7	3.9	0.1	<.01
FFQ Year 5	4064	9.2	5.1	6258	12.9	6.9	3.7	0.1	<.01
FFQ Year 6	2769	9.4	5.1	4220	12.5	6.4	3.2	0.1	<.01
FFQ Year 7	1021	9.4	5.3	1594	12.5	6.5	3.1	0.2	<.01
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.3	0.3	0.40
4DFR Year 1	805	7.4	3.4	1171	12.7	6.2	5.3	0.2	<.01
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.6	0.5	<.01
24 Hr Recall, Year 2	214	8.3	5.7	244	12.5	7.6	4.2	0.6	<.01
24 Hr Recall, Year 3	204	8.5	5.6	247	12.3	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	164	8.8	4.9	190	12.0	7.4	3.2	0.7	<.01
24 Hr Recall, Year 5	66	9.8	7.3	124	12.4	8.6	2.7	1.3	<.01
24 Hr Recall, Year 6	38	9.0	5.7	51	12.2	6.7	3.1	1.3	<.01
24 Hr Recall, Year 6 Cohort	222	8.8	4.8	373	11.6	5.8	2.8	0.5	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	19471	3.6	1.8	29216	3.6	1.8	0.0	0.0	0.69
FFQ Year 1	18015	5.0	2.3	26688	3.8	2.0	1.2	0.0	<.01
FFQ Year 2	5898	5.1	2.4	8628	3.9	2.0	1.2	0.0	<.01
FFQ Year 3	3233	5.2	2.5	4877	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	4671	5.1	2.4	7343	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	4042	5.1	2.5	6233	3.9	2.1	1.3	0.0	<.01
FFQ Year 6	2749	5.1	2.5	4200	3.8	2.0	1.3	0.1	<.01
FFQ Year 7	1013	5.0	2.4	1592	3.8	2.0	1.2	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19469	4.7	2.5	29214	4.8	2.5	0.0	0.0	0.42
FFQ Year 1	18011	5.1	2.7	26678	4.2	2.3	0.8	0.0	<.01
FFQ Year 2	5897	4.9	2.5	8622	4.1	2.2	0.7	0.0	<.01
FFQ Year 3	3231	4.6	2.5	4872	4.0	2.2	0.7	0.1	<.01
FFQ Year 4	4667	4.4	2.4	7331	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	4039	4.4	2.3	6227	3.9	2.2	0.5	0.0	<.01
FFQ Year 6	2749	4.4	2.5	4197	3.8	2.1	0.6	0.1	<.01
FFQ Year 7	1013	4.3	2.2	1592	3.8	2.1	0.5	0.1	<.01

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

Figure 3.1
Nutrient Intake: % Energy from Fat[1]

Data as of: February 28, 2002

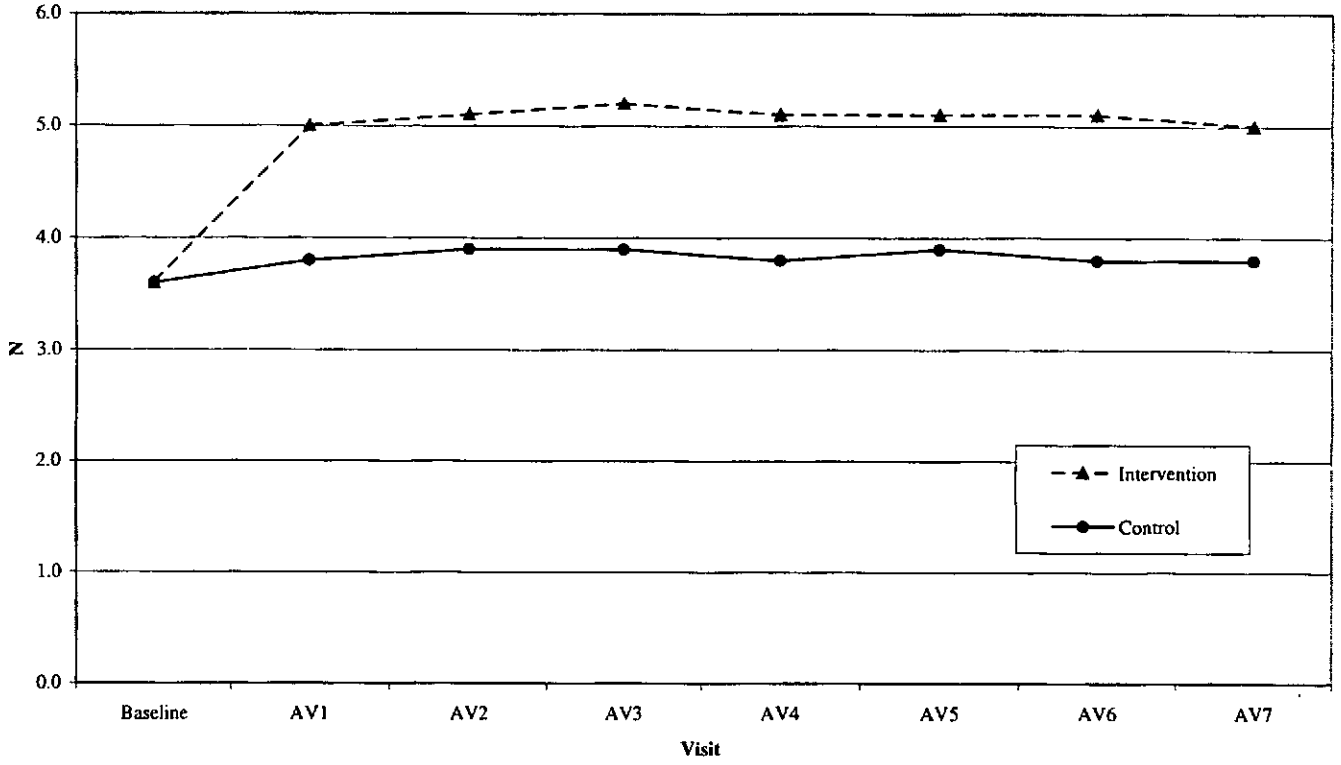


[1] Baseline % energy from fat values are about 3% higher in both groups due to the use of FFQ % energy from fat as an exclusionary criterion during screening.

Figure 3.1 (continued)
Nutrient Intake

Data as of: February 28, 2002

Fruit & Vegetable Servings per Day



Grain Servings per Day

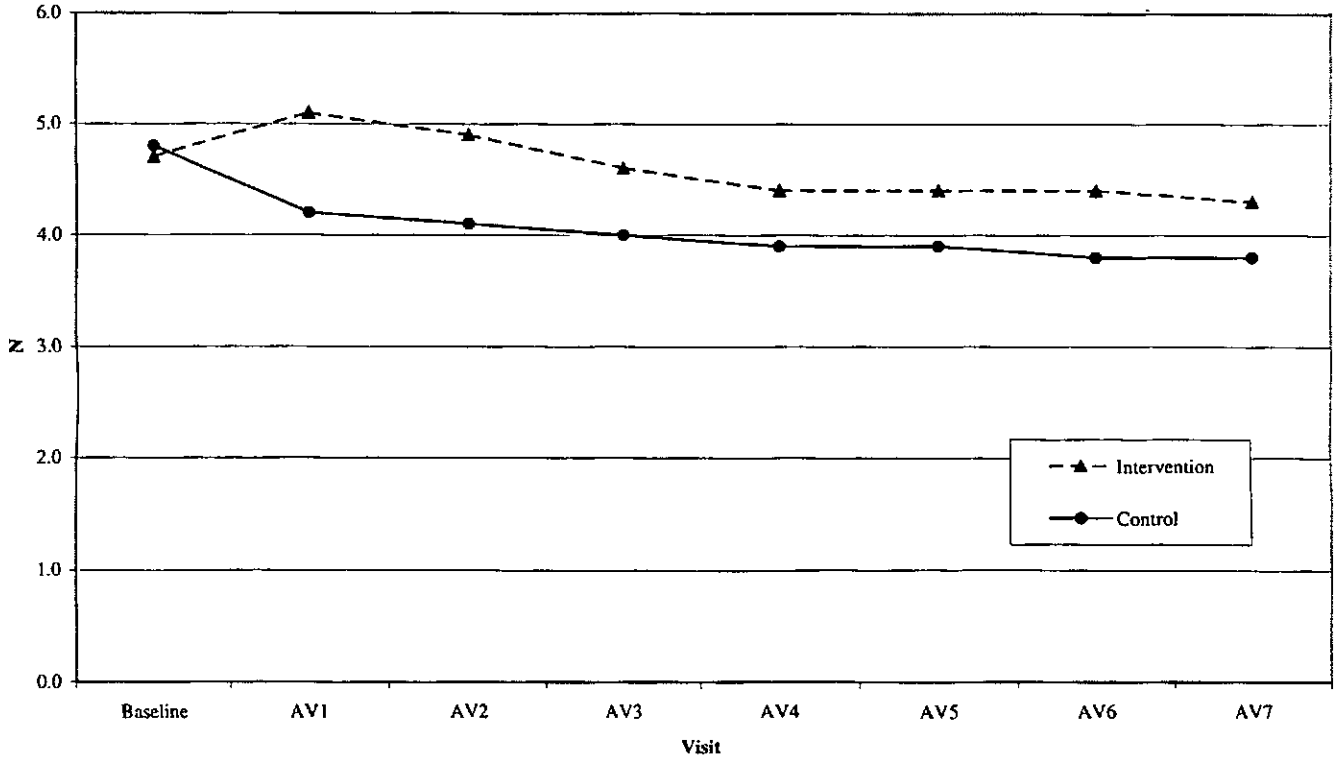


Table 3.3
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals[1]

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
% Energy from Fat									
FFQ Baseline	15862	38.8	5.0	23753	38.8	4.9	0.0	0.1	0.47
FFQ Year 1	14669	25.3	7.6	21760	36.2	6.9	10.9	0.1	<.01
FFQ Year 2	4863	26.5	7.7	6997	36.6	7.0	10.1	0.1	<.01
FFQ Year 3	2820	27.9	8.0	4345	37.5	7.0	9.6	0.2	<.01
FFQ Year 4	4350	28.4	8.2	6870	37.7	7.1	9.3	0.1	<.01
FFQ Year 5	3604	28.8	8.4	5569	37.8	7.3	9.0	0.2	<.01
FFQ Year 6	1086	29.4	8.4	1582	37.8	7.1	8.4	0.3	<.01
4DFR Baseline	691	32.4	6.5	1038	33.0	6.9	0.6	0.3	0.06
4DFR Year 1	622	21.6	7.5	892	33.1	6.9	11.5	0.4	<.01
24 Hr Recall, Post-baseline	186	23.4	9.4	205	32.1	7.7	8.7	0.9	<.01
24 Hr Recall, Year 1	172	22.1	7.8	200	32.7	7.6	10.6	0.8	<.01
24 Hr Recall, Year 2	177	23.5	9.4	183	32.5	8.0	8.9	0.9	<.01
24 Hr Recall, Year 3	155	24.7	9.4	185	32.7	8.7	8.0	1.0	<.01
24 Hr Recall, Year 3 Cohort	618	24.8	8.5	928	33.3	7.7	8.5	0.4	<.01
24 Hr Recall, Year 4	122	24.6	9.3	130	34.2	9.2	9.7	1.2	<.01
24 Hr Recall, Year 5	36	30.0	10.3	63	35.3	8.0	5.4	1.9	<.01
Total Energy (kcal)									
FFQ Baseline	15862	1779.6	701.3	23753	1786.2	705.8	6.7	7.2	0.47
FFQ Year 1	14669	1468.3	533.5	21760	1587.9	644.4	119.6	6.4	<.01
FFQ Year 2	4863	1470.5	537.0	6997	1577.5	628.0	107.0	11.1	<.01
FFQ Year 3	2820	1471.0	535.2	4345	1575.6	646.9	104.5	14.6	<.01
FFQ Year 4	4350	1439.4	538.3	6870	1568.6	642.2	129.1	11.7	<.01
FFQ Year 5	3604	1469.9	545.9	5569	1566.1	644.5	96.3	13.0	<.01
FFQ Year 6	1086	1463.4	568.0	1582	1548.2	619.4	84.9	23.6	<.01
4DFR Baseline	691	1687.7	454.9	1038	1712.7	468.6	25.0	22.7	0.30
4DFR Year 1	622	1404.7	362.1	892	1621.0	446.6	216.3	21.6	<.01
24 Hr Recall, Post-baseline	186	1499.1	417.7	205	1640.0	524.3	140.9	48.3	<.01
24 Hr Recall, Year 1	172	1477.2	424.4	200	1654.0	488.8	176.8	47.9	<.01
24 Hr Recall, Year 2	177	1426.6	426.9	183	1583.4	498.7	156.8	49.0	0.01
24 Hr Recall, Year 3	155	1446.7	441.7	185	1546.5	498.9	99.8	51.6	0.06
24 Hr Recall, Year 3 Cohort	618	1421.1	388.4	928	1571.0	489.0	150.0	23.4	<.01
24 Hr Recall, Year 4	122	1441.0	411.3	130	1545.0	474.7	104.0	56.1	0.09
24 Hr Recall, Year 5	36	1505.8	558.4	63	1648.7	562.8	142.9	117.3	0.21

(continues)

[1] Defined as women randomized after 6/15/95.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals[1]

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Total Fat (g)									
FFQ Baseline	15862	77.4	34.6	23753	77.6	34.6	0.2	0.4	0.63
FFQ Year 1	14669	41.6	22.0	21760	64.9	32.0	23.2	0.3	<.01
FFQ Year 2	4863	43.5	22.8	6997	65.0	31.5	21.5	0.5	<.01
FFQ Year 3	2820	46.1	23.8	4345	66.6	32.8	20.5	0.7	<.01
FFQ Year 4	4350	45.9	24.0	6870	66.7	32.6	20.8	0.6	<.01
FFQ Year 5	3604	47.6	25.0	5569	66.8	33.1	19.2	0.6	<.01
FFQ Year 6	1086	48.2	24.9	1582	65.9	31.7	17.7	1.1	<.01
4DFR Baseline	691	61.5	23.3	1038	63.8	25.1	2.2	1.2	0.12
4DFR Year 1	622	33.6	14.9	892	60.5	23.9	27.0	1.1	<.01
24 Hr Recall, Post-baseline	186	39.7	22.1	205	60.2	27.7	20.5	2.5	<.01
24 Hr Recall, Year 1	172	36.0	16.3	200	61.5	25.4	25.4	2.3	<.01
24 Hr Recall, Year 2	177	38.2	22.2	183	58.4	26.0	20.2	2.6	<.01
24 Hr Recall, Year 3	155	40.6	22.3	185	57.6	27.1	16.9	2.7	<.01
24 Hr Recall, Year 3 Cohort	618	39.6	18.6	928	59.7	25.9	20.1	1.2	<.01
24 Hr Recall, Year 4	122	40.3	22.0	130	60.6	28.0	20.2	3.2	<.01
24 Hr Recall, Year 5	36	50.2	27.2	63	67.8	33.3	17.6	6.5	<.01
Saturated Fat (g)									
FFQ Baseline	15862	27.2	13.2	23753	27.2	13.1	0.0	0.1	0.81
FFQ Year 1	14669	14.2	8.1	21760	22.6	11.9	8.5	0.1	<.01
FFQ Year 2	4863	14.8	8.4	6997	22.7	11.8	7.9	0.2	<.01
FFQ Year 3	2820	15.6	9.0	4345	23.1	12.3	7.5	0.3	<.01
FFQ Year 4	4350	15.6	9.0	6870	23.3	12.4	7.7	0.2	<.01
FFQ Year 5	3604	16.2	9.3	5569	23.4	12.6	7.2	0.2	<.01
FFQ Year 6	1086	16.4	9.2	1582	23.1	12.2	6.7	0.4	<.01
4DFR Baseline	691	20.0	8.8	1038	20.8	9.5	0.8	0.5	0.16
4DFR Year 1	622	10.3	5.3	892	19.3	8.3	9.0	0.4	<.01
24 Hr Recall, Post-baseline	186	13.0	8.0	205	20.0	9.7	7.0	0.9	<.01
24 Hr Recall, Year 1	172	11.3	5.9	200	20.4	10.2	9.1	0.9	<.01
24 Hr Recall, Year 2	177	12.0	8.2	183	19.0	9.2	7.0	0.9	<.01
24 Hr Recall, Year 3	155	13.2	7.9	185	19.3	10.9	6.1	1.0	<.01
24 Hr Recall, Year 3 Cohort	618	12.2	6.8	928	19.7	9.3	7.4	0.4	<.01
24 Hr Recall, Year 4	122	12.9	8.4	130	19.9	10.3	7.0	1.2	<.01
24 Hr Recall, Year 5	36	16.3	8.1	63	22.8	11.3	6.5	2.1	<.01

(continues)

[1] Defined as women randomized after 6/15/95.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals[1]

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Polyunsaturated Fat (g)									
FFQ Baseline	15862	15.1	7.4	23753	15.1	7.4	0.0	0.1	0.56
FFQ Year 1	14669	7.9	4.4	21760	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	4863	8.3	4.6	6997	12.5	6.6	4.2	0.1	<.01
FFQ Year 3	2820	8.9	4.7	4345	13.0	6.8	4.1	0.1	<.01
FFQ Year 4	4350	8.9	4.8	6870	12.9	6.7	4.0	0.1	<.01
FFQ Year 5	3604	9.2	5.2	5569	12.9	6.9	3.7	0.1	<.01
FFQ Year 6	1086	9.4	5.1	1582	12.7	6.4	3.3	0.2	<.01
4DFR Baseline	691	12.8	5.7	1038	13.5	6.3	0.7	0.3	0.06
4DFR Year 1	622	7.4	3.5	892	12.9	6.5	5.5	0.3	<.01
24 Hr Recall, Post-baseline	186	8.3	5.1	205	12.4	7.4	4.1	0.6	<.01
24 Hr Recall, Year 1	172	7.6	4.3	200	12.6	6.2	4.9	0.6	<.01
24 Hr Recall, Year 2	177	8.3	5.4	183	12.2	7.3	4.0	0.7	<.01
24 Hr Recall, Year 3	155	8.4	5.8	185	11.6	6.2	3.2	0.7	<.01
24 Hr Recall, Year 3 Cohort	618	8.6	4.5	928	12.2	7.0	3.5	0.3	<.01
24 Hr Recall, Year 4	122	8.7	5.1	130	12.6	8.0	3.9	0.9	<.01
24 Hr Recall, Year 5	36	10.4	9.0	63	14.0	10.9	3.6	2.1	0.02
Fruits and Vegetables (servings)									
FFQ Baseline	15821	3.6	1.8	23707	3.6	1.8	0.0	0.0	0.64
FFQ Year 1	14620	5.0	2.3	21704	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	4848	5.1	2.4	6979	3.9	2.0	1.2	0.0	<.01
FFQ Year 3	2817	5.2	2.5	4339	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	4343	5.2	2.5	6863	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	3584	5.1	2.4	5549	3.8	2.1	1.3	0.0	<.01
FFQ Year 6	1081	5.0	2.5	1576	3.8	2.0	1.2	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15819	4.7	2.5	23705	4.8	2.5	0.0	0.0	0.20
FFQ Year 1	14616	5.0	2.6	21695	4.2	2.3	0.8	0.0	<.01
FFQ Year 2	4847	4.8	2.5	6974	4.1	2.2	0.7	0.0	<.01
FFQ Year 3	2815	4.6	2.5	4334	4.0	2.2	0.6	0.1	<.01
FFQ Year 4	4339	4.4	2.4	6853	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	3581	4.4	2.3	5545	3.9	2.2	0.5	0.0	<.01
FFQ Year 6	1081	4.3	2.5	1573	3.7	2.0	0.6	0.1	<.01

[1] Defined as women randomized after 6/15/95.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.4
Nutrient Intake Monitoring in American Indian/Alaskan Native Women[1]

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
% Energy from Fat									
FFQ Baseline	88	39.5	5.7	114	40.0	5.2	0.5	0.8	0.49
FFQ Year 1[4]	73	27.5	8.9	96	38.0	8.0	10.5	1.3	<.01
FFQ Year 2[5]	28	26.9	8.8	32	38.2	6.8	11.3	2.0	<.01
FFQ Year 3[6]	18	31.3	8.9	41	38.0	7.0	6.7	2.1	<.01
FFQ Year 4[7]	23	30.3	9.3	28	39.9	7.6	9.6	2.4	<.01
FFQ Year 5[8]	18	27.4	7.8	16	39.9	7.8	12.5	2.7	<.01
FFQ Year 6[9]	10	33.3	7.7	16	40.3	7.3	6.9	3.0	0.04
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	18	1680.5	679.9	16	1366.0	724.8	314.5	241.0	0.11
FFQ Year 6	10	1130.6	508.2	16	1842.9	432.0	712.3	186.3	<.01
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	18	52.1	27.5	16	63.6	43.0	11.5	12.2	0.45
FFQ Year 6	10	41.5	19.5	16	82.5	23.2	41.0	8.8	<.01
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

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

Table 3.4 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women[1]

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Saturated Fat (g)									
FFQ Baseline	88	26.9	14.2	114	27.9	14.1	1.0	2.0	0.42
FFQ Year 1[4]	73	17.4	11.0	96	23.7	18.0	6.2	2.4	<.01
FFQ Year 2[5]	28	15.5	9.9	32	23.3	14.9	7.8	3.3	<.01
FFQ Year 3[6]	18	19.8	13.9	41	22.9	11.9	3.0	3.5	0.27
FFQ Year 4[7]	23	17.2	8.4	28	28.3	16.6	11.2	3.8	<.01
FFQ Year 5[8]	18	18.4	11.9	16	22.0	17.0	3.6	5.0	0.49
FFQ Year 6[9]	10	14.3	8.2	16	28.9	11.0	14.7	4.0	<.01
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	18	9.7	4.0	16	11.8	8.2	2.1	2.2	0.60
FFQ Year 6	10	8.3	4.6	16	15.6	4.8	7.3	1.9	<.01
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	18	5.6	2.4	16	2.7	1.4	2.9	0.7	<.01
FFQ Year 6	10	4.3	2.6	16	3.4	2.0	0.9	0.9	0.44
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	18	4.6	2.5	16	3.8	2.2	0.7	0.8	0.29
FFQ Year 6	10	3.3	2.6	16	5.1	2.2	1.8	1.0	0.06

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

Table 3.4 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	431	37.7	4.4	674	38.4	4.7	0.7	0.3	0.02
FFQ Year 1[3]	408	25.8	7.3	628	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]	100	29.4	8.3	184	37.4	6.7	8.1	0.9	<.01
FFQ Year 5[7]	103	28.5	8.0	148	36.7	7.3	8.3	1.0	<.01
FFQ Year 6[8]	26	27.2	6.4	56	37.8	5.5	10.5	1.4	<.01
FFQ Year 7[9]	7	27.5	10.3	10	37.9	7.9	10.4	4.4	0.05
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)									
FFQ Baseline	431	1699.9	722.7	674	1674.9	711.3	25.0	44.1	0.50
FFQ Year 1	408	1502.1	587.6	628	1524.0	635.7	21.9	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	100	1474.7	616.2	184	1495.3	602.8	20.7	75.5	0.93
FFQ Year 5	103	1512.0	585.7	148	1470.8	753.3	41.2	88.5	0.19
FFQ Year 6	26	1636.6	588.8	56	1536.1	568.8	100.5	136.5	0.47
FFQ Year 7	7	1527.4	507.7	10	1233.0	381.5	294.4	215.0	0.19
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)									
FFQ Baseline	431	71.9	34.1	674	72.2	34.8	0.4	2.1	0.99
FFQ Year 1	408	43.5	23.5	628	62.4	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	100	49.2	29.1	184	62.8	29.5	13.7	3.7	<.01
FFQ Year 5	103	49.1	27.8	148	60.6	35.5	11.5	4.2	<.01
FFQ Year 6	26	49.9	24.0	56	65.1	27.4	15.3	6.3	0.01
FFQ Year 7	7	49.7	32.9	10	53.8	28.3	4.1	14.9	0.57
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

[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 (12%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 13 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 3 (12%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 3 (43%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: February 28, 2002

	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[3]	408	13.5	8.0	628	19.6	10.8	6.0	0.6	<.01
FFQ Year 2[4]	147	14.3	8.5	213	19.2	11.9	5.0	1.1	<.01
FFQ Year 3[5]	107	14.8	10.1	152	18.1	9.8	3.3	1.3	<.01
FFQ Year 4[6]	100	15.4	10.3	184	19.7	9.4	4.3	1.2	<.01
FFQ Year 5[7]	103	15.3	9.3	148	19.1	12.1	3.9	1.4	<.01
FFQ Year 6[8]	26	15.6	9.0	56	20.7	9.7	5.1	2.2	0.01
FFQ Year 7[9]	7	16.0	12.2	10	16.9	10.6	0.9	5.6	0.64
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	408	9.1	5.0	628	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	100	10.6	6.2	184	13.3	6.5	2.7	0.8	<.01
FFQ Year 5	103	10.6	7.6	148	13.0	7.7	2.4	1.0	<.01
FFQ Year 6	26	10.4	4.8	56	13.8	5.6	3.4	1.3	<.01
FFQ Year 7	7	10.6	6.5	10	10.4	5.6	0.2	2.9	0.93
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	406	4.7	2.4	628	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	99	4.7	2.4	184	3.2	1.9	1.5	0.3	<.01
FFQ Year 5	103	5.1	2.2	148	3.6	2.1	1.5	0.3	<.01
FFQ Year 6	26	5.8	2.7	56	3.8	1.7	2.0	0.5	0.01
FFQ Year 7	7	4.5	1.6	10	2.7	1.3	1.8	0.7	0.02
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	5.0	2.6	674	4.8	2.3	0.2	0.1	0.43
FFQ Year 1	406	5.8	2.7	628	4.5	2.1	1.3	0.2	<.01
FFQ Year 2	146	5.4	2.7	213	4.3	2.4	1.1	0.3	<.01
FFQ Year 3	107	5.1	2.4	152	4.2	2.2	0.9	0.3	<.01
FFQ Year 4	99	5.1	2.4	184	4.4	2.1	0.7	0.3	0.01
FFQ Year 5	103	5.1	2.3	148	4.4	3.0	0.7	0.4	<.01
FFQ Year 6	26	5.9	2.8	56	4.3	2.1	1.6	0.6	0.04
FFQ Year 7	7	6.4	2.9	10	3.4	1.1	3.0	1.0	<.01

[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 (12%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 13 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 3 (12%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 3 (43%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: February 28, 2002

	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]	612	29.4	8.0	828	36.4	7.3	7.0	0.4	<.01
FFQ Year 3[5]	351	29.4	7.9	514	38.2	7.2	8.8	0.5	<.01
FFQ Year 4[6]	433	30.3	8.0	717	37.6	7.4	7.2	0.5	<.01
FFQ Year 5[7]	417	31.0	8.7	601	37.3	7.7	6.3	0.5	<.01
FFQ Year 6[8]	315	31.0	8.0	458	37.5	7.7	6.6	0.6	<.01
FFQ Year 7[9]	51	32.0	7.9	105	36.9	6.6	4.9	1.2	<.01
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)									
FFQ 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	1492.5	774.5	109.9	21.8	<.01
FFQ Year 2	612	1392.3	717.6	828	1449.7	724.9	57.3	38.5	0.34
FFQ Year 3	351	1391.5	636.9	514	1537.1	791.3	145.5	50.7	0.02
FFQ Year 4	433	1344.8	626.1	717	1452.9	755.4	108.1	43.2	0.05
FFQ Year 5	417	1373.5	601.9	601	1375.2	694.0	1.7	41.9	0.81
FFQ Year 6	315	1298.5	558.6	458	1398.8	763.3	100.4	50.3	0.19
FFQ Year 7	51	1328.2	568.0	105	1338.0	749.5	9.8	118.8	0.63
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)									
FFQ 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	612	46.4	32.5	828	60.1	36.0	13.7	1.8	<.01
FFQ Year 3	351	46.4	27.3	514	66.3	38.6	19.9	2.4	<.01
FFQ Year 4	433	45.7	26.3	717	61.6	36.2	15.9	2.0	<.01
FFQ Year 5	417	47.9	26.8	601	58.4	35.2	10.5	2.0	<.01
FFQ Year 6	315	45.2	24.7	458	59.4	37.2	14.2	2.4	<.01
FFQ Year 7	51	47.0	24.8	105	56.8	36.3	9.8	5.6	0.22
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

[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] 51 (12%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 36 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 27 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 1 (2%) Black/African American Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: February 28, 2002

	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[3]	1860	14.3	9.2	2629	20.5	12.8	6.2	0.3	<.01
FFQ Year 2[4]	612	15.3	11.8	828	19.8	12.3	4.5	0.6	<.01
FFQ Year 3[5]	351	15.1	9.6	514	21.8	13.4	6.7	0.8	<.01
FFQ Year 4[6]	433	14.8	9.2	717	20.3	12.6	5.5	0.7	<.01
FFQ Year 5[7]	417	15.4	9.1	601	19.1	12.4	3.7	0.7	<.01
FFQ Year 6[8]	315	14.6	8.3	458	19.4	12.9	4.9	0.8	<.01
FFQ Year 7[9]	51	15.3	9.6	105	19.1	13.1	3.8	2.1	0.14
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	612	9.1	6.2	828	12.1	7.5	2.9	0.4	<.01
FFQ Year 3	351	9.3	5.6	514	13.4	8.0	4.1	0.5	<.01
FFQ Year 4	433	9.3	5.5	717	12.6	7.7	3.3	0.4	<.01
FFQ Year 5	417	9.7	5.6	601	12.0	7.8	2.4	0.4	<.01
FFQ Year 6	315	9.2	5.5	458	12.1	7.7	2.9	0.5	<.01
FFQ Year 7	51	9.9	5.6	105	11.1	6.8	1.2	1.1	0.46
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	611	4.5	2.6	823	3.5	2.2	1.0	0.1	<.01
FFQ Year 3	351	4.8	2.7	514	3.7	2.3	1.0	0.2	<.01
FFQ Year 4	433	4.9	2.8	717	3.5	2.2	1.4	0.1	<.01
FFQ Year 5	415	4.8	2.8	600	3.5	2.1	1.3	0.2	<.01
FFQ Year 6	315	4.4	2.5	456	3.5	2.1	1.0	0.2	<.01
FFQ Year 7	51	4.8	2.8	105	3.3	2.0	1.5	0.4	<.01
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	611	4.2	2.6	822	3.7	2.4	0.4	0.1	<.01
FFQ Year 3	351	4.2	2.7	514	3.8	2.5	0.4	0.2	0.01
FFQ Year 4	433	4.0	2.5	715	3.6	2.4	0.4	0.1	<.01
FFQ Year 5	414	4.0	2.3	599	3.5	2.2	0.5	0.1	<.01
FFQ Year 6	315	3.7	2.1	455	3.4	2.1	0.4	0.2	<.01
FFQ Year 7	51	3.5	1.8	105	3.5	2.3	0.0	0.4	0.65

[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] 51 (12%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 36 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 27 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 1 (2%) Black/African American Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: February 28, 2002

	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	303	36.9	7.6	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]	153	31.0	8.1	274	36.9	7.2	6.0	0.8	<.01
FFQ Year 5[7]	125	28.7	8.5	204	37.1	7.1	8.3	0.9	<.01
FFQ Year 6[8]	77	29.7	8.9	121	36.7	5.9	7.0	1.0	<.01
FFQ Year 7[9]	18	30.4	8.7	27	36.2	6.2	5.8	2.2	0.02
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	303	1620.4	767.6	209.1	62.1	<.01
FFQ Year 3	131	1534.3	638.4	195	1576.7	710.7	42.4	77.1	0.80
FFQ Year 4	153	1411.1	653.7	274	1531.6	767.7	120.5	73.6	0.12
FFQ Year 5	125	1401.2	698.2	204	1568.8	907.3	167.6	94.8	0.14
FFQ Year 6	77	1275.3	733.7	121	1494.0	727.4	218.6	106.4	0.02
FFQ Year 7	18	1173.7	357.6	27	1239.1	405.9	65.4	117.9	0.67
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	303	68.1	38.5	24.3	2.9	<.01
FFQ Year 3	131	52.3	31.8	195	66.1	34.8	13.8	3.8	<.01
FFQ Year 4	153	48.8	27.5	274	63.7	35.9	14.9	3.3	<.01
FFQ Year 5	125	46.1	31.5	204	66.6	44.4	20.5	4.5	<.01
FFQ Year 6	77	42.2	28.5	121	61.4	33.2	19.2	4.6	<.01
FFQ Year 7	18	38.9	14.8	27	49.5	18.1	10.6	5.1	0.05
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

[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] 15 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 20 (16%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 9 (12%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 2 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: February 28, 2002

	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[3]	617	15.0	9.8	914	21.7	14.3	6.7	0.7	<.01
FFQ Year 2[4]	226	14.4	8.4	303	23.0	14.2	8.6	1.1	<.01
FFQ Year 3[5]	131	17.4	12.0	195	22.1	12.5	4.8	1.4	<.01
FFQ Year 4[6]	153	16.0	9.9	274	21.3	12.5	5.3	1.2	<.01
FFQ Year 5[7]	125	15.1	10.6	204	22.6	15.7	7.5	1.6	<.01
FFQ Year 6[8]	77	13.7	10.3	121	21.0	12.5	7.3	1.7	<.01
FFQ Year 7[9]	18	13.0	5.5	27	16.2	6.8	3.2	1.9	0.13
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	303	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	153	9.4	5.5	274	12.5	7.2	3.0	0.7	<.01
FFQ Year 5	125	9.2	7.1	204	12.8	9.3	3.6	1.0	<.01
FFQ Year 6	77	8.5	5.9	121	11.9	6.8	3.4	0.9	<.01
FFQ Year 7	18	7.9	4.5	27	9.9	4.3	2.0	1.3	0.09
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	303	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	153	4.7	2.7	274	3.2	2.1	1.6	0.2	<.01
FFQ Year 5	124	4.7	2.4	204	3.2	2.1	1.5	0.3	<.01
FFQ Year 6	76	4.5	2.5	121	3.1	2.2	1.4	0.3	<.01
FFQ Year 7	18	4.0	3.1	27	3.0	2.0	1.0	0.8	0.20
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	303	4.9	3.1	0.0	0.3	0.51
FFQ Year 3	130	5.1	3.0	195	4.7	2.9	0.4	0.3	0.32
FFQ Year 4	153	4.4	2.9	274	4.6	2.9	0.2	0.3	0.35
FFQ Year 5	124	4.4	3.2	204	4.8	3.6	0.4	0.4	0.34
FFQ Year 6	76	4.5	3.5	121	4.5	3.0	0.0	0.5	0.52
FFQ Year 7	18	3.9	1.8	27	4.5	2.4	0.6	0.7	0.40

[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] 15 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 20 (16%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 9 (12%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 2 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in White Women

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	15872	38.7	5.0	23891	38.7	4.9	0.0	0.1	0.93
FFQ Year 1[3]	14898	24.6	7.3	22149	36.0	6.8	11.3	0.1	<.01
FFQ Year 2[4]	4829	25.8	7.5	7161	36.2	7.0	10.3	0.1	<.01
FFQ Year 3[5]	2586	27.3	7.9	3930	37.2	7.1	9.9	0.2	<.01
FFQ Year 4[6]	3907	28.0	8.1	6052	37.7	7.0	9.6	0.2	<.01
FFQ Year 5[7]	3358	28.5	8.2	5224	37.8	7.3	9.3	0.2	<.01
FFQ Year 6[8]	2320	29.1	8.2	3523	37.5	7.1	8.4	0.2	<.01
FFQ Year 7[9]	933	29.7	7.9	1438	37.5	6.9	7.8	0.3	<.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	15872	1795.1	687.8	23891	1797.1	677.4	2.0	7.0	0.62
FFQ Year 1	14898	1485.6	509.0	22149	1599.0	611.4	113.4	6.1	<.01
FFQ Year 2	4829	1493.1	497.1	7161	1590.6	597.6	97.5	10.4	<.01
FFQ Year 3	2586	1483.9	511.1	3930	1583.6	618.6	99.7	14.6	<.01
FFQ Year 4	3907	1456.9	517.2	6052	1584.1	615.2	127.2	11.9	<.01
FFQ Year 5	3358	1484.1	522.1	5224	1592.5	614.0	108.4	12.8	<.01
FFQ Year 6	2320	1480.4	535.6	3523	1563.7	604.0	83.4	15.4	<.01
FFQ Year 7	933	1488.0	532.3	1438	1571.5	631.9	83.5	25.0	0.02
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	15872	77.8	34.1	23891	77.9	33.4	0.0	0.3	0.65
FFQ Year 1	14898	40.9	20.6	22149	64.8	30.5	23.9	0.3	<.01
FFQ Year 2	4829	43.0	20.2	7161	64.9	30.1	21.9	0.5	<.01
FFQ Year 3	2586	45.4	22.5	3930	66.3	31.5	21.0	0.7	<.01
FFQ Year 4	3907	45.8	23.3	6052	67.2	31.7	21.3	0.6	<.01
FFQ Year 5	3358	47.5	24.0	5224	67.9	31.9	20.4	0.6	<.01
FFQ Year 6	2320	48.1	23.7	3523	66.0	30.9	17.9	0.8	<.01
FFQ Year 7	933	49.6	25.7	1438	66.6	32.4	16.9	1.3	<.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

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4373 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1096 (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] 650 (17%) White Intervention women had <=20% energy from fat at year 4.
[7] 508 (15%) White Intervention women had <=20% energy from fat at year 5.
[8] 268 (12%) White Intervention women had <=20% energy from fat at year 6.
[9] 92 (10%) White Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in White Women

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	15872	27.7	13.2	23891	27.6	12.8	0.1	0.1	0.95
FFQ Year 1[3]	14898	14.1	7.8	22149	22.9	11.6	8.8	0.1	<.01
FFQ Year 2[4]	4829	14.7	7.5	7161	22.9	11.4	8.1	0.2	<.01
FFQ Year 3[5]	2586	15.5	8.6	3930	23.4	12.0	7.8	0.3	<.01
FFQ Year 4[6]	3907	15.8	8.8	6052	23.8	12.2	8.0	0.2	<.01
FFQ Year 5[7]	3358	16.4	9.1	5224	24.1	12.3	7.7	0.2	<.01
FFQ Year 6[8]	2320	16.4	8.6	3523	23.4	12.1	7.0	0.3	<.01
FFQ Year 7[9]	933	17.2	9.6	1438	23.6	12.6	6.5	0.5	<.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	15872	15.2	7.4	23891	15.2	7.3	0.0	0.1	0.47
FFQ Year 1	14898	7.7	4.1	22149	12.4	6.4	4.7	0.1	<.01
FFQ Year 2	4829	8.1	4.1	7161	12.3	6.2	4.2	0.1	<.01
FFQ Year 3	2586	8.6	4.4	3930	12.7	6.5	4.1	0.1	<.01
FFQ Year 4	3907	8.8	4.7	6052	12.8	6.5	4.0	0.1	<.01
FFQ Year 5	3358	9.1	4.8	5224	13.0	6.6	3.9	0.1	<.01
FFQ Year 6	2320	9.4	5.0	3523	12.5	6.2	3.2	0.2	<.01
FFQ Year 7	933	9.4	5.3	1438	12.7	6.5	3.2	0.3	<.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	15810	3.7	1.8	23818	3.7	1.8	0.0	0.0	0.17
FFQ Year 1	14829	5.2	2.3	22074	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	4811	5.2	2.3	7134	4.0	2.0	1.2	0.0	<.01
FFQ Year 3	2581	5.3	2.4	3916	4.0	2.0	1.3	0.1	<.01
FFQ Year 4	3899	5.2	2.4	6038	3.9	2.0	1.3	0.0	<.01
FFQ Year 5	3339	5.2	2.4	5200	3.9	2.1	1.3	0.0	<.01
FFQ Year 6	2302	5.2	2.5	3505	3.9	2.0	1.3	0.1	<.01
FFQ Year 7	925	5.0	2.4	1436	3.8	2.0	1.2	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15808	4.7	2.4	23817	4.8	2.4	0.0	0.0	0.21
FFQ Year 1	14826	5.1	2.6	22066	4.2	2.2	0.9	0.0	<.01
FFQ Year 2	4810	5.0	2.4	7129	4.1	2.1	0.8	0.0	<.01
FFQ Year 3	2579	4.6	2.5	3911	3.9	2.1	0.7	0.1	<.01
FFQ Year 4	3895	4.4	2.3	6028	3.9	2.1	0.5	0.0	<.01
FFQ Year 5	3337	4.4	2.2	5195	3.9	2.1	0.5	0.0	<.01
FFQ Year 6	2302	4.4	2.4	3503	3.8	2.0	0.6	0.1	<.01
FFQ Year 7	925	4.4	2.2	1436	3.8	2.0	0.5	0.1	<.01

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4373 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1096 (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] 650 (17%) White Intervention women had <=20% energy from fat at year 4.
[7] 508 (15%) White Intervention women had <=20% energy from fat at year 5.
[8] 268 (12%) White Intervention women had <=20% energy from fat at year 6.
[9] 92 (10%) White Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: February 28, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ 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]	65	29.4	8.3	102	37.1	7.3	7.7	1.2	<.01
FFQ Year 5[7]	43	28.3	8.9	65	37.5	7.5	9.2	1.6	<.01
FFQ Year 6[8]	21	31.2	6.1	46	38.8	7.0	7.6	1.8	<.01
FFQ Year 7[9]	6	32.7	7.2	11	36.4	9.2	3.7	4.3	0.38
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)									
FFQ 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	65	1404.2	619.8	102	1506.0	674.6	101.7	103.8	0.42
FFQ Year 5	43	1474.8	578.8	65	1476.1	570.7	1.3	112.8	0.81
FFQ Year 6	21	1773.1	536.2	46	1485.0	677.9	288.1	167.9	0.03
FFQ Year 7	6	1371.9	740.7	11	1871.7	843.8	499.8	411.5	0.18
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)									
FFQ 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	65	46.9	30.8	102	63.4	33.9	16.5	5.2	<.01
FFQ Year 5	43	47.2	26.6	65	62.5	29.1	15.3	5.5	<.01
FFQ Year 6	21	62.4	26.4	46	65.1	37.7	2.6	9.1	0.99
FFQ Year 7	6	45.8	15.4	11	73.3	29.6	27.4	13.1	0.03
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

[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] 10 (15%) Unknown Intervention women had <=20% energy from fat at year 4.
[7] 9 (21%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: February 28, 2002

	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]	65	15.5	10.4	102	22.0	12.4	6.5	1.9	<.01
FFQ Year 5[7]	43	15.3	8.9	65	21.0	10.2	5.7	1.9	<.01
FFQ Year 6[8]	21	21.3	10.8	46	21.7	14.1	0.4	3.5	0.92
FFQ Year 7[9]	6	16.9	5.4	11	27.5	13.4	10.6	5.8	0.06
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	65	9.4	6.6	102	12.5	7.6	3.1	1.1	<.01
FFQ Year 5	43	9.7	5.6	65	12.5	6.4	2.8	1.2	0.03
FFQ Year 6	21	12.2	5.2	46	13.1	7.5	0.9	1.8	0.84
FFQ Year 7	6	7.2	2.7	11	12.5	5.2	5.2	2.3	0.03
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	64	5.0	2.7	102	3.9	2.2	1.0	0.4	0.04
FFQ Year 5	43	5.1	2.8	65	3.7	2.4	1.4	0.5	0.01
FFQ Year 6	20	6.0	2.3	46	4.1	2.3	1.9	0.6	<.01
FFQ Year 7	6	4.0	2.7	11	7.2	3.8	3.2	1.8	0.13
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	264	4.8	2.7	393	4.7	2.7	0.1	0.2	0.71
FFQ Year 1	239	5.0	3.0	353	4.2	2.4	0.8	0.2	<.01
FFQ Year 2	78	4.7	2.4	123	4.2	2.3	0.4	0.3	0.31
FFQ Year 3	46	4.7	3.0	59	4.2	2.8	0.5	0.6	0.41
FFQ Year 4	64	4.3	2.5	102	3.9	2.1	0.4	0.4	0.37
FFQ Year 5	43	4.7	2.4	65	4.0	2.3	0.7	0.5	0.14
FFQ Year 6	20	5.5	2.4	46	3.5	2.1	2.0	0.6	<.01
FFQ Year 7	6	4.4	4.0	11	4.3	2.4	0.1	1.5	0.78

[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] 10 (15%) Unknown Intervention women had <=20% energy from fat at year 4.
[7] 9 (21%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 7.

Table 3.5
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: February 28, 2002

	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			20.1%				20.1%				20.1%	
Age												
60-69	6526				6526				6526			
50-54 vs. 60-69	2586	0.47			2586	0.44			2586	0.57		
55-59 vs. 60-69	3792	0.59			3792	0.45			3792	0.47		
70-79 vs. 60-69	2274	-1.29 **			2274	-1.18 **			2274	-1.25 **		
Ethnicity												
White	12473				12473				12473			
American Indian vs. White	62	2.93			62	3.02			62	2.69		
Asian/Pacific Islander vs. White	345	-0.21			345	-0.37			345	-0.43		
Black vs. White	1606	-1.73 **			1606	-1.87 **			1606	-1.34 **		
Hispanic vs. White	508	-1.17			508	-0.82			508	-0.90		
Unknown vs. White	184	0.19			184	0.05			184	0.08		
Education												
Post H.S.	12006				12006				12006			
0-8 Years vs. Post H.S.	155	-1.06			155	-1.39			155	-0.94		
Some H.S. or Diploma vs. Post H.S.	3017	-0.19			3017	0.02			3017	-0.05		
Family Income												
≥75K	2741				2741				2741			
<20K vs. ≥75K	2645	0.33			2645	0.29			2645	0.42		
20-35K vs. ≥75K	3505	0.23			3505	0.27			3505	0.35		
35-50K vs. ≥75K	3159	0.30			3159	0.35			3159	0.36		
50-75K vs. ≥75K	3128	0.29			3128	0.27			3128	0.30		
HRT Randomized												
No	12707				12707				12707			
Yes vs. No	2471	0.57			2471	0.65			2471	0.71 *		
Visit			22.8%	(2.7%)			22.8%	(2.7%)			22.8%	(2.7%)
Visit Year												
AV-3	426				426				426			
AV-2 vs. AV-3	18	5.01			18	4.42			18	5.06		
AV-4 vs. AV-3	3479	0.95			3479	0.91			3479	0.52		
AV-5 vs. AV-3	5065	0.72			5065	0.67			5065	0.39		
AV-6 vs. AV-3	3914	0.56			3914	0.45			3914	0.18		
AV-7 vs. AV-3	2276	0.34			2276	0.16			2276	-0.05		
Clinic Effect			24.8%	(2.0%)			24.8%	(2.0%)			24.8%	(2.0%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			29.0%	(4.2%)								
None	11161											
1 vs. None	882	4.48 **										
2 vs. None	1235	5.45 **										
3 vs. None	1111	6.20 **										
4+ vs. None	789	7.60 **										
# Sessions Completed in Previous 12 Months												
None					10308		29.5%	(4.7%)				
1 vs. None					413	3.76 **						
2 vs. None					852	6.09 **						
3 vs. None					1267	6.67 **						
4+ vs. None					2338	8.50 **						
# Fat Scores Provided in Previous 12 Months												
None									11232		30.4%	(5.6%)
1 vs. None									693	4.04 **		
2 vs. None									774	6.17 **		
3 vs. None									1023	6.59 **		
4+ vs. None									1456	8.20 **		

[1] Model adjusted for clinic effects.
* P-value <0.05 from a two-sided test.
** P-value <0.01 from a two-sided test.

Table 3.6
Body Weight

Data as of: February 28, 2002

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	S.D.	N	Mean	S.D.	Mean[2]	S.E.	p-value
All Participants									
Baseline	19524	76.8	16.7	29271	76.7	16.5	-0.1	0.2	0.36
Year 1	18151	74.4	16.8	26683	76.3	16.8	1.9	0.2	<.01
Year 2	16701	75.4	17.2	25052	76.7	16.9	1.3	0.2	<.01
Year 3	16670	75.7	17.1	25394	76.8	16.8	1.1	0.2	<.01
Year 4	14756	76.0	17.1	22782	76.7	16.7	0.7	0.2	<.01
Year 5	10194	76.0	16.9	15765	76.7	16.7	0.7	0.2	<.01
Year 6	5479	76.0	16.3	8403	76.4	16.2	0.5	0.3	0.11
Year 7	2100	75.9	16.5	3246	75.7	15.7	-0.1	0.4	0.79
Participants Aged 70-79									
Baseline	3246	73.0	14.7	4870	72.9	14.5	-0.1	0.3	0.82
Year 1	3010	70.7	15.2	4486	72.6	15.4	1.9	0.4	<.01
Year 2	2786	71.1	15.0	4173	72.6	15.3	1.5	0.4	<.01
Year 3	2754	71.1	15.4	4197	72.2	14.8	1.1	0.4	<.01
Year 4	2332	71.0	15.2	3579	71.6	14.4	0.6	0.4	0.14
Year 5	1427	70.0	14.4	2203	71.0	14.4	0.9	0.5	0.06
Year 6	668	69.8	14.0	1045	70.6	13.7	0.8	0.7	0.24
Year 7	252	70.8	16.5	422	70.2	13.9	-0.7	1.2	0.59
Participants with Revised Fat Gram Goals[3]									
Baseline	15848	77.0	17.0	23738	77.0	16.9	-0.0	0.2	0.80
Year 1	14692	74.6	17.1	21612	76.6	17.1	2.0	0.2	<.01
Year 2	13438	75.5	17.3	20204	77.0	17.2	1.5	0.2	<.01
Year 3	13473	75.8	17.3	20560	77.0	17.0	1.2	0.2	<.01
Year 4	11683	76.0	17.2	18070	76.9	16.8	0.8	0.2	<.01
Year 5	7218	76.0	17.2	11175	76.9	16.9	0.8	0.3	<.01
Year 6	2505	76.0	16.2	3797	77.0	16.9	1.0	0.4	0.02
Year 7	27	80.1	22.4	9	68.5	11.3	-11.6	7.8	0.05

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.
[3] For revised fat gram goals:
Intervention group is defined as women randomized to Intervention after 6/15/95 that have revised fat gram goals.
Control group is defined as women randomized to Control after 6/15/95.

Table 3.6 (continued)
Body Weight by Race/Ethnicity

Data as of: February 28, 2002

Body Weight (kg)[1]	Intervention N	Intervention Mean	Intervention S.D.	Control N	Control Mean	Control S.D.	Difference Mean[2]	Difference S.E.	Difference p-value
American Indian/Alaskan									
Baseline	87	77.8	14.4	114	80.9	17.0	3.1	2.3	0.17
Year 1	74	75.6	15.0	93	81.3	16.9	5.7	2.5	0.02
Year 2	66	76.9	18.7	91	83.5	18.1	6.6	3.0	0.03
Year 3	67	75.5	15.5	94	83.6	17.6	8.1	2.7	<.01
Year 4	64	76.2	15.8	84	84.5	18.9	8.3	2.9	<.01
Year 5	48	78.0	15.6	54	86.4	17.4	8.4	3.3	0.01
Year 6	25	77.4	15.6	27	83.0	15.9	5.6	4.4	0.20
Year 7	8	75.0	16.3	7	78.4	10.5	3.4	7.2	0.64
Asian/Pacific Islander									
Baseline	431	63.4	13.2	674	63.4	14.4	-0.1	0.9	0.93
Year 1	414	62.5	14.7	636	62.8	12.9	0.3	0.9	0.78
Year 2	392	62.7	14.1	615	63.0	12.4	0.3	0.8	0.73
Year 3	392	63.1	13.5	614	63.9	14.7	0.7	0.9	0.43
Year 4	329	63.1	12.5	554	63.5	13.6	0.4	0.9	0.68
Year 5	216	61.6	11.8	361	63.1	12.2	1.4	1.0	0.17
Year 6	65	61.4	10.7	119	61.0	11.1	-0.4	1.7	0.80
Year 7	13	70.0	32.6	17	62.1	9.7	-7.8	8.3	0.42
Black/African American									
Baseline	2133	85.3	18.2	3126	85.1	18.5	-0.1	0.5	0.79
Year 1	1891	84.3	19.3	2662	84.9	19.0	0.6	0.6	0.28
Year 2	1714	84.9	18.8	2504	85.2	19.0	0.4	0.6	0.54
Year 3	1695	85.2	19.3	2511	85.2	18.8	-0.0	0.6	0.94
Year 4	1463	85.4	19.2	2180	85.6	18.3	0.2	0.6	0.74
Year 5	1001	85.3	19.1	1533	85.9	19.2	0.6	0.8	0.43
Year 6	525	84.6	18.6	789	85.0	18.4	0.4	1.0	0.73
Year 7	162	84.1	17.0	238	84.0	17.6	-0.1	1.8	0.94
Hispanic/Latino									
Baseline	750	75.2	16.0	1094	73.7	15.2	-1.5	0.7	0.05
Year 1	638	74.2	16.6	935	73.2	15.5	-1.0	0.8	0.22
Year 2	570	74.4	16.1	863	73.9	15.8	-0.5	0.9	0.60
Year 3	545	75.3	16.9	866	74.3	16.5	-1.0	0.9	0.28
Year 4	481	75.7	17.0	773	73.8	14.8	-1.9	0.9	0.04
Year 5	321	74.8	16.3	507	74.3	13.9	-0.5	1.1	0.66
Year 6	153	75.2	17.0	227	73.6	14.9	-1.6	1.6	0.35
Year 7	43	73.3	12.5	69	69.2	14.1	-4.1	2.6	0.11
White									
Baseline	15858	76.1	16.1	23869	76.1	15.9	-0.0	0.2	0.87
Year 1	14895	73.4	15.9	22012	75.8	16.1	2.3	0.2	<.01
Year 2	13753	74.6	16.6	20655	76.2	16.3	1.6	0.2	<.01
Year 3	13765	74.9	16.4	20988	76.2	16.2	1.3	0.2	<.01
Year 4	12242	75.2	16.5	18911	76.2	16.2	1.0	0.2	<.01
Year 5	8507	75.3	16.3	13135	76.0	16.1	0.7	0.2	<.01
Year 6	4668	75.2	15.7	7170	75.8	15.7	0.6	0.3	0.04
Year 7	1862	75.2	16.1	2888	75.3	15.3	0.1	0.5	0.80
Unknown									
Baseline	265	78.3	18.4	394	76.4	16.8	-1.9	1.4	0.18
Year 1	239	77.6	20.4	345	77.0	18.0	-0.6	1.6	0.71
Year 2	206	76.2	18.7	324	77.3	18.5	1.1	1.7	0.52
Year 3	206	77.0	17.6	321	77.1	18.2	0.1	1.6	0.93
Year 4	177	76.4	18.6	280	76.2	16.3	-0.2	1.7	0.91
Year 5	101	76.6	17.3	175	77.8	20.0	1.2	2.4	0.61
Year 6	43	79.4	17.8	71	76.4	16.0	-3.0	3.2	0.37
Year 7	12	83.2	19.0	27	73.4	17.8	-9.8	6.3	0.14

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.

Table 3.7
Reasons for Stopping DM[1]

Data as of: February 28, 2002

Reasons[2]	(N = 2272)	
Personal/family		
Demands of work	252	11.1%
Family illness, emergency, or other family demands[3]	296	13.0%
Financial problems	9	0.4%
Lack of cooperation/support from family/friends[4]	42	1.8%
Living in nursing home	22	1.0%
Issues of interest in study[5]	231	10.2%
Travel		
Too far to CC	121	5.3%
Moved out of area or refuses to be followed at another CC	13	0.6%
Other Travel Issues[6]	63	2.8%
Visits & Procedures		
Doesn't like visits/calls	49	2.2%
Doesn't like required forms or safety procedures[7]	47	2.1%
Problems with other procedures[8]	11	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]	31	1.4%

(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 3.7 (continued)
Reasons for Stopping DM[1]

Data as of: February 28, 2002

Reasons[2]	(N = 2272)	
Symptoms		
GI Problems[3]	1	< 0.1%
Hair/Skin Changes	0	0.0%
Weight loss/gain	5	0.2%
HRT Related Symptoms[4]	4	0.2%
Other[5]	7	0.3%
Health Conditions		
Disease and/or health conditions[6]	74	3.3%
Communication difficulties[7]	42	1.8%
Intervention		
Doesn't like randomized nature of intervention	11	0.5%
Expected some benefit from intervention	35	1.5%
Feels guilty/unhappy or like a failure for not meeting study goals	16	0.7%
Pill Issues[8]	6	0.3%
CaD Issues[9]	1	< 0.1%
HRT Issues[10]	2	< 0.1%
Problem with DM group nutritionist or group members	32	1.4%
Doesn't like attending DM intervention classes	60	2.6%
Doesn't like self-monitoring	39	1.7%
Doesn't like budgeting fat grams	3	0.1%
Health concerns regarding long-term risk/benefits of low fat diet	16	0.7%
Unhappy that not losing weight	18	0.8%
Not in control of meal preparation	12	0.5%
Too difficult to meet or maintain dietary goals	40	1.8%
Doesn't like eating low fat diet	26	1.1%
Doesn't like eating 5 vegetables/fruits per day	1	< 0.1%
Doesn't like eating 6 grains per day	7	0.3%
Feels fat gram goal is unrealistic	5	0.2%
Eating pattern conflicts with personal health beliefs	25	1.1%
Other Health Issues		
Worried about costs if adverse effects occur	1	< 0.1%
Expected more health care	15	0.7%
Advised not to participate by health care provider[11]	22	1.0%
Study conflicts with other health issues[12]	31	1.4%
Other		
Other reasons not listed above	467	20.6%
Refuses to give a reason	94	4.1%

[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 3.8
Reasons for Stopping DM by Age at Screening and Race/Ethnicity[1]

Data as of February 28, 2002

	All (N = 19,542)		Age at Screening: 50 – 54 (N = 2,783)		55 –59 (N = 4,424)		60 –69 (N = 9,087)		70 –79 (N = 3,248)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	2272	11.6%	371	13.3%	518	11.7%	920	10.1%	463	14.3%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	296	13.0%	47	12.7%	73	14.1%	119	12.9%	57	12.3%
Demands of work	252	11.1%	78	21.0%	75	14.5%	83	9.0%	16	3.5%
Issues of interest in study[6]	231	10.2%	38	10.2%	62	12.0%	90	9.8%	41	8.9%
Too far to CC	121	5.3%	26	7.0%	33	6.4%	47	5.1%	15	3.2%
Other ("Other reasons not listed above")	467	20.6%	81	21.8%	130	25.1%	180	19.6%	76	16.4%

	Race/Ethnicity: American Indian/ Alaskan (N = 88)		Asian/Pacific Islander (N = 431)		Black/African American (N = 2,135)		Hispanic/Latino (N = 751)		White (N = 15,872)		Unknown (N = 265)	
	N	%[7]	N	%[7]	N	%[7]	N	%[7]	N	%[7]	N	%[7]
Women Stopping Intervention	18	20.5%	49	11.4%	314	14.7%	161	21.4%	1686	10.6%	44	16.6%
REASONS FOR STOPPING[3]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]
Family illness, emergency, or other family demands[5]	2	11.1%	3	6.1%	35	11.1%	27	16.8%	223	13.2%	6	13.6%
Demands of work	1	5.6%	5	10.2%	48	15.3%	17	10.6%	178	10.6%	3	6.8%
Issues of interest in study[6]	3	16.7%	4	8.2%	36	11.5%	8	5.0%	176	10.4%	4	9.1%
Too far to CC	2	11.1%	3	6.1%	7	2.2%	6	3.7%	102	6.0%	1	2.3%
Other ("Other reasons not listed above")	5	27.8%	9	18.4%	51	16.2%	50	31.1%	343	20.3%	9	20.5%

[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 category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of DM intervention participants in the same age 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".
[7] Percentages are of DM intervention participants in the same race/ethnicity category.
[8] Percentages are of DM intervention participants in the same race/ethnicity category who stopped DM intervention.

Table 3.9
Blood Specimen Analysis: DM Participants

Data as of: February 28, 2002

	N	Mean[1]	S.D.[1]
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	2731	0.08	0.08
AV-1	2501	0.08	0.07
AV-1 – Baseline	2426	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	2731	0.30	0.28
AV-1	2501	0.30	0.29
AV-1 – Baseline	2426	0.00	0.22
Alpha-tocopherol (µg/ml)			
Baseline	2731	16.28	7.30
AV-1	2501	16.96	7.52
AV-1 – Baseline	2426	0.76	5.49
Gamma-tocopherol (µg/ml)			
Baseline	2731	2.21	1.42
AV-1	2500	1.85	1.31
AV-1 – Baseline	2425	-0.36	0.92
Beta-Cryptoxanthine (µg/ml)			
Baseline	2731	0.09	0.07
AV-1	2500	0.09	0.07
AV-1 - Baseline	2425	0.00	0.06
Lycopene (µg/ml)			
Baseline	2731	0.41	0.19
AV-1	2501	0.41	0.19
AV-1 – Baseline	2426	-0.01	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	2731	0.21	0.10
AV-1	2501	0.22	0.10
AV-1 – Baseline	2426	0.00	0.07
Retinol (µg/ml)			
Baseline	2731	0.61	0.15
AV-1	2501	0.62	0.15
AV-1 – Baseline	2426	0.00	0.10

(continues)

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

Table 3.9 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 28, 2002

	N	Mean[1]	S.D.[1]
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2640	130.69	32.41
AV-1	2399	130.70	32.64
AV-1 - Baseline	2276	-0.24	22.36
Factor VII C (%)[2]			
Baseline	2595	129.82	30.74
AV-1	2368	127.30	30.37
AV-1 - Baseline	2211	-2.82	22.49
Fibrinogen (mg/dl)			
Baseline	2630	299.80	60.77
AV-1	2392	297.59	60.62
AV-1 - Baseline	2264	-2.55	49.77
Hormones/Other			
Glucose (mg/dl)			
Baseline	2729	100.17	26.76
AV-1	2493	98.82	26.23
AV-1 - Baseline	2418	-1.33	18.98
Insulin (μIU/ml)			
Baseline	2661	11.69	8.77
AV-1	2431	11.30	10.33
AV-1 - Baseline	2320	-0.31	8.54

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 28, 2002

	N	Mean[1]	S.D.[1]
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	2730	157.45	86.55
AV-1	2499	159.31	86.45
AV-1 – Baseline	2424	2.51	54.98
Total Cholesterol (mg/dl)			
Baseline	2730	224.13	38.13
AV-1	2499	217.41	37.32
AV-1 – Baseline	2424	-6.62	26.66
LDL-C (mg/dl)			
Baseline	2680	133.82	35.18
AV-1	2454	126.49	34.05
AV-1 – Baseline	2360	-6.91	23.77
HDL-C (mg/dl)			
Baseline	2722	59.05	15.68
AV-1	2497	59.27	15.30
AV-1 – Baseline	2416	-0.08	8.79
HDL-2 (mg/dl)			
Baseline	2662	18.29	8.17
AV-1	2456	18.84	8.36
AV-1 – Baseline	2329	0.31	4.97
HDL-3 (mg/dl)			
Baseline	2664	40.86	9.05
AV-1	2457	40.47	8.58
AV-1 – Baseline	2332	-0.51	5.55
Lp(a) (mg/dl)			
Baseline	2693	25.96	26.14
AV-1	2466	25.11	25.93
AV-1 – Baseline	2366	-0.65	10.20

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

Table 3.10
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 28, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	74	0.05	0.04
AV-1	58	0.06	0.05
AV-1 – Baseline	57	0.01	0.04
Beta-Carotene (µg/ml)			
Baseline	74	0.25	0.24
AV-1	58	0.27	0.31
AV-1 – Baseline	57	0.00	0.20
Alpha-tocopherol (µg/ml)			
Baseline	74	18.18	10.41
AV-1	58	18.10	9.60
AV-1 – Baseline	57	1.00	5.58
Gamma-tocopherol (µg/ml)			
Baseline	74	2.20	1.27
AV-1	58	1.80	1.22
AV-1 – Baseline	57	-0.41	0.84
Beta-Cryptoxanthine (µg/ml)			
Baseline	74	0.07	0.04
AV-1	58	0.07	0.04
AV-1 - Baseline	57	0.01	0.04
Lycopene (µg/ml)			
Baseline	74	0.36	0.17
AV-1	58	0.35	0.16
AV-1 – Baseline	57	0.00	0.13
Lutein and Zeaxanthin (µg/ml)			
Baseline	74	0.20	0.13
AV-1	58	0.20	0.10
AV-1 – Baseline	57	0.00	0.06
Retinol (µg/ml)			
Baseline	74	0.61	0.15
AV-1	58	0.60	0.16
AV-1 – Baseline	57	-0.01	0.08

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 28, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	71	136.94	31.58
AV-1	56	138.29	30.70
AV-1 - Baseline	54	0.72	18.41
Factor VII C (%)[1]			
Baseline	71	131.42	29.79
AV-1	56	127.55	26.77
AV-1 – Baseline	54	-2.04	14.64
Fibrinogen (mg/dl)			
Baseline	71	305.41	66.58
AV-1	56	312.86	75.90
AV-1 - Baseline	54	4.89	54.99
Hormones/Other			
Glucose (mg/dl)			
Baseline	74	105.54	33.02
AV-1	58	102.17	21.11
AV-1 - Baseline	57	-3.11	17.66
Insulin (μIU/ml)			
Baseline	69	13.31	7.90
AV-1	56	12.09	6.16
AV-1 – Baseline	52	-1.10	4.70

(continues)

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

Table 3.10 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 28, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	73	183.51	91.72
AV-1	57	170.98	88.64
AV-1 – Baseline	55	-1.87	52.17
Total Cholesterol (mg/dl)			
Baseline	73	218.42	34.36
AV-1	57	210.86	36.96
AV-1 – Baseline	55	-7.84	23.63
LDL-C (mg/dl)			
Baseline	71	127.08	33.42
AV-1	54	123.00	33.59
AV-1 – Baseline	52	-5.42	20.42
HDL-C (mg/dl)			
Baseline	73	55.62	15.88
AV-1	57	56.05	15.58
AV-1 – Baseline	55	-0.07	7.51
HDL-2 (mg/dl)			
Baseline	70	16.94	8.07
AV-1	56	17.41	7.86
AV-1 – Baseline	52	0.27	4.41
HDL-3 (mg/dl)			
Baseline	71	38.83	8.31
AV-1	56	38.21	8.59
AV-1 – Baseline	53	-0.25	5.01
Lp(a) (mg/dl)			
Baseline	71	21.48	20.85
AV-1	56	20.38	19.84
AV-1 – Baseline	54	0.69	9.69

Table 3.10 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 28, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	194	0.10	0.10
AV-1	176	0.10	0.10
AV-1 – Baseline	174	-0.00	0.10
Beta-Carotene (µg/ml)			
Baseline	194	0.44	0.42
AV-1	176	0.48	0.53
AV-1 – Baseline	174	0.05	0.40
Alpha-tocopherol (µg/ml)			
Baseline	194	19.35	9.96
AV-1	176	19.48	11.01
AV-1 – Baseline	174	0.34	6.81
Gamma-tocopherol (µg/ml)			
Baseline	194	1.68	1.18
AV-1	176	1.30	0.98
AV-1 – Baseline	174	-0.38	0.85
Beta-Cryptoxanthine (µg/ml)			
Baseline	194	0.18	0.17
AV-1	176	0.19	0.18
AV-1 - Baseline	174	0.01	0.14
Lycopene (µg/ml)			
Baseline	194	0.38	0.21
AV-1	176	0.37	0.19
AV-1 – Baseline	174	-0.02	0.18
Lutein and Zeaxanthin (µg/ml)			
Baseline	194	0.27	0.12
AV-1	176	0.28	0.12
AV-1 – Baseline	174	0.01	0.09
Retinol (µg/ml)			
Baseline	194	0.61	0.14
AV-1	176	0.62	0.15
AV-1 – Baseline	174	0.01	0.09

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 28, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	188	130.96	29.85
AV-1	167	130.84	29.26
AV-1 - Baseline	161	-0.96	20.48
Factor VII C (%)[1]			
Baseline	188	126.67	24.61
AV-1	167	126.11	26.33
AV-1 - Baseline	161	-1.03	18.59
Fibrinogen (mg/dl)			
Baseline	189	290.03	57.67
AV-1	167	284.84	57.04
AV-1 - Baseline	162	-6.69	53.11
Hormones/Other			
Glucose (mg/dl)			
Baseline	194	99.77	18.15
AV-1	176	100.55	23.78
AV-1 - Baseline	174	0.29	19.27
Insulin (µIU/ml)			
Baseline	188	10.24	5.58
AV-1	168	10.02	5.92
AV-1 - Baseline	164	-0.28	3.78

(continues)

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

Table 3.10 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 28, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	193	171.96	92.30
AV-1	176	172.70	94.01
AV-1 – Baseline	173	0.05	60.11
Total Cholesterol (mg/dl)			
Baseline	193	219.75	35.95
AV-1	176	213.29	33.31
AV-1 – Baseline	173	-7.59	24.36
LDL-C (mg/dl)			
Baseline	186	127.87	34.91
AV-1	170	120.72	30.18
AV-1 – Baseline	164	-8.60	25.08
HDL-C (mg/dl)			
Baseline	193	58.23	13.48
AV-1	176	59.91	14.05
AV-1 – Baseline	173	1.27	8.38
HDL-2 (mg/dl)			
Baseline	189	18.05	7.21
AV-1	174	19.51	7.32
AV-1 – Baseline	168	1.10	4.53
HDL-3 (mg/dl)			
Baseline	189	40.39	8.00
AV-1	174	40.50	8.34
AV-1 – Baseline	168	0.17	5.36
Lp(a) (mg/dl)			
Baseline	190	18.31	16.20
AV-1	175	16.41	14.04
AV-1 – Baseline	170	-2.14	12.79

Table 3.10 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 28, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	778	0.06	0.08
AV-1	696	0.07	0.07
AV-1 – Baseline	674	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	778	0.31	0.34
AV-1	696	0.32	0.30
AV-1 – Baseline	674	0.00	0.22
Alpha-tocopherol (µg/ml)			
Baseline	778	13.95	6.04
AV-1	696	14.55	6.12
AV-1 – Baseline	674	0.48	4.71
Gamma-tocopherol (µg/ml)			
Baseline	778	2.54	1.35
AV-1	696	2.27	1.31
AV-1 – Baseline	674	-0.20	0.91
Beta-Cryptoxanthine (µg/ml)			
Baseline	778	0.09	0.06
AV-1	696	0.09	0.06
AV-1 - Baseline	674	-0.00	0.06
Lycopene (µg/ml)			
Baseline	778	0.40	0.21
AV-1	696	0.38	0.20
AV-1 – Baseline	674	-0.01	0.19
Lutein and Zeaxanthin (µg/ml)			
Baseline	778	0.23	0.11
AV-1	696	0.24	0.11
AV-1 – Baseline	674	0.01	0.08
Retinol (µg/ml)			
Baseline	778	0.55	0.15
AV-1	696	0.55	0.14
AV-1 – Baseline	674	0.01	0.09

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 28, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	750	114.89	27.06
AV-1	677	115.55	27.53
AV-1 - Baseline	635	0.91	20.62
Factor VII C (%)[1]			
Baseline	730	118.33	30.11
AV-1	665	116.39	26.76
AV-1 - Baseline	609	-1.91	21.04
Fibrinogen (mg/dl)			
Baseline	748	321.11	66.58
AV-1	677	319.72	66.75
AV-1 - Baseline	635	-3.43	49.17
Hormones/Other			
Glucose (mg/dl)			
Baseline	778	106.88	37.04
AV-1	693	107.01	38.20
AV-1 - Baseline	671	0.70	26.78
Insulin (μIU/ml)			
Baseline	766	14.32	17.77
AV-1	686	13.94	10.91
AV-1 - Baseline	658	-0.23	6.17

(continues)

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

Table 3.10 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 28, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	778	119.73	53.08
AV-1	696	118.85	48.10
AV-1 – Baseline	674	0.58	36.42
Total Cholesterol (mg/dl)			
Baseline	778	220.25	41.98
AV-1	696	216.27	41.42
AV-1 – Baseline	674	-3.46	25.92
LDL-C (mg/dl)			
Baseline	777	137.81	39.42
AV-1	695	132.77	39.29
AV-1 – Baseline	672	-4.53	24.23
HDL-C (mg/dl)			
Baseline	777	58.50	15.06
AV-1	696	59.78	15.02
AV-1 – Baseline	673	0.96	8.16
HDL-2 (mg/dl)			
Baseline	766	18.30	7.83
AV-1	689	19.37	8.62
AV-1 – Baseline	657	0.78	4.96
HDL-3 (mg/dl)			
Baseline	766	40.18	8.64
AV-1	689	40.35	8.02
AV-1 – Baseline	657	0.10	5.16
Lp(a) (mg/dl)			
Baseline	766	38.57	27.55
AV-1	691	37.97	27.97
AV-1 – Baseline	660	0.00	11.85

Table 3.10 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 28, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	304	0.09	0.10
AV-1	268	0.09	0.07
AV-1 – Baseline	261	-0.00	0.10
Beta-Carotene (µg/ml)			
Baseline	304	0.30	0.41
AV-1	268	0.28	0.27
AV-1 – Baseline	261	-0.01	0.35
Alpha-tocopherol (µg/ml)			
Baseline	304	15.99	7.06
AV-1	268	17.01	7.71
AV-1 – Baseline	261	1.26	5.94
Gamma-tocopherol (µg/ml)			
Baseline	304	2.12	1.35
AV-1	268	1.89	1.40
AV-1 – Baseline	261	-0.25	0.94
Beta-Cryptoxanthine (µg/ml)			
Baseline	304	0.11	0.10
AV-1	268	0.11	0.09
AV-1 - Baseline	261	-0.01	0.09
Lycopene (µg/ml)			
Baseline	304	0.43	0.21
AV-1	268	0.41	0.19
AV-1 – Baseline	261	-0.02	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	304	0.20	0.10
AV-1	268	0.20	0.10
AV-1 – Baseline	261	-0.00	0.08
Retinol (µg/ml)			
Baseline	304	0.55	0.13
AV-1	268	0.57	0.13
AV-1 – Baseline	261	0.02	0.09

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 28, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	292	123.52	27.45
AV-1	254	124.28	28.84
AV-1 - Baseline	241	2.02	21.59
Factor VII C (%)[1]			
Baseline	285	123.49	28.28
AV-1	244	121.88	27.43
AV-1 - Baseline	229	0.34	21.10
Fibrinogen (mg/dl)			
Baseline	291	305.49	65.72
AV-1	253	309.02	70.72
AV-1 - Baseline	240	-0.18	55.83
Hormones/Other			
Glucose (mg/dl)			
Baseline	303	101.84	32.88
AV-1	267	105.04	35.37
AV-1 - Baseline	259	1.56	20.97
Insulin (μIU/ml)			
Baseline	295	13.48	8.60
AV-1	264	13.29	11.77
AV-1 - Baseline	252	-0.41	8.83

(continues)

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

Table 3.10 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 28, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	304	162.20	74.64
AV-1	268	165.55	76.95
AV-1 – Baseline	261	2.52	54.45
Total Cholesterol (mg/dl)			
Baseline	304	217.42	34.74
AV-1	268	211.75	35.63
AV-1 – Baseline	261	-4.50	25.14
LDL-C (mg/dl)			
Baseline	299	130.02	32.07
AV-1	263	124.25	33.22
AV-1 – Baseline	254	-5.89	22.66
HDL-C (mg/dl)			
Baseline	304	55.16	13.69
AV-1	268	55.39	12.67
AV-1 – Baseline	261	1.38	7.92
HDL-2 (mg/dl)			
Baseline	299	16.27	6.53
AV-1	265	16.84	6.84
AV-1 – Baseline	256	0.79	4.83
HDL-3 (mg/dl)			
Baseline	299	38.53	8.03
AV-1	265	38.54	7.60
AV-1 – Baseline	256	0.67	5.16
Lp(a) (mg/dl)			
Baseline	303	20.75	22.48
AV-1	264	19.30	19.99
AV-1 – Baseline	257	-1.04	7.88

Table 3.10 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	1327	0.08	0.08
AV-1	1255	0.08	0.07
AV-1 – Baseline	1212	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	1327	0.29	0.26
AV-1	1255	0.30	0.27
AV-1 – Baseline	1212	0.01	0.21
Alpha-tocopherol (µg/ml)			
Baseline	1327	16.46	7.23
AV-1	1255	17.16	7.43
AV-1 – Baseline	1212	0.79	5.50
Gamma-tocopherol (µg/ml)			
Baseline	1327	2.19	1.43
AV-1	1254	1.82	1.31
AV-1 – Baseline	1211	-0.39	0.93
Beta-Cryptoxanthine (µg/ml)			
Baseline	1327	0.08	0.06
AV-1	1254	0.09	0.07
AV-1 - Baseline	1211	0.00	0.05
Lycopene (µg/ml)			
Baseline	1327	0.41	0.19
AV-1	1255	0.41	0.19
AV-1 – Baseline	1212	-0.01	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	1327	0.21	0.10
AV-1	1255	0.21	0.10
AV-1 – Baseline	1212	0.00	0.07
Retinol (µg/ml)			
Baseline	1327	0.63	0.15
AV-1	1255	0.63	0.15
AV-1 – Baseline	1212	0.00	0.10

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	1285	133.03	32.74
AV-1	1199	132.97	32.99
AV-1 - Baseline	1139	-0.47	22.67
Factor VII C (%)[1]			
Baseline	1267	131.72	30.77
AV-1	1191	129.05	30.81
AV-1 - Baseline	1113	-3.18	22.90
Fibrinogen (mg/dl)			
Baseline	1277	297.02	59.14
AV-1	1193	294.43	58.41
AV-1 - Baseline	1127	-2.46	49.42
Hormones/Other			
Glucose (mg/dl)			
Baseline	1326	99.21	24.82
AV-1	1251	97.36	23.57
AV-1 - Baseline	1209	-1.79	17.66
Insulin (μIU/ml)			
Baseline	1289	11.31	6.90
AV-1	1209	10.90	10.28
AV-1 - Baseline	1146	-0.32	8.94

(continues)

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

Table 3.10 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	1329	161.16	88.95
AV-1	1255	163.56	89.10
AV-1 – Baseline	1214	2.93	56.73
Total Cholesterol (mg/dl)			
Baseline	1329	225.13	37.82
AV-1	1255	217.95	36.96
AV-1 – Baseline	1214	-7.11	26.89
LDL-C (mg/dl)			
Baseline	1296	133.76	34.74
AV-1	1225	125.95	33.38
AV-1 – Baseline	1173	-7.27	23.73
HDL-C (mg/dl)			
Baseline	1322	59.37	15.86
AV-1	1253	59.41	15.46
AV-1 – Baseline	1207	-0.33	8.91
HDL-2 (mg/dl)			
Baseline	1285	18.40	8.27
AV-1	1225	18.86	8.40
AV-1 – Baseline	1149	0.20	4.97
HDL-3 (mg/dl)			
Baseline	1286	41.11	9.18
AV-1	1226	40.60	8.70
AV-1 – Baseline	1151	-0.68	5.61
Lp(a) (mg/dl)			
Baseline	1309	24.94	25.94
AV-1	1234	24.15	25.81
AV-1 – Baseline	1179	-0.68	10.00

Table 3.10 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 28, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	54	0.08	0.08
AV-1	48	0.08	0.08
AV-1 – Baseline	48	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	54	0.27	0.22
AV-1	48	0.27	0.21
AV-1 – Baseline	48	0.01	0.13
Alpha-tocopherol (µg/ml)			
Baseline	54	17.31	9.14
AV-1	48	17.12	9.40
AV-1 – Baseline	48	-0.32	6.54
Gamma-tocopherol (µg/ml)			
Baseline	54	2.14	1.16
AV-1	48	2.01	1.05
AV-1 – Baseline	48	-0.11	0.76
Beta-Cryptoxanthine (µg/ml)			
Baseline	54	0.11	0.11
AV-1	48	0.10	0.06
AV-1 - Baseline	48	-0.01	0.08
Lycopene (µg/ml)			
Baseline	54	0.41	0.20
AV-1	48	0.40	0.20
AV-1 – Baseline	48	-0.01	0.18
Lutein and Zeaxanthin (µg/ml)			
Baseline	54	0.22	0.12
AV-1	48	0.23	0.16
AV-1 – Baseline	48	0.01	0.10
Retinol (µg/ml)			
Baseline	54	0.60	0.19
AV-1	48	0.59	0.15
AV-1 – Baseline	48	0.00	0.11

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 28, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	54	122.80	29.36
AV-1	46	117.07	27.58
AV-1 - Baseline	46	-2.28	24.54
Factor VII C (%)[1]			
Baseline	54	124.19	29.15
AV-1	45	120.33	24.54
AV-1 - Baseline	45	0.24	21.75
Fibrinogen (mg/dl)			
Baseline	54	303.07	65.04
AV-1	46	299.48	64.12
AV-1 - Baseline	46	-8.85	39.70
Hormones/Other			
Glucose (mg/dl)			
Baseline	54	98.13	24.54
AV-1	48	100.52	25.50
AV-1 - Baseline	48	0.63	11.85
Insulin (μIU/ml)			
Baseline	54	10.05	5.84
AV-1	48	10.77	5.60
AV-1 - Baseline	48	0.44	3.29

(continues)

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

Table 3.10 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 28, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	53	164.81	100.03
AV-1	47	156.70	77.06
AV-1 – Baseline	47	-5.06	60.23
Total Cholesterol (mg/dl)			
Baseline	53	227.85	36.95
AV-1	47	228.19	34.97
AV-1 – Baseline	47	-2.96	26.93
LDL-C (mg/dl)			
Baseline	51	135.41	35.38
AV-1	47	135.53	34.62
AV-1 – Baseline	45	-1.62	24.69
HDL-C (mg/dl)			
Baseline	53	59.77	16.73
AV-1	47	61.23	15.74
AV-1 – Baseline	47	0.81	9.88
HDL-2 (mg/dl)			
Baseline	53	19.72	10.47
AV-1	47	20.62	10.35
AV-1 – Baseline	47	0.38	6.46
HDL-3 (mg/dl)			
Baseline	53	40.06	7.72
AV-1	47	40.62	7.03
AV-1 – Baseline	47	0.43	6.08
Lp(a) (mg/dl)			
Baseline	54	23.89	29.23
AV-1	46	21.20	20.78
AV-1 – Baseline	46	-0.57	9.08

Table 3.11
Bone Mineral Density[1] Analysis: DM Participants

Data as of: February 28, 2002

	N	Mean	S.D.
Whole Body Scan			
Baseline	3593	1.03	0.11
AV1	3260	1.03	0.11
AV3	3074	1.04	0.11
AV6	1819	1.06	0.12
AV1 % Change from baseline BMD[2]	3219	0.17	2.49
AV3 % Change from baseline BMD[3]	3036	1.27	3.58
AV6 % Change from baseline BMD[4]	1790	2.38	5.07
Spine Scan			
Baseline	3518	0.99	0.17
AV1	3185	1.00	0.17
AV3	3004	1.01	0.17
AV6	1789	1.02	0.17
AV1 % Change from baseline BMD[2]	3160	0.72	3.83
AV3 % Change from baseline BMD[3]	2981	2.12	5.20
AV6 % Change from baseline BMD[4]	1776	3.39	6.71
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3275	0.87	0.14
AV3	3097	0.88	0.14
AV6	1856	0.88	0.14
AV1 % Change from baseline BMD[2]	3254	-0.04	2.76
AV3 % Change from baseline BMD[3]	3070	0.98	4.17
AV6 % Change from baseline BMD[4]	1837	0.90	5.15

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.12
Bone Mineral Density[1] Analysis: DM Participants by Race/Ethnicicty

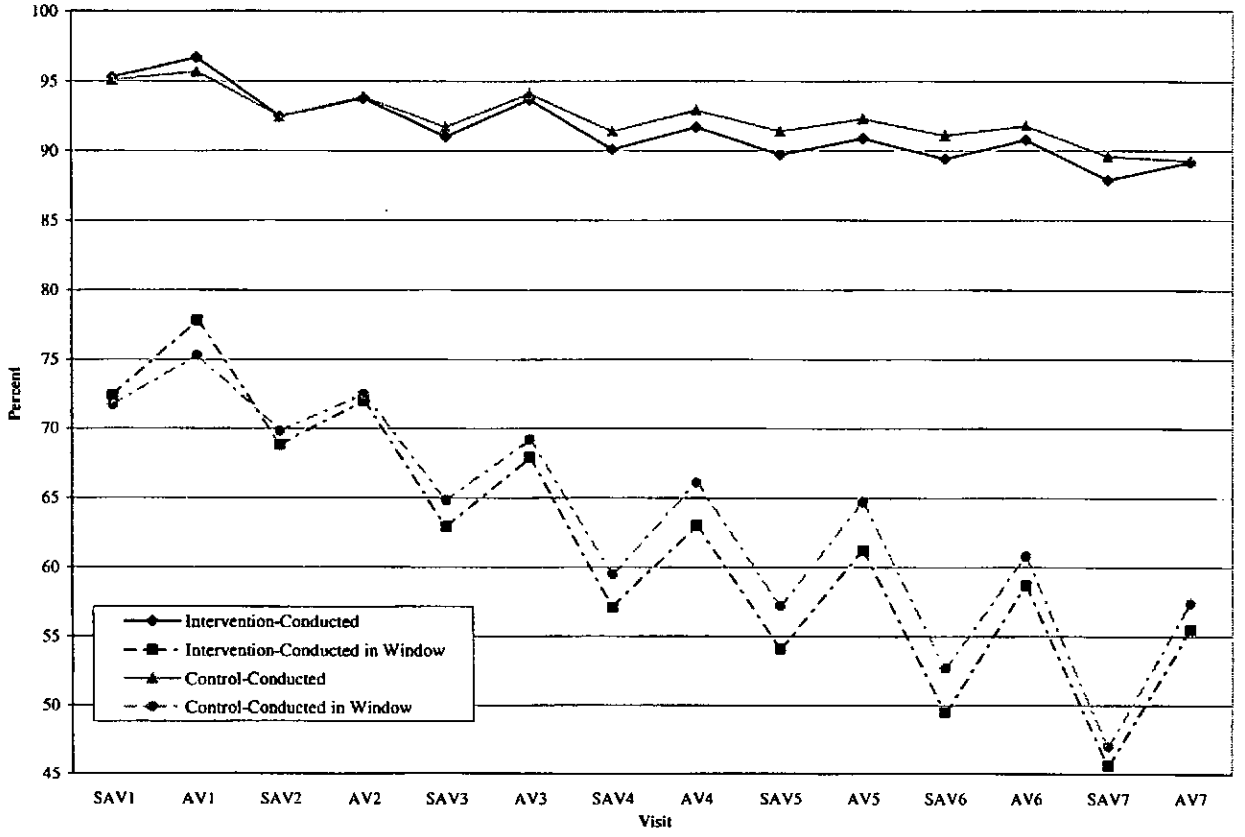
Data as of: February 28, 2002

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
Baseline	580	1.07	0.11	195	1.05	0.11	2761	1.01	0.10
AV1	511	1.08	0.11	152	1.05	0.11	2554	1.01	0.10
AV3	493	1.10	0.12	152	1.05	0.12	2387	1.02	0.11
AV6	254	1.09	0.12	96	1.09	0.14	1435	1.05	0.12
AV1 % Change from baseline BMD[2]	505	0.99	2.97	151	-0.33	2.24	2521	0.04	2.36
AV3 % Change from baseline BMD[3]	488	1.98	2.88	151	0.65	4.45	2356	1.16	3.63
AV6 % Change from baseline BMD[4]	252	0.44	3.27	96	4.31	6.89	1409	2.59	5.09
Spine Scan									
Baseline	575	1.07	0.18	190	0.98	0.16	2696	0.97	0.16
AV1	506	1.08	0.18	148	0.98	0.16	2488	0.98	0.16
AV3	490	1.09	0.19	148	0.96	0.15	2324	0.99	0.17
AV6	249	1.11	0.18	93	0.98	0.15	1413	1.01	0.17
AV1 % Change from baseline BMD[2]	500	0.79	4.31	147	0.15	4.36	2471	0.74	3.67
AV3 % Change from baseline BMD[3]	485	2.08	5.15	147	0.04	5.97	2308	2.28	5.13
AV6 % Change from baseline BMD[4]	247	2.75	6.88	93	1.32	7.03	1403	3.66	6.64
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	0.88	0.14	2566	0.85	0.13
AV3	496	0.99	0.15	152	0.88	0.15	2407	0.86	0.13
AV6	263	0.97	0.15	97	0.88	0.14	1462	0.87	0.13
AV1 % Change from baseline BMD[2]	510	0.84	2.86	151	-0.62	2.94	2551	-0.18	2.66
AV3 % Change from baseline BMD[3]	492	1.40	3.82	150	0.80	5.76	2387	0.91	4.09
AV6 % Change from baseline BMD[4]	261	-1.12	4.84	96	1.88	5.84	1447	1.18	5.05

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.13
Adherence to Follow-up Contacts

Data as of: February 28, 2002



Contact		Due N	Conducted N	Conducted %	Conducted in Window N	Conducted in Window %
Semi-Annual Contact 1	Intervention	19542	18630	95.3	14153	72.4
	Control	29294	27867	95.1	20991	71.7
Annual Visit 1	Intervention	19542	18888	96.7	15198	77.8
	Control	29294	28021	95.7	22053	75.3
Semi-Annual Contact 2	Intervention	19542	18069	92.5	13449	68.8
	Control	29294	27088	92.5	20443	69.8
Annual Visit 2	Intervention	19542	18337	93.8	14066	72.0
	Control	29294	27506	93.9	21243	72.5
Semi-Annual Contact 3	Intervention	19542	17787	91.0	12296	62.9
	Control	29294	26866	91.7	18983	64.8
Annual Visit 3	Intervention	19542	18302	93.7	13263	67.9
	Control	29294	27567	94.1	20260	69.2
Semi-Annual Contact 4	Intervention	19539	17606	90.1	11156	57.1
	Control	29289	26760	91.4	17415	59.5
Annual Visit 4	Intervention	18088	16582	91.7	11395	63.0
	Control	27134	25218	92.9	17930	66.1
Semi-Annual Contact 5	Intervention	15609	14006	89.7	8440	54.1
	Control	23421	21414	91.4	13386	57.2
Annual Visit 5	Intervention	12668	11515	90.9	7759	61.2
	Control	18979	17520	92.3	12270	64.7
Semi-Annual Visit 6	Intervention	9448	8448	89.4	4681	49.5
	Control	14187	12918	91.1	7471	52.7
Annual Visit 6	Intervention	6598	5993	90.8	3876	58.7
	Control	9863	9051	91.8	5997	60.8
Semi-Annual Visit 7	Intervention	4337	3814	87.9	1976	45.6
	Control	6472	5800	89.6	3042	47.0
Annual Visit 7	Intervention	2667	2379	89.2	1481	55.5
	Control	3977	3552	89.3	2283	57.4

Table 3.14
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: February 28, 2002

	DM Participants (N = 48,836)	
	N	%
Vital Status/Participation		
Deceased	1114	2.3
Alive: Current Participation[1]	44776	91.7
Alive: Recent Participation[2]	1125	2.3
Alive: Past/Unknown Participation[3]	94	0.2
Stopped Follow-Up[4]	1014	2.1
Lost to Follow-Up[5]	713	1.5

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 3.15
Locally Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: February 28, 2002

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48836		6961		11043		22714		8118	
Mean follow-up (months)	61.9		68.2		64.2		59.8		59.2	
Cancer										
Breast cancer[1]	1211	(0.48%)	132	(0.33%)	276	(0.47%)	577	(0.51%)	226	(0.56%)
Invasive breast cancer	962	(0.38%)	92	(0.23%)	219	(0.37%)	470	(0.42%)	181	(0.45%)
Non-invasive breast cancer	263	(0.10%)	40	(0.10%)	62	(0.10%)	114	(0.10%)	47	(0.12%)
Ovarian cancer	117	(0.05%)	17	(0.04%)	22	(0.04%)	47	(0.04%)	31	(0.08%)
Endometrial cancer[2]	169	(0.12%)	20	(0.09%)	39	(0.11%)	77	(0.12%)	33	(0.15%)
Colorectal cancer	313	(0.12%)	20	(0.05%)	50	(0.08%)	161	(0.14%)	82	(0.20%)
Other cancer[3]	1149	(0.46%)	102	(0.26%)	183	(0.31%)	573	(0.51%)	291	(0.73%)
Total cancer	2883	(1.14%)	285	(0.72%)	553	(0.94%)	1399	(1.24%)	646	(1.61%)
Cardiovascular										
CHD[4]	719	(0.29%)	41	(0.10%)	83	(0.14%)	341	(0.30%)	254	(0.63%)
CHD death[5]	141	(0.06%)	6	(0.02%)	13	(0.02%)	66	(0.06%)	56	(0.14%)
Total MI[6]	628	(0.25%)	36	(0.09%)	74	(0.13%)	297	(0.26%)	221	(0.55%)
Clinical MI	601	(0.24%)	31	(0.08%)	72	(0.12%)	283	(0.25%)	215	(0.54%)
Evolving Q-wave MI[7]	28	(0.01%)	5	(0.01%)	2	(<0.01%)	15	(0.01%)	6	(0.01%)
Possible evolving Q-wave MI[7]	118	(0.05%)	17	(0.04%)	19	(0.03%)	51	(0.05%)	31	(0.08%)
Angina	1039	(0.41%)	60	(0.15%)	137	(0.23%)	538	(0.48%)	304	(0.76%)
CABG/PTCA	985	(0.39%)	41	(0.10%)	127	(0.22%)	506	(0.45%)	311	(0.78%)
Carotid artery disease	184	(0.07%)	6	(0.02%)	22	(0.04%)	86	(0.08%)	70	(0.17%)
Congestive heart failure	561	(0.22%)	27	(0.07%)	59	(0.10%)	252	(0.22%)	223	(0.56%)
Stroke	555	(0.22%)	26	(0.07%)	49	(0.08%)	251	(0.22%)	229	(0.57%)
PVD	138	(0.05%)	4	(0.01%)	18	(0.03%)	67	(0.06%)	49	(0.12%)
CHD[4]/Possible evolving Q-wave MI	833	(0.33%)	58	(0.15%)	102	(0.17%)	388	(0.34%)	285	(0.71%)
Coronary disease[8]	2174	(0.86%)	131	(0.33%)	270	(0.46%)	1078	(0.95%)	695	(1.74%)
Total cardiovascular disease	2871	(1.14%)	161	(0.41%)	338	(0.57%)	1420	(1.25%)	952	(2.38%)
Fractures										
Hip fracture	220	(0.09%)	9	(0.02%)	18	(0.03%)	89	(0.08%)	104	(0.26%)
Vertebral fracture	253	(0.10%)	12	(0.03%)	26	(0.04%)	109	(0.10%)	106	(0.26%)
Other fracture[3]	3275	(1.30%)	411	(1.04%)	659	(1.12%)	1537	(1.36%)	668	(1.67%)
Total fracture	3640	(1.45%)	427	(1.08%)	696	(1.18%)	1690	(1.49%)	827	(2.07%)
Deaths										
Cardiovascular deaths	300	(0.12%)	12	(0.03%)	23	(0.04%)	141	(0.12%)	124	(0.31%)
Cancer deaths	504	(0.20%)	32	(0.08%)	60	(0.10%)	252	(0.22%)	160	(0.40%)
Other known cause	163	(0.06%)	10	(0.03%)	18	(0.03%)	67	(0.06%)	68	(0.17%)
Unknown cause	58	(0.02%)	4	(0.01%)	8	(0.01%)	28	(0.02%)	18	(0.04%)
Not yet adjudicated	89	(0.04%)	7	(0.02%)	10	(0.02%)	42	(0.04%)	30	(0.07%)
Total death	1114	(0.44%)	65	(0.16%)	119	(0.20%)	530	(0.47%)	400	(1.00%)

[1] Excludes five cases with borderline malignancy.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] 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.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.15 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: February 28, 2002

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39763	659
Mean follow-up (months)	60.3	58.1	60.4	57.6	62.5	57.4
Cancer						
Breast cancer[1]	2 (0.20%)	23 (0.43%)	77 (0.29%)	28 (0.32%)	1070 (0.52%)	11 (0.35%)
Invasive breast cancer	2 (0.20%)	19 (0.36%)	58 (0.22%)	22 (0.25%)	854 (0.41%)	7 (0.22%)
Non-invasive breast cancer	0 (0.00%)	4 (0.07%)	21 (0.08%)	6 (0.07%)	228 (0.11%)	4 (0.13%)
Ovarian cancer	1 (0.10%)	1 (0.02%)	11 (0.04%)	2 (0.02%)	99 (0.05%)	3 (0.10%)
Endometrial cancer[2]	0 (0.00%)	1 (0.03%)	11 (0.09%)	7 (0.15%)	147 (0.12%)	3 (0.17%)
Colorectal cancer	3 (0.30%)	5 (0.09%)	40 (0.15%)	13 (0.15%)	247 (0.12%)	5 (0.16%)
Other cancer[3]	4 (0.39%)	14 (0.26%)	89 (0.34%)	25 (0.28%)	1004 (0.48%)	13 (0.41%)
Total cancer	10 (0.99%)	44 (0.82%)	222 (0.84%)	71 (0.80%)	2505 (1.21%)	31 (0.98%)
Cardiovascular						
CHD[4]	1 (0.10%)	7 (0.13%)	69 (0.26%)	13 (0.15%)	622 (0.30%)	7 (0.22%)
CHD death[5]	0 (0.00%)	1 (0.02%)	18 (0.07%)	1 (0.01%)	119 (0.06%)	2 (0.06%)
Total MI[6]	1 (0.10%)	7 (0.13%)	60 (0.23%)	13 (0.15%)	540 (0.26%)	7 (0.22%)
Clinical MI	1 (0.10%)	7 (0.13%)	56 (0.21%)	13 (0.15%)	518 (0.25%)	6 (0.19%)
Evolving Q-wave MI[7]	0 (0.00%)	0 (0.00%)	4 (0.02%)	0 (0.00%)	23 (0.01%)	1 (0.03%)
Possible evolving Q-wave MI[7]	1 (0.10%)	3 (0.06%)	18 (0.07%)	3 (0.03%)	92 (0.04%)	1 (0.03%)
Angina	2 (0.20%)	13 (0.24%)	137 (0.52%)	26 (0.29%)	849 (0.41%)	12 (0.38%)
CABG/PTCA	1 (0.10%)	9 (0.17%)	86 (0.32%)	21 (0.24%)	860 (0.42%)	8 (0.25%)
Carotid artery disease	2 (0.20%)	3 (0.06%)	19 (0.07%)	1 (0.01%)	157 (0.08%)	2 (0.06%)
Congestive heart failure	0 (0.00%)	3 (0.06%)	102 (0.39%)	14 (0.16%)	434 (0.21%)	8 (0.25%)
Stroke	3 (0.30%)	14 (0.26%)	71 (0.27%)	10 (0.11%)	449 (0.22%)	8 (0.25%)
PVD	1 (0.10%)	0 (0.00%)	26 (0.10%)	1 (0.01%)	108 (0.05%)	2 (0.06%)
CHD[4]/Possible evolving Q-wave MI	2 (0.20%)	10 (0.19%)	87 (0.33%)	16 (0.18%)	710 (0.34%)	8 (0.25%)
Coronary disease[8]	4 (0.39%)	23 (0.43%)	290 (1.10%)	54 (0.61%)	1776 (0.86%)	27 (0.86%)
Total cardiovascular disease	10 (0.99%)	38 (0.71%)	374 (1.41%)	65 (0.73%)	2348 (1.13%)	36 (1.14%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.02%)	7 (0.03%)	3 (0.03%)	206 (0.10%)	3 (0.10%)
Vertebral fracture	0 (0.00%)	5 (0.09%)	4 (0.02%)	6 (0.07%)	236 (0.11%)	2 (0.06%)
Other fracture[3]	12 (1.18%)	51 (0.95%)	187 (0.71%)	74 (0.84%)	2915 (1.41%)	36 (1.14%)
Total fracture	12 (1.18%)	56 (1.05%)	195 (0.74%)	81 (0.91%)	3255 (1.57%)	41 (1.30%)
Deaths						
Cardiovascular deaths	1 (0.10%)	4 (0.07%)	43 (0.16%)	4 (0.05%)	244 (0.12%)	4 (0.13%)
Cancer deaths	1 (0.10%)	4 (0.07%)	44 (0.17%)	11 (0.12%)	437 (0.21%)	7 (0.22%)
Other known cause	5 (0.49%)	0 (0.00%)	26 (0.10%)	4 (0.05%)	126 (0.06%)	2 (0.06%)
Unknown cause	0 (0.00%)	0 (0.00%)	6 (0.02%)	1 (0.01%)	51 (0.02%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	5 (0.09%)	10 (0.04%)	3 (0.03%)	71 (0.03%)	0 (0.00%)
Total death	7 (0.69%)	13 (0.24%)	129 (0.49%)	23 (0.26%)	929 (0.45%)	13 (0.41%)

[1] Excludes five cases with borderline malignancy.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] 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.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.16
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: February 28, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48836	6961	11043	22714	8118
Mean follow-up (months)	61.9	68.2	64.2	59.8	59.2
Hospitalizations					
Ever	17522 (6.96%)	1861 (4.70%)	3287 (5.57%)	8477 (7.49%)	3897 (9.74%)
Two or more	7709 (3.06%)	718 (1.81%)	1292 (2.19%)	3705 (3.27%)	1994 (4.98%)
Other					
DVT[1]	324 (0.13%)	20 (0.05%)	51 (0.09%)	155 (0.14%)	98 (0.26%)
Pulmonary embolism	203 (0.08%)	10 (0.03%)	36 (0.06%)	100 (0.09%)	57 (0.14%)
Diabetes (treated)	2164 (0.90%)	300 (0.78%)	498 (0.87%)	994 (0.92%)	372 (0.98%)
Gallbladder disease[2]	2557 (1.21%)	391 (1.11%)	589 (1.17%)	1205 (1.30%)	372 (1.15%)
Hysterectomy	1023 (0.72%)	155 (0.69%)	236 (0.66%)	471 (0.75%)	161 (0.74%)
Glaucoma	3158 (1.30%)	314 (0.81%)	617 (1.07%)	1557 (1.43%)	670 (1.81%)
Osteoporosis	6697 (2.82%)	655 (1.69%)	1188 (2.08%)	3374 (3.18%)	1480 (4.14%)
Osteoarthritis[3]	6437 (4.20%)	909 (3.15%)	1463 (3.70%)	2998 (4.61%)	1067 (5.39%)
Rheumatoid arthritis	1858 (0.77%)	259 (0.67%)	421 (0.74%)	859 (0.79%)	319 (0.84%)
Intestinal polyps	4529 (1.93%)	554 (1.44%)	1000 (1.78%)	2244 (2.15%)	731 (2.05%)
Lupus	307 (0.12%)	51 (0.13%)	69 (0.12%)	149 (0.13%)	38 (0.10%)
Kidney stones[3]	719 (0.37%)	95 (0.33%)	163 (0.37%)	353 (0.40%)	108 (0.34%)
Cataracts[3]	9580 (5.44%)	540 (1.85%)	1513 (3.42%)	5365 (6.67%)	2162 (9.76%)
Pills for hypertension	7893 (4.48%)	1066 (3.35%)	1743 (3.91%)	3674 (4.84%)	1410 (5.94%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39763	659
Mean follow-up (months)	60.3	58.1	60.4	57.6	62.5	57.4
Hospitalizations						
Ever	64 (6.31%)	239 (4.47%)	1877 (7.09%)	542 (6.12%)	14591 (7.05%)	209 (6.63%)
Two or more	39 (3.84%)	77 (1.44%)	849 (3.21%)	212 (2.39%)	6444 (3.11%)	88 (2.79%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	28 (0.11%)	4 (0.05%)	288 (0.14%)	4 (0.13%)
Pulmonary embolism	2 (0.20%)	1 (0.02%)	16 (0.06%)	2 (0.02%)	178 (0.09%)	4 (0.13%)
Diabetes (treated)	13 (1.38%)	64 (1.27%)	426 (1.82%)	121 (1.46%)	1509 (0.75%)	31 (1.04%)
Gallbladder disease[2]	10 (1.38%)	40 (0.83%)	204 (0.86%)	99 (1.48%)	2170 (1.26%)	34 (1.26%)
Hysterectomy	3 (0.62%)	19 (0.56%)	67 (0.57%)	27 (0.57%)	902 (0.75%)	5 (0.28%)
Glaucoma	14 (1.44%)	61 (1.18%)	447 (1.81%)	119 (1.39%)	2480 (1.24%)	37 (1.25%)
Osteoporosis	29 (3.01%)	155 (3.06%)	358 (1.40%)	241 (2.92%)	5825 (2.99%)	89 (3.05%)
Osteoarthritis[3]	28 (4.84%)	142 (3.71%)	671 (4.28%)	276 (4.66%)	5225 (4.17%)	95 (4.97%)
Rheumatoid arthritis	15 (1.65%)	32 (0.62%)	341 (1.38%)	149 (1.77%)	1291 (0.64%)	30 (1.00%)
Intestinal polyps	25 (2.67%)	93 (1.90%)	484 (1.96%)	150 (1.77%)	3708 (1.93%)	69 (2.38%)
Lupus	3 (0.30%)	3 (0.06%)	44 (0.17%)	10 (0.11%)	244 (0.12%)	3 (0.10%)
Kidney stones[3]	4 (0.54%)	14 (0.33%)	69 (0.34%)	37 (0.53%)	584 (0.37%)	11 (0.45%)
Cataracts[3]	42 (6.15%)	195 (5.10%)	930 (5.00%)	314 (4.75%)	7960 (5.53%)	139 (6.23%)
Pills for hypertension	32 (4.88%)	170 (4.75%)	876 (6.60%)	323 (4.90%)	6398 (4.27%)	94 (4.42%)

[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 3.17
Sensitivity of DM Study Power to Adherence Assumptions[1]

Outcome	Year	Intervention Effect[1] (%)	Percentage of Cases[2]		Power (%)	
			Control	Intervention	Design[3]	Revised[4]
Breast Cancer						
	2001	11	1.98	1.86	28	18
		12	1.99	1.85	35	22
		14	1.99	1.83	44	27
	2004	11	2.86	2.61	63	46
		12	2.86	2.57	75	56
		14	2.86	2.54	86	67
Colorectal Cancer						
	2001	18	1.08	0.97	37	18
		20	1.08	0.96	45	21
		22	1.09	0.95	52	25
	2004	18	1.64	1.40	83	51
		20	1.63	1.37	90	60
		22	1.63	1.24	95	69

[1] Analysis has not been updated from that of August 31, 2001.
[2] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.
[3] C-I % Energy from fat: 13% at AV-1, 11% at year 10
[4] C-I % Energy from fat: 11% at AV-1, 9% at year 10. 8.5 follow-up years, using observed control rates for years 1-5 and adjustment toward design rates thereafter.

4. CaD Component

4.1 Recruitment

Table 4.1 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%.

4.2 Adherence

Table 4.2 presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report (see *Figure 4.1*) and is now 56%-64% (adherence summary was 57%-63% in the last progress report). At AV-4, which is nearly complete, 96% of visits due have been conducted, 2% of women have stopped taking the CaD study medication, and 86% completed the pill collection procedure. AV-4 adherence continues to improve over time, with 68% of women taking 80% or more of their study medication in the most recent time interval (*Figure 4.1*). The adherence summary remains low primarily because about 20-37% of women on study medication take less than 80% of their CaD pills.

Table 4.3 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 now account for re-starting CaD, which results in lower rates than seen in previous reports. At every annual visit, the observed drop-out rates are lower than design assumptions. Interval drop-out rates range from 3.0-4.1%, which compares favorably to the 5.9% design assumption. At AV-4, the cumulative drop-out rate was 13.0% (design assumption was 19.2%). By AV-6 and AV-7, observed rates are below the design assumption by 10%.

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 8.0% have indicated that they were advised by their physician to discontinue these supplements. 715 women (8.4%) reported health problems or diseases, 2285 women (27.0%) reported symptoms not known to be related to the intervention, and 492 women (5.8%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (11.4%) followed by not liking the randomized nature of the intervention (4.2%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 22.7% of women. Four common reasons for stopping CaD are shown first by age, and then by race/ethnicity, in *Table 4.5*. No strong associations by age 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 older women. These reasons were reported with similar frequency by women in the various race/ethnicity subgroups.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of February 28, 2002, 1,775 (4.9%) women were taking alendronate, 245 (0.7%) were taking calcitonin, and 569 (1.6%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 presents the mean bone mineral density levels at AV-1, AV-3, and AV-6 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 2 times as large as those observed at AV-3 for the spine and whole body but only slightly larger at the hip. *Table 4.7* presents the mean bone mineral density levels and percent change according to race/ethnicity. The number of Black/African American and Hispanic/Latino women who have data available at AV-6 is still relatively small. However, at AV-3 the rates of change relative to AV-1 were generally in the range of 1-2% gains for all skeletal sites.

4.4 Vital Status

Table 4.8 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*. 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, 1.8% of the participants are lost-to-follow-up or have stopped follow-up, and 1.9% 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 4.1 years, suggesting that approximately 11.7% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

4.5 Outcomes

Table 4.9 contains counts of the number of locally verified major WHI outcomes for CaD participants. In this table only outcomes that took place after randomization in the CaD trial are included. Approximately 4% 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 147 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 (184 cases) is approximately 80%, the number of invasive breast cancer cases (569 cases) is approximately 110%, and the number of CHD cases is about 70% of what was expected (458 cases).

Table 4.10 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 4.11 presents estimates of the CaD Study power using revised assumptions based on observed incidence rates in the control group for years 1-4. These have *not* been updated since the August 31, 2001 report.

4.6 Issues

During this period of follow-up, the focus remains primarily on maximizing adherence and retention in all components of the WHI Clinical Trial. Work continues on identifying and implementing strategies to improve adherence to CaD study medication. In August/September 2001, the WHI Adherence and Retention Working Group asked PIs and CC staff at all local CCs to complete an Adherence and Retention survey designed to identify perceived challenges and barriers for improving adherence and retention in each CT component (DM, HRT, and CaD) and possible solutions. This information was summarized and reviewed by the appropriate WHI Advisory committees. One suggestion made by WHI staff was that a CaD Handbook be developed to promote adherence in the CaD Trial and reinforce its importance. The CaD committee has overseen the development of a draft handbook, which is currently under review and revision. In addition, the CaD committee is organizing the development of brief articles on special CaD-relevant topics for publication in the WHI Matters newsletter.

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

Data as of: February 28, 2002

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5157	118%	14%	10
55-59	8265	94%	23%	20
60-69	16520	84%	46%	45
70-79	6340	58%	17%	25
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3315		9%	
Hispanic	1502		4%	
White	30155		83%	
Unknown	440		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

Data as of: February 28, 2002

	Due	Conducted		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[1] <50%		Medication Rate[1] 50%-80%		Medication Rate[1] 80% +		Adherence Summary[2]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Semi-Annual Contact-2	33047	32214	97	26176	79	1270	4	230	1	32795	99	5718	17	6711	20	20366	62	62
Annual Visit-2	33047	32264	98	25855	78	1167	4	548	2	33019	98	5635	17	6240	19	21144	64	64
Annual Visit -3	36243	35203	97	26515	73	886	2	640	2	31913	98	4560	14	5127	16	22226	70	62
Annual Visit -4	33461	31965	96	22947	69	648	2	793	3	27500	97	3172	12	4004	15	20324	74	61
Annual Visit -5	22580	21311	94	14966	66	433	2	688	4	17368	96	1896	11	2380	14	13092	75	59
Annual Visit -6	11342	10661	94	7145	63	155	1	367	4	8252	96	826	10	1097	13	6329	77	57
Annual Visit -7	4326	4001	92	2598	60	63	1	177	6	3017	94	275	9	360	12	2382	79	56

[1] Medication rate calculated as the number of pills taken divided by the number of days since bottle(s) were dispensed.
[2] 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.

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

Data as of: February 28, 2002

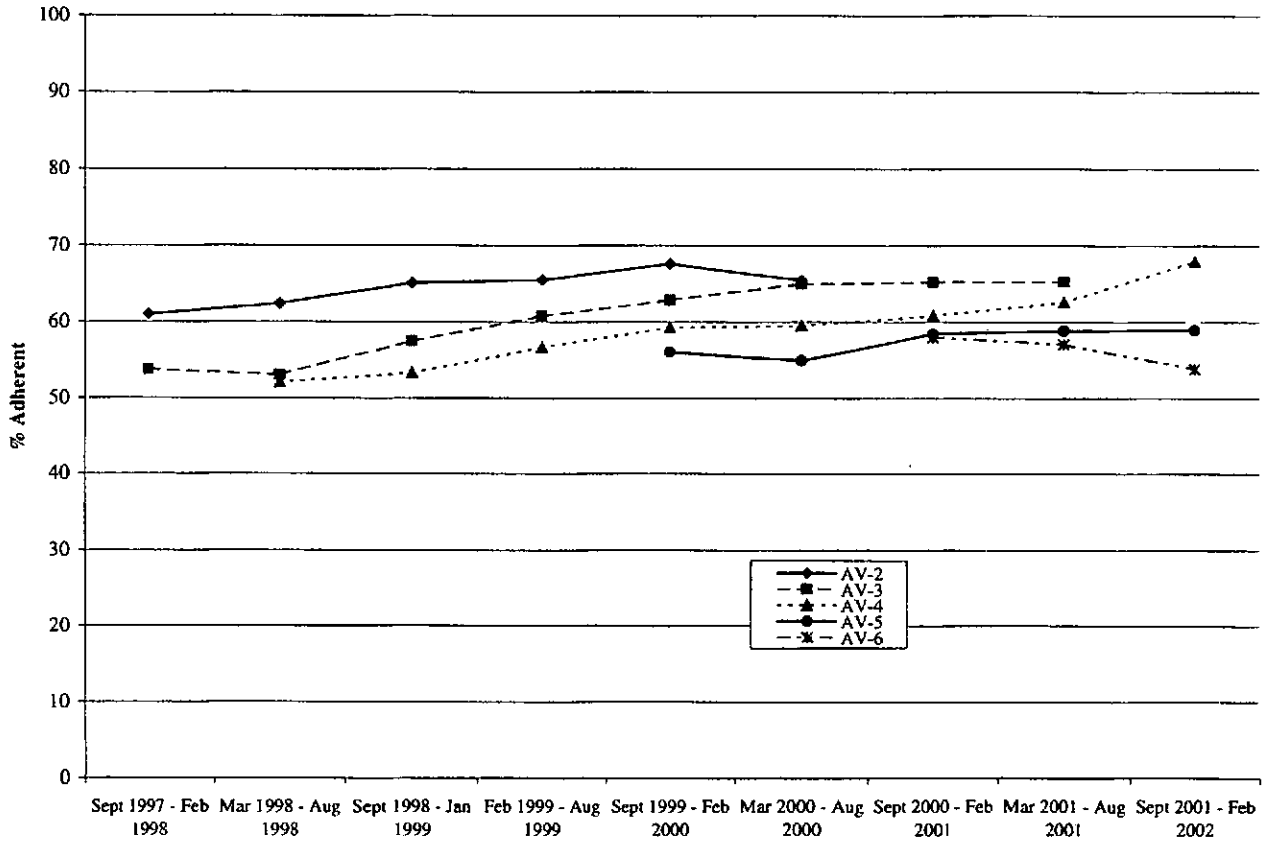


Table 4.3
CaD Drop-Out Rates by Follow-Up Time

Data as of: February 28, 2002

	Design			Observed			
	Int	Cum		Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]							
AV-2	8.8	8.8		7.2	0.3	7.4	7.4
AV-3	5.9	14.2		2.5	0.6	3.1	10.3
AV-4	5.9	19.2		2.0	1.0	3.0	13.0
AV-5	5.9	24.0		1.9	1.4	3.3	15.9
AV-6	5.9	28.5		1.4	1.9	3.3	18.7
AV-7	5.9	32.7		1.5	2.6	4.1	22.0

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

Table 4.4
Reasons for Stopping CaD[1]

Data as of: February 28, 2002

Reasons[2]	(N = 8468)	
Personal/family		
Demands of work	184	2.2%
Family illness, emergency or other family demands[3]	327	3.9%
Financial problems	12	0.1%
Lack of cooperation/support from family/friends[4]	53	0.6%
Living in nursing home	24	0.3%
Issues of interest in study[5]	260	3.1%
Travel		
Too far to CC	208	2.5%
Moved out of area or refuses to be followed at another CC	77	0.9%
Other travel issues[6]	83	1.0%
Visits & Procedures		
Doesn't like visits, calls	74	0.9%
Doesn't like required forms or safety procedures[7]	76	0.9%
Problems with other procedures[8]	32	0.4%
Worried about health effects of medical tests/procedures	29	0.3%
Wants results of blood analyses	3	<0.1%
Wants results of bone mineral density	2	<0.1%
Problems with CC[9]	50	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: February 28, 2002

Reasons[2]	(N = 8468)	
Symptoms		
Bloating/gas	148	1.7%
Constipation	180	2.1%
Other gastrointestinal problems	201	2.4%
HRT Related Symptoms[3]	40	0.5%
Other[4]	2285	27.0%
Health Conditions		
Hypercalcemia	125	1.5%
Renal calculi	122	1.4%
Osteoporosis	61	0.7%
Other Diseases/Health Conditions[5]	715	8.4%
Communication difficulties[6]	62	0.7%
Intervention		
Doesn't like randomized nature of intervention	357	4.2%
Expected some benefit from intervention	49	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	20	0.2%
Takes too many pills	226	2.7%
Other pill issues[7]	962	11.4%
HRT Issues[8]	117	1.4%
DM Issues[9]	17	0.2%
Wants to take her own calcium	271	3.2%
Feels diet is already sufficient in calcium/Vit D	29	0.3%
Taking more than the max allowable IU of Vit D	29	0.3%
Taking Calcitrol	17	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	9	0.1%
Expected more health care	21	0.2%
Advised not to participate by health care provider[10]	674	8.0%
Study conflicts with other health issues[11]	492	5.8%
Other		
Other reasons not listed above	1926	22.7%
Refuses to give a reason	136	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 February 28, 2002

	All (N = 36,282)		Age at Screening: 50 – 54 (N = 5,157)		55 –59 (N = 8,265)		60 –69 (N = 16,520)		70 –79 (N = 6,340)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	8468	23.3%	1366	26.5%	1929	23.3%	3561	21.6%	1612	25.4%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Doesn't like randomized nature of intervention	357	4.2%	61	4.5%	80	4.1%	157	4.4%	59	3.7%
Other pill issues[5]	962	11.4%	151	11.1%	228	11.8%	406	11.4%	177	11.0%
Advised not to participate by health care provider[6]	674	8.0%	71	5.2%	147	7.6%	313	8.8%	143	8.9%
Study conflicts with other health issues[7]	492	5.8%	64	4.7%	97	5.0%	221	6.2%	110	6.8%

	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	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]
Women Stopping CaD	38	25.5%	156	21.6%	901	27.2%	416	27.7%	6838	22.7%	119	27.0%
REASONS FOR STOPPING[3]	N	%[9]	N	%[9]	N	%[9]	N	%[9]	N	%[9]	N	%[9]
Doesn't like randomized nature of intervention	0	0.0%	3	1.9%	32	3.6%	8	1.9%	309	4.5%	5	4.2%
Other pill issues[5]	6	15.8%	19	12.2%	87	9.7%	51	12.3%	788	11.5%	11	9.2%
Advised not to participate by health care provider[6]	2	5.3%	6	3.8%	58	6.4%	30	7.2%	570	8.3%	8	6.7%
Study conflicts with other health issues[7]	1	2.6%	6	3.8%	41	4.6%	18	4.3%	418	6.1%	8	6.7%

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

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

Data as of: February 28, 2002

	N	Mean	S.D.
Whole Body Scan			
AV1	2425	1.02	0.10
AV3	2261	1.03	0.11
AV6	1193	1.05	0.12
AV3 % Change from AV1 BMD[2]	2188	1.42	3.36
AV6 % Change from AV1 BMD[3]	1156	2.90	4.98
Spine Scan			
AV1	2350	0.99	0.16
AV3	2209	1.01	0.17
AV6	1181	1.02	0.17
AV3 % Change from AV1 BMD[2]	2139	1.58	4.22
AV6 % Change from AV1 BMD[3]	1146	3.04	5.85
Hip Scan			
AV1	2431	0.86	0.14
AV3	2284	0.87	0.14
AV6	1220	0.88	0.14
AV3 % Change from AV1 BMD[2]	2210	1.28	3.55
AV6 % Change from AV1 BMD[3]	1180	1.44	4.76

[1] Measured in (g/cm^2).
[2] Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100.
[3] Percent Change from BMD is defined as ((AV6-AV1)/AV1)x100.

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

Data as of: February 28, 2002

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
AV1	278	1.08	0.11	123	1.04	0.12	1986	1.01	0.10
AV3	263	1.10	0.11	116	1.05	0.12	1846	1.02	0.11
AV6	116	1.09	0.12	58	1.12	0.16	998	1.05	0.12
AV3 % Change from AV1 BMD[2]	259	1.22	3.01	104	2.20	4.36	1791	1.41	3.34
AV6 % Change from AV1 BMD[3]	114	1.06	3.55	47	6.55	7.78	975	2.95	4.85
Spine Scan									
AV1	274	1.07	0.18	120	0.98	0.17	1918	0.98	0.16
AV3	260	1.08	0.19	114	0.97	0.15	1799	1.00	0.17
AV6	116	1.09	0.17	57	1.00	0.16	987	1.02	0.17
AV3 % Change from AV1 BMD[2]	256	1.15	4.40	101	0.32	4.18	1748	1.76	4.17
AV6 % Change from AV1 BMD[3]	114	1.82	6.13	46	2.24	5.94	966	3.21	5.81
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	1868	0.86	0.13
AV6	121	0.97	0.14	59	0.90	0.14	1019	0.87	0.13
AV3 % Change from AV1 BMD[2]	260	0.85	.3.16	103	1.68	4.67	1813	1.32	3.52
AV6 % Change from AV1 BMD[3]	118	-1.00	4.45	48	3.64	4.39	994	1.64	4.70

[1] Measured in (g/cm^2).
[2] Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100.
[3] Percent Change from BMD is defined as ((AV6-AV1)/AV1)x100.

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

Data as of: February 28, 2002

	CaD Participants (N=36,282)	
	N	%
Vital Status/Participation		
Deceased	672	1.9
Alive: Current Participation[1]	34264	94.4
Alive: Recent Participation[2]	645	1.8
Alive: Past/Unknown Participation[3]	37	0.1
Stopped Follow-Up[4]	359	1.0
Lost to Follow-Up[5]	305	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
Locally Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: February 28, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5157	8265	16520	6340
Mean follow-up (months)	48.9	54.5	51.0	47.1	46.1
Fractures					
Hip fracture	147 (0.10%)	5 (0.02%)	12 (0.03%)	57 (0.09%)	73 (0.30%)
Vertebral fracture	150 (0.10%)	5 (0.02%)	16 (0.05%)	62 (0.10%)	67 (0.27%)
Other fracture[1]	2066 (1.40%)	266 (1.14%)	415 (1.18%)	951 (1.47%)	434 (1.78%)
Total fracture	2294 (1.55%)	274 (1.17%)	438 (1.25%)	1042 (1.61%)	540 (2.22%)
Cancer					
Colorectal cancer	184 (0.12%)	14 (0.06%)	28 (0.08%)	89 (0.14%)	53 (0.22%)
Breast cancer[2]	717 (0.49%)	81 (0.35%)	171 (0.49%)	339 (0.52%)	126 (0.52%)
Invasive breast cancer	569 (0.39%)	61 (0.26%)	134 (0.38%)	272 (0.42%)	102 (0.42%)
Non-invasive breast cancer	153 (0.10%)	20 (0.09%)	38 (0.11%)	70 (0.11%)	25 (0.10%)
Ovarian cancer	65 (0.04%)	8 (0.03%)	14 (0.04%)	27 (0.04%)	16 (0.07%)
Endometrial cancer[3]	104 (0.12%)	13 (0.10%)	23 (0.11%)	50 (0.13%)	18 (0.13%)
Other cancer[1]	690 (0.47%)	64 (0.27%)	119 (0.34%)	327 (0.50%)	180 (0.74%)
Total cancer	1721 (1.17%)	179 (0.76%)	346 (0.99%)	815 (1.26%)	381 (1.56%)
Cardiovascular					
CHD[4]	458 (0.31%)	29 (0.12%)	42 (0.12%)	216 (0.33%)	171 (0.70%)
CHD death[5]	99 (0.07%)	7 (0.03%)	10 (0.03%)	40 (0.06%)	42 (0.17%)
Total MI[6]	390 (0.26%)	24 (0.10%)	34 (0.10%)	189 (0.29%)	143 (0.59%)
Clinical MI	361 (0.24%)	20 (0.09%)	32 (0.09%)	175 (0.27%)	134 (0.55%)
Evolving Q-wave MI[7]	30 (0.02%)	4 (0.02%)	2 (0.01%)	15 (0.02%)	9 (0.04%)
Possible evolving Q-wave MI[7]	99 (0.07%)	13 (0.06%)	17 (0.05%)	40 (0.06%)	29 (0.12%)
Angina	627 (0.42%)	29 (0.12%)	84 (0.24%)	305 (0.47%)	209 (0.86%)
CABG/PTCA	630 (0.43%)	29 (0.12%)	74 (0.21%)	312 (0.48%)	215 (0.88%)
Carotid artery disease	117 (0.08%)	3 (0.01%)	12 (0.03%)	57 (0.09%)	45 (0.18%)
Congestive heart failure	361 (0.24%)	13 (0.06%)	39 (0.11%)	167 (0.26%)	142 (0.58%)
Stroke	335 (0.23%)	13 (0.06%)	36 (0.10%)	140 (0.22%)	146 (0.60%)
PVD	88 (0.06%)	3 (0.01%)	12 (0.03%)	40 (0.06%)	33 (0.14%)
CHD[4]/Possible evolving Q-wave MI	553 (0.37%)	42 (0.18%)	59 (0.17%)	253 (0.39%)	199 (0.82%)
Coronary disease[8]	1396 (0.95%)	78 (0.33%)	174 (0.50%)	660 (1.02%)	484 (1.99%)
Total cardiovascular disease	1825 (1.24%)	94 (0.40%)	223 (0.64%)	870 (1.34%)	638 (2.62%)
Deaths					
Cardiovascular deaths	182 (0.12%)	10 (0.04%)	16 (0.05%)	76 (0.12%)	80 (0.33%)
Cancer deaths	305 (0.21%)	23 (0.10%)	37 (0.11%)	147 (0.23%)	98 (0.40%)
Other known cause	86 (0.06%)	4 (0.02%)	10 (0.03%)	37 (0.06%)	35 (0.14%)
Unknown cause	40 (0.03%)	2 (0.01%)	5 (0.01%)	19 (0.03%)	14 (0.06%)
Not yet adjudicated	59 (0.04%)	6 (0.03%)	10 (0.03%)	27 (0.04%)	16 (0.07%)
Total death	672 (0.45%)	45 (0.19%)	78 (0.22%)	306 (0.47%)	243 (1.00%)

[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] Excludes five cases with borderline malignancy.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "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)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of: February 28, 2002

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)	48.6	44.9	47.7	46.8	49.2	45.1
Fractures						
Hip fracture	0 (0.00%)	2 (0.07%)	4 (0.03%)	2 (0.03%)	139 (0.11%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	2 (0.07%)	2 (0.02%)	5 (0.09%)	138 (0.11%)	3 (0.18%)
Other fracture[1]	9 (1.49%)	26 (0.96%)	102 (0.77%)	49 (0.84%)	1861 (1.50%)	19 (1.15%)
Total fracture	9 (1.49%)	28 (1.04%)	106 (0.81%)	56 (0.96%)	2074 (1.68%)	21 (1.27%)
Cancer						
Colorectal cancer	2 (0.33%)	3 (0.11%)	19 (0.14%)	7 (0.12%)	152 (0.12%)	1 (0.06%)
Breast cancer[2]	1 (0.17%)	10 (0.37%)	40 (0.30%)	21 (0.36%)	642 (0.52%)	3 (0.18%)
Invasive breast cancer	1 (0.17%)	8 (0.30%)	30 (0.23%)	18 (0.31%)	509 (0.41%)	3 (0.18%)
Non-invasive breast cancer	0 (0.00%)	2 (0.07%)	11 (0.08%)	3 (0.05%)	137 (0.11%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	1 (0.04%)	5 (0.04%)	0 (0.00%)	59 (0.05%)	0 (0.00%)
Endometrial cancer[3]	1 (0.40%)	0 (0.00%)	2 (0.04%)	2 (0.06%)	98 (0.13%)	1 (0.11%)
Other cancer[1]	3 (0.50%)	12 (0.44%)	45 (0.34%)	15 (0.26%)	610 (0.49%)	5 (0.30%)
Total cancer	7 (1.16%)	26 (0.96%)	110 (0.84%)	42 (0.72%)	1526 (1.23%)	10 (0.60%)
Cardiovascular						
CHD[4]	1 (0.17%)	2 (0.07%)	41 (0.31%)	10 (0.17%)	398 (0.32%)	6 (0.36%)
CHD death[5]	0 (0.00%)	1 (0.04%)	16 (0.12%)	2 (0.03%)	79 (0.06%)	1 (0.06%)
Total MI[6]	1 (0.17%)	2 (0.07%)	29 (0.22%)	9 (0.15%)	343 (0.28%)	6 (0.36%)
Clinical MI	1 (0.17%)	2 (0.07%)	26 (0.20%)	9 (0.15%)	318 (0.26%)	5 (0.30%)
Evolving Q-wave MI[7]	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	26 (0.02%)	1 (0.06%)
Possible evolving Q-wave MI[7]	0 (0.00%)	3 (0.11%)	15 (0.11%)	3 (0.05%)	78 (0.06%)	0 (0.00%)
Angina	1 (0.17%)	6 (0.22%)	59 (0.45%)	23 (0.39%)	532 (0.43%)	6 (0.36%)
CABG/PTCA	1 (0.17%)	5 (0.19%)	46 (0.35%)	22 (0.38%)	548 (0.44%)	8 (0.48%)
Carotid artery disease	1 (0.17%)	2 (0.07%)	8 (0.06%)	0 (0.00%)	106 (0.09%)	0 (0.00%)
Congestive heart failure	1 (0.17%)	3 (0.11%)	50 (0.38%)	11 (0.19%)	291 (0.24%)	5 (0.30%)
Stroke	3 (0.50%)	10 (0.37%)	35 (0.27%)	7 (0.12%)	275 (0.22%)	5 (0.30%)
PVD	1 (0.17%)	0 (0.00%)	14 (0.11%)	0 (0.00%)	72 (0.06%)	1 (0.06%)
CHD[4]/Possible evolving Q-wave MI	1 (0.17%)	5 (0.19%)	55 (0.42%)	13 (0.22%)	473 (0.38%)	6 (0.36%)
Coronary disease[8]	2 (0.33%)	14 (0.52%)	148 (1.12%)	42 (0.72%)	1173 (0.95%)	17 (1.03%)
Total cardiovascular disease	6 (1.00%)	24 (0.89%)	196 (1.49%)	49 (0.84%)	1527 (1.23%)	23 (1.39%)
Deaths						
Cardiovascular deaths	0 (0.00%)	3 (0.11%)	31 (0.24%)	3 (0.05%)	144 (0.12%)	1 (0.06%)
Cancer deaths	0 (0.00%)	8 (0.30%)	26 (0.20%)	4 (0.07%)	264 (0.21%)	3 (0.18%)
Other known cause	2 (0.33%)	0 (0.00%)	10 (0.08%)	0 (0.00%)	73 (0.06%)	1 (0.06%)
Unknown cause	1 (0.17%)	0 (0.00%)	4 (0.03%)	0 (0.00%)	34 (0.03%)	1 (0.06%)
Not yet adjudicated	0 (0.00%)	3 (0.11%)	5 (0.04%)	2 (0.03%)	49 (0.04%)	0 (0.00%)
Total death	3 (0.50%)	14 (0.52%)	76 (0.58%)	9 (0.15%)	564 (0.46%)	6 (0.36%)

[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] Excludes five cases with borderline malignancy.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "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: February 28, 2002

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	36282		5157		8265		16520		6340	
Mean follow-up (months)	48.9		54.5		51.0		47.1		46.1	
Hospitalizations										
Ever	10985	(7.44%)	1145	(4.89%)	2070	(5.90%)	5210	(8.04%)	2560	(10.51%)
Two or more	4314	(2.92%)	400	(1.71%)	729	(2.08%)	2007	(3.10%)	1178	(4.83%)
Other										
DVT[1]	222	(0.15%)	13	(0.06%)	40	(0.12%)	95	(0.15%)	74	(0.31%)
Pulmonary embolism	122	(0.08%)	6	(0.03%)	25	(0.07%)	59	(0.09%)	32	(0.13%)
Diabetes (treated)	1495	(1.06%)	225	(0.99%)	352	(1.04%)	661	(1.07%)	257	(1.11%)
Gallbladder disease[2]	1508	(1.21%)	223	(1.08%)	386	(1.28%)	684	(1.27%)	215	(1.08%)
Hysterectomy	565	(0.65%)	82	(0.61%)	137	(0.63%)	263	(0.70%)	83	(0.61%)
Glaucoma	1988	(1.39%)	205	(0.89%)	395	(1.15%)	955	(1.53%)	433	(1.90%)
Osteoporosis	4223	(3.00%)	383	(1.66%)	759	(2.23%)	2068	(3.36%)	1013	(4.57%)
Osteoarthritis[3]	4099	(4.48%)	587	(3.43%)	960	(4.04%)	1870	(4.90%)	682	(5.50%)
Rheumatoid arthritis	1075	(0.76%)	165	(0.73%)	261	(0.77%)	460	(0.74%)	189	(0.82%)
Intestinal polyps	2720	(1.97%)	335	(1.48%)	602	(1.80%)	1326	(2.21%)	457	(2.10%)
Lupus	177	(0.12%)	32	(0.14%)	43	(0.12%)	73	(0.11%)	29	(0.12%)
Kidney stones[3]	353	(0.30%)	47	(0.27%)	90	(0.33%)	156	(0.30%)	60	(0.30%)
Cataracts[3]	6600	(6.38%)	390	(2.26%)	1069	(4.05%)	3587	(7.77%)	1554	(11.43%)
Pills for hypertension	5697	(5.39%)	748	(3.91%)	1268	(4.69%)	2591	(5.81%)	1090	(7.27%)

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)	48.6		44.9		47.7		46.8		49.2		45.1	
Hospitalizations												
Ever	43	(7.13%)	135	(5.00%)	1040	(7.90%)	363	(6.20%)	9280	(7.50%)	124	(7.50%)
Two or more	25	(4.15%)	40	(1.48%)	416	(3.16%)	132	(2.25%)	3653	(2.95%)	48	(2.90%)
Other												
DVT[1]	2	(0.34%)	0	(0.00%)	16	(0.12%)	4	(0.07%)	198	(0.16%)	2	(0.12%)
Pulmonary embolism	3	(0.50%)	0	(0.00%)	9	(0.07%)	2	(0.03%)	106	(0.09%)	2	(0.12%)
Diabetes (treated)	7	(1.26%)	45	(1.77%)	253	(2.15%)	106	(1.92%)	1065	(0.89%)	19	(1.22%)
Gallbladder disease[2]	8	(1.77%)	26	(1.06%)	99	(0.83%)	70	(1.55%)	1288	(1.24%)	17	(1.23%)
Hysterectomy	1	(0.40%)	8	(0.46%)	27	(0.48%)	14	(0.43%)	511	(0.69%)	4	(0.43%)
Glaucoma	11	(1.91%)	33	(1.27%)	255	(2.06%)	103	(1.81%)	1569	(1.31%)	17	(1.08%)
Osteoporosis	13	(2.27%)	80	(3.07%)	209	(1.64%)	162	(2.95%)	3706	(3.14%)	53	(3.43%)
Osteoarthritis[3]	19	(5.01%)	77	(3.97%)	375	(4.70%)	208	(5.24%)	3366	(4.42%)	54	(5.04%)
Rheumatoid arthritis	10	(1.87%)	18	(0.70%)	187	(1.53%)	92	(1.64%)	753	(0.63%)	15	(0.96%)
Intestinal polyps	15	(2.70%)	45	(1.81%)	261	(2.12%)	93	(1.65%)	2278	(1.97%)	28	(1.84%)
Lupus	3	(0.51%)	1	(0.04%)	21	(0.16%)	5	(0.09%)	146	(0.12%)	1	(0.06%)
Kidney stones[3]	2	(0.43%)	8	(0.36%)	21	(0.20%)	23	(0.50%)	295	(0.30%)	4	(0.30%)
Cataracts[3]	34	(7.92%)	109	(5.67%)	548	(5.91%)	260	(5.98%)	5579	(6.46%)	70	(5.87%)
Pills for hypertension	23	(6.09%)	106	(5.73%)	572	(8.34%)	258	(5.71%)	4677	(5.13%)	61	(5.76%)

[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.

Table 4.11
Sensitivity of CaD Study Power to Adherence and Incidence Rate Assumptions[1]
Revised Sample Size of 36,282

	Year	Intervention Effect[1] (%)	Percentage of Cases[2] Control	Percentage of Cases[2] Intervention	Design[3]	Revised Assumptions[4]
Hip Fractures						
	2001	20	1.61	1.36	57	24
		27	1.62	1.31	74	33
		33	1.62	1.26	86	43
	2004	20	2.84	2.35	86	51
		27	2.85	2.25	96	67
		33	2.85	2.15	99	81
Combined Fractures[5]						
	2001	19	6.48	5.54	98	79
		23	6.50	5.36	>99	92
		28	6.51	5.18	>99	98
	2004	19	10.22	8.62	>99	99
		23	10.24	8.30	>99	>99
		28	10.25	7.98	>99	>99
Colorectal Cancer						
	2001	18	0.90	0.80	22	14
		20	0.90	0.79	26	17
		22	0.90	0.78	30	19
	2004	18	1.48	1.22	68	46
		20	1.49	1.20	77	55
		22	1.49	1.18	84	62

[1] Analysis has not been updated from that of August 31, 2001.
[2] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.
[3] For design, the calculations were based on n = 35,000.
[4] For revised assumption, calculations were based on n = 36,282 and 7.5 years of follow-up for years 1 though 9. Control incidence rates for years 1-4 were based on observed data and adjustment thereafter accordingly.
[5] Proximal femur, distal forearm, proximal humerus, pelvis, vertebra.

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* 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 a clinic visit at year 6 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 VCCs in Fall 1997.

5.3 Completeness of Annual Mail Follow-up

Table 5.2 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 are 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 the OS Exposure Update (*Form 48*), but falls short of the optimal goal (98%) for completion of the Medical History Update (*Form 33*). For years 2, 4, 5, and 6 the rates of 94.2% (Y2), 93.5% (Y4), 95.0% (Y5), and 94.1% (Y6) exceed the 94% (Y2), 92% (Y4), 91% (Y5), and 90% (Y6) goals for the Exposure Update.

5.4 Completeness of Year 3 Clinic Visit

Table 5.3 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 2/28/02, 95.6% overall completed medical history updates (*Form 33*) and 82.2% provided blood samples (*Form 100*). Of those due for the year 6 visit, 88.4% completed medical history updates (*Form 33*) and 80.3% completed a bone densitometry (*Form 87*).

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 (overall) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline AV-3 along with % change from baseline for the three types of scans available: whole body, spine, and hip. Baseline and % change is also given using only those women who have an AV-3 bone scan, as nearly 3,000 of the women with a baseline do not have an AV-3 measure. The current data suggest overall a small increase in bone density over three 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 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.* 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 1.9% of the participants are lost-to-follow-up, and an additional 1.3% of the participants have stopped follow-up. 2.7% of the OS participants are deceased. Compared to six months ago, the percentage of participants who were lost-to-follow-up or stopped follow-up increased by 0.2%. Over the same period, participation levels has remained stable, as 89.7% of the participants are considered current, the same percentage as six months ago.

5.7 Outcomes

Table 5.7 contains counts of the number of locally verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 5% 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. Compared to the incidence rates used in the CT design, we have about 125% 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. For most outcomes categories there are now hundreds of events, which should make it possible to do interesting etiological analyses.

Table 5.8 contains counts of the number of self-reports for some outcomes that are not locally 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 and 5.10, contain counts of outcomes relative to their AV-3. These tables count the *first* event of a particular type, thus a participant who reports, say, an Angina 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: February 28, 2002

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12386	13%
55-59	17321	18%
60-69	41196	44%
70-79	22773	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2671	3%
Black	7634	8%
Hispanic	3609	4%
White	78017	83%
Unknown	1324	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: February 28, 2002

	# 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	93,469	93,283	99.8%	86,656	92.9%	2,829	42.7%	89,485	95.7%
VCC	41,637	41,603	99.9%	38,421	92.4%	1,689	53.1%	40,110	96.3%
NCC	51,832	51,680	99.7%	48,235	93.3%	1,140	33.1%	49,375	95.3%
Year 2	93,042	91,404	98.2%	86,317	94.4%	N/A		87,615	94.2%
VCC	41,456	40,710	98.2%	38,479	94.5%	N/A		39,100	94.3%
NCC	51,586	50,694	98.3%	47,838	94.4%	N/A		48,515	94.0%
Year 4	54,188	53,120	98.0%	49,568	93.3%	N/A		50,671	93.5%
VCC	25,607	25,039	97.8%	23,278	93.0%	N/A		23,737	92.7%
NCC	28,581	28,081	98.3%	26,290	93.6%	N/A		26,934	94.2%
Year 5	26,691	26,250	98.3%	24,808	94.5%	558	38.7%	25,366	95.0%
VCC	13,730	13,556	98.7%	12,740	94.0%	295	36.2%	13,035	94.9%
NCC	12,961	12,694	97.9%	12,068	95.1%	263	42.0%	12,331	95.1%
Year 6[6]	1,822	1,789	98.2%	1,685	94.2%	N/A		1,714	94.1%
VCC	1,791	1,759	98.2%	1,656	94.1%	N/A		1,685	94.1%
NCC	31	30	96.8%	29	96.7%	N/A		29	93.5%

[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 Task Completeness

Data as of: February 28, 2002

	Task	# Due[1]	# Done[2]	% Done
Year 3	Form 33 - Medical History Update	80,469	76,898	95.6%
	Form 38 - Daily Life	80,469	71,279	88.6%
	Form 44 - Current Medications	80,469	68,490	85.1%
	Form 45 - Current Supplements	80,469	68,403	85.0%
	Form 60 - Food Frequency Quest	80,469	71,382	88.7%
	Form 80 - Physical Measures	80,469	66,913	83.2%
	Form 100 - Blood Collection	80,469	66,163	82.2%
	Form 143 - Follow-up	80,469	70,972	88.2%
Year 6[3]	Form 33 - Medical History Update	757	669	88.4%
	Form 80 - Physical Measures	757	614	81.1%
	Form 87 - Bone Densitometry	757	608	80.3%
	Form 146 - Follow-up	757	652	86.1%

[1] Includes all Year 3/6 contacts due through 4/30/01. 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: February 28, 2002

	N	Mean	S.D.
Whole Body Scan			
Baseline	6388	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5066	1.01	0.11
Baseline (for ppts. with an AV6 scan)	2573	1.02	0.11
AV3	5123	1.02	0.11
AV6	2593	1.03	0.12
AV3 % Change from baseline BMD[2]	5059	0.92	3.63
AV6 % Change from baseline BMD[3]	2568	1.81	5.30
Spine Scan			
Baseline	6269	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4992	0.97	0.17
Baseline (for ppts. with an AV6 scan)	2524	0.98	0.17
AV3	5028	0.99	0.17
AV6	2531	1.01	0.18
AV3 % Change from baseline BMD[2]	4984	1.67	5.14
AV6 % Change from baseline BMD[3]	2519	3.74	6.96
Hip Scan			
Baseline	6417	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5135	0.84	0.14
Baseline (for ppts. with an AV6 scan)	2615	0.84	0.13
AV3	5173	0.85	0.14
AV6	2622	0.84	0.14
AV3 % Change from baseline BMD[2]	5103	0.49	4.35
AV6 % Change from baseline BMD[3]	2592	0.25	5.30

[1] Measured in (g/cm^2).
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[3] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

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

Data as of: February 28, 2002

	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	824	1.04	0.11	462	1.01	0.11	4923	1.00	0.10	46	1.01	0.12
Baseline (for ppts. with an AV3 scan)	74	1.02	0.12	22	1.03	0.09	567	1.05	0.11	323	1.01	0.10	4045	1.01	0.10	35	1.01	0.12
Baseline (for ppts. with an AV6 scan)	16	1.08	0.15	9	1.01	0.09	257	1.05	0.11	90	1.05	0.10	2189	1.01	0.10	12	1.01	0.13
AV3	77	1.03	0.13	22	1.03	0.11	574	1.06	0.12	338	1.03	0.11	4076	1.01	0.11	36	1.01	0.10
AV6	16	1.10	0.16	9	1.03	0.13	260	1.05	0.12	90	1.09	0.13	2206	1.03	0.12	12	1.01	0.14
AV3 % Change from baseline BMD[2]	74	0.67	4.44	22	-0.03	5.44	567	1.52	3.35	322	1.51	4.43	4039	0.80	3.56	35	0.51	2.91
AV6 % Change from baseline BMD[3]	16	1.41	5.06	9	1.63	5.64	257	0.42	3.80	90	3.48	6.04	2184	1.92	5.40	12	-0.69	4.00
Spine Scan																		
Baseline	109	0.99	0.17	25	0.95	0.12	815	1.04	0.18	454	0.95	0.16	4821	0.97	0.17	45	0.99	0.19
Baseline (for ppts. with an AV3 scan)	74	0.99	0.15	22	0.96	0.12	570	1.04	0.17	315	0.95	0.16	3977	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	16	1.07	0.19	8	0.94	0.11	247	1.05	0.18	90	0.99	0.17	2151	0.97	0.16	12	1.01	0.28
AV3	77	1.00	0.16	22	0.96	0.12	572	1.05	0.19	328	0.95	0.16	3994	0.98	0.17	35	0.95	0.17
AV6	16	1.11	0.15	8	0.95	0.12	247	1.07	0.20	90	0.99	0.18	2158	1.01	0.18	12	1.04	0.30
AV3 % Change from baseline BMD[2]	74	-0.04	5.75	22	0.22	4.62	570	1.16	5.53	314	0.30	5.42	3970	1.90	5.02	34	0.84	5.17
AV6 % Change from baseline BMD[3]	16	4.33	7.07	8	1.09	3.86	247	2.49	6.28	90	0.32	6.97	2146	4.03	6.99	12	3.19	7.42
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	463	0.83	0.13	4947	0.83	0.13	46	0.85	0.14
Baseline (for ppts. with an AV3 scan)	74	0.88	0.15	22	0.82	0.10	580	0.93	0.15	324	0.83	0.12	4100	0.83	0.13	35	0.83	0.12
Baseline (for ppts. with an AV6 scan)	16	0.96	0.19	9	0.77	0.08	260	0.92	0.15	90	0.86	0.12	2227	0.83	0.13	13	0.82	0.16
AV3	77	0.88	0.15	22	0.82	0.09	585	0.94	0.15	338	0.85	0.13	4115	0.83	0.13	36	0.82	0.12
AV6	16	0.96	0.16	9	0.79	0.08	261	0.90	0.15	90	0.88	0.13	2233	0.83	0.13	13	0.81	0.17
AV3 % Change from baseline BMD[2]	73	-0.29	5.04	22	0.81	4.42	580	0.38	4.03	322	1.70	5.07	4071	0.43	4.30	35	-0.66	4.75
AV6 % Change from baseline BMD[3]	16	-0.02	6.89	9	2.58	6.62	259	-1.45	4.73	90	2.39	5.63	2205	0.36	5.28	13	-1.97	6.76

[1] Measured in (g/cm^2).
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[3] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

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

Data as of: February 28, 2002

	OS Participants (N=93,676)	
	N	%
Vital Status/Participation		
Deceased	2532	2.7
Alive: Current Participation[1]	84056	89.7
Alive: Recent Participation[2]	3698	3.9
Alive: Past/Unknown Participation[3]	339	0.4
Stopped Follow-Up[4]	1254	1.3
Lost to Follow-Up[5]	1797	1.9

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

Data as of: February 28, 2002

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number enrolled	93676		12386		17321		41196		22773	
Mean follow-up (months)	54.0		57.7		56.3		52.9		52.1	
Cardiovascular										
CHD[1]	1150	(0.27%)	35	(0.06%)	99	(0.12%)	467	(0.26%)	549	(0.55%)
CHD death[2]	299	(0.07%)	4	(0.01%)	16	(0.02%)	101	(0.06%)	178	(0.18%)
Clinical MI	939	(0.22%)	31	(0.05%)	88	(0.11%)	390	(0.21%)	430	(0.43%)
Angina	1773	(0.42%)	76	(0.13%)	176	(0.22%)	812	(0.45%)	709	(0.72%)
CABG/PTCA	1662	(0.39%)	52	(0.09%)	164	(0.20%)	770	(0.42%)	676	(0.68%)
Carotid artery disease	360	(0.09%)	22	(0.04%)	26	(0.03%)	138	(0.08%)	174	(0.18%)
Congestive heart failure	1088	(0.26%)	33	(0.06%)	90	(0.11%)	443	(0.24%)	522	(0.53%)
Stroke	912	(0.22%)	25	(0.04%)	67	(0.08%)	353	(0.19%)	467	(0.47%)
PVD	250	(0.06%)	10	(0.02%)	23	(0.03%)	97	(0.05%)	120	(0.12%)
Coronary disease[3]	3606	(0.86%)	138	(0.23%)	340	(0.42%)	1564	(0.86%)	1564	(1.58%)
Total cardiovascular disease	4865	(1.15%)	190	(0.32%)	434	(0.53%)	2040	(1.12%)	2201	(2.22%)
Cancer										
Breast cancer[4]	2294	(0.54%)	231	(0.39%)	412	(0.51%)	1062	(0.58%)	589	(0.60%)
Invasive breast cancer	1904	(0.45%)	195	(0.33%)	340	(0.42%)	868	(0.48%)	501	(0.51%)
Non-invasive breast cancer	411	(0.10%)	40	(0.07%)	77	(0.09%)	203	(0.11%)	91	(0.09%)
Ovarian cancer	207	(0.05%)	19	(0.03%)	36	(0.04%)	89	(0.05%)	63	(0.06%)
Endometrial cancer[5]	289	(0.12%)	25	(0.07%)	39	(0.08%)	135	(0.13%)	90	(0.16%)
Colorectal cancer	487	(0.12%)	26	(0.04%)	60	(0.07%)	215	(0.12%)	186	(0.19%)
Other cancer[6]	2088	(0.50%)	145	(0.24%)	258	(0.32%)	948	(0.52%)	737	(0.74%)
Total cancer	5223	(1.24%)	438	(0.74%)	787	(0.97%)	2385	(1.31%)	1613	(1.63%)
Fractures										
Hip fracture	459	(0.11%)	12	(0.02%)	39	(0.05%)	150	(0.08%)	258	(0.26%)
Vertebral fracture[7]	56	(0.17%)	4	(0.08%)	5	(0.08%)	19	(0.13%)	28	(0.35%)
Other fracture[6,7]	441	(1.32%)	58	(1.18%)	74	(1.18%)	176	(1.24%)	133	(1.66%)
Total fracture[8]	930	N/A	73	N/A	115	N/A	335	N/A	407	N/A
Deaths										
Cardiovascular deaths	643	(0.15%)	16	(0.03%)	36	(0.04%)	221	(0.12%)	370	(0.37%)
Cancer deaths	1069	(0.25%)	61	(0.10%)	122	(0.15%)	454	(0.25%)	432	(0.44%)
Other known cause	376	(0.09%)	18	(0.03%)	44	(0.05%)	146	(0.08%)	168	(0.17%)
Unknown cause	201	(0.05%)	10	(0.02%)	15	(0.02%)	76	(0.04%)	100	(0.10%)
Not yet adjudicated	243	(0.06%)	9	(0.02%)	22	(0.03%)	98	(0.05%)	114	(0.12%)
Total death	2532	(0.60%)	114	(0.19%)	239	(0.29%)	995	(0.55%)	1184	(1.20%)

[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] Excludes six cases with borderline malignancy.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] 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.
[7] For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[8] 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)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: February 28, 2002

Outcomes	Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	421	2671	7634	3609	78017	1324
Mean follow-up (months)	50.4	52.6	50.0	46.7	54.8	51.5
Cardiovascular						
CHD[1]	7 (0.40%)	23 (0.20%)	99 (0.31%)	21 (0.15%)	981 (0.28%)	19 (0.33%)
CHD death[2]	2 (0.11%)	6 (0.05%)	42 (0.13%)	2 (0.01%)	241 (0.07%)	6 (0.11%)
Clinical MI	6 (0.34%)	19 (0.16%)	69 (0.22%)	20 (0.14%)	811 (0.23%)	14 (0.25%)
Angina	9 (0.51%)	34 (0.29%)	150 (0.47%)	45 (0.32%)	1520 (0.43%)	15 (0.26%)
CABG/PTCA	7 (0.40%)	28 (0.24%)	102 (0.32%)	42 (0.30%)	1460 (0.41%)	23 (0.41%)
Carotid artery disease	3 (0.17%)	4 (0.03%)	19 (0.06%)	9 (0.06%)	318 (0.09%)	7 (0.12%)
Congestive heart failure	8 (0.45%)	17 (0.15%)	124 (0.39%)	19 (0.14%)	905 (0.25%)	15 (0.26%)
Stroke	6 (0.34%)	28 (0.24%)	89 (0.28%)	16 (0.11%)	758 (0.21%)	15 (0.26%)
PVD	2 (0.11%)	3 (0.03%)	30 (0.09%)	4 (0.03%)	206 (0.06%)	5 (0.09%)
Coronary disease[3]	18 (1.02%)	61 (0.52%)	325 (1.02%)	78 (0.56%)	3082 (0.86%)	42 (0.74%)
Total cardiovascular disease	26 (1.47%)	91 (0.78%)	444 (1.39%)	104 (0.74%)	4136 (1.16%)	64 (1.13%)
Cancer						
Breast cancer[4]	4 (0.23%)	40 (0.34%)	135 (0.42%)	61 (0.43%)	2033 (0.57%)	21 (0.37%)
Invasive breast cancer	3 (0.17%)	30 (0.26%)	111 (0.35%)	47 (0.33%)	1695 (0.48%)	18 (0.32%)
Non-invasive breast cancer	1 (0.06%)	10 (0.09%)	25 (0.08%)	14 (0.10%)	357 (0.10%)	4 (0.07%)
Ovarian cancer	0 (0.00%)	3 (0.03%)	10 (0.03%)	5 (0.04%)	188 (0.05%)	1 (0.02%)
Endometrial cancer[5]	0 (0.00%)	5 (0.07%)	6 (0.04%)	5 (0.07%)	267 (0.13%)	6 (0.18%)
Colorectal cancer	1 (0.06%)	8 (0.07%)	56 (0.18%)	9 (0.06%)	410 (0.12%)	3 (0.05%)
Other cancer[6]	8 (0.45%)	35 (0.30%)	133 (0.42%)	41 (0.29%)	1840 (0.52%)	31 (0.55%)
Total cancer	13 (0.73%)	88 (0.75%)	328 (1.03%)	120 (0.85%)	4613 (1.29%)	61 (1.07%)
Fractures						
Hip fracture	2 (0.11%)	7 (0.06%)	7 (0.02%)	5 (0.04%)	432 (0.12%)	6 (0.11%)
Vertebral fracture[7]	1 (0.22%)	0 (0.00%)	1 (0.02%)	2 (0.09%)	52 (0.20%)	0 (0.00%)
Other fracture[6,7]	6 (1.33%)	2 (1.50%)	24 (0.57%)	20 (0.93%)	386 (1.47%)	3 (1.41%)
Total fracture[8]	9 N/A	9 N/A	31 N/A	26 N/A	846 N/A	9 N/A
Deaths						
Cardiovascular deaths	5 (0.28%)	14 (0.12%)	75 (0.24%)	8 (0.06%)	531 (0.15%)	10 (0.18%)
Cancer deaths	5 (0.28%)	17 (0.15%)	88 (0.28%)	23 (0.16%)	920 (0.26%)	16 (0.28%)
Other known cause	8 (0.45%)	4 (0.03%)	31 (0.10%)	19 (0.14%)	307 (0.09%)	7 (0.12%)
Unknown cause	2 (0.11%)	2 (0.02%)	32 (0.10%)	8 (0.06%)	155 (0.04%)	2 (0.04%)
Not yet adjudicated	3 (0.17%)	16 (0.14%)	27 (0.08%)	13 (0.09%)	183 (0.05%)	1 (0.02%)
Total death	23 (1.30%)	53 (0.45%)	253 (0.79%)	71 (0.51%)	2096 (0.59%)	36 (0.63%)

[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] Excludes six cases with borderline malignancy.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] 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.
[7] For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[8] 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: February 28, 2002

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	93676		12386		17321		41196		22773	
Mean follow-up (months)	54.0		57.7		56.3		52.9		52.1	
Hospitalizations										
Ever	29287	(6.95%)	2730	(4.58%)	4189	(5.15%)	13029	(7.17%)	9339	(9.44%)
Two or more	11777	(2.79%)	931	(1.56%)	1436	(1.77%)	5172	(2.85%)	4238	(4.28%)
Other										
DVT[1]	399	(0.10%)	34	(0.06%)	45	(0.06%)	178	(0.10%)	142	(0.15%)
Pulmonary embolism	244	(0.06%)	26	(0.04%)	31	(0.04%)	101	(0.06%)	86	(0.09%)
Diabetes (treated)	2796	(0.69%)	329	(0.57%)	507	(0.64%)	1278	(0.73%)	682	(0.72%)
Gallbladder disease[2]	3497	(0.98%)	548	(1.04%)	685	(0.97%)	1556	(1.03%)	708	(0.87%)
Hysterectomy	1921	(0.78%)	279	(0.79%)	389	(0.77%)	886	(0.84%)	367	(0.66%)
Glaucoma	4580	(1.14%)	446	(0.76%)	679	(0.86%)	2084	(1.20%)	1371	(1.51%)
Osteoporosis	13706	(3.55%)	1309	(2.28%)	2080	(2.69%)	6337	(3.82%)	3980	(4.65%)
Osteoarthritis[3]	9838	(4.00%)	1195	(2.78%)	1713	(3.21%)	4428	(4.36%)	2502	(5.24%)
Rheumatoid arthritis	2810	(0.70%)	401	(0.70%)	552	(0.71%)	1115	(0.65%)	742	(0.80%)
Intestinal polyps	7326	(1.92%)	835	(1.47%)	1325	(1.74%)	3410	(2.09%)	1756	(2.05%)
Lupus	638	(0.15%)	102	(0.17%)	127	(0.16%)	276	(0.15%)	133	(0.14%)
Kidney stones[3]	1260	(0.39%)	165	(0.38%)	235	(0.39%)	531	(0.38%)	329	(0.43%)
Cataracts[3]	15892	(5.78%)	788	(1.80%)	1981	(3.32%)	8289	(6.78%)	4834	(9.83%)
Pills for hypertension	12797	(4.25%)	1421	(2.87%)	2241	(3.53%)	5535	(4.38%)	3600	(5.80%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	421		2671		7634		3609		78017		1324	
Mean follow-up (months)	50.4		52.6		50.0		46.7		54.8		51.5	
Hospitalizations												
Ever	149	(8.42%)	508	(4.34%)	2295	(7.21%)	814	(5.79%)	25149	(7.05%)	372	(6.55%)
Two or more	66	(3.73%)	184	(1.57%)	932	(2.93%)	266	(1.89%)	10172	(2.85%)	157	(2.77%)
Other												
DVT[1]	2	(0.12%)	2	(0.02%)	29	(0.09%)	6	(0.04%)	358	(0.10%)	2	(0.04%)
Pulmonary embolism	1	(0.06%)	3	(0.03%)	19	(0.06%)	1	(0.01%)	218	(0.06%)	2	(0.04%)
Diabetes (treated)	33	(2.19%)	97	(0.87%)	456	(1.63%)	178	(1.36%)	1996	(0.58%)	36	(0.66%)
Gallbladder disease[2]	22	(1.57%)	49	(0.46%)	225	(0.80%)	145	(1.32%)	3010	(1.00%)	46	(0.97%)
Hysterectomy	3	(0.34%)	33	(0.43%)	84	(0.58%)	71	(0.93%)	1698	(0.80%)	32	(0.97%)
Glaucoma	28	(1.73%)	149	(1.34%)	539	(1.85%)	156	(1.17%)	3642	(1.07%)	66	(1.21%)
Osteoporosis	61	(3.76%)	412	(3.85%)	587	(1.94%)	435	(3.37%)	12001	(3.69%)	210	(4.04%)
Osteoarthritis[3]	41	(4.11%)	289	(3.52%)	808	(4.37%)	438	(4.76%)	8114	(3.95%)	148	(4.29%)
Rheumatoid arthritis	23	(1.42%)	59	(0.53%)	427	(1.48%)	237	(1.82%)	2009	(0.59%)	55	(1.04%)
Intestinal polyps	27	(1.66%)	177	(1.69%)	590	(2.02%)	220	(1.67%)	6216	(1.93%)	96	(1.88%)
Lupus	7	(0.40%)	12	(0.10%)	61	(0.19%)	32	(0.23%)	515	(0.15%)	11	(0.19%)
Kidney stones[3]	12	(0.89%)	20	(0.22%)	141	(0.56%)	77	(0.69%)	989	(0.36%)	21	(0.47%)
Cataracts[3]	57	(4.94%)	414	(5.46%)	1154	(5.35%)	494	(4.81%)	13533	(5.86%)	240	(6.45%)
Pills for hypertension	54	(4.83%)	365	(4.43%)	1091	(7.00%)	534	(5.07%)	10571	(4.03%)	182	(4.57%)

[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 Locally Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of: February 28, 2002

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	726	424
CHD death[3]	162	137
Clinical MI	611	328
Angina	1309	464
CABG/PTCA	1119	543
Carotid artery disease	245	115
Congestive heart failure	689	399
Stroke	551	361
PVD	191	59
Coronary disease[4]	2497	1109
Total cardiovascular disease	3326	1539
Cancer		
Breast cancer[5]	1553	741
Invasive breast cancer	1267	637
Non-invasive breast cancer	301	110
Ovarian cancer	147	60
Endometrial cancer	197	92
Colorectal cancer	334	153
Other cancer[6]	1376	712
Total cancer	3541	1682
Fractures		
Hip fracture[7]	280	179
Vertebral fracture[7]	34	22
Other fracture[6, 7]	274	166
Total fracture[7]	578	351
Deaths		
Cardiovascular deaths	345	298
Cancer deaths	560	509
Deaths: other known cause	203	173
Deaths: unknown cause	83	118
Deaths: not yet adjudicated	55	188
Total death	1246	1286

[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 completed at least 3 years of follow-up.
[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] Excludes six cases with borderline malignancy.
[6] 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.
[7] 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: February 28, 2002

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19033	10254
DVT[2]	225	174
Pulmonary embolism	129	115
Diabetes (treated)	1729	1067
Gallbladder disease[3]	2114	1383
Hysterectomy	1241	680
Glaucoma	2728	1852
Osteoporosis	8655	5051
Osteoarthritis[4]	6285	3553
Rheumatoid arthritis	1710	1100
Intestinal polyps	4367	2959
Lupus	346	292
Kidney stones[3]	639	621
Cataracts[3]	9076	6816
Pills for hypertension	8090	4707

[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 completed at least 3 years of follow-up.
[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*) 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.

The monitoring analysis is conducted on outcomes as classified by the local adjudicator. Currently, about 94% of the self-reports have been adjudicated. We do *not* report on the self-reports for which the adjudication process is not yet finished. We feel that we have now reached the stage in the study where the fraction of the self-reports that are not yet adjudicated is sufficiently small that omitting unadjudicated self-reports does not distort the larger picture.

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 Outcomes Data Quality

Tables 6.1-6.2 – 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 96% of self-reported outcomes in the CT and 95% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 54% of the outcomes in the CT and 56% of the outcomes in the OS have been closed within 90 days of self-report and 73% (CT) and 77% (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.)

Since 1997, the percentage of forms that were adjudicated within 90 days has increased from about 40% to almost 70%, and the percentage of forms that were adjudicated within 180 days has increased from about 60% to almost 90%. At the same time, the percentage of forms that are more than a year old that have not yet been adjudicated has been reduced to 0.4%. Currently, 32 of the 40 clinics have ten or fewer outstanding *Forms 33D* that are more than a year old.

Figures 6.1-6.2 – 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. The CCC continues to work closely with the Outcomes-PMC to develop reports and other tools that will facilitate timely outcomes processing by the CCs. The two current areas of emphasis of the OPMC are assisting clinics in closing out the few really old cases, and assisting the remaining clinics that are lagging behind in the timeliness of outcomes processing.

Tables 6.3-6.4 – 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).

Since the previous report the rules regarding which cases are centrally adjudicated have changed. The current rules are:

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

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

- Primary cancer, hip fracture, self reports of primary cancer and hip fracture that are denied locally: all cases are centrally adjudicated.

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

Tables 6.5-6.6 – Agreement of Central Adjudications with Local Adjudications have been modified to reflect these changes. In particular, we added a column for which cases are called forward for central adjudication. These tables 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.

Tables 6.5 and 6.6 show how many outcomes were identified by local adjudicators, but denied central. The new *Tables 6.7 and 6.8 – Source of Central Confirmed Outcomes* shows outcomes that were identified by the central adjudicators, but not by the local adjudicators. Approximately 16%(CT)-19%(OS) of the MIs that were identified by central adjudicators were not found by local adjudicators. All of these MIs were identified on cases that were called forward for "related" events, such as angina, CHF, and CABG/PTCA. Currently few cases have been reviewed for self-reports that were denied locally and did not have a related outcome. 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. Cancer of the uterus and upper leg fractures are reviewed centrally specifically for this reason.

Tables 6.9-6.10 – 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 80-90%. 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.

6.4 Outcomes Data Summary

Table 6.11 – Locally Verified Outcomes (Annualized Percentages) by Age and Ethnicity for CT contains the number of locally verified outcomes for the major WHI outcomes categories. Since about 5% 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 95% of the invasive breast cancer, 75% of the colorectal cancer and 35% of the hip fracture, and 60% 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 Ethnicity for CT 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 6.3-6.4).* 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 Confirmed Other Cancers and *Table 6.14 – Locally Confirmed 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.

6.5 ECG Data

Electrocardiograms (ECGs) are given to all CT participants at baseline and in years 3, 6, and 9. The ECGs are sent to EPICARE (Pentti Rauthaharju, PI), which subcontracts to the CCC. EPICARE provides the CCC with a comprehensive analysis of each individual ECG, as well as with a serial analysis of the follow-up ECGs of a participant relative to that participant's baseline ECG. This serial analysis is intended to identify silent MIs: MIs that are detected by this ECG analysis, but were not reported by the participant. As of February 28, 2002, the CCC had received serial analysis on 57,912 CT participants whose year 3 ECGs and/or their year 6 ECGs had been analyzed by EPICARE.

Table 6.15 – Cross-tabulation of ECG Codes Suggesting an MI and Locally Confirmed and Self-Reported MI for All CT Participants shows the relation between MIs that have been identified prior to the follow-up ECG and incident MIs as identified by the ECG analysis. A total of 44 evolving Q-wave MIs have been identified. We note that 18 of these MIs were also identified by the regular outcomes reporting process. The remaining 26 evolving Q-wave MIs are thus the "definite silent MIs." *Table 6.15* also gives the number of possible silent MIs.

6.6 Vital Status

Table 6.16 – Cause of Death: CT and OS Participants (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 have completed the first NDI search. Results of this investigation are detailed in *Table 6.17*. The NDI search identified 26 women as dead, whose death had not otherwise been ascertained by WHI. The death of an additional 10 participants was also identified by WHI, but their death was not yet adjudicated. For these participants we used the cause of death based on the NDI provided ICD code, in *Table 6.16*.

As of the February 28, 2002 database, there were 1,659 deaths in the CT and 2,532 in the OS. Of the 1,659 CT deaths, there were 1,364 (82%) for which a final adjudication (or NDI report) was available, and an additional 155 (9%) for which a temporary adjudication was available. These 1,659 CT deaths include 105 that were first reported after July 1 of this year. Of the 1,554 that were first reported before January 1, 2002, 87% have a final adjudication and 10% have a temporary one, giving us cause of death information on 97% of those CT deaths. For the OS there is cause of death information on 90% of all deaths, and 93% of all deaths that were reported before January 1, 2002.

Table 6.18 – 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 2.4% of the CT participants are deceased, we do not know the vital status of about 1.5% of the CT participants, and 2.0% of the participants request no further follow-up. In addition, we lack recent outcomes information on an additional 0.2% of the 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 5.2 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 9.8% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.1 to 7.2%.

Table 6.19 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.16* but about the OS. For OS, the participants are considered lost-to-follow-up if we have not received a *Form 33* within the last 24 months. Approximately 3.2% 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: February 28, 2002

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	3922	269	7%	777	20%	3918	100%	4	<1%
1996 July-December	1383	308	22%	717	52%	1383	100%	0	0%
1997 January-June	2177	766	35%	1332	61%	2175	100%	2	<1%
1997 July-December	2546	979	38%	1516	60%	2545	100%	1	<1%
1998 January-June	3576	1665	47%	2783	78%	3576	100%	0	0%
1998 July-December	4159	2362	57%	3338	80%	4154	100%	5	<1%
1999 January-June	4602	2833	62%	3807	83%	4596	100%	6	<1%
1999 July-December	4469	2870	64%	3697	83%	4459	100%	10	<1%
2000 January-June	4709	3104	66%	3965	84%	4673	99%	36	1%
2000 July-December	4408	2995	68%	3826	87%	4369	99%	39	1%
2001 January	897	620	69%	775	86%	872	97%	25	3%
2001 February	800	559	70%	694	87%	775	97%	25	3%
2001 March	985	689	70%	866	88%	959	97%	26	3%
2001 April	771	562	73%	684	89%	741	96%	30	4%
2001 May	922	670	73%	832	90%	878	95%	44	5%
2001 June	826	583	71%	746	90%	791	96%	35	4%
2001 July	835	575	69%	752	90%	787	94%	48	6%
2001 August	836	571	68%	752	90%	760	91%	76	9%
2001 September	711	517	73%	646	91%	646	91%	65	9%
2001 October	943	629	67%	823	87%	823	87%	120	13%
2001 November	787	538	68%	602	76%	602	76%	185	24%
2001 December	635	441	69%	441	69%	441	69%	194	31%
2002 January	925	379	41%	379	41%	379	41%	546	59%
2002 February	594	87	15%	87	15%	87	15%	507	85%
Total	47418	25571	54%	34837	73%	45389	96%	2029	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.

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

Data as of: February 28, 2002

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	85	36%	128	54%	238	100%	0	0%
1996 July-December	1310	308	24%	703	54%	1308	100%	2	<1%
1997 January-June	2153	850	39%	1408	65%	2151	100%	2	<1%
1997 July-December	2296	710	31%	1360	59%	2296	100%	0	0%
1998 January-June	2833	1269	45%	2037	72%	2833	100%	0	0%
1998 July-December	3804	2005	53%	2901	76%	3802	100%	2	<1%
1999 January-June	4753	2846	60%	3929	83%	4747	100%	6	<1%
1999 July-December	4220	2530	60%	3420	81%	4211	100%	9	<1%
2000 January-June	5929	3787	64%	4903	83%	5908	100%	21	<1%
2000 July-December	4312	2840	66%	3649	85%	4247	98%	65	2%
2001 January	854	603	71%	735	86%	829	97%	25	3%
2001 February	721	501	69%	634	88%	698	97%	23	3%
2001 March	1003	628	63%	867	86%	971	97%	32	3%
2001 April	868	588	68%	753	87%	836	96%	32	4%
2001 May	1108	761	69%	967	87%	1045	94%	63	6%
2001 June	818	530	65%	698	85%	762	93%	56	7%
2001 July	909	654	72%	810	89%	856	94%	53	6%
2001 August	1013	671	66%	884	87%	915	90%	98	10%
2001 September	693	505	73%	620	89%	620	89%	73	11%
2001 October	777	478	62%	664	85%	664	85%	113	15%
2001 November	657	425	65%	490	75%	490	75%	167	25%
2001 December	639	408	64%	408	64%	408	64%	231	36%
2002 January	879	351	40%	351	40%	351	40%	528	60%
2002 February	606	86	14%	86	14%	86	14%	520	86%
Total	43393	24419	56%	33405	77%	41272	95%	2121	5%

[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

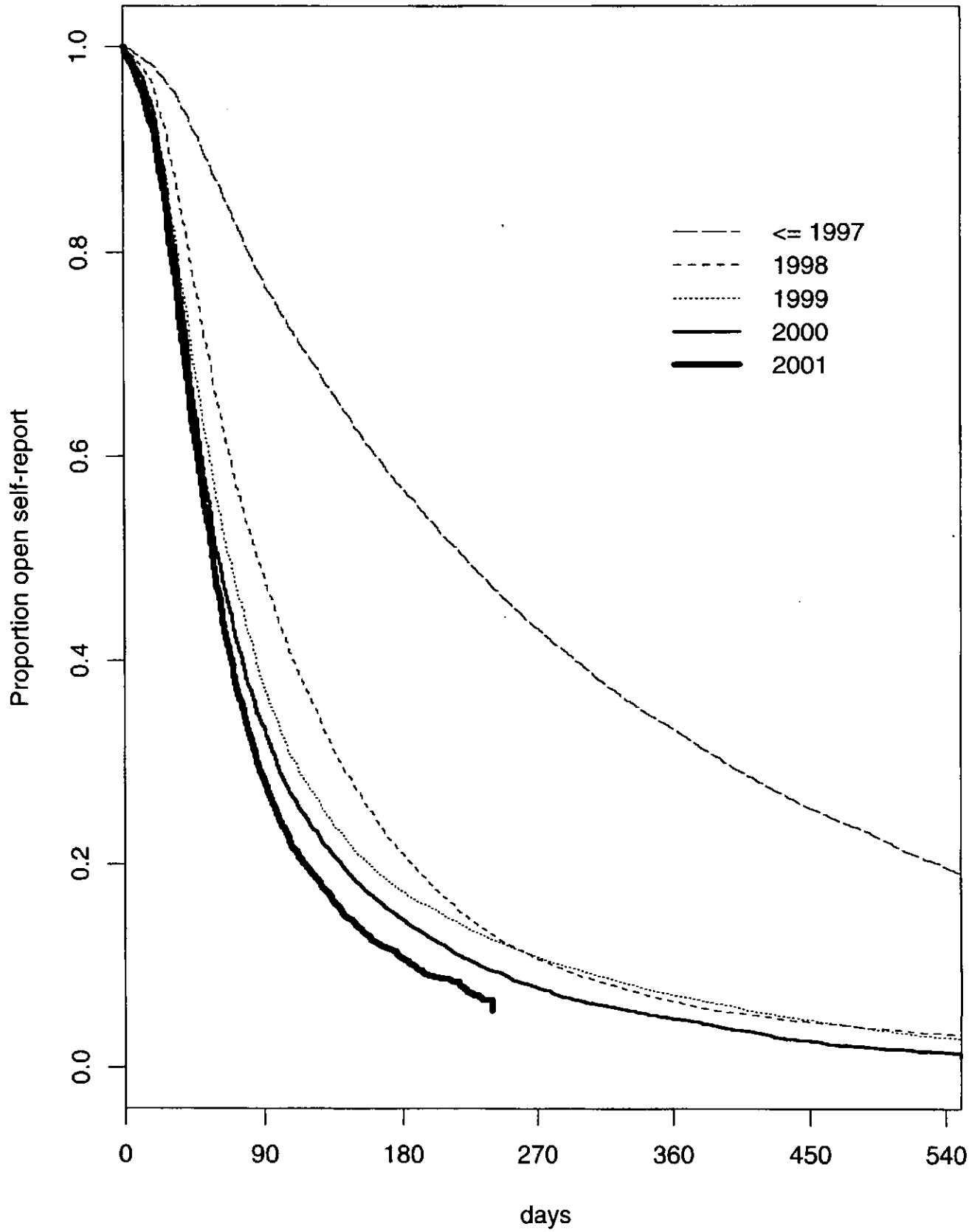


Figure 6.2 Observational Study Timeliness per Period of Self-Report

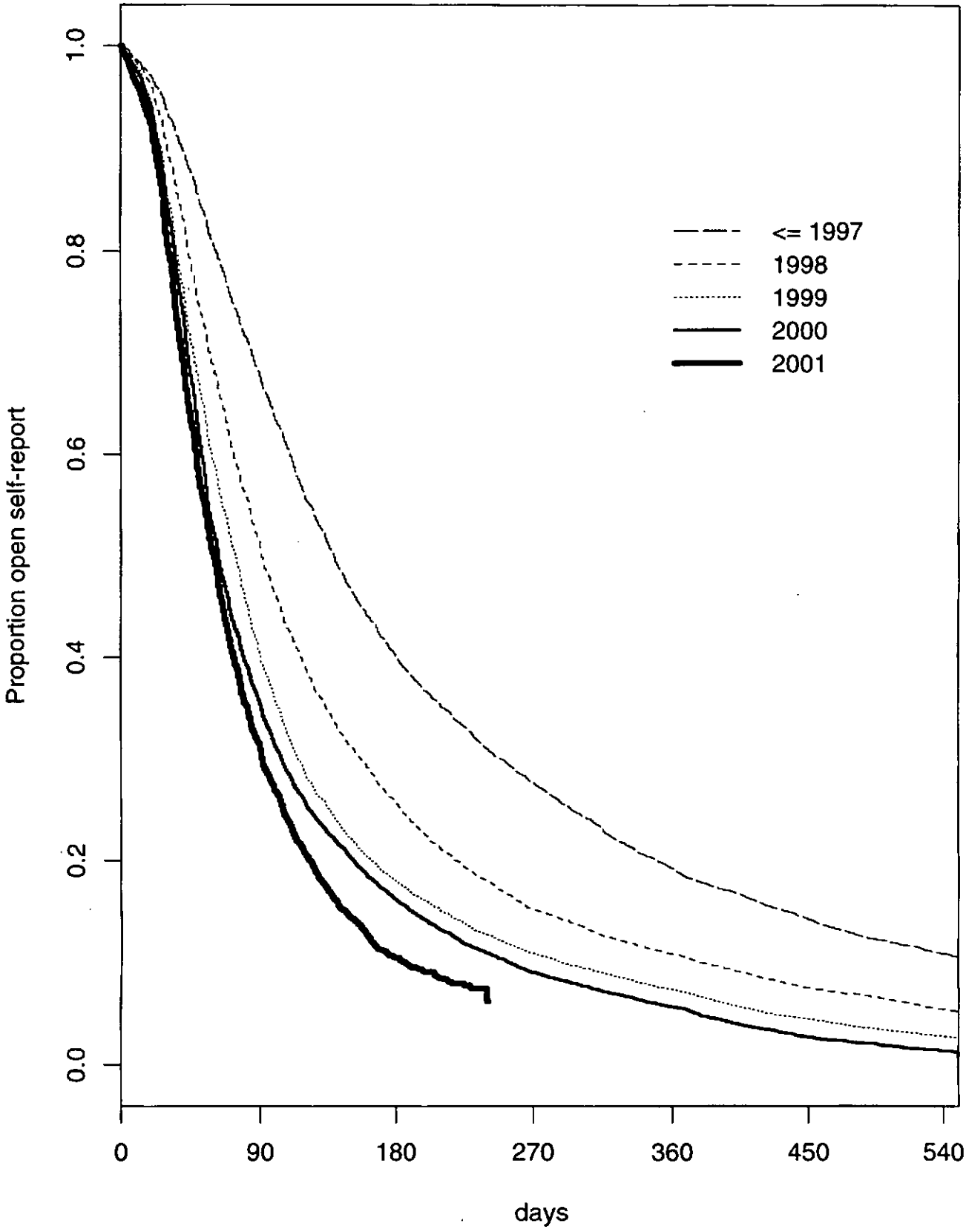


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: February 28, 2002

	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	855	805	94%	574	(71%)	127	(16%)	94	(12%)	10	(1%)
Angina[2]	1695	1598	94%	753	(47%)	73	(5%)	742	(46%)	30	(2%)
Congestive heart failure	552	518	94%	374	(72%)	33	(6%)	103	(20%)	8	(2%)
CABG/PTCA	1843	1723	93%	1372	(80%)	137	(8%)	190	(11%)	24	(1%)
Carotid artery disease[3]	255	240	94%	198	(83%)	25	(10%)	13	(5%)	4	(2%)
Stroke/TIA[4]	1377	1283	93%	982	(77%)	61	(5%)	219	(17%)	21	(2%)
PVD	178	167	94%	99	(59%)	23	(14%)	42	(25%)	3	(2%)
DVT[5]	267	245	92%	178	(73%)	33	(13%)	29	(12%)	5	(2%)
Pulmonary embolism[5]	132	123	93%	104	(85%)	6	(5%)	13	(11%)	0	(0%)
Cancers											
Breast cancer	1723	1604	93%	1538	(96%)	1	(<1%)	57	(4%)	8	(<1%)
Ovarian cancer	171	157	92%	115	(73%)	31	(20%)	7	(4%)	4	(3%)
Endometrial cancer	214	209	98%	163	(78%)	23	(11%)	21	(10%)	2	(1%)
Colorectal cancer	478	444	93%	388	(87%)	26	(6%)	28	(6%)	2	(<1%)
Other cancer[6]	1953	1794	92%	1355	(76%)	96	(5%)	309	(17%)	34	(2%)
Fractures											
Hip fracture	366	345	94%	280	(81%)	25	(7%)	36	(10%)	4	(1%)
Vertebral fracture	650	605	93%	309	(51%)	24	(4%)	249	(41%)	23	(4%)
Other fracture	5856	5578	95%	4531	(81%)	53	(1%)	833	(15%)	161	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 199 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, 3 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 302 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: February 28, 2002

	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	808	757	94%	503	(66%)	139	(18%)	100	(13%)	15	(2%)
Angina[2]	1985	1859	94%	823	(44%)	115	(6%)	881	(47%)	40	(2%)
Congestive heart failure	673	619	92%	455	(74%)	43	(7%)	109	(18%)	12	(2%)
CABG/PTCA	2091	1953	93%	1501	(77%)	180	(9%)	236	(12%)	36	(2%)
Carotid artery disease[3]	312	291	93%	232	(80%)	31	(11%)	23	(8%)	5	(2%)
Stroke/TIA[4]	1601	1479	92%	1083	(73%)	72	(5%)	291	(20%)	33	(2%)
PVD	247	232	94%	131	(56%)	32	(14%)	64	(28%)	5	(2%)
Cancers											
Breast cancer	2502	2341	94%	2141	(91%)	13	(1%)	153	(7%)	34	(1%)
Ovarian cancer	224	207	92%	146	(71%)	32	(15%)	27	(13%)	2	(1%)
Endometrial cancer	278	256	92%	197	(77%)	36	(14%)	19	(7%)	4	(2%)
Colorectal	530	497	94%	415	(84%)	30	(6%)	43	(9%)	9	(2%)
Other cancer[5]	2566	2368	92%	1642	(69%)	164	(7%)	495	(21%)	67	(3%)
Fractures											
Hip fracture	512	477	93%	377	(79%)	3	(1%)	84	(18%)	13	(3%)
Vertebral fracture	80	72	90%	45	(63%)	5	(7%)	17	(24%)	5	(7%)
Other fracture	629	599	95%	439	(73%)	12	(2%)	126	(21%)	22	(4%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 164 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, 5 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 362 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: February 28, 2002

	Locally confirmed N	Called forward for central adjudication N	% [1]	Centrally adjudicated N	% [2]	In agreement N	% [3]
Cardiovascular							
Clinical MI	893	741	83%	586	79%	494	84%
Angina [4]	1564	1341	86%	1059	79%	795	75%
Congestive heart failure	833	672	81%	503	75%	377	75%
CABG/PTCA	1487	1233	83%	960	78%	927	97%
DVT [5]	233	233	100%	153	66%	129	84%
Pulmonary embolism [5]	140	140	100%	91	65%	81	89%
Stroke	798	379	47%	48	13%	45	94%
Cancers							
Breast cancer	1560	1560	100%	1253	80%	1248	100%
Invasive	1230	1230	100%	982	80%	964	98%
Non-invasive	330	330	100%	271	82%	231	85%
Ovarian cancer	139	139	100%	110	79%	87	79%
Endometrial cancer	202	202	100%	157	78%	151	96%
Colorectal cancer	435	435	100%	328	75%	321	98%
Fractures							
Hip fracture	350	350	100%	301	86%	287	95%

[1] Percentage is relative to locally confirmed cases.
[2] Percentage is relative to cases called forward for central adjudication.
[3] Percentage is relative to centrally adjudicated cases.
[4] Participants with a confirmed MI no longer require adjudication of angina.
[5] HRT only.

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

Data as of: February 28, 2002

	Locally confirmed N	Called forward for central adjudication N	% [1]	Centrally adjudicated N	% [2]	In agreement N	% [3]
Cardiovascular							
Clinical MI	939	668	71%	516	77%	422	82%
Angina [4]	1773	1364	77%	1103	81%	854	77%
Congestive heart failure	1088	747	69%	586	78%	464	79%
CABG/PTCA	1662	1201	72%	955	80%	908	95%
Cancers							
Breast cancer	2205	2205	100%	1699	77%	1664	98%
Invasive	1815	1815	100%	1382	76%	1312	95%
Non-Invasive	390	390	100%	317	81%	254	80%
Ovarian cancer	187	187	100%	146	78%	120	82%
Endometrial cancer	278	278	100%	217	78%	198	91%
Colorectal cancer	464	464	100%	356	77%	334	94%
Fractures							
Hip fracture	459	459	100%	384	84%	374	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: February 28, 2002

	Centrally confirmed N	Reason for central investigation: Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	Denied self-reports reviewed by CCC N
Cardiovascular								
Clinical MI	573	484	84%	89	16%	0	0%	9
Angina	964	767	80%	193	20%	4	<1%	NA
Congestive heart failure	436	363	83%	73	17%	0	0%	NA
CABG/PTCA	960	917	96%	42	4%	1	<1%	NA
DVT	132	127	96%	5	4%	0	0%	NA
Pulmonary embolism	84	81	96%	3	4%	0	0%	NA
Stroke	45	45	100%	0	0%	0	0%	0
Cancers								
Breast cancer	1254	1252	100%	1	<1%	1	<1%	17
Ovarian cancer	91	87	96%	3	3%	1	1%	6
Endometrial cancer	162	150	93%	11	7%	1	1%	7
Colorectal cancer	325	323	99%	2	1%	0	0%	10
Fractures								
Hip fracture	294	287	98%	7	2%	0	0%	16

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

Data as of: February 28, 2002

	Centrally confirmed N	Reason for central investigation						Denied self-reports reviewed by CCC N
		Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	
Cardiovascular								
Clinical MI	506	410	81%	96	19%	0	0%	7
Angina	1032	836	81%	193	19%	3	<1%	NA
Congestive heart failure	516	458	89%	57	11%	1	<1%	NA
CABG/PTCA	930	895	96%	35	4%	0	0%	NA
Cancers								
Breast cancer	1668	1667	100%	1	<1%	0	0%	41
Ovarian cancer	126	120	95%	6	5%	0	0%	9
Endometrial cancer	222	197	89%	23	10%	2	1%	6
Colorectal cancer	338	335	99%	3	1%	0	0%	23
Fractures								
Hip fracture	376	374	99%	1	<1%	1	<1%	12

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

Data as of: February 28, 2002

	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	1357	1024	(75%)	843	(82%)	80	(8%)	101	(10%)
Cardiovascular									
Atherosclerotic cardiac[3]	218	169	(78%)	142	(84%)	12	(7%)	15	(9%)
Cerebrovascular	103	75	(73%)	67	(89%)	1	(1%)	7	(9%)
Pulmonary embolism	6	5	(83%)	3	(60%)	1	(20%)	1	(20%)
Other cardiovascular	83	53	(64%)	25	(47%)	19	(36%)	9	(17%)
Unknown cardiovascular	24	16	(67%)	1	(6%)	8	(50%)	7	(44%)
Total cardiovascular deaths	434	318	(73%)	238	(75%)	41	(13%)	39	(12%)
Cancer									
Breast cancer	21	16	(76%)	15	(94%)	0	(0%)	1	(6%)
Ovarian cancer	49	34	(69%)	31	(91%)	2	(6%)	1	(3%)
Endometrial cancer	5	5	(100%)	4	(80%)	1	(20%)	0	(0%)
Colorectal cancer	67	53	(79%)	48	(91%)	2	(4%)	3	(6%)
Other cancer	477	380	(80%)	355	(93%)	13	(3%)	12	(3%)
Unknown cancer site	32	23	(72%)	13	(57%)	10	(43%)	0	(0%)
Total cancer deaths	651	511	(78%)	466	(91%)	28	(5%)	17	(3%)
Accident/injury									
Homicide	5	4	(80%)	3	(75%)	1	(25%)	0	(0%)
Accident	36	31	(86%)	26	(84%)	3	(10%)	2	(6%)
Suicide	6	5	(83%)	5	(100%)	0	(0%)	0	(0%)
Other injury	3	2	(67%)	0	(0%)	1	(50%)	1	(50%)
Total accidental deaths	50	42	(84%)	34	(81%)	5	(12%)	3	(7%)
Other									
Other known cause	168	117	(70%)	87	(74%)	2	(2%)	28	(24%)
Unknown cause	54	36	(67%)	18	(50%)	4	(11%)	14	(39%)
Total deaths - other causes	222	153	(69%)	105	(69%)	6	(4%)	42	(27%)

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

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

Data as of: February 28, 2002

	Closed Local[1]	Closed Central N	%	Confirmed Cause N	%[2]	Related Cause N	%[2]	Unrelated Cause N	%[2]
Final adjudicated death	1987	1352	(68%)	1090	(81%)	115	(9%)	147	(11%)
Cardiovascular									
Atherosclerotic cardiac[3]	282	176	(62%)	135	(77%)	15	(9%)	26	(15%)
Cerebrovascular	134	85	(63%)	76	(89%)	4	(5%)	5	(6%)
Pulmonary embolism	16	8	(50%)	5	(63%)	0	(0%)	3	(38%)
Other cardiovascular	127	89	(70%)	36	(40%)	37	(42%)	16	(18%)
Unknown cardiovascular	29	17	(59%)	1	(6%)	11	(65%)	5	(29%)
Total cardiovascular deaths	588	375	(64%)	253	(67%)	67	(18%)	55	(15%)
Cancer									
Breast cancer	118	88	(75%)	82	(93%)	3	(3%)	3	(3%)
Ovarian cancer	62	44	(71%)	42	(95%)	0	(0%)	2	(5%)
Endometrial cancer	15	10	(67%)	6	(60%)	4	(40%)	0	(0%)
Colorectal cancer	82	55	(67%)	51	(93%)	1	(2%)	3	(5%)
Other cancer	637	456	(72%)	423	(93%)	16	(4%)	17	(4%)
Unknown cancer site	57	39	(68%)	29	(74%)	9	(23%)	1	(3%)
Total cancer deaths	971	692	(71%)	633	(91%)	33	(5%)	26	(4%)
Accident/injury									
Homicide	4	4	(100%)	4	(100%)	0	(0%)	0	(0%)
Accident	49	38	(78%)	33	(87%)	2	(5%)	3	(8%)
Suicide	15	13	(87%)	10	(77%)	1	(8%)	2	(15%)
Other injury	2	1	(50%)	1	(100%)	0	(0%)	0	(0%)
Total accidental deaths	70	56	(80%)	48	(86%)	3	(5%)	5	(9%)
Other									
Other known cause	272	186	(68%)	140	(75%)	4	(2%)	42	(23%)
Unknown cause	86	43	(50%)	16	(37%)	8	(19%)	19	(44%)
Total deaths - other causes	358	229	(64%)	156	(68%)	12	(5%)	61	(27%)

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

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

Data as of: February 28, 2002

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68133		9190		14664		31392		12887	
Mean follow-up (months)	61.0		67.2		63.4		59.3		58.2	
Cardiovascular										
CHD[1]	1085	(0.31%)	64	(0.12%)	114	(0.15%)	490	(0.32%)	417	(0.67%)
CHD death[2]	233	(0.07%)	12	(0.02%)	22	(0.03%)	96	(0.06%)	103	(0.16%)
Total MI[3]	930	(0.27%)	55	(0.11%)	97	(0.13%)	422	(0.27%)	356	(0.57%)
Clinical MI	893	(0.26%)	50	(0.10%)	95	(0.12%)	402	(0.26%)	346	(0.55%)
Evolving Q-wave MI[4]	61	(0.02%)	7	(0.01%)	4	(0.01%)	32	(0.02%)	18	(0.03%)
Possible evolving Q-wave MI[4]	209	(0.06%)	24	(0.05%)	32	(0.04%)	85	(0.05%)	68	(0.11%)
Angina	1564	(0.45%)	76	(0.15%)	202	(0.26%)	763	(0.49%)	523	(0.84%)
CABG/PTCA	1487	(0.43%)	61	(0.12%)	180	(0.23%)	729	(0.47%)	517	(0.83%)
Carotid artery disease	289	(0.08%)	6	(0.01%)	34	(0.04%)	135	(0.09%)	114	(0.18%)
Congestive heart failure	833	(0.24%)	38	(0.07%)	90	(0.12%)	354	(0.23%)	351	(0.56%)
Stroke	821	(0.24%)	29	(0.06%)	75	(0.10%)	365	(0.24%)	352	(0.56%)
PVD	217	(0.06%)	9	(0.02%)	25	(0.03%)	105	(0.07%)	78	(0.12%)
CHD[1]/Possible evolving Q-wave MI	1265	(0.37%)	88	(0.17%)	140	(0.18%)	561	(0.36%)	476	(0.76%)
Coronary disease[5]	3271	(0.94%)	185	(0.36%)	394	(0.51%)	1536	(0.99%)	1156	(1.85%)
Total cardiovascular disease	4316	(1.25%)	222	(0.43%)	494	(0.64%)	2043	(1.32%)	1557	(2.49%)
Cancer										
Breast cancer[6]	1562	(0.45%)	163	(0.32%)	326	(0.42%)	752	(0.48%)	321	(0.51%)
Invasive breast cancer	1233	(0.36%)	118	(0.23%)	258	(0.33%)	598	(0.39%)	259	(0.41%)
Non-invasive breast cancer	345	(0.10%)	45	(0.09%)	74	(0.10%)	162	(0.10%)	64	(0.10%)
Ovary cancer	154	(0.04%)	17	(0.03%)	27	(0.03%)	72	(0.05%)	38	(0.06%)
Endometrial cancer[7]	202	(0.10%)	21	(0.07%)	44	(0.09%)	94	(0.11%)	43	(0.12%)
Colorectal cancer	442	(0.13%)	25	(0.05%)	61	(0.08%)	227	(0.15%)	129	(0.21%)
Other cancer[8]	1603	(0.46%)	131	(0.25%)	250	(0.32%)	780	(0.50%)	442	(0.71%)
Total cancer	3858	(1.11%)	351	(0.68%)	688	(0.89%)	1873	(1.21%)	946	(1.51%)
Fractures										
Hip fracture	350	(0.10%)	12	(0.02%)	20	(0.03%)	131	(0.08%)	187	(0.30%)
Vertebral fracture	374	(0.11%)	16	(0.03%)	38	(0.05%)	154	(0.10%)	166	(0.27%)
Other fracture[8]	4716	(1.36%)	557	(1.08%)	870	(1.12%)	2210	(1.43%)	1079	(1.73%)
Total fracture	5276	(1.52%)	579	(1.13%)	917	(1.18%)	2428	(1.57%)	1352	(2.16%)
Deaths										
Cardiovascular deaths	467	(0.13%)	19	(0.04%)	39	(0.05%)	201	(0.13%)	208	(0.33%)
Cancer deaths	713	(0.21%)	42	(0.08%)	81	(0.10%)	352	(0.23%)	238	(0.38%)
Other known cause	239	(0.07%)	15	(0.03%)	26	(0.03%)	98	(0.06%)	100	(0.16%)
Unknown cause	100	(0.03%)	8	(0.02%)	12	(0.02%)	43	(0.03%)	37	(0.06%)
Not yet adjudicated	140	(0.04%)	9	(0.02%)	15	(0.02%)	66	(0.04%)	50	(0.08%)
Total death	1659	(0.48%)	93	(0.18%)	173	(0.22%)	760	(0.49%)	633	(1.01%)

[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] Excludes nine cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] 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)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: February 28, 2002

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55526	938
Mean follow-up (months)	58.9	57.5	59.9	57.0	61.6	56.8
Cardiovascular						
CHD[1]	3 (0.21%)	12 (0.16%)	104 (0.30%)	25 (0.18%)	924 (0.32%)	17 (0.38%)
CHD death[2]	1 (0.07%)	4 (0.05%)	36 (0.10%)	4 (0.03%)	185 (0.06%)	3 (0.07%)
Total MI[3]	2 (0.14%)	11 (0.15%)	81 (0.23%)	22 (0.16%)	798 (0.28%)	16 (0.36%)
Clinical MI	2 (0.14%)	11 (0.15%)	77 (0.22%)	22 (0.16%)	767 (0.27%)	14 (0.32%)
Evolving Q-wave MI[4]	0 (0.00%)	0 (0.00%)	4 (0.01%)	2 (0.01%)	51 (0.02%)	4 (0.09%)
Possible evolving Q-wave MI[4]	1 (0.07%)	4 (0.05%)	27 (0.08%)	6 (0.04%)	169 (0.06%)	2 (0.05%)
Angina	5 (0.35%)	22 (0.30%)	183 (0.53%)	48 (0.35%)	1289 (0.45%)	17 (0.38%)
CABG/PTCA	4 (0.28%)	13 (0.18%)	131 (0.38%)	40 (0.29%)	1283 (0.45%)	16 (0.36%)
Carotid artery disease	3 (0.21%)	4 (0.05%)	24 (0.07%)	1 (0.01%)	255 (0.09%)	2 (0.05%)
Congestive heart failure	3 (0.21%)	7 (0.10%)	139 (0.40%)	21 (0.15%)	652 (0.23%)	11 (0.25%)
Stroke	5 (0.35%)	20 (0.27%)	99 (0.28%)	19 (0.14%)	668 (0.23%)	10 (0.23%)
PVD	2 (0.14%)	0 (0.00%)	33 (0.09%)	3 (0.02%)	177 (0.06%)	2 (0.05%)
CHD[1]/Possible evolving Q-wave MI	4 (0.28%)	16 (0.22%)	128 (0.37%)	31 (0.23%)	1067 (0.37%)	19 (0.43%)
Coronary disease[5]	10 (0.70%)	39 (0.54%)	399 (1.14%)	96 (0.70%)	2684 (0.94%)	43 (0.97%)
Total cardiovascular disease	18 (1.26%)	60 (0.82%)	519 (1.49%)	115 (0.84%)	3550 (1.25%)	54 (1.22%)
Cancer						
Breast cancer[6]	2 (0.14%)	31 (0.43%)	105 (0.30%)	37 (0.27%)	1375 (0.48%)	12 (0.27%)
Invasive breast cancer	2 (0.14%)	26 (0.36%)	80 (0.23%)	29 (0.21%)	1088 (0.38%)	8 (0.18%)
Non-invasive breast cancer	0 (0.00%)	5 (0.07%)	28 (0.08%)	8 (0.06%)	300 (0.11%)	4 (0.09%)
Ovary cancer	1 (0.07%)	1 (0.01%)	13 (0.04%)	2 (0.01%)	134 (0.05%)	3 (0.07%)
Endometrial cancer[7]	1 (0.16%)	1 (0.02%)	11 (0.07%)	7 (0.09%)	179 (0.10%)	3 (0.12%)
Colorectal cancer	3 (0.21%)	9 (0.12%)	52 (0.15%)	18 (0.13%)	355 (0.12%)	5 (0.11%)
Other cancer[8]	7 (0.49%)	25 (0.34%)	125 (0.36%)	41 (0.30%)	1388 (0.49%)	17 (0.38%)
Total cancer	14 (0.98%)	67 (0.92%)	297 (0.85%)	100 (0.73%)	3344 (1.17%)	36 (0.81%)
Fractures						
Hip fracture	0 (0.00%)	2 (0.03%)	12 (0.03%)	5 (0.04%)	328 (0.12%)	3 (0.07%)
Vertebral fracture	0 (0.00%)	7 (0.10%)	5 (0.01%)	6 (0.04%)	353 (0.12%)	3 (0.07%)
Other fracture[8]	17 (1.19%)	74 (1.02%)	248 (0.71%)	121 (0.89%)	4209 (1.48%)	47 (1.06%)
Total fracture	17 (1.19%)	81 (1.11%)	262 (0.75%)	129 (0.94%)	4735 (1.66%)	52 (1.17%)
Deaths						
Cardiovascular deaths	2 (0.14%)	7 (0.10%)	74 (0.21%)	7 (0.05%)	372 (0.13%)	5 (0.11%)
Cancer deaths	2 (0.14%)	14 (0.19%)	63 (0.18%)	15 (0.11%)	612 (0.21%)	7 (0.16%)
Other known cause	5 (0.35%)	1 (0.01%)	31 (0.09%)	4 (0.03%)	196 (0.07%)	2 (0.05%)
Unknown cause	1 (0.07%)	0 (0.00%)	11 (0.03%)	1 (0.01%)	85 (0.03%)	2 (0.05%)
Not yet adjudicated	0 (0.00%)	6 (0.08%)	15 (0.04%)	6 (0.04%)	112 (0.04%)	1 (0.02%)
Total death	10 (0.70%)	28 (0.38%)	194 (0.56%)	33 (0.24%)	1377 (0.48%)	17 (0.38%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes nine cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] 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: February 28, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68133	9190	14664	31392	12887
Mean follow-up (months)	61.0	67.2	63.4	59.3	58.2
Hospitalizations					
Ever	24514 (7.07%)	2431 (4.72%)	4320 (5.58%)	11632 (7.50%)	6131 (9.80%)
Two or more	10852 (3.13%)	952 (1.85%)	1704 (2.20%)	5101 (3.29%)	3095 (4.95%)
Other					
DVT[1]	501 (0.15%)	31 (0.06%)	74 (0.10%)	229 (0.15%)	167 (0.28%)
Pulmonary embolism	286 (0.08%)	14 (0.03%)	45 (0.06%)	137 (0.09%)	90 (0.15%)
Diabetes (treated)	3026 (0.91%)	422 (0.85%)	645 (0.87%)	1377 (0.93%)	582 (0.98%)
Gallbladder disease[2]	3461 (1.19%)	499 (1.10%)	787 (1.19%)	1626 (1.27%)	549 (1.09%)
Hysterectomy	1345 (0.67%)	178 (0.60%)	294 (0.61%)	638 (0.71%)	235 (0.67%)
Glaucoma	4434 (1.33%)	408 (0.81%)	816 (1.08%)	2170 (1.46%)	1040 (1.80%)
Osteoporosis	9442 (2.89%)	828 (1.64%)	1566 (2.09%)	4661 (3.20%)	2387 (4.27%)
Osteoarthritis[3]	8578 (5.59%)	1141 (3.03%)	1868 (3.57%)	3968 (4.42%)	1601 (5.14%)
Rheumatoid arthritis	2578 (0.77%)	356 (0.71%)	585 (0.78%)	1148 (0.77%)	489 (0.83%)
Intestinal polyps	6079 (1.89%)	685 (1.37%)	1247 (1.69%)	3042 (2.12%)	1105 (1.99%)
Lupus	429 (0.12%)	68 (0.13%)	97 (0.13%)	206 (0.13%)	58 (0.09%)
Kidney stones[3]	994 (0.51%)	125 (0.33%)	213 (0.36%)	473 (0.39%)	183 (0.37%)
Cataracts[3]	13462 (7.65%)	698 (1.84%)	1974 (3.39%)	7420 (6.75%)	3370 (9.79%)
Pills for hypertension	11255 (4.61%)	1396 (3.36%)	2337 (3.96%)	5181 (4.91%)	2341 (6.16%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55526	938
Mean follow-up (months)	58.9	57.5	59.9	57.0	61.6	56.8
Hospitalizations						
Ever	100 (6.97%)	339 (4.66%)	2548 (7.31%)	808 (5.91%)	20427 (7.17%)	292 (6.58%)
Two or more	55 (3.84%)	118 (1.62%)	1162 (3.33%)	319 (2.33%)	9080 (3.19%)	118 (2.66%)
Other						
DVT[1]	2 (0.14%)	1 (0.01%)	46 (0.14%)	8 (0.06%)	440 (0.16%)	4 (0.09%)
Pulmonary embolism	4 (0.28%)	2 (0.03%)	23 (0.07%)	3 (0.02%)	250 (0.09%)	4 (0.09%)
Diabetes (treated)	18 (1.39%)	87 (1.28%)	575 (1.87%)	200 (1.57%)	2101 (0.76%)	45 (1.08%)
Gallbladder disease[2]	16 (1.52%)	57 (0.86%)	279 (0.90%)	151 (1.45%)	2909 (1.23%)	49 (1.30%)
Hysterectomy	4 (0.62%)	21 (0.45%)	84 (0.55%)	37 (0.49%)	1191 (0.70%)	8 (0.31%)
Glaucoma	21 (1.54%)	88 (1.26%)	585 (1.80%)	199 (1.51%)	3484 (1.27%)	57 (1.37%)
Osteoporosis	42 (3.09%)	223 (3.23%)	489 (1.46%)	358 (2.81%)	8201 (3.06%)	129 (3.12%)
Osteoarthritis[3]	42 (0.11%)	191 (0.37%)	872 (0.97%)	436 (1.40%)	6901 (5.50%)	136 (7.11%)
Rheumatoid arthritis	19 (1.47%)	51 (0.73%)	461 (1.42%)	243 (1.86%)	1761 (0.64%)	43 (1.02%)
Intestinal polyps	30 (2.28%)	119 (1.78%)	622 (1.91%)	219 (1.68%)	5011 (1.89%)	78 (1.91%)
Lupus	4 (0.28%)	6 (0.08%)	59 (0.17%)	20 (0.15%)	337 (0.12%)	3 (0.07%)
Kidney stones[3]	7 (0.02%)	25 (0.04%)	94 (0.08%)	57 (0.12%)	798 (0.50%)	13 (0.53%)
Cataracts[3]	60 (0.16%)	265 (0.45%)	1244 (1.13%)	506 (1.47%)	11202 (7.78%)	185 (8.30%)
Pills for hypertension	50 (5.36%)	244 (4.94%)	1160 (6.66%)	504 (4.94%)	9165 (4.41%)	132 (4.49%)

[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 Confirmed Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: February 28, 2002

	CT		OS	
Number of participants	68133		93676	
Mean follow-up time (months)	61.0		54.0	
Ppts with other cancer	1603	(0.46%)	2088	(0.44%)
Accessory sinus	0	(0.00%)	0	(0.00%)
Adrenal gland	1	(<0.01%)	3	(<0.01%)
Anus	8	(<0.01%)	9	(<0.01%)
Biliary tract, parts of (other/unspecified)	23	(0.01%)	14	(<0.01%)
Bladder	91	(0.03%)	114	(0.03%)
Bones/joints/articular cartilage (limbs)	3	(<0.01%)	4	(<0.01%)
Bones/joints/articular cartilage (other)	2	(<0.01%)	2	(<0.01%)
Brain	47	(0.01%)	54	(0.01%)
Cervix	38	(0.01%)	27	(0.01%)
Connective/subcutaneous/soft tissues	6	(<0.01%)	10	(<0.01%)
Endocrine glands, related structures	2	(<0.01%)	1	(<0.01%)
Esophagus	12	(<0.01%)	19	(<0.01%)
Eye and adnexa	3	(<0.01%)	3	(<0.01%)
Genital organs	14	(<0.01%)	8	(<0.01%)
Kidney	71	(0.02%)	93	(0.02%)
Larynx	9	(<0.01%)	5	(<0.01%)
Leukemia	69	(0.02%)	79	(0.02%)
Liver	17	(<0.01%)	19	(<0.01%)
Lung	299	(0.09%)	366	(0.09%)
Lymph nodes	8	(<0.01%)	3	(<0.01%)
Lymphoma,Hodgkins	9	(<0.01%)	8	(<0.01%)
Lymphoma,Non-Hodgkins	133	(0.04%)	177	(0.04%)
Melanoma of the skin	200	(0.06%)	274	(0.07%)
Multiple myeloma	65	(0.02%)	49	(0.01%)
Oral (mouth)	10	(<0.01%)	11	(<0.01%)
Palate	3	(<0.01%)	4	(<0.01%)
Pancreas	83	(0.02%)	85	(0.02%)
Parotid gland (Stensen's duct)	3	(<0.01%)	11	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	3	(<0.01%)
Pyriform sinus	0	(0.00%)	0	(0.00%)
Respiratory system, intrathoracic, other	5	(<0.01%)	8	(<0.01%)
Salivary glands, major (other/unspecified)	1	(<0.01%)	4	(<0.01%)
Stomach	15	(<0.01%)	24	(0.01%)
Thyroid	49	(0.01%)	59	(0.01%)
Tongue, part of (other/unspecified)	14	(<0.01%)	8	(<0.01%)
Urinary organs (other/unspecified)	3	(<0.01%)	12	(<0.01%)
Uterus, not otherwise specified	19	(0.01%)	41	(0.01%)
Other/unknown site of cancer	193	(0.06%)	264	(0.06%)
Other/unknown cancers reported on death form	98	(0.03%)	233	(0.00%)

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

Data as of: February 28, 2002

	CT		OS[1]	
Locally confirmed				
Number of participants	68133		6365	
Mean follow-up time (months)	61.0		63.0	
Ppts with other fractures	4727	(1.36%)	440	(1.32%)
Ankle	835	(0.24%)	69	(0.21%)
Carpal bone(s) in wrist	114	(0.03%)	8	(0.02%)
Clavicle or collar bone	74	(0.02%)	8	(0.02%)
Elbow, not otherwise specified	8	(<0.01%)	0	(0.00%)
Humerus, shaft/unspecified	47	(0.01%)	5	(0.01%)
Humerus, upper end	486	(0.14%)	39	(0.12%)
Humerus, lower end	58	(0.02%)	6	(0.02%)
Metacarpal bone(s)	171	(0.05%)	11	(0.03%)
Patella	208	(0.06%)	19	(0.06%)
Pelvis	167	(0.05%)	24	(0.07%)
Radius or ulna	1319	(0.38%)	133	(0.40%)
Sacrum and coccyx	47	(0.01%)	8	(0.02%)
Scapula	20	(0.01%)	4	(0.01%)
Shaft of femur	60	(0.02%)	4	(0.01%)
Tarsal/metatarsal bones	810	(0.23%)	85	(0.25%)
Tibia and fibula	406	(0.12%)	25	(0.07%)
Tibial plateau	96	(0.03%)	7	(0.02%)
Upper radius/ulna	254	(0.07%)	23	(0.07%)
Unknown other fracture	3	(<0.01%)	1	(<0.01%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			54.0	
Elbow			381	(0.09%)
Foot			1428	(0.34%)
Hand			254	(0.06%)
Knee			469	(0.11%)
Lower Arm			2021	(0.48%)
Lower Leg			1598	(0.38%)
Pelvis			328	(0.08%)
Tailbone			102	(0.02%)
Upper Arm			806	(0.19%)
Upper Leg			188	(0.04%)
Vertebra			841	(0.20%)
Other Fracture			1781	(0.42%)

[1] Other fractures for OS Participants are only confirmed in the three bone density clinics.

Table 6.15
Cross-tabulation of ECG Codes Suggesting an Incident MI and Locally Confirmed and Self-Reported MI for All CT Participants

Data as of: February 28, 2002

	No Locally Confirmed MI or Open Self-Report of MI	Locally Confirmed MI[1]	Total
All CT Participants			
No significant Q or ST-T evolution[2]	54668	284	54952
Borderline Q-wave change[3]	1679	38	1717
Ischemic ST-T evolution[4]	1011	37	1048
Possible evolving Q-wave MI[5]	133[6]	18	151
Evolving Q-wave MI[7]	26[8]	18	44
Total	57517	395	57912
HRT Participants			
No significant Q or ST-T evolution[2]	21845	134	21979
Borderline Q-wave change[3]	721	16	737
Ischemic ST-T evolution[4]	465	15	480
Possible evolving Q-wave MI[5]	62[6]	7	69
Evolving Q-wave MI[7]	9[8]	11	20
Total	23102	183	23285
DM Participants			
No significant Q or ST-T evolution[2]	39258	188	39446
Borderline Q-wave change[3]	1164	26	1190
Ischemic ST-T evolution[4]	687	25	712
Possible evolving Q-wave MI[5]	81[6]	16	97
Evolving Q-wave MI[7]	19[8]	9	28
Total	41209	264	41473
CaD Participants			
No significant Q or ST-T evolution[2]	30998	93	31091
Borderline Q-wave change[3]	975	14	989
Ischemic ST-T evolution[4]	538	13	551
Possible evolving Q-wave MI[5]	77[6]	6	83
Evolving Q-wave MI[7]	18[8]	8	26
Total	32606	134	32740

[1] Includes only locally confirmed MIs that took place before the latest follow-up ECG.
[2] Novacode Incident MI code I.5.0.
[3] Novacode Incident MI code I.5.7.
[4] Novacode Incident MI code I.5.5, I.5.6.1, and I.5.6.2.
[5] Novacode Incident MI code I.5.3 and I.5.4.
[6] Cases in this cell are possible evolving Q-wave MIs.
[7] Novacode Incident MI code I.5.1 and I.5.2.
[8] Cases in this cell are definite evolving Q-wave MIs.

Table 6.16
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: February 28, 2002

	CT		OS	
Number Randomized	68133		93676	
Mean Follow-up Time (months)	61.0		54.0	
Total death	1659	(0.48%)	2532	(0.60%)
Adjudicated death	1519	(0.44%)	2289	(0.54%)
Final adjudicated death	1357	(0.39%)	1987	(0.47%)
Temporary adjudicated death	155	(0.04%)	284	(0.07%)
Identified by NDI search	7	(<0.01%)	18	(<0.01%)
Cardiovascular				
Atherosclerotic cardiac	233	(0.07%)	299	(0.07%)
CHD deaths adjudicated before 10/99	86	(0.02%)	82	(0.02%)
Definite CHD deaths adjudicated after 10/99	89	(0.03%)	110	(0.03%)
Possible CHD deaths adjudicated after 10/99	58	(0.02%)	107	(0.03%)
Cerebrovascular	108	(0.03%)	150	(0.04%)
Pulmonary embolism	7	(<0.01%)	18	(<0.01%)
Other cardiovascular	91	(0.03%)	140	(0.03%)
Unknown cardiovascular	28	(0.01%)	36	(0.01%)
Total cardiovascular deaths	467	(0.13%)	643	(0.15%)
Cancer				
Breast cancer	25	(0.01%)	132	(0.03%)
Ovarian cancer	55	(0.02%)	69	(0.02%)
Endometrial cancer	6	(<0.01%)	16	(<0.01%)
Colorectal cancer	74	(0.02%)	86	(0.02%)
Other cancer	516	(0.15%)	701	(0.17%)
Unknown cancer site	37	(0.01%)	65	(0.02%)
Total cancer deaths	713	(0.21%)	1069	(0.25%)
Accident/injury				
Homicide	5	(<0.01%)	4	(<0.01%)
Accident	40	(0.01%)	54	(0.01%)
Suicide	6	(<0.01%)	15	(<0.01%)
Other injury	4	(<0.01%)	4	(<0.01%)
Total accidental deaths	55	(0.02%)	77	(0.02%)
Other				
Other known cause	184	(0.05%)	299	(0.07%)
Unknown cause	100	(0.03%)	201	(0.05%)
Total deaths – other causes	284	(0.08%)	500	(0.12%)

Table 6.17
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		27	1.2[5]	N/A	
Only identified using NDI	N/A		26	1.2[6]	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] 1 of these participants was a CT participant, 26 were OS participants.
[6] 8 of these participants were CT participants, 18 were OS participants.

Table 6.18
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: February 28, 2002

	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	40	2.3	1631	94.9	15	0.9	0	0.0	18	1.0	15	0.9	1719
Birmingham	50	2.7	1705	93.1	31	1.7	0	0.0	29	1.6	17	0.9	1832
Bowman	31	2.0	1358	89.2	54	3.5	0	0.0	54	3.5	26	1.7	1523
Brigham	48	2.1	2196	95.2	40	1.7	1	0.0	1	0.0	20	0.9	2306
Buffalo	42	2.6	1543	96.1	3	0.2	0	0.0	14	0.9	3	0.2	1605
Chapel Hill	36	2.3	1466	95.4	1	0.1	0	0.0	27	1.8	6	0.4	1536
Chicago	52	3.2	1495	91.9	9	0.6	1	0.1	41	2.5	28	1.7	1626
Chi-Rush	35	2.6	1198	90.3	25	1.9	0	0.0	30	2.3	39	2.9	1327
Cincinnati	26	1.9	1294	93.0	9	0.6	1	0.1	48	3.5	13	0.9	1391
Columbus	46	3.0	1463	94.4	3	0.2	0	0.0	26	1.7	12	0.8	1550
Detroit	18	1.3	1174	85.2	56	4.1	47	3.4	75	5.4	8	0.6	1378
GWU-DC	31	2.0	1439	95.1	24	1.6	1	0.1	14	0.9	4	0.3	1513
Gainesville	55	2.7	1937	93.7	15	0.7	1	0.0	47	2.3	12	0.6	2067
Honolulu	23	1.6	1259	89.4	69	4.9	0	0.0	38	2.7	19	1.3	1408
Houston	19	1.5	1110	87.3	73	5.7	3	0.2	56	4.4	10	0.8	1271
Iowa City	62	2.5	2328	95.7	5	0.2	0	0.0	17	0.7	21	0.9	2433
Irvine	29	1.8	1479	91.2	20	1.2	7	0.4	48	3.0	39	2.4	1622
L.A.	37	2.2	1584	94.3	10	0.6	0	0.0	30	1.8	19	1.1	1680
La Jolla	57	2.6	1705	79.0	231	10.7	22	1.0	7	0.3	136	6.3	2158
Madison	27	1.7	1505	96.7	3	0.2	0	0.0	17	1.1	4	0.3	1556
Medlantic	49	3.3	1334	89.2	38	2.5	3	0.2	37	2.5	35	2.3	1496
Memphis	65	3.7	1544	88.5	56	3.2	8	0.5	58	3.3	13	0.7	1744
Miami	27	1.8	1098	73.9	167	11.2	2	0.1	47	3.2	145	9.8	1486
Milwaukee	34	2.1	1560	94.5	7	0.4	0	0.0	43	2.6	7	0.4	1651
Minneapolis	55	2.8	1886	94.9	28	1.4	0	0.0	18	0.9	1	0.1	1988
NY-City	42	2.2	1708	90.9	55	2.9	4	0.2	19	1.0	52	2.8	1880
Nevada	48	3.2	1414	95.0	8	0.5	0	0.0	15	1.0	3	0.2	1488
Newark	54	2.2	2163	88.3	119	4.9	0	0.0	79	3.2	35	1.4	2450
Oakland	34	2.2	1505	95.9	3	0.2	0	0.0	18	1.1	10	0.6	1570
Pawtucket	60	2.3	2480	93.7	24	0.9	0	0.0	62	2.3	21	0.8	2647
Pittsburgh	53	3.2	1581	95.4	5	0.3	0	0.0	16	1.0	2	0.1	1657
Portland	42	2.6	1476	90.4	43	2.6	1	0.1	36	2.2	35	2.1	1633
San Antonio	19	1.4	1226	88.5	3	0.2	3	0.2	100	7.2	35	2.5	1386
Seattle	51	2.8	1666	92.6	38	2.1	1	0.1	25	1.4	19	1.1	1800
Stanford	35	2.0	1677	95.3	3	0.2	5	0.3	33	1.9	7	0.4	1760
Stonybrook	29	2.1	1280	94.4	21	1.5	0	0.0	18	1.3	8	0.6	1356
Torrance	24	2.4	874	86.8	44	4.4	1	0.1	28	2.8	36	3.6	1007
Tucson	77	3.7	1827	87.8	39	1.9	2	0.1	43	2.1	92	4.4	2080
U.C. Davis	60	3.1	1727	89.9	75	3.9	8	0.4	38	2.0	12	0.6	1920
Worcester	37	2.3	1545	94.6	30	1.8	0	0.0	3	0.2	18	1.1	1633
Total	1659	2.4	62440	91.6	1502	2.2	122	0.2	1373	2.0	1037	1.5	68133

[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 6.19
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: February 28, 2002

	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	53	2.2	2319	94.2	70	2.8	0	0.0	11	0.4	10	0.4	2463
Birmingham	88	3.5	2183	86.3	137	5.4	3	0.1	56	2.2	62	2.5	2529
Bowman	52	2.3	1972	88.5	84	3.8	2	0.1	32	1.4	85	3.8	2227
Brigham	35	1.2	2834	96.2	57	1.9	6	0.2	3	0.1	11	0.4	2946
Buffalo	97	4.3	2113	94.0	19	0.8	0	0.0	12	0.5	7	0.3	2248
Chapel Hill	46	2.2	1989	95.5	33	1.6	0	0.0	13	0.6	2	0.1	2083
Chicago	56	3.0	1733	91.7	41	2.2	5	0.3	19	1.0	35	1.9	1889
Chi-Rush	59	2.9	1822	88.9	71	3.5	1	0.0	38	1.9	58	2.8	2049
Cincinnati	63	2.8	1981	88.1	51	2.3	18	0.8	36	1.6	100	4.4	2249
Columbus	48	2.2	2104	94.8	47	2.1	2	0.1	9	0.4	9	0.4	2219
Detroit	34	1.6	1680	79.5	228	10.8	111	5.3	50	2.4	9	0.4	2112
GWU-DC	67	3.0	2135	95.0	37	1.6	2	0.1	3	0.1	3	0.1	2247
Gainesville	73	2.6	2607	93.4	37	1.3	1	0.0	51	1.8	23	0.8	2792
Honolulu	43	2.0	1901	90.0	88	4.2	0	0.0	63	3.0	18	0.9	2113
Houston	62	2.9	1883	88.4	105	4.9	4	0.2	64	3.0	12	0.6	2130
Iowa City	60	1.9	2952	94.6	36	1.2	0	0.0	26	0.8	46	1.5	3120
Irvine	55	2.5	2064	92.6	26	1.2	4	0.2	40	1.8	41	1.8	2230
L.A.	46	2.1	1990	90.7	119	5.4	0	0.0	26	1.2	14	0.6	2195
La Jolla	111	3.2	2818	81.4	243	7.0	37	1.1	11	0.3	243	7.0	3463
Madison	58	2.9	1899	95.9	13	0.7	0	0.0	8	0.4	3	0.2	1981
Medlantic	59	2.7	1956	89.2	113	5.2	6	0.3	19	0.9	40	1.8	2193
Memphis	69	2.7	2114	84.0	209	8.3	6	0.2	65	2.6	53	2.1	2516
Miami	36	2.6	991	72.1	146	10.6	6	0.4	27	2.0	168	12.2	1374
Milwaukee	51	2.3	2030	90.4	101	4.5	1	0.0	18	0.8	45	2.0	2246
Minneapolis	59	2.2	2407	88.3	217	8.0	0	0.0	24	0.9	20	0.7	2727
NY-City	80	2.8	2625	90.4	86	3.0	18	0.6	23	0.8	71	2.4	2903
Nevada	110	5.1	2020	92.9	27	1.2	0	0.0	13	0.6	4	0.2	2174
Newark	69	2.0	2893	85.8	230	6.8	4	0.1	41	1.2	136	4.0	3373
Oakland	68	3.3	1944	94.7	13	0.6	0	0.0	27	1.3	1	0.0	2053
Pawtucket	91	2.5	3277	91.3	96	2.7	62	1.7	28	0.8	34	0.9	3588
Pittsburgh	73	3.8	1641	85.6	125	6.5	0	0.0	53	2.8	25	1.3	1917
Portland	50	2.2	2063	92.4	54	2.4	2	0.1	43	1.9	20	0.9	2232
San Antonio	43	2.2	1670	86.0	86	4.4	1	0.1	110	5.7	32	1.6	1942
Seattle	66	4.0	1496	90.0	38	2.3	8	0.5	17	1.0	38	2.3	1663
Stanford	83	3.1	2446	91.6	80	3.0	1	0.0	53	2.0	6	0.2	2669
Stonybrook	44	2.2	1775	87.5	142	7.0	1	0.0	12	0.6	54	2.7	2028
Torrance	47	3.1	1283	85.4	60	4.0	11	0.7	34	2.3	68	4.5	1503
Tucson	104	3.7	2286	82.2	191	6.9	2	0.1	38	1.4	161	5.8	2782
U.C. Davis	76	3.3	2057	90.7	94	4.1	7	0.3	22	1.0	13	0.6	2269
Worcester	48	2.1	2103	93.9	48	2.1	7	0.3	16	0.7	17	0.8	2239
Total	2532	2.7	84056	89.7	3698	3.9	339	0.4	1254	1.3	1797	1.9	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 until plasma or serum is separated. In addition, urine samples are collected on both CT and OS participants at the three Bone Density sites at baseline, year 1 and year 9 for CT, and year 3 for OS participants. Plasma, serum, RBCs, buffy coat, and urine aliquots are then 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). The insulin assay that MRL has used since the beginning of the study has been phased out by the manufacturer. A special effort was made to ship the remaining Year 3 samples from the CT 6% subsample to MRL so that they could be completed while the old insulin kits were still available. In 2001, Year 3 samples were sent to MRL in 2 large batches for analysis. MRL is expected to complete the analyses of these Year 3 samples by the end of May 2002. A final shipment of the CT 6% Year 3 subsample specimens will be sent by the end of May 2002. Analysis of Year 6 bloods will begin later this year, with insulin assays on Year 6 and 9 samples done using the new method. See *Sections 2* and *3* in this report for presentation of the laboratory results for HRT and DM.

MRL has also completed the analysis of the 1% OS Measurement Precision Study (OS-MPS) participants. 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 prepares up to four daughter aliquots containing 3 micrograms DNA each and divides the remaining DNA into parent aliquots containing up to 200 micrograms DNA each, depending on the quantity of DNA extracted. BioServe sends the extracted DNA aliquots to McKesson for storage and/or distribution to DNA testing laboratories.

To date, BioServe has completed the DNA extraction of over 1,700 samples, including all of the samples for the CVD Biomarker Case Control Study of CHD, Stroke, and VTE in the HRT Clinical Trial and for ancillary study #83, Paul Ridker, Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study.

CVD Biomarker Case-Control Study of CHD, Stroke, and VTE in the HRT 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. All phase I and phase II DNA samples were

sent to Leiden, and results from all but the phase II VTE samples have been received, with these final results expected by the end of May 2002. The University of Vermont was contracted to perform the thrombosis analyses for the study. The phase I and phase II samples were sent to Vermont in October 2001. Completion of the phase I thrombosis analyses at Vermont is expected by the end of 2002.

MRL is expected to complete the phase I and phase II lipid analyses for the study in April of this year.

Hormones

Esoterix (Calabasas Hills, CA; formerly Endocrine Sciences) has completed hormone analyses on baseline and year 1 samples for 120 of the 300 participants included in the approved paper "Correlates of endogenous sex hormone concentrations in WHI". Samples from the remaining 180 participants will be sent in monthly batches of 30 participants over the next 6 months.

In addition, Esoterix will conduct a pilot study of the correlation between the standard Esoterix assay for total estradiol which uses 1.0 ml of serum and the alternative Vitros IRA assay which uses only 0.1 ml of serum. Four aliquots of serum from 50 nonrandomized participants who were not on HRT will be sent to Esoterix by early June for use in this pilot study. Results are expected by July.

Ancillary Studies

Analyses of blood samples for ancillary study #83, Paul Ridker, Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study, were completed last year. Samples for core analytes will be sent to MRL for analyses later this year. Analyses of bloods for ancillary study #110, Kathryn Rexrode, Sex Steroid Hormones and Risk of Coronary Heart Disease: A nested Case Control Study were partially completed last year. The remaining analyses for ancillary study #110 as well as the analyses of samples for ancillary study #129, Howard Strickler, Association of Diabetes and Insulin-like Growth Factor-I with Risks of Colorectal, Breast and Endometrial Cancers are on hold pending the results of the estradiol assay pilot study being conducted by Esoterix.

Six ancillary studies were reviewed for the 2002 blood competition. Lab review for the 2002B competition is due September 15.

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; Judy Hsia, George Washington Clinical Center PI; Maggie Dailey, Michelle Naughton, Steve Rapp, Sara Wilcox, CFC; and Barb Cochrane, Julie Hunt, Andrea LaCroix, Bernedine Lund, and Lesley Tinker, CCC. Membership of the Outcomes PMC (O-PMC) includes Anne McTiernan, CCC, chair; David Curb, Honolulu Clinical Center PI; Marian Limacher, Gainesville Clinical Center PI; Ronald Prineas, CFC; Jacques Rossouw, Project Office; and Charles Kooperberg, Bernedine Lund, and Lori Proulx-Burns, CCC.

Since September 1, 2001, the A&R PMC held five conference call, reviewing 6 Clinical Centers on each call. Information reviewed about each Clinical Center includes: 1) cumulative and recent measures of participant intervention and follow-up status; 2) HRT and CaD adherence levels; 3) DM C-I and DM intervention measures; and 4) cumulative and recent measures of completion of required tasks. Each performance measure is compared to study goals, study-wide averages, and performance in the last 3-12 month period. At the request of the PMC, many of the CCs submitted copies of their Biannual Technical Reports in the materials they sent to the PMC for review before review on the conference calls. A&R PMC held targeted conference calls with two CCs and held a follow-up conference call with one of the CCs.

In the same period, the O-PMC held four conference calls, reviewing 5-7 Clinical Centers on each call. 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. In addition, the O-PMC made targeted conference calls with two CCs to discuss issues with outcomes processing in more detail and to provide direction and interim goals for improving performance, and made two follow-up calls to one CC and one follow-up call to another CC to assess their progress on reaching interim goals set for them by the O-PMC. Both CCs receiving the follow-up calls had made substantial progress on decreasing their backlog of outcomes cases.

The PMC report showing data as of February 28, 2002, is in *Tables 8.1-8.5*. Several changes were made to the PMC report. The study design assumptions or study goals, based on the average number of follow-up years and where available, were added for measures in the report. The

definition of % Stopped in the DM, HRT, CaD, and OS tables was changed to include deaths to allow for comparison to the percent stopped design assumption. For the Outcomes table, columns for Cases Not Assembled, Cases Not Adjudicated, and Cases Open > 16 Weeks, each showing data for the previous 12 months, were added. In addition, the column for Close Cases < 16 Weeks was changed from cumulative to previous 12 months data, to better reflect the increased efforts CCs are putting into outcomes processing.

Table 8.1
Performance Monitoring Committee Report
Data as of 2/28/02

DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Mar 01 - Feb 02[3]		Jun -Nov 01		Cum Feb 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	13.0	1	11.0	1	93.5	1	6.3	2
Oakland	11.6	1	10.6	1	96.9	1	4.0	1
Iowa City	11.2	1	8.6	1	95.3	1	4.1	1
Madison	11.1	1	9.6	1	94.4	1	4.0	1
Columbus	11.0	1	9.6	1	95.1	1	6.4	2
Stanford	10.9	1	8.7	1	94.9	1	5.5	1
Milwaukee	10.8	1	10.1	1	97.9	1	4.7	1
Seattle	10.6	1	7.6	2	90.5	2	7.2	2
Pittsburgh	10.6	1	8.5	1	96.7	1	4.5	1
Minneapolis	10.5	1	7.3	3	91.4	2	6.3	2
GWU-DC	10.5	2	8.6	1	89.6	2	5.4	1
Irvine	10.0	2	7.6	2	86.9	3	6.3	2
Chicago	9.7	2	8.2	1	91.2	2	12.6	4
Portland	9.7	2	7.4	2	84.7	3	7.8	3
Gainesville	9.5	2	8.1	2	89.7	2	8.4	3
Torrance	9.3	2	7.7	2	79.9	4	11.8	4
Worcester	9.3	2	6.5	3	92.4	2	6.6	2
Chapel Hill	9.3	2	8.0	2	94.2	1	4.4	1
LA	9.1	2	6.6	3	87.7	3	8.3	3
UC Davis	9.0	2	6.5	4	82.1	4	8.6	3
Brigham	8.9	3	7.0	3	89.5	2	5.9	1
Pawtucket	8.8	3	7.3	2	90.5	2	7.7	2
Memphis	8.7	3	5.7	4	85.4	3	10.6	4
Tucson	8.6	3	7.4	2	88.3	3	10.6	4
Buffalo	8.8	3	6.9	3	96.4	1	6.0	2
Bowman	8.5	3	7.1	3	88.4	3	9.2	3
Newark	8.5	3	6.8	3	77.2	4	9.8	3
Stony Brook	8.5	3	6.7	3	89.3	2	7.0	2
Houston	8.5	3	7.5	2	81.6	4	7.3	2
Atlanta	8.2	3	6.5	4	86.4	3	4.7	1
Chi-Rush	8.2	4	7.3	3	87.6	3	10.0	3
Cincinnati	8.1	4	6.2	4	92.7	2	10.6	4
Honolulu	7.9	4	5.5	4	83.5	4	8.1	3
LaJolla	7.8	4	7.1	3	76.9	4	10.4	4
NYC	7.7	4	7.8	2	88.4	3	10.2	3
Detroit	7.2	4	5.2	4	73.1	4	11.4	4
Birmingham	6.8	4	4.9	4	84.2	3	9.4	3
San Antonio	6.3	4	5.5	4	79.4	4	15.9	4
Medlantic	5.7	4	3.9	4	75.9	4	11.4	4
Miami	5.1	4	5.6	4	67.1	4	19.7	4
CC Average	**9.1**		**7.3**		**87.5**		**8.2**	
Ave F/U 5.1 yr	Design Assumption 12.0				Goal ≥ 90%		Design Assumption 14.5	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)

[2] Based on FFQs collected after randomization through AV7.

[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 2/28/02

HRT

	Adherence Summary ≥ 80%				Task Completeness Jun-Nov 01				% Stopped[5]	
	Average[1]		Mar 01-Feb 02[2]		Form 10[3]		Form 85[4]		Cum Feb 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	78.6	1	77.0	1	98.1	2	94.4	1	23.6	1
Iowa City	73.2	1	66.9	1	98.6	1	95.9	1	28.5	1
Stanford	68.7	1	64.1	1	98.3	1	77.1	4	32.7	1
Minneapolis	68.6	1	64.5	1	96.6	2	95.2	1	31.5	1
Brigham	67.0	1	63.6	1	99.0	1	92.9	1	34.2	1
Cincinnati	66.9	1	62.8	1	97.8	2	89.3	2	35.9	2
Milwaukee	66.3	1	58.1	2	98.6	1	89.1	2	30.3	1
Portland	65.4	1	62.4	1	93.9	3	91.5	1	28.1	1
Madison	65.3	1	61.1	1	98.1	2	98.0	1	38.5	2
Gainesville	65.0	1	59.7	1	98.1	2	90.4	2	42.9	3
Chapel Hill	64.4	2	54.0	2	98.1	2	94.3	1	33.5	1
Nevada	62.9	2	60.4	1	98.9	1	91.0	2	35.5	2
Pittsburgh	62.6	2	57.1	2	93.1	3	94.1	1	36.4	2
Pawtucket	62.2	2	59.7	2	99.5	1	88.6	2	41.3	3
LA	62.1	2	52.1	3	93.0	4	88.6	2	35.3	1
Chicago	61.4	2	59.3	2	98.7	1	88.8	2	38.9	2
Worcester	60.8	2	58.3	2	95.8	3	93.7	1	39.5	2
Birmingham	60.8	2	54.9	2	96.1	2	85.8	3	38.1	2
Torrance	60.3	2	58.5	2	96.8	2	84.5	3	41.3	3
Honolulu	58.4	2	52.5	3	91.0	4	84.7	3	32.9	1
UC Davis	57.5	3	53.0	3	95.8	3	88.8	2	40.0	3
Columbus	57.3	3	54.8	2	99.3	1	94.9	1	40.3	3
Seattle	57.2	3	54.9	2	95.9	2	84.2	3	40.1	3
GWU-DC	57.0	3	51.0	3	95.8	3	84.0	4	40.1	3
Newark	56.9	3	51.2	3	91.5	4	84.5	3	35.9	2
Buffalo	55.2	3	51.7	3	99.1	1	85.9	3	40.7	3
Memphis	55.1	3	51.4	3	93.1	3	83.2	4	44.2	4
Stony Brook	54.9	3	46.1	4	95.6	3	86.0	3	43.7	3
Irvine	54.8	3	49.2	4	92.0	4	78.4	4	38.4	2
LaJolla	54.7	3	51.6	3	83.4	4	73.3	4	36.6	2
Chi-Rush	54.2	4	50.1	3	94.1	3	87.2	3	42.8	3
Atlanta	52.2	4	51.8	3	98.9	1	87.4	2	44.1	4
Bowman	51.9	4	45.4	4	90.9	4	85.7	3	44.0	4
Tucson	51.5	4	47.1	4	95.0	3	82.4	4	46.5	4
San Antonio	50.7	4	49.2	4	95.7	3	80.7	4	44.7	4
NYC	49.3	4	47.0	4	92.9	4	86.6	3	46.4	4
Detroit	48.9	4	44.0	4	82.7	4	80.9	4	45.9	4
Houston	47.9	4	38.8	4	81.4	4	74.9	4	52.1	4
Medlantic	44.9	4	40.7	4	96.8	2	89.7	2	45.2	4
Miami	32.2	4	32.6	4	79.5	4	62.9	4	59.6	4
CC Average	**59.5**		**55.0**		**95.2**		**87.2**		**38.7**	
Ave F/U 5.0 yr	-		-		Goal ≥ 90%		Goal ≥ 90%		Design Assump. 28.4	

[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 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 stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 8.3
Performance Monitoring Committee Report
Data as of 2/28/02

CaD

	Adherence Summary ≥ 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Mar 01 - Feb 02[2]		Jun-Nov 01		Cum Feb 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.8	1	84.0	1	99.8	1	10.4	1
Iowa City	72.4	1	73.2	1	99.1	1	14.2	1
Stanford	71.5	1	73.4	1	98.2	2	18.5	1
Minneapolis	69.5	1	70.5	1	96.5	3	15.6	1
Nevada	67.8	1	70.7	1	99.5	1	17.5	1
Columbus	67.7	1	66.6	1	98.9	1	21.4	2
Gainesville	66.1	1	65.2	1	98.3	2	26.3	3
Brigham	63.5	1	63.7	1	98.8	1	23.0	2
Pawtucket	63.0	1	65.3	1	99.3	1	24.0	3
Chi-Rush	62.9	1	63.0	2	94.6	3	27.5	4
Chapel Hill	62.3	2	62.9	2	99.1	1	15.6	1
Portland	62.2	2	63.2	2	94.9	3	21.5	2
Pittsburgh	62.1	2	62.7	2	94.5	3	23.6	2
Milwaukee	61.4	2	61.5	2	98.8	1	18.3	1
Honolulu	60.9	2	61.5	2	91.7	4	25.4	3
Worcester	60.4	2	62.3	2	96.7	2	17.3	1
Madison	59.6	2	58.8	3	98.3	2	19.5	2
Cincinnati	59.4	2	66.9	1	98.1	2	24.8	3
LA	58.3	2	58.5	3	95.4	3	25.3	3
Torrance	58.1	2	62.3	2	93.5	4	23.2	2
GWU-DC	57.7	3	57.6	3	97.2	2	22.4	2
Buffalo	57.4	3	63.5	2	99.0	1	19.0	1
Bowman	57.0	3	60.1	3	94.2	3	23.0	2
Seattle	56.8	3	57.0	3	91.4	4	25.3	3
UC Davis	56.0	3	59.2	3	93.9	4	23.9	3
LaJolla	55.3	3	57.1	3	82.6	4	21.6	2
Birmingham	55.2	3	61.2	2	97.6	2	18.7	1
Atlanta	53.4	3	59.6	3	99.0	1	26.5	3
Chicago	52.8	3	55.6	4	98.7	2	28.8	4
Stony Brook	52.7	3	50.5	4	94.7	3	27.3	4
San Antonio	52.7	4	55.7	3	97.6	2	27.5	4
Tucson	52.5	4	58.8	3	95.0	3	32.2	4
Irvine	52.3	4	52.3	4	94.1	3	26.3	3
NYC	51.0	4	54.1	4	95.5	3	28.6	4
Houston	48.2	4	46.0	4	83.4	4	30.2	4
Memphis	48.2	4	52.7	4	91.2	4	33.5	4
Detroit	47.1	4	48.2	4	88.6	4	30.7	4
Newark	46.3	4	50.9	4	93.0	4	25.5	3
Medlantic	45.0	4	49.1	4	97.7	2	22.5	2
Miami	32.1	4	39.1	4	80.3	4	43.3	4
CC Average	**58.5**		**60.7**		**95.6**		**23.3**	
Ave F/U 4.1 yr	-		-		Goal ≥ 90%		Design Assump. 19.6	

[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 CCC750-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 2/28/02

OS

	Task Completeness - Year 3[1] Nov 00-Apr 01[2]				% Stopped[3]	
	Form 100		Form 143		Cum Feb 02	
	%	Quartile	%	Quartile	%	Quartile
UC Davis	-	-	-	-	4.9	2
Buffalo	-	-	-	-	5.2	2
Chicago	-	-	-	-	5.8	3
Seattle	-	-	-	-	7.6	3
Bowman	-	-	-	-	7.7	4
Pittsburgh	-	-	-	-	8.5	4
Madison	93.8	1	97.9	1	3.5	1
Nevada	92.0	1	96.2	1	5.9	3
NYC	90.0	1	91.7	2	6.0	3
Iowa City	89.7	1	96.6	1	4.2	1
Gainesville	89.4	1	95.9	1	5.3	2
Oakland	89.3	1	95.5	1	4.7	2
Brigham	88.8	1	97.0	1	1.7	1
Columbus	88.1	1	92.5	2	3.2	1
Honolulu	86.8	1	90.1	2	5.9	3
Atlanta	86.5	1	95.7	1	3.0	1
Pawtucket	86.0	2	95.1	1	4.4	2
Chi-Rush	85.1	2	92.5	2	7.5	3
Portland	84.7	2	94.8	1	5.1	2
GWU-DC	84.5	2	91.8	2	3.2	1
LaJolla	84.2	2	85.5	3	11.3	4
Torrance	84.1	2	90.9	2	10.0	4
Minneapolis	84.0	2	94.3	2	3.8	1
Milwaukee	84.0	2	87.6	3	5.1	2
Chapel Hill	83.9	2	95.6	1	2.9	1
Stanford	81.8	2	88.8	2	5.4	2
Worcester	81.5	3	88.4	2	3.8	1
Medlantic	80.1	3	83.9	3	5.4	2
Birmingham	78.7	3	80.9	3	8.3	4
LA	77.6	3	87.7	3	3.9	1
Newark	77.1	3	81.2	3	7.7	4
Irvine	76.9	3	76.9	4	6.2	3
Houston	75.0	3	89.3	2	6.6	3
Stony Brook	74.8	3	83.5	3	5.6	3
Tucson	70.2	3	78.7	3	11.9	4
Memphis	67.5	3	77.6	3	7.4	3
San Antonio	65.3	4	82.4	3	9.6	4
Detroit	63.4	4	74.9	4	4.4	2
Cincinnati	63.3	4	77.2	4	9.5	4
Miami	50.7	4	57.5	4	17.2	4
CC Average	**81.0**		**88.4**		**6.1**	
Ave F/U 4.5 yr	Goal ≥ 90%		Goal ≥ 91.5%		-	

[1] From *WHIP1445-Task Completeness;* complete if encounter date is -3/+15 months from AV3 target date. Six CCs have no OS Year 3 visits due in the time period.

[2] 6-month period ending 10 months before data as of date to allow for 10 month lag in completeness

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

Table 8.5
Performance Monitoring Committee Report
Data as of 2/28/02

Outcomes

	Task Completeness						Outcomes Processing May 01 – Feb 02							
	CT Form 33[1] Jun-Nov 01		OS Form 33[2] Nov 00 -Apr 01		Form 33D[3] Mar 01-Feb 02		Cases Assembled ≤ 12 weeks[4]		Cases Adjudicated ≤ 14 days[5]		Cases Open > 16 weeks[6]		Cases Closed ≤ 16 weeks[6]	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Buffalo	98.6	1	95.6	2	99.3	1	92.1	2	99.0	1	14.5	1	91.3	1
Oakland	97.8	1	98.2	1	97.2	2	92.1	2	76.5	3	25.5	2	78.9	3
Madison	97.8	1	99.3	1	98.3	2	93.9	1	59.0	4	18.6	2	84.7	2
Chapel Hill	97.8	1	99.5	1	98.5	1	97.2	1	89.1	3	2.3	1	97.8	1
Iowa City	97.7	1	94.7	2	96.5	3	92.5	2	69.5	4	16.9	2	88.7	1
Nevada	97.5	1	98.9	1	97.9	2	91.7	2	85.3	3	21.3	2	85.8	2
Atlanta	97.0	1	97.0	1	97.2	2	90.5	2	81.1	3	33.9	3	80.0	3
Stanford	96.8	1	95.6	2	99.2	1	95.3	1	91.9	2	29.5	2	88.1	1
Minneapolis	96.1	1	95.8	1	91.3	4	95.6	1	63.9	4	21.4	2	90.6	1
Columbus	96.0	1	97.5	1	94.4	3	77.0	4	76.7	3	32.2	3	72.4	3
Milwaukee	96.0	2	94.1	2	94.0	4	78.2	4	49.2	4	44.0	4	60.9	4
Brigham	95.6	2	93.6	3	99.6	1	93.2	1	70.1	4	15.6	1	87.0	2
Gainesville	95.4	2	96.8	1	98.6	1	88.4	3	97.7	1	13.9	1	84.5	2
Stony Brook	95.0	2	91.8	3	94.6	3	87.9	3	95.5	2	34.2	3	80.8	2
Worcester	94.5	2	95.1	2	98.3	2	94.2	1	88.2	3	8.6	1	89.2	1
GWU-DC	94.4	2	99.3	1	98.2	2	82.2	3	99.7	1	40.2	4	78.7	3
Chicago	94.4	2	94.3	2	98.1	2	92.1	2	98.8	1	37.1	3	71.2	3
Pittsburgh	94.3	2	90.0	3	99.7	1	92.5	1	100.0	1	9.8	1	85.4	2
Pawtucket	94.2	2	94.1	3	93.1	4	90.0	2	59.3	4	31.7	3	72.9	3
Seattle	94.1	2	87.4	4	96.3	3	92.3	2	90.1	2	21.0	2	86.3	2
Cincinnati	93.7	3	89.6	4	96.6	3	72.9	4	99.0	1	43.1	4	45.4	4
Birmingham	93.6	3	91.6	3	98.5	2	54.2	4	99.4	1	39.4	4	35.9	4
LA	93.1	3	94.6	2	93.4	4	64.7	4	93.5	2	46.0	4	30.9	4
Portland	91.7	3	94.5	2	96.7	3	94.7	1	89.7	2	40.5	4	90.3	1
Irvine	91.3	3	96.5	1	91.3	4	79.7	3	89.0	3	28.9	2	64.4	3
NYC	90.8	3	92.1	3	99.0	1	86.8	3	90.1	2	42.6	4	75.1	3
Medlantic	90.4	3	92.7	3	95.4	3	90.7	2	83.6	3	6.4	1	83.9	2
Chi-Rush	89.9	3	93.5	3	96.4	3	81.1	3	97.3	1	16.7	2	85.5	2
San Antonio	89.6	3	89.2	4	99.4	1	96.8	1	95.8	2	24.6	2	86.7	2
UC Davis	89.1	3	93.3	3	95.5	3	89.8	3	100.0	1	30.3	3	87.8	1
Bowman	88.9	4	88.1	4	75.5	4	50.4	4	89.6	2	38.6	4	24.3	4
Tucson	88.8	4	84.9	4	96.9	3	89.8	2	98.9	1	13.2	1	89.4	1
Memphis	88.7	4	87.4	4	97.4	2	99.3	1	91.2	2	5.3	1	92.7	1
Honolulu	88.1	4	95.2	2	86.7	4	82.4	3	68.0	4	49.2	4	45.8	4
Newark	87.2	4	88.6	4	97.6	2	75.5	4	73.5	4	33.3	3	65.5	3
Houston	86.3	4	95.3	2	87.6	4	61.6	4	72.6	4	49.6	4	41.0	4
Torrance	84.9	4	92.0	3	93.5	4	80.6	3	79.2	3	16.2	1	58.1	4
Detroit	81.3	4	84.0	4	99.0	1	75.3	4	96.3	2	33.1	3	50.8	4
LaJolla	78.5	4	86.5	4	87.2	4	79.5	3	44.7	4	34.1	3	62.9	3
Miami	68.2	4	76.1	4	98.7	1	73.9	4	73.9	3	31.2	3	52.7	4
CC Ave	**92.0**		**92.9**		**95.8**		**86.0**		**84.6**		**30.5**		**74.9**	
Goals	≥ 96%		≥ 96.3%		≥ 97.1%		≥ 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 30 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.

These tables represent the current information available to the relevant committees. Updates are clearly needed. Status reports for papers or ancillary studies may be sent to the CCC, attention Sundara Murphy. The CCC requests one reprint from each published manuscript for study archives.

Table 9.1
Publications

MS ID	Title	Authors	Data Focus	Stage	Reference
1	Informed Consent in the Women's Health Initiative Clinical Trial and Observational Study	**McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	Gen.	11	Journal of Women's Health 4(5):519-29, 1995
4	The Women's Health Initiative: Overview of the Nutrition Component	**Tinker**, Burrows, Henry, Patterson, Van Horn, Rupp	Gen.	11	Nutrition and Women's Health, pp. 510-542, 1996.
5	Women Health Initiative: Why Now? What is it? What's New?	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	Gen.	11	American Psychologist. 52(2):101-116, 1997 Feb.
6	Low-fat Diet Practices of Older Women: "Prevalence and Implication for Dietary Assessment"	**Patterson**, Kristal, Coates, Ritenbaugh, Van Horn, Caggiula, Snetselaar, Tylavsky	Gen.	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	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	Gen.	11	Journal of the American Medical Women's Association. 50(2):50-5, 1995 Mar-Apr
8	Design of the WHI Clinical Trial and Observational Study	**Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	Gen.	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	**Freedman**, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	CT	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	**Prentice**, Rossouw, Johnson, Freedman, McTiernan	CT	11	Menopause 3(2):71-76, 1996
12	Factors Associated with Insurance Status among Participants in the WHI	**Hsia**, Sofaer, Kiefe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington	Gen.	11	Journal of Women's Health & Gender-Based Medicine 9(8):881-889, 2000
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	**Valanis**, Bowen, Bassford, Whitlock, Charney, Carter	CT	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	**Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	Gen.	11	Clinical Journal of Women's Health. 1(5):225-34, 2001 Dec

MS ID	Title	Authors	Data Focus	Stage	Reference
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	**Wassertheil-Smoller**, Anderson, Psaty, Black, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	OS	11	Hypertension 2000;36:780-89
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	**Wang**, Anderson, Prentice	Gen.	11	Biometrics. 55, 711-717 (1999)
27	The Effects of Insurance Coverage and Ethnicity on Mammography Utilization in a Postmenopausal Population	**Bush**, Langer	Gen.	11	Western Journal of Medicine 168:236-40, 1998
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	**Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins	Gen.	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	**Larisch**, Talavera, Langer, Velasquez, Elder	Gen.	11	
40	The Health Impact of Domestic Violence in Older Women	**Mouton**, Furniss, Lasser, Rovi	OS	11	Journal of Women's Health & Gender-Based Medicine 1999:8(9):1173-1179
43	Sleep Complaints of Postmenopausal Women	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	CT	11	Clinical Journal of Women's Health 1:244-252, 2001
59	Risk Factors for Kidney Stones in Postmenopausal Women in the Southern United States	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	Gen.	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	**Shumaker**, Bowen	WHIMS	11	Controlled Clinical Trials 19:604-621
63	Health Insurance as a Determinant of Cancer Screening in WHI OS Participants	**Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	OS	11	Preventive Medicine 2000;31:261-270
69	Correlates of Serum Lypocene in Older Women	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	CT	11	Nutrition and Cancer 2000:36:163-69.
70	Correlates of Serum Alpha- and Gamma-Tocopherol in the WHI	**White**, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	CT	11	Annals of Epidemiology 2001;11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status	**Liu**	Gen.	11	Menopausal Medicine, Vol.6(2), p.1-4, 1998
86	The Effects of Physical and Emotional Status on Adherence to a Low-fat Dietary Pattern in the Women's Health Initiative	**Tinker**, Perri, Bowen, Patterson, Parker, Wodarski, McIntosh, Sevick	CT	11	
88	Estimating Normal Hemogram Values for Postmenopausal Women	**Assaf**, Carleton, Miller, Coccio	Gen.	11	Clinical Journal of Women's Health Vol. 1, No. 1, December 2000, 23-28

MS ID	Title	Authors	Data Focus	Stage	Reference
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	**Rossouw**, Hurd	CT	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	**Wilcox**, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	Gen.	11	Controlled Clinical Trials, 22 (3), 279-289
108	Cross-Sectional Geometry and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	**Nelson**, Hendrix	CT	11	
10	A Comprehensive Data Management System for Multicenter Studies	**Anderson**, Davis, Koch	Gen.	10	
30	Completeness of Purchase Mailing Lists for Identifying Older Women	**Falkner**, Wactawski-Wende, Trevisan	CT	10	
61	WHI Halfway Paper (100K Paper)	**Langer**, Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	Gen.	10	
67	Yogurt Consumption is Associated with Healthy Behaviors in Post-Menopausal Women	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, vitolins, Himes, Parker	OS	10	
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	**Jeffcoat**, Lewis, Reddy, Wang, Redford	Gen.	10	Periodontics 2000
76	Labeling as a Predictor of Dietary Maintenance	**Hopkins**, Burrows, Bowen, Tinker	CT	10	
91	Compliance with National Cholesterol Education Program Dietary and Lifestyle Guidelines Among Older Women with Self-reported Hypercholesterolemia: The Women's Health Initiative	**Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	OS	10	
93	Fat Intake in Husbands of Women in the Dietary Component of the Women's Health Initiative	**Shikany**	Gen.	10	
142	Coronary Artery Calcification in African-American and White Women	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Hsia, Klouj	OS	10	
13	Depression and Cardiovascular Sequelae in Post-Menopausal Women	**Wassertheil-Smoller**, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	Gen.	9	
16	Caloric Requirements and Dietary Self-report	**Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	Gen.	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
22	Pelvic Organ Prolapse: Gravity and Gravidity	**Hendrix**, Clark, Nygaard, Aragaki, Barnabei, McTiernan	CT	9	
26	Special Populations Recruitment for the WHI: Success and Limitations	**Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	Gen.	9	
34	The Relationship between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	**Johnson**, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	Gen.	9	
39	Hormone Replacement Therapy and Dietary Fat Intake Influence on Blood Lipids and Insulin in Postmenopausal Women	**Chlebowski**, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan	Gen.	9	
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine**, Shumaker, Naughton, Kaplan, Kripke, Bowen	Gen.	9	
66	Walking, Vigorous Exercise, and Incidence of Cardiovascular Disease in an Ethnically Diverse Cohort of Women	**Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	OS	9	
73	Innovative Strategies for Monitoring and Enhancing Clinic Performance in the WHI Clinical Trial: The Creation of the Performance Monitoring Committee	**Pottern**, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker	Gen.	9	
83	A Prospective Study of Physical Activity and the Risk of Breast Cancer in Women Aged 50 - 79 Years	**McTiernan**, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	Gen.	9	
84	Research Staff Turnover and Participant Adherence in the WHI	**Jackson**, Berman, Snetselaar, Granek, Boe, Huber, Milas, Spivak, Chlebowski	CT	9	
85	Women's Health Initiative: Rationale, Design and Progress Report	**Johnson**, Anderson, Barad, Stefanick, McNagny	CT	9	
95	The Effects of Widowhood on Physical Health, Mental Health, and Health Behaviors; the Women's Health Initiative	**Wilcox**, Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger, Cochrane	OS	9	
98	Patterns of Antioxidant Supplement Use in Participants in the Women's Health Initiative	**Shikany**, Patterson, Agurs-Collins, Anderson	Gen.	9	
99	Risk Factor Clustering in the Insulin Resistance Syndrome and its Relationship to Cardiovascular Disease In White, Black, Hispanic, and Asian Postmenopausal Women	**Howard**, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	OS	9	
100	The Yield of Six-Month Recall Mammography on Screening Mammograms	**Yasmeen**, Romano, Pettinger, Chlebowski, Lane, Robbins, Hendrix	Gen.	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	**Johnson**, Williams, Fouad	CT	9	
107	Vigorous Leisure Activity Through Women's Adult Life: The Women's Health Initiative	**Wilcox**, Heiss, Pettinger, Brunner, Daugherty, King, McTiernan	OS	9	
109	NCI Monograph: Approaches to Research Trials Recruitment in Hispanic Communities: Review and Recommendations	**Larkey**	Gen.	9	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	**Bowen**, Green Vizenor, Vu, Kreuter, Rolls	OS	9	
112	Results of an Adjunct Dietary Intervention Program in the Women's Health Initiative	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	OS	9	
115	Prevalence and 3-year Incidence of Abuse in Older Women	**Mouton**, Rodabough, Rovi, Hunt, Brzyski		9	
120	Obesity, Body Size, and Risk of Postmenopausal Breast Cancer: The Women's Health Initiative	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	OS	9	
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	**LaCroix**, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson	OS	9	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	**Kearney**, Rosal, Ockene, Churchill	CT	9	
128	Inflammatory Biomarkers, Hormone Replacement Therapy, and Risk of First Myocardial Infarction: A Prospective Analysis from the Women's Health Initiative Observational Study	**Pradhan**, Manson, Rossouw, Siscovick, Mouton, Wallace, Jackson, Pettinger, Ridker	OS	9	
132	Second Malignancy and Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	**Rosenberg**, Greenland, Khandekar, Ascensao, Lpez	Gen.	9	
135	Radiographic Measurements, Bone Mineral Density and the Singh Index in the Proximal Femur of White and African-American Postmenopausal Women	**Barondess**, Singh, Hendrix, Nelson		9	
149	Health Status of Postmenopausal White Women with Back and Leg Pain Living in the Community: A Pilot Study	**Vogt**, Lauerman, Chirumbole, Kuller	OS	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
155	Changes in Food Choices in Response to an Intensive Low-fat Dietary Intervention: Early Results from the Women's Health Initiative	**Patterson**, Kristal, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, Van Horn, Rodabough	CT	9	
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	**Pastore**, Carter, Hulka, Wells	Gen.	8	
102	Cardiovascular Outcomes Related to Anti-Hypertensive Drug Therapy in Older Women: The Women's Health Initiative Observational Study	**Wassertheil-Smoller**, Psaty, Greenland, Margolis, Oberman, Kotchen, Mouton, Hilkert, Black, Anderson, Trevisan, Aragaki	OS	8	
187	Estrogens and Cardiovascular Disease	**Rossouw**	OS	8	
198	Aspects of the Management and Coordination of The Women's Health Initiative	**Cochrane**, Lund, Anderson, Prentice	Gen.	8	
29	Effects of Diet Intervention on Motivation to make other Health Related Changes	**Langer**, Lo	CT	7	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	**Agurs-Collins**, Adams-Campbell, Psaro, Howard	Gen.	7	
57	Regional Differences in Stroke Morbidity at Baseline in the WHI	**Johnson**, Hall, Oberman, Sheps, Hulka, Hays, Baum, Schenken, Burke, Limacher, Anderson, Jeppson	Gen.	7	
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	**Creech**	CT	7	
81	The Prevalence of Urinary Incontinence in WHI Women	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	Gen.	7	
134	Creative Self-Monitoring Tools in the Dietary Modification Component of the Women's Heath Initiative	**Mossavar-Rahmani**, Hendry, Bragg, Brewer, Freed, Kinzel, Pederson, Soule, Vosburg	CT	7	
31	Comparisons between Never Smokers, Former Smokers, and Current Smokers in the WHI	**Ockene**, Bowen, Robbins, Brunner, Shikany, Wagenknecht	OS	6	
36	Prevalence of Silent MI	**Sagar**, Kotchen, Wong, Graettinger, Burke, Van Vorhees, McIntosh	CT	6	
68	Reliability and Physiologic Correlates of the Physical Activity Questionnaire in the WHI	**Morimoto**, White, Wang, Stefanick, Siscovick, Cauley, Strickland, Rebar, Rodrigues, Going, Frid	CT	6	

MS ID	Title	Authors	Data Focus	Stage	Reference
78	Association Between Antioxidants and BMD in an Ethnically Diverse Population of Older Women	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	Gen.	6	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	Gen.	6	
25	Hormone Replacement Therapy Effects on the Resting ECG	**Greenland**, Daugherty, Frishman, Kadish, Limacher, Schwartz	CT	5	
38	The Relationship of Selected Dietary Components and Risk of Adenoma and Colorectal Cancer among Postmenopausal Women: WHI	**Frank**, Agurs-Collins, Gams, Garland, Khandekar, Paskett, Wylie-Rosette, Pettinger	Gen.	5	
41	Determinants of Fasting Hyperinsulinemia	**Manson**, LaCroix, Haan, Rodrigues, Wagenknecht, Johnson, Allen, Hendrix	Gen.	5	
49	Patterns of Use and Characteristics Associated with HRT among Postmenopausal Women	**Dunn**, Greenland, Woods, Stovall, Bartholow, Francis	Gen.	5	
51	The Relationship of Quality of Social Support to Frequency of Cancer Screening Behaviors among Postmenopausal Women	**Lane**, Taylor, Glanz, Elam, Klaskala, Powell, Messina, Smith	Gen.	5	
52	Nutrient Intake of Women with Diabetes in the WHI Observational Study Cohort	**Tinker**, Gams, Lee, Smith, West, Snetselaar, Caggiula	Gen.	5	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	**Paskett**, Sherman, Andersen, Hays, McDonald, Naughton	OS	5	
87	Incidence and Correlates of Hip and Knee Replacement in the WHI	**Wallace**, Chang, Nevitt, LaCroix, Kaplan, Sturm	Gen.	5	
92	Comparison of Self-report, Discharge Diagnosis, and Adjudication of Cardiovascular Events in the WHI	**Heckbert**, Hsia, Kooperberg, McTiernan, Curb, Barbour, Gaziano, Safford, Psaty, Frishman	Gen.	5	
106	Utility of Body Mass Index (BMI) as a Proxy for Obesity Among White, Black, Asian, Native American and Hispanic Post-menopausal Women	**Going**, Chen, Tinker, Stefanick, St. Jeor, Lewis	Gen.	5	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	OS	5	
129	Thrombotic Markers for Coronary Heart Disease in Women	**LaCroix**, Trevisan, Langer, Lewis, hsia, Oberman, Kotchen, Ridker	OS	5	
130	Cross-sectional Analysis of Association Between Hormone Replacement Therapy and Thrombotic and Inflammatory Markers for CHD in Women	**Langer**, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker	OS	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
145	Inverse Association of Breast Cancer with the Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): Prospective Results from the Women's Health Initiative	**Harris**, Jackson, Frid, McTiernan, Anderson, White, Chlebowski, Ascensao	OS	5	
151	History of Estrogen and Oral Contraceptive Use and Cognitive Function: Results from the Women's Health Initiative Memory Study	**Rapp**, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker	WHIMS	5	
152	The Impact of Magnesium Intake on Bone Mass and Risk of Fracture in the Women's Health Initiative Observational Study	**Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	OS	5	
153	Metabolic Syndrome and Depression	**Wylie-Rosette**, Cochrane, Perri, Rapp, Rosal	CT	5	
154	Does Acidogenic Diet Contribute to the Incidence of Hip Fracture?	**Barzel**, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	OS	5	
156	Incidence of Systemic Lupus Erythematosus in the Women's Health Initiative	**Assaf**, Cyr, Crowley, Coccio	OS	5	
163	Racial/Ethnic Differences in Breast Cancer Incidence Rates	**Chlebowski**, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan	OS	5	
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	**Margolis**, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	OS	5	
166	Tea Consumption, Bone Mineral Density and Osteoporotic Fractures: Results from the Women's Health Initiative Study	**Chen**, Hakin, Mays, Caan, LaCroix, Ritenbaugh, Robbins, Barad	OS	5	
174	HMG Co-A Reductase Inhibitor (Statin) Use and the Risk of Breast Cancer in the Women's Health Initiative Observational Study	**Cauley**, LaCroix, Chlebowski, Margolis, McTiernan, Vitolins, Furberg, Bauer	OS	5	
177	Validity of Self-Reports of Fractures among Postmenopausal Women in a Prospective Study Results from the Women's Health Initiative	**Chen**, Bassford, LaCroix, Kooperberg, Jackson, Cauley, Kipersztok, Borne	Gen.	5	
20	Correlates of Endogenous Sex Hormone Concentrations in WHI	**McTiernan**, Wactawski-Wende, Chen, Meilahn, La Valluer, Cummings, Hiatt, Baum, Hulka, Wang, McNagny	CT	4	
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	**Howard**, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetselaar	Gen.	4	

MS ID	Title	Authors	Data Focus	Stage	Reference
18	The Relationship of Dietary Phytoestrogens to Menopausal Symptoms and Major Morbidity in Postmenopausal Women	**Assaf**, Cyr, Coccio, Hixson	CT	3	
45	Socio-demographic Determinants of Folic Acid Intake	**Beresford**, Kritchevsky, Vitolins, Wodarski	Gen.	3	
47	Is a "Too Low" Fat Diet a Marker of Health or Disease	**Gilligan**, Snetselaar, St. Jeor, Van Horn, Stefanick, Kotchen, Patterson	CT	3	
54	Current Treatment Patterns in Women with Hypercholesterolemia	**Manson**, Freed, Chae	Gen.	3	
56	Psychometric Evaluation of the Urinary Incontinence Scale	**Levine**, Shumaker, Naughton, Kaplan, Bowen	Gen.	3	
90	Passive Smoke Exposure in Childhood and Adulthood and Prevalent Coronary Heart Disease in Women Enrolled in the WHI	**Wagenknecht**, Frishman, Wong, Ockene	OS	3	
117	Correlates of Session Completion and Self-monitoring of Food Intake among Minority Participants Enrolled in the Women's Health Initiative (WHI) Dietary Modification Intervention during the First Year of Intervention	**Rosal**, Ockene, Mossavar-Rahmani, Margolis, Paskett, Thomson		3	
118	Association Between Depressive Symptomatology and Physical Activity in Post-menopausal Women	**Ockene**, Rosal, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson	Gen.	3	
121	Quality of Life in Healthy Women and in Breast Cancer Survivors	**Haan**	Gen.	3	
140	Is Hysterectomy Status an Independent Determinant of Framingham Risk?	**Hsia**, Rossouw, Limacher, Wassertheil-Smoller, Margolis, McGovern, Oberman, Barad	Gen.	3	
148	Outcomes of Pap Smears on Postmenopausal Women	**Yasmeen**, Barad, Romano, Hubbell, La Valluer, Johnson, Lane, McIntosh, Hendrix		3	
159	Endogenous Sex Steroid Hormone and Risk of Coronary Heart Disease in Postmenopausal Women	**Rexrode**, Manson, Kuller, McTiernan, Stefanick, Heckbert, White	OS	3	
160	Correlation of Endogenous Sex Steroid Hormones with Inflammatory and Thrombotic Markers in Postmenopausal Women	**Rexrode**, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern	OS	3	
173	Relationships Between Blood Pressure, Hypertension, and Hypertension Therapy and Measures of Cognition Among WHIMS Women At Baseline	**Johnson**, Espeland, Mouton, Margolis, Masaki, Murphy, Wassertheil-Smoller, Prineas	WHIMS	3	

MS ID	Title	Authors	Data Focus	Stage	Reference
186	Diabetes Prevention with Statins, ACE Inhibitors and HRT	**Hsia**, Howard, Limacher, Oberman, Safford, Allen, Torrens, Lawson	Gen.	3	
189	Dietary Adherence in the WHI Dietary Modification Trial	**Patterson**, Prentice, Tinker, Perri, Parker, Mossavar-Rahmani, Rosal, Van Horn, Caan	CT	3	
190	The Relation of HDL Cholesterol to Left Ventricular Size in the Women's Health Initiative	**Oberman**, Ko, Lasser, LaCroix, Wylie	CT	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
86=Dropped

Table 9.2
Ancillary Studies

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Charles Mouton	Robert Schenken	yes	yes	none	OS	217/217	no	10/02-9/05	pending
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Tom Rohan	S. Wassertheil-Smoller	yes		none	OS	3500/3500	yes	4/03-3/06	pending
151	Behavioral Management of Urinary Incontinence in African-American Women	Coralese Ruff	Barbara V. Howard	no		none	OS	150	no		dropped
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	yes	none	OS	all OS women	no	5/02-4/04	funded
149	DNA Repair Genetic Polymorphisms and Breast Cancer Risk	Jennifer Hu	Electra Paskett	yes	yes	none	2001 OS Blood Comp	800/800	yes		pending
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Priesler	Henry Black	yes	yes	none	2001 OS Blood Com	59/177	yes		pending
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson	yes	yes		2001 OS Blood Com	93/279	yes		pending
144	Interactions of Polymorphisms in Selected Genes of Thrombogenic & Thrombolytic Systems with Hormone Replacement Therapy as Risk Factors for Atherothrombotic Events in Postmenopausal Women	James Liu	Margery Gass	no			2001 OS Blood Com		no		dropped

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding Dates	Funding Status
143	Treatment of Elevated Cholesterol Among US Postmenopausal Women	Robert Kaplan	Sylvia Smoller	no		none	2001 OS Blood Com	2250	yes		dropped
142	Thrombosis-related Genes in Population Subgroups Narrowly Defined by Race, Ethnicity, and Place of Birth	Robert Kaplan	Sylvia Smoller	no		none	2001 OS Blood Com	600	yes		dropped
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	yes	yes	none	OS	80	no	04/01-06/01	funded
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Electra Paskett	yes	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	yes	none	OS	1060/2120	yes		pending
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	yes	yes	none	HRT	400	no	7/01-6/06	funded
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	Lew Kuller	yes	yes	none	2000 OS Blood Comp	400	yes		funded
133	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso, JoAnn Manson	JoAnn Manson	yes	yes	none	2000 OS Blood Comp	800/800	yes		pending
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu, JoAnn Manson	JoAnn Manson	yes	yes	none	2000 OS Blood Comp	3840	yes		pending

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding 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	yes	all	DM, HRT		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	yes	none	2000 OS Blood Comp	5775	yes	2/02-2/06	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	yes	none	2000 OS Blood Comp	6500	yes		pending
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	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	yes	all	OS Umbrella Study	2100	yes		pending
125	Osteoporosis in Caribbean Hispanic Women	Ellen Cohen	S. Wassertheil-Smoller	yes	yes	none	OS	500	no		dropped
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Joylin Namie	Robert Langer	yes	yes	none	DM	90-150	no	6/00-12/00	funded

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	yes	yes	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Carrie Cottreau, Lewis Kuller	Lew Kuller	yes	yes	none	OS Blood Comp	206	yes		pending
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	yes	Pittsburgh, Arizona	OS	4000	no	12/00 - 11/04	pending
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Chrisitine L. Coy		yes	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	yes	none	OS	400	no	2/01-1/04	funded
115	Diabetes In Postmenopausal Women	Barbara V. Howard	Barbara V. Howard	yes	yes	all	OS Umbrella Study	93726	yes		dropped
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford	yes	yes	none	OS	1000	yes	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	JoAnn Manson	yes	yes	none	1998 OS Blood Comp	700	yes	4/1/00 - 3/31/03	funded
108	Gene-environment effects and colorectal cancer	Rowan Chlebowski/Henry Lin	Rowan Chlebowski Harbor UCLA	yes	yes	none	2001 OS Blood Comp	800/800	yes		pending
106	Gene-Diet Interactions in Human Breast Cancer Risk	Jennifer Hu	Electra Paskett			none	1998 OS Blood Comp	800/800	yes		dropped
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	yes	yes	Iowa, Portland, Wisconsin	1998 OS Blood Comp	2880	yes	4/1/00 - 3/31/04	funded

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding Dates	Funding Status
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	yes	yes	none	OS	150	no	7/1/99 - 6/30/02	funded
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker		yes	yes		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	yes	none	OS	120	no	10/98 - 9/98	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes	yes	none	OS	775	yes	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski Harbor UCLA	yes	yes	none	ALL	40	yes	12/1/98 - 3/31/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	N/A	none	OS	1000	yes	4/2002-4/2006	pending
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson		yes	yes	none	1998 OS Blood Comp	720	yes	4/1/00 - 3/31/04	funded
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez	David Curb	yes	N/A	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer	yes	no	none	OS	725	no	3/11/98 - 6/30/99	funded
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard				none	CT		no	N/A	pending
90	Biomarkers and Hip Fracture	Steve Cummings	Steve Cummings	yes	yes	none	OS Umbrella Study	400/400	yes		pending

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding 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	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	yes	none	DM+OS	260	yes	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	yes	none	OS Umbrella Study	1300	yes	7/1/99 - 6/30/03	funded
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	yes	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	N/A	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	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	N/A	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	yes	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	yes	La Jolla, San Antonio, Tucson	OS	228	yes	5/1/97 - 4/30/98	funded

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding Dates	Funding Status
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	yes	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		yes	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	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		yes	N/A	51	OS	1040	no	ongoing	funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	yes	all	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines		yes	yes	none	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	Mary Haan	yes	yes		HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	John Robbins	yes	yes	none	HRT	110	no	6 year study	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	yes	yes	none	DM Partners		no	12/1/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	yes	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	Alice Thomson	yes	yes	none	DM	260	no	9/1/96 - 8/31/98	funded

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding Dates	Funding Status
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	yes	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	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	yes	none	DM	150	no	5/1/96 - 4/30/97	funded
40	Ethnic and age differences in use of Mammography	S. Wasserthe il-Smoller	S. Wassertheil-Smoller	yes	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	yes	all except #18	HRT	4800	no	5/1/96 - 4/30/02	funded
36	Hormone Replacement Therapy and Changes in Mammographic Density	Gerardo Heiss		yes	yes		HRT	NA	no	1/98 - 12/01	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	yes	yes	none	HRT	330	no	12/1/96 - 12/31/02	funded
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	yes	yes	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	yes	yes	none	OS	300	no	N/A	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	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	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	yes	yes	none	OS	1000	no	10/25/94 - 10/24/96	funded

AS #	Title	Study PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	yes	none	OS	1300	no	9/16/96 - 09/15/01	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	yes	N/A	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	yes	N/A	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	yes	N/A	none	OS	600	yes	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	N/A	none	OS	650	no	6/1/95 - 5/31/02	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	yes	N/A	none	DM	160	no	4/1/95 - 9/30/96	funded