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Implementing a Low-Fat Eating Plan in the Women's Intervention Nutrition Study

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Abstract

The Women's Intervention Nutrition Study is a randomized clinical trial designed to evaluate if a lifestyle intervention targeting fat intake reduction influences breast cancer recurrence in women with early stage, resected disease receiving conventional cancer management. This report details the concept, content, and implementation of the low-fat eating plan used in the dietary intervention group of this trial. Intervention group participants were given a daily fat gram goal. The intervention was delivered by centrally trained, registered dietitians who applied behavioral, cognitive, and motivational counseling techniques. The low-fat eating plan was implemented in an intensive phase with eight biweekly (up to Month 4), individual counseling sessions followed by a maintenance phase (Month 5 up to and including Year 5) with registered dietitian visits every 3 months and optional monthly group sessions. Self-monitoring (daily fat gram counting and recording), goal setting, and motivational interviewing strategies were key components. Dietary fat intake was equivalent at baseline and consistently lower in the intervention compared with the control group at all time points (percent energy from fat at 60 months $23.2\% \pm 8.4\%$ vs $31.2\% \pm 8.9\%$, respectively, $P < 0.0001$) and was associated with mean 6.1 lb mean weight difference between groups ($P = 0.005$) at 5 years (baseline and 5 years, respectively: control 160.0 ± 35.0 and 161.7 ± 32.8 lb; intervention 160.2 ± 35.1 and 155.6 ± 32.1 lb). Together with previously reported efficacy results, this information suggests that a lifestyle intervention that reduces dietary fat intake and is associated with modest weight loss may favorably influence breast cancer recurrence. The Women's Intervention Nutrition Study low-fat eating plan can serve as a model for implementing such a long-term dietary intervention in clinical practice.

The relationship between dietary fat intake and breast cancer outcome has been examined in a total of 14 observational studies with seven studies demonstrating a significant association between lower fat intake and lower recurrence risk (1,2). The Women's Intervention Nutrition Study (WINS) is a multicenter, randomized controlled clinical trial to directly address this issue, testing the effect of a dietary intervention designed to reduce fat intake on breast cancer recurrence in women receiving conventional cancer management for early stage disease. The WINS intervention significantly reduced dietary fat intake, associated with moderate weight loss, and interim efficacy results suggested clinical outcomes were

improved (3). Details of the WINS dietary intervention, including its conceptual basis, content, implementation processes, and its influence on dietary and anthropometric endpoints are reported to inform use in clinical practice.

METHODS

The goal of the dietary intervention (the WINS low-fat eating plan) was to reduce the percentage of total energy intake from fat down to 15% while maintaining nutritional adequacy. This goal was based on findings from feasibility trials indicating that a 15% goal would result in a sustained reduction of fat intake of about 20% of energy intake (4,5). Randomization for this trial was 40:60 for the low-fat intervention vs control group to save resources at minimal loss in statistical power. Control group subjects were provided a US Department of Agriculture Dietary Guidelines pamphlet at baseline and educational handouts to address any suboptimal nutrient intakes identified from annual dietary recalls.

WINS Study Population

The WINS protocol details have been previously described (3). Briefly, participants had histologically confirmed, resected invasive breast cancer, were between 48 and 79 years of age, and were within 365 days of cancer surgery. Acceptable adjuvant systemic cancer therapy was required and dietary intake had to be >20% of energy from fat at baseline. For eligibility, fat intake was estimated from three unannounced telephone 24-hour recalls (including one weekend day) over 2 weeks. Acceptable adjuvant therapy included radiation, select chemotherapies (required for hormone receptor negative cancers), and tamoxifen for receptor positive cancers. The institutional review board of each participating institution approved the study and all participants gave written informed consent. A CONSORT trial flow diagram has been previously published (3).

Study Organization: Standardizing Treatment Delivery

To address uniformity of practice and quality control, session-by-session protocols described topics and information to be addressed. Study registered dietitians (RDs) were trained centrally on diet intervention, behavior change strategies, and anthropometric data collection. Training continued with monthly conference calls and annual workshops incorporating training on motivational interviewing. Ongoing trial management was facilitated by site visits from the WINS Nutrition Intervention Coordinating Unit. Whenever possible, the same RD counseled the same participant to promote a provider/participant relationship and provide continuity of the intervention.

Dietary Intake Assessment

Adherence to the low-fat eating plan was monitored by unannounced 24-hour telephone recalls (6,7). Centrally trained interviewers blinded to randomization called participants at baseline, 3 months, and annually from central locations with information entered into the Nutrition Data System for Research interactive software. Annual dietary intakes were estimated from two nonconsecutive telephone recalls (one on a weekend day) (6).

Intervention Schedule During Intensive Intervention and Maintenance Phases

At study entry, intervention group participants were given a daily fat gram goal calculated based on body weight in pounds divided by six, with all goals set between 20 and 30 grams (following the procedure described in Figure 1) (8). For example, if a woman weighed 180 lb her daily goal was no more than 30 g fat. Participants were also advised not to fall too far below their goal to support adequate micronutrient and essential fatty acid intake.

The low-fat eating plan was initiated with an initial intensive intervention phase followed by a maintenance phase. During the intensive phase, participants met individually with the RD every 2 weeks for eight sessions lasting about 1 hour each. In the maintenance phase, subsequent RD visits were held quarterly, and optional monthly group sessions were offered. After 5 years, participants' clinic visits were reduced to biannual with biannual phone contacts between visits.

The Five Low-Fat Eating Plan Principles: Selecting and Preparing Foods

The low-fat eating plan was based primarily on the social cognitive theory of behavior change (9) and included goal setting, self-monitoring (fat gram counting and recording), modeling, and social support. Relapse prevention and management techniques (10) were used to maintain adherence. To promote tailoring of counseling, the Transtheoretical Model of Change (11) was combined with motivational interviewing techniques (12). This included the development and use of the Motivational Action Plan as a data collection instrument and counseling tool designed to maintain or improve long-term adherence to the low-fat diet (13).

Reducing dietary fat intake involved three general strategies: substitution (of low-fat foods and cooking methods for those high in fat), elimination (of high-fat foods), and reduction (in portion sizes of high-fat foods) based on the five low-fat eating plan principles: reduce the amount of oils and high-fat spreads, dressings, and sauces; choose low-fat dairy products; choose low-fat fish, poultry, meat, and egg whites or egg substitutes and eat smaller portions of these foods; eat more fruits, vegetables, legumes, and grain products; and substitute low-fat desserts, snacks, and beverages for high-fat items (14,15).

Instructional materials for the application of the low-fat eating plan were developed to address common barriers to successful behavior change, including:

Appetite—The difference between appetite and physiological hunger and identification and management of appetite triggers and hunger.

Environmental Cues—The influence of external cues for eating, such as sensory triggers (sight and smell of food), availability of food, and time of day.

High-Risk Situations—Such as holidays, restaurant dining, special occasions, and emotional cues.

Negative Thinking—Self-defeating thoughts.

Social Eating—Strategies to manage challenging social situations.

Implementing the Low-Fat Eating Plan

The WINS low-fat eating plan incorporates four discrete behavior steps: learning the low-fat eating plan, counting fat grams, setting goals, and removing roadblocks (see Figure 2). These four steps encompass the five basic principles for selecting and preparing low-fat foods. The topics and objectives of the intensive intervention visits are outlined in Figure 3. Each visit introduced new information and identified relevant behavior goals designed to reduce fat intake. Depending on individual assimilation, the four behavioral steps were commonly completed in four, three, or even two visits at the discretion of the RD. Subsequent sessions were used to identify problems and provide counseling to promote long-term adherence. Counseling sessions typically included a review of goals since the last visit, review of prior fat intake, assessment and discussion of progress and/or problem areas, and formal setting of behavioral goals for the next visit.

The calculated fat gram goal provided a daily quantitative target for their dietary fat intake reduction. Participants were instructed to keep a written record of their fat gram intake daily using a previously developed *Keeping Score* book and Fat Gram Counter (14). Emphasized concepts included consideration of portion size, use of the Nutrition Facts Label, and tips for estimation of fat grams in mixed dishes and for food eaten away from home.

Setting individualized goals was an integral component of the low-fat eating plan. In the goal setting process workable solutions to problems encountered in lowering fat intake were developed. Each goal was stated in behavioral terms and included a concrete and verifiable outcome. A goal could be “to include cheese with less than 3 g fat per slice in my lunch sandwich instead of the cheese I now use for the next month.” Goals were recorded on a personal Goal Card, and study RDs documented their status on a Goal Setting Summary document. This document was reviewed centrally, and follow-up with the RD at their clinical center was provided to address adherence issues. An overview of the WINS low-fat eating plan is outlined in Figure 4.

Counseling on the Low-Fat Eating Plan

The crux of the low-fat eating plan was individualized counseling to initially educate and then guide participants to long-term maintenance of a low-fat diet through awareness of eating habits and the ability to identify and manage personal barriers to low-fat eating. Counseling used the participant-centered model and incorporated motivational interviewing strategies to facilitate behavior change and maintain long-term adherence, which was facilitated by use of the Motivational Action Plan. During the last intensive intervention phase visit, participants developed a long-range plan to maintain fat intake reduction. Relapse prevention and management skills needed for management of personal barriers were discussed and incorporated into the plan, including problem-solving techniques and coping skills.

Other Adherence Strategies

Other adherence strategies used in WINS included monthly group sessions, group-specific newsletters, monthly group specific, quarterly mailings, and study-wide incentives. Group sessions were designed to provide support and modeling through group discussions, and build upon information provided in individual sessions through role-playing, demonstrations, and the sharing of practical experiences.

Statistical Analysis

The nutrient intake and anthropometrics presentations are reconfigurations of previously reported results (3). Differences in baseline variables between and within groups were analyzed using *t* tests or paired *t* tests. The *t* tests were performed to compare differences in the nutrient intakes and anthropometric variables, and corresponding 95% confidence intervals are reported.

RESULTS

A total of 2,437 women were randomly assigned, 975 to the dietary intervention and 1,462 to the control group. Dietary data is available for at least three of six time periods after baseline on 80% of participants. In the control group, 66 were lost to follow-up and 106 discontinued study participation. In the intervention group, 45 were lost to follow-up and 170 discontinued the dietary intervention. Only six women cited that they “did not like the low-fat eating plan” as the reason.

Dietary fat intakes were closely comparable at baseline ($29.6\% \pm 6.7\%$ and $29.6\% \pm 7.1\%$ of energy intake from fat for intervention and controls groups, respectively). After 1 year, dietary fat intake was reduced to a greater degree in the intervention compared to the control group, and the reduction was maintained throughout the study. At 5 years, the daily fat gram intake was 53.9 ± 26.7 g in the control group and 34.9 ± 18.4 g in the intervention group ($P < 0.0001$), representing $31.4\% \pm 23.2\%$ and $23.2\% \pm 8.4\%$ of energy as fat in the control and intervention groups, respectively (see the Table). At baseline body weight was closely comparable in the randomization groups (160.2 ± 35.1 lb and 160.0 ± 35.0 lb in intervention and control groups, respectively). After 1 year, body weight was lower in the intervention group and a difference was maintained between groups throughout the study. At 5 years, control group women weighed an average of 161.7 ± 32.8 lb compared to 155.6 ± 32.1 lb for intervention group women ($P = 0.005$).

DISCUSSION

The WINS low-fat eating plan resulted in significant and sustained reductions in both fat intake as well as body weight. These results, together with outcomes from other full scale trials (16–18) indicate that demanding lifestyle interventions involving significant modification of dietary intake can be successfully implemented over extended periods of time (16–19). In an interim efficacy report from the WINS trial, breast cancer recurrence was less frequent in women randomized to the intervention group and subgroup analyses suggested a larger effect on hormone receptor negative breast cancers (3). Analyses relating

dietary adherence to breast cancer outcome await completion of ongoing nonintervention follow-up.

Successful lowering of fat intake by WINS participants was characterized by several types of dietary changes. Those classified as “strictly adherent” who met their fat gram goal not only decreased their intake of discretionary fat from oils, sweets and fat, but also reduced their intake of sweet breads, pastries, and desserts; cheese; poultry, beef, pork, and lamb; nuts and seeds; and eggs to a greater degree than did those who were not strictly adherent (15). As total fat intake was reduced in WINS intervention participants, daily intake of saturated fats were reduced from 19 to 10 g, monosaturated fats from 22 to 12 g, and polyunsaturated fats from 12 to 6 g and a modest increase in fiber from 18 to 20 g was seen. These differences all were statistically significant compared to controls and were maintained through 72 months (3).

Few other randomized trials have evaluated lifestyle intervention on breast cancer outcomes. The Women’s Healthy Eating and Living (WHEL) trial evaluated a dietary intervention targeting vegetable, fruit, and fiber increase as well as fat intake reduction in women with early stage, resected breast cancer. Although increases in vegetable, fruit, and fiber intake were achieved, the WHEL program had no effect on breast cancer recurrence (20). The WHEL and WINS trials differ in several respects, most notably, the modest reduction in fat intake and the absence of weight loss in the WHEL trial (21). Specifically, in WHEL, the percent of energy from fat was 28.5% at baseline, 27.1% at 48 months, and 28.9% at 72 months—substantially higher than that seen in the WINS trial at the same benchmarks (see the Table).

The Women’s Health Initiative Dietary Modification (WHI-DM) trial, a primary prevention study of 48,386 postmenopausal women, evaluated the influence of a low-fat dietary pattern on primary breast cancer prevention (22). Dietary intervention was initiated with 16 group sessions and individual RD counseling was not provided. While 9% fewer breast cancers were seen in the intervention group, the difference was not significant ($P = 0.07$). The reduction in fat intake in percent of energy comparing intervention to control group was similar in the WHI-DM and WINS trials. However, higher baseline fat intakes in WHI DM participants led to higher post intervention levels, especially because WHI-DM dietary adherence faltered over time.

WINS used the multiple-pass 24-hour recall method to assess fat intake annually, an approach that has received validation in several settings (23,24). WINS procedures were designed to minimize reporting bias by blinding WINS clinic RDs to actual food intake reported by participants and using independent, off-site interviews to perform recalls (7). However, errors in measurement of dietary intake can be problematic with any approach especially regarding underreporting. Nonetheless, the decrease in dietary fat intake reported by the intervention group was supported by the significantly lower and sustained differences in mean body weight seen compared with the control group.

During the 5.2-year study period, a total of 22% of intervention group participants were either lost to follow-up or discontinued the dietary intervention, representing a study

limitation. However, adherence to prescribed treatment, even within the scope of established breast cancer therapy, is problematic. For example, when evaluated in clinical practice settings, adjuvant tamoxifen use was prematurely discontinued by 30% to 50% of patients before completion of a scheduled 5-year course (25).

CONCLUSIONS

The WINS low-fat eating plan is a comprehensive, theory-based lifestyle intervention that resulted in reduced fat intake, modest weight loss and a suggested favorable affect on breast cancer recurrence especially in postmenopausal women with hormone receptor negative disease. A description of the methodology used in implementing this low-fat eating plan can serve as a model for its use by RDs in clinical practice.

Because both reduced fat intake and modest weight loss were seen in the WINS dietary intervention group, the relative contribution of each to breast cancer clinical outcome cannot be determined. Therefore, replication of this intervention in practice should target both fat intake and sustained, modest weight loss (3,26,27).

The intensive intervention phase was implemented in eight biweekly visits. The 16 topics presented during these eight visits were provided at a pace dependent on the RD's assessment of the participant's grasp of the presented information. The self-monitoring of fat intake with daily use of the *Keeping Score* book represents a critically important early behavior that rapidly increased knowledge regarding the fat content of food choices. It is our impression dealing with such a motivated population that the intervention phase could be completed with fewer visits perhaps four or less. We can provide no information on the efficacy of a less intensive program because only one intervention strategy was employed in WINS. However, results from other successful lifestyle programs suggest that, ongoing multiyear contacts and development of supportive partnering relationships between participants and the intervening RDs are needed to prevent dietary relapses (27,28). The 3-month schedule of RD contacts was sufficient and likely necessary to maintain long-term adherence.

In the WINS trial dietary intakes for clinical trial purposes were assessed using 24-hour telephone recalls. However, for the purposes of monitoring adherence in clinical practice, body weight measurements and reviews of keeping score books should be sufficient to guide RD counseling efforts.

Finally, in clinical settings, reimbursement for dietary services in cancer populations may be limited. Formal cost and time assessment analyses are beyond the scope of the current report (29). However, in relative terms the total incurred cost (eg, RD time and printed support materials) would be less than those involved in just one course (usually 2 to 3 weeks) of chemotherapy with current adjuvant regimens (30–32) or approximately 6 months of a scheduled 5-year course of aromatase inhibitor use (33).

The information in this report presents a strategy for implementing the WINS low-fat eating plan in clinical practice. If a breast cancer patient in consultation with an RD asks, "What

can I do to prevent breast cancer from recurring?” the WINS low-fat eating plan may be one answer.

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The fat gram goal is calculated as a participant's weight in pounds at baseline, divided by 6, with the constraint that the goal may not exceed 30 g nor be less than 20 g.

This calculation is derived by multiplying the baseline weight by 13.4 kcal/lb (which represents the average energy allowance for adult women older than age 50 years within a range of light to moderate activity, based on World Health Organization equations for the calculation of resting energy expenditure [8]), then multiplying by 15% (our target goal for fat as percent of energy intake), and by 75% (to account for an approximate reduction in energy intake of 25% when changing to a low-fat diet), and finally dividing by 9 (the number of kilocalories per gram of fat).

The cutoff range of 20 to 30 g for the fat gram goal corresponds with weights ranging from 120 to 180 lb. Women who weigh <120 lb or >180 lb are prescribed a fat gram goal of 20 or 30 g, respectively. This ensures a conservative fat intake level for someone who weighs little but is very active and for someone who is very heavy but is quite active.

Figure 1.

Calculation of Women's Intervention Nutrition Study (WINS) dietary intervention participants' daily fat gram goals to facilitate consumption of the WINS low-fat diet that is up to 15% energy as fat.

Low-fat eating plan step	Primary concepts
I. Introduction of the low-fat eating plan	What is fat? Decreasing the amount of fat you eat Identifying low-fat foods
II. Count fat grams	Calculate individual fat gram goal Energy and fat Reading food labels Self-monitoring
III. Set goals	Characteristics of behavior goals The 5 low-fat eating plan principles: 1. Reduce the amount of oils and high-fat dressings and sauces. 2. Choose low-fat dairy products. 3. Choose low-fat fish, poultry, meat, and egg whites or egg substitutes. Eat smaller portions. 4. Eat more fruits, vegetables, legumes, and grain products. 5. Substitute low-fat desserts, snacks, and beverages for high-fat items.
IV. Remove roadblocks	Identifying problems. Learning different responses: 1. Common roadblocks 2. Your appetite 3. A tempting environment 4. High-risk situations 5. Feelings of failure and negative thinking 6. Social eating

Figure 2.

Four steps of the Women's Intervention Nutrition Study low-fat eating plan.

Intensive intervention visit	Topics	Objectives
1	LFEP ^a Self-monitoring	Describe goals and steps of LFEP. Describe role of fat in the diet. State benefits of lowering fat intake. Identify foods that are high-, medium-, and low-fat. Explain how to lower fat in diet through substitution and low-fat cooking methods. Describe purpose and application of self-monitoring. Describe how to record intake. Describe methods for estimating portion size.
2	Counting fat grams Setting goals	State fat gram goal. Explain counting daily fat grams, including use of Nutrition Facts Label. Illustrate counting fat grams. Describe process of goal setting. Identify individual behavior goals. Identify level of fat gram intake to be achieved before next visit.
3	LFEP principles	Describe the 5 LFEP principles. Identify problem foods using food diary. State 1-2 behavioral goals based on LFEP principles. Identify level of fat gram intake to be achieved before next visit.
4	Removing roadblocks	Describe common roadblocks to adherence. Identify 1 personal roadblock. Identify 1 goal for managing personal roadblock.
5	Individual module ^b : Menu planning	Identify personal factors that influence meal patterns. Plan menus using menu planning guidelines. Identify acceptable foods to include in menus. Develop a menu plan for a week. Choose a recipe from the WINS recipe book
6	Individual module ^b : Recipe modification	Identify sources of fat and appropriate low-fat substitutes in frequently used recipes. Discuss low-fat cooking methods. Calculate fat grams per serving in modified recipes.
7	Individual module ^b : Selecting fast and easy meals	State how low-fat convenience foods and fast foods can fit into the LFEP. Identify appropriate low-fat convenience foods. Identify meals from staple ingredients that can be prepared in 20 minutes or less.
8	Individual module ^b : Eating out	Select appropriate low-fat items from restaurant menus of various cuisines, including ethnic. Demonstrate assertiveness via role playing when requesting menu modifications. State appropriate portions to remain within limits of the fat gram goal for foods rich in fat (eg, share dessert). State a plan in advance to support low-fat eating (eg, eating less fat during previous meals or snacking on low-fat foods to reduce appetite before eating out). Consult resources with fat gram content of foods. Calculate fat gram content per serving of food item. Select foods with reduced fat content.
9	Individual module ^b : Quick guide for recipes and food labels	State how thoughts can affect success. Identify negative thoughts about diet change. Identify ways to turn around negative thoughts into positive ones.
10	Individual module ^b : Positive and negative self-talk	Identify specific sensory, activity, emotional, special event, or people cues that stimulate high-fat eating. State how to distinguish appetite from hunger. Identify and discuss any habitual high-fat eating patterns. Identify strategies to minimize high-fat eating cues.
11	Individual module ^b : Coping with appetite and food cues	Plan lunchtime selections. Select low-fat lunches.
12	Individual module ^b : Packing your lunch	Calculate and state contribution of fat from desserts. Identify and select low-fat desserts. State how to use portion control for high-fat choices.
13	Individual module ^b : Low-fat desserts	List meals that include fat grams.
14	WINS breakfast, lunch, and dinner suggestions	Identify suggestions for snacks and specific snack ideas with fat gram content.
15	Healthful eating on WINS	Identify individual strategies for maintaining adherence to the LFEP and meeting fat gram goal, including self-monitoring, stimulus awareness and management, problem solving, cognitive restructuring, and contingency management.
16	Individual modules focused on planning for long-term adherence	

Figure 3.

Topics and objectives of the Women's Intervention Nutrition Study (WINS) intensive intervention visits. ^aLFEP = low-fat eating plan. ^bIndividual modules contain supplementary information for participants to promote adherence to the LFEP, and are provided based on individual needs and interests.

Timeline	Frequency of nutrition contacts	Format of nutrition contacts	Intermediary/process goal to achieve intervention of up to 15% of energy intake as fat	Activity goal	Add-on features
Months 1 to 4 Intensive intervention phase	Every other week	In-person counseling session with a registered dietitian (includes weight measurement)	Teach LFEP modules Apply LFEP	Record daily food diary (<i>Keeping Score</i> booklet) Stay within daily fat gram goal (<i>Keeping Score</i> booklet) Personalize LFEP (discussion of personal issues pertaining to module contents, quizzes, exercises) Set and achieve personal diet goals supporting the low fat eating intervention (goal card) Accumulation of behavioral goals on Goal Setting Summary	WINS Low Fat Eating newsletter Inclusion of close family member or support person during relevant sessions Provision of sample menu plans focused on fat gram consumption
Month 5 to Year 5 Follow-up Phase	Every 3 months	In-person counseling session with a registered dietitian (includes weight measurement)	Maintain low fat eating Motivational Action Plan to achieve sustained (starts at Month 18 and repeats on Month 30, 42, and 54)	Encourage recording of daily food diary (<i>Keeping Score</i> booklet) Set and achieve personal diet goals supporting the low fat eating intervention (goal card) Accumulation of behavioral goals on Goal Setting Summary Utilizing the Motivational Action Plan, explore, discuss, and address roadblocks to low-fat eating as time evolves and new issues arise in participants' lives	WINS Low Fat Eating Newsletter Optional monthly group sessions At annual anniversary, comprehensive dietary assessment is discussed Month 57: Long-term intervention plan is established with registered dietitian

Figure 4.
Overview of the Women's Intervention Nutrition Study (WINS) low-fat eating plan (LFEP) lifestyle intervention.

Percent energy intake from fat by Women's Intervention Nutrition Study (WINS) dietary intervention group compared to the WINS control group at baseline and annually thereafter to 6 years^a

Table

Group	Energy Intake from Fat (%)						
	Follow-Up Interval (mo)						
	Baseline	12	24	36	48	60	72
Dietary intervention	29.637.1	20.337.8	21.238.2	21.738.4	22.638.5	23.238.4	23.039.2
Control	29.636.7	29.238.2	30.138.3	30.738.7	30.538.7	31.238.9	31.438.2

^aInformation on dietary intake was available for 975 and 1,461 of women in the dietary intervention group and the control group, respectively, at baseline; for 840 and 1,328 women, respectively, at Year 1; for 654 and 1,077 women, respectively, at Year 3; and for 380 and 648 women, respectively, at Year 5.