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13. ABSTRACT (Maximum 200 Words)
The purpose of this project was to evaluate the effect(s) of increasing fruit and vegetable intake on oxidative DNA damage and lipid peroxidation in a population of women at elevated risk for breast cancer.
The rationale that underlies the work conducted was based on evidence that the occurrence of DNA mutations are essential steps in carcinogenesis and that these mutagenic events can result from oxidative stress, even in the absence of exogenous carcinogens. The effects of consuming a recipe-defined diet designed to provide on average three (control) or ten (intervention) servings of fruits and vegetables per day for a total of 8 weeks on measures of oxidative damage to DNA and lipids was determined. The accrual goal of enrolling 200 subjects in this project was exceeded. A total of 213 individuals completed the dietary intervention. Sample analysis and data evaluation are reported.

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Table of Contents

Introduction

Oxidative damage to cellular macromolecules, especially DNA, is a pro-mutagenic event that has been reported to be associated with the risk for mutation, and the occurrence of mutations is known to be involved in the development of cancer. Such oxidative cellular damage has been specifically implicated in the development of breast cancer. Thus, it has been proposed that levels of oxidative cellular damage serve as biomarkers for breast cancer risk. Based on this information, the goal of the work reported was to determine if levels of oxidative cellular damage to DNA, determined as 8-hydroxydeoxyguanosine (8-OHdG), or lipid, determined as 8-isoprostane F-2-alpha (8-EPG), could be modulated by diet. Our specific working hypothesis was that levels of 8-OHdG in DNA isolated from peripheral lymphocytes and the concentration of 8-EPG excreted in urine would be reduced in women who consumed a diet that was high (> 10 servings per day) versus low (< 5 servings per day) in vegetables and fruit. The study was conducted in 5 installments of 2 months each. The first began in September of 2001, the last was concluded in March of 2002. A total of 264 women completed the eligibility questionnaire, 264 completed visit 1 and began the study, and 213 completed the study.

Report Body

Approved Statement of Work During the negotiations involved in the award of this grant, reductions in the scope of the originally proposed work plan were implemented based on the review group's critique of the application. Accompanying reductions in the budget were also made. The final approved Statement of Work is as follows:

To test whether an increase in consumption of fruits and vegetables will decrease indicators of oxidative cellular damage in women at high risk for breast cancer occurrence or reoccurrence.

a. Initiate recruitment 2 months prior to initiation of a study group into the investigation.
b. Conduct intervention in a total of 2 study groups.
c. Perform laboratory analyses .
d. Evaluate results.
e. Repeat steps a-d an additional three times. We anticipate that recruitment will be completed during year three, and that laboratory and statistical analyses will continue throughout the project.
f. Summarize results and write reports and manuscripts.

Study Design Study participants were given a cook book containing menus and recipes that prescribed all the foods that were to be consumed during the study. Food records were maintained to document everything that was consumed. Focus groups conducted before initiating the main intervention identified convenience as a significant potential barrier to remaining on study. Therefore, approximately 40% of all lunch or dinner entrees were prepared by a retail delicatessen and provided to study participants. At the initiation of the study and at 2 week intervals thereafter, samples of blood and 3 consecutive day first void urine specimens were obtained. Key elements of the experimental design were:

•For the initial 2 weeks (run-in phase), everyone consumed a cuisine menu that was low in fat (30%: 10:10:10, S:MS:PS)[S= saturated fat, MS= monounsaturated fat, PS= polyunsaturated fat] and that provided 2-4 servings of vegetables and fruit per day depending on caloric needs

•For the next six weeks participants were assigned (randomized) to one of two diet groups that differed in amount of vegetables and fruit

–The GR group consumed on average 3.6 servings of vegetables and fruit per day

–The VF group consumed on average 9.3 servings of vegetables and fruit per day

•Both groups consumed similar amounts of protein, fat, and carbohydrate
•During the last 2 weeks the GR group crossed over to the VF diet
•About one-third of lunch or dinner entrees were provided by a retail delicatessen.

In addition to eligibility and contact information, data were collected on medications and dietary supplements, lifestyle, and follow-up compliance, knowledge and self-efficacy. An inventory of completed questionnaires and lab data is shown in Table 1.

Table 1 Completed Questionnaires and Lab Data

Challenge installments	Eligibility	Lifestyle	Meds & Supp	Follow Up	**Lab Data Baseline**	**Lab Data Visit 5**	**Loss Rate***
1	45	33	40	31	**42**	**34**	**19.0%**
2	44	44	42	34	**42**	**36**	**14.3%**
3	26	29	28	21	**29**	**23**	**20.7%**
4	65	65	65	49	**65**	**52**	**20.0%**
5	84	67	67	56	**86**	**68**	**20.9%**
Total	264	238	242	191	**264**	**213**	**19.3%**

*Loss rate computed between Visit 1 and Visit 5.

Summary of Project Implementation As noted in the original application, this project was based on pilot work in which we studied the effects of a two-week recipe defined diet on oxidative markers. Upon commencement of work on this project, a multi-pronged plan of attack was implemented. Its elements included: 1) modification of the recipe-defined menus for use in an 8-week intervention study; 2) development and testing of intervention materials; and 3) further evaluation of the candidate oxidative markers. As reported in the First Annual Report, significant progress was made and recruitment was initiated. Effort during the remainder of the project was focused on recruitment, conducting the intervention, and the evaluation of the dietary records and biological specimens that were obtained.

Modification of the Recipe Defined Menus

a. Focus group analysis of two-week dietary intervention program

Subjects that had participated in previous two-week dietary intervention studies were invited to attend focus group meetings to elicit their comments and suggestions on the menus, recipes, and other aspects of the dietary intervention in which they had participated. Open-ended questions were used to promote discussion of the aspects of the two-week dietary intervention that needed to be changed if subjects were to follow the intervention for a period of 8 weeks. The following barriers were identified: 1) the amount of time required for "in home" meal preparation including the weighing of all food items, i.e. lack of convenience, 2) difficulty of eating meals out of home, 3) inability to follow the diet while traveling and during normal business activities, e.g. business lunches and dinners, 4) exclusion of "favorite foods", 5) meal repetition, 6) limitations on the consumption of alcoholic beverages, 7) prohibition of nutritional supplement use.

b. Modification of the dietary intervention program

Based on the results of the focus groups, the project staff defined four elements of the intervention program for discussion and analysis. They were: convenience, flexibility, choice, limitations.

Convenience The primary barrier identified in the focus groups was lack of convenience. To address this issue several strategies were evaluated. They included: 1) the use of convenience foods that could be purchased from local grocery stores, 2) the use of a feeding study approach in which the majority of the meals would be provided to subjects, 3) the identification of the amounts and types of vegetables and fruit to be consumed each day without further specification of foods to be eaten, 4) the development of convenience foods for use in the study. Given the significance of this barrier, considerable time and effort was committed to evaluating these alternatives. The results of those deliberations can be summarized as follows.

The use of convenience foods that could be purchased from local grocery stores This approach is deemed to have considerable merit relative to the ultimate translatability of the intervention strategy to large segments of the population. However, the majority of the convenience foods provided as meals contain limited amounts of vegetables and almost no fruit, the variety of vegetables and fruit are limited, and such products are expensive, can be high in calories, and their quality control is unknown. For these reasons, this approach was not further pursued.

The use of a feeding study approach in which the majority of the meals would be provided to subjects This approach was deemed desirable because of the control that it would provide of the foods consumed. However, this approach has shortcomings for this study population. The population has a mean age of 48,and the majority of women are employed full time. This approach would be likely to exclude the possibility of many women to participate, and they would not learn the skills necessary to translate the principles of the intervention into their daily lives. This intervention would also be expensive to implement. For these reasons, this approach was not further pursued.

T***he identification of the amounts and types of vegetables and fruit to be consumed each day without further specification of foods to be eaten.*** Ultimately, this approach may offer the greatest opportunity for translation; however, at this stage of hypothesis testing, the loss of control over other aspects of the diet that is inherent in this approach was considered unacceptable. For this reason, this approach was not further pursued.

The development of convenience foods for use in the study. This approach was considered to offer the greatest opportunity for successful implementation because it would allow the use of many of the recipes developed for the original diet while keeping most elements of the menu plan intact. Moreover, this approach also addressed the concerns identified when the use of convenience foods was considered (see above). To pursue this approach, local grocery chains that prepare entrees on site were identified and discussions of interest and feasibility were initiated. The Wild Oats foodchain expressed interest and had staff that were headed by a certified chef with considerable experience in the conversion of recipes for individuals for quantity production. For reasons of feasibility, the ability to prepare all recipes and provide them in a "frozen format" was deemed essential. Further aspects of this activity are presented under "Intervention material development and testing".
The other major change made was to switch from the use of scales to weigh all foods to the use of standard household measures, i.e. cups.

Flexibility In our analysis of the focus group data, a number of barriers identified were related to the lack of flexibility in the ability to accommodate business activities, trips, and other personal activities, all of which necessitate the eating of meals out of the home environment. Further discussions with former study participants indicated that one solution that would address this situation would be to allow two meals per week to be "free meals", i.e. not prescribed by the menu plan. It was decided that this approach should be incorporated into the dietary intervention plan. However, we decided that at this stage of hypothesis testing, that the need for out-of-town travel for more than two days

during the intervention would serve as a basis for non inclusion in the study. However, it was also agreed that this decision be regularly scrutinized.

Choice Suggestions for the incorporation of new food items into the diet were considered in conjunction with the repetitive use of certain food items. Menus were modified accordingly. For example, there was considerable interest in the inclusion of chocolate which was added in equal amounts to both the low and high vegetable and fruit diets. However, the decision to use a two week menu plan which repeated 4 times was considered important to hypothesis testing and this element of experimental design was retained.

Limitations In concert with the focus group results, we decided to permit the consumption of red wine (or grape juice) on a daily basis. However, given the fact that the menu plan met or exceeded the RDA's for all nutrients, we affirmed the decision to require that participants refrain for taking vitamin and mineral supplements.

2. Development and evaluation of modified dietary intervention

a. Development of intervention materials

In order to incorporate the use of our previously developed recipes for provision in frozen form by a local grocery chain, the following process was used. The menu plan was reviewed for recipes that would be satisfactory when frozen. Our goal was to identify about one-half the food selections that could be provided to study participants in a convenience format. Once this task was successfully completed, the following approach was used for quantity food preparation:

1. Convert recipe from gram weights to cup measures
2. Resize recipes (now in cup measures) from 4 servings to 50 servings
3. Determine serving sizes for 4 calorie levels for each recipe
4. Wild Oats tests recipes at food service quantity portions (50 servings)
5. "Focus group" taste tests
6. Recipe revision, as needed (needed to adjust spices alot of times)
7. Wild Oats retesting of recipes, as needed

The cook book which is the primary intervention tool and that is specifically tailored to each individual's caloric requirements was then completely revised to reflect these changes.

b. Evaluation of the modified intervention

In order to evaluate the suitability and feasibility of the modified menu plan, 40 subjects were recruited and randomly assigned to either the low or high vegetable and fruit intervention groups. The primary goal was for study participants to identify problems in the menus and intervention approach that would inhibit their ability to follow the menu plan for a total of eight weeks.

Thirty-five subjects completed the study. The evaluation of study results is broken into the four areas that we outlined in our effort to overcome initially identified barriers.

Convenience The use of the local grocery store to provide frozen entrée's was deemed highly desirable by study participants. Subjects were able to successfully obtain all entrees on a weekly basis without significant problems. No confusion of foods between the two study groups occurred. Moreover, the grocery store personnel found that the system worked well, did not disrupt their normal activities, and the management and staff were excited to participate in the project.

Flexibility Subjects indicated that the ability to have two "free meals" a week provided adequate flexibility such that longer term adherence to the menu plan would be possible.

Choice Relative to the acceptability of food items and the variety of foods in the menus, significant and extensive feedback was obtained. The net effect of the feedback was that the cookbook still required substantial modifications. As discussed below, these modifications were implemented and evaluated in a subsequent focus group.

Limitations The ability to consume a glass of wine or grape juice was considered acceptable by the majority of study participants. It was determined that extensive discussion of the nutritional adequacy of diets addressed the majority of concerns about the use of supplements was satisfied. However, it was also determined that because of the health opinions of some individuals, that prohibition of supplement use is a key issue to discuss during subject recruitment.

c. Further modification of the intervention cookbook

Key issues that were identified were the need for modification of the recipes for the "convenience entrees", and the need for greater variation of and flexibility in the selection of foods to avoid dropout during an eight week intervention. Based on the suggestions obtained, recipes were modified and retested, and a new approach to increase flexibility was developed. In order to increase food choices, we used the principle that has been an underlying guide to vegetable and fruit selection for the menu plan, i.e. that food items from the same botanical family generally have more similar chemical composition than those in different botanical families. An exchange list for the "non grocery store supplied convenience items". For vegetable or fruit selections, subjects will given choices, but the choices are limited to items from the same botanical family. While we do lose some control over dietary composition, the evaluation of this approach was given enthusiastic support during focus group analysis.

Summary of the Dietary Intervention

Briefly the approach was:

- An exchange system based diet designed to give participants choices
- Three meals and two or more snacks per day.
- Low fat diets: 30% kcal as fat: 10:10:10
- Diets met Recommended Dietary Allowances, the Dietary Guidelines, and the USDA Food Pyramid guidelines
- Because of this, participants were asked not to use of dietary supplements during the study
- All subjects were given a cookbook defining everything to be eaten during the 8-week intervention
  - Participants were allowed 2 free meals per week
- Alcohol consumption was limited to 1 drink per day
- Food logs were maintained throughout the intervention

Nutrition Content One of the nutritional goals for the program was to make all 3 of the diets (run-in, grain, and vegetable and fruit as similar as possible in macronutrient content (protein, fat, and carbohydrates). They were also designed to meet at least 66 percent of the Recommended Dietary Allowance (RDAs) values as is suggested for research diets. In order to make the diets more convenient and flexible, exchange options and vendor-prepared meals were provided. The dietary patterns given the participants were intended to be less than 30% of calories from fat, about 55% of calories from carbohydrates and about 15% of calories from protein. Vegetables and fruits were designed to average 3 to 5 servings in the grain and run-in diets and 10 to 14 servings in the VF diet. The menus were designed to include broad botanical family diversity. However, because of the exchange list design of the experiment, that provided participants the opportunity to make specific

choices about their diets on a daily basis, it was important to determine what was actually eaten based on the food records that were maintained by each study participant.

Table 2 shows the intake of selected nutrients from food records kept by all study participants while consuming the run-in, high fruit and vegetable and/or grain diets.

Table 2		diet			
		F and V	Grain	Run In	Overall
Energy	**Mean**	1809	1705	1735	1762
% calories from fat	**Mean**	30	27	28	29
% calories from SFA	**Mean**	8	9	10	9
% calories from MUFA	**Mean**	13	10	11	12
% calories from PUFA	**Mean**	7	5	5	6
% calories from carbohydrate	**Mean**	56	55	56	55
% calories from protein	**Mean**	16	19	17	17
Total Dietary Fiber	**Mean**	34	21	19	26
Cholesterol	**Mean**	122	168	135	137
Sodium	**Mean**	2531	2511	3009	2659
Total Vitamin A Activity (Retinol Activity Equivalents)	**Mean**	1158	660	748	919
Vitamin C (ascorbic acid)	**Mean**	279	96	97	182
Total Vitamin E Activity (total alpha-tocopherol equivalents)	**Mean**	13	8	8	10
Folate	**Mean**	555	357	420	468
Calcium	**Mean**	910	915	911	912
Magnesium	**Mean**	409	335	316	365
Iron	**Mean**	17	13	15	15
Zinc	**Mean**	9	8	8	9

These data indicate that the study diets, as eaten, gave results similar to those intended based on menu design.

Table 3 shows the number of servings of fruits and vegetables consumed per day by botanical family based on food records. These data indicate that there was approximately a 2.6 fold difference between study groups in the amount of vegetable and fruit consumed (the diets as eaten). These values are somewhat lower than we had anticipated based on the recipes and menus that were given each participant.

Table 3 Average Daily Servings of Fruit & Vegetables by Botanical Family			
Botanical Family	**FV[1]**	**GR**	**RUN IN**
Compositeae	0.18899	0.13056	0.05738
Solanaceae	1.56921	0.57821	0.82672
Agaricaceae	0.05393	0.00705	0.00663
Malvaceae	0.00010	.	0.00024
Order Laminariales	0.00035	.	0.00006
Convolvulaceae	0.07673	0.00246	0.00107
Cyperaceae	0.00171	0.00075	0.00056
Euphorbiaceae	0.00018	.	.
Liliaceae	0.99490	0.42826	0.38328
Rosaceae	1.05025	0.51469	0.12088
Musaceae	0.55171	0.40555	0.02918
Anacardiaceae	0.00033	0.00046	0.00009
Ericaceae	0.01961	0.04135	0.00172
Palmae	0.00010	0.00002	0.00045
Moraceae	0.00017	.	.
Rutaceae	0.96509	0.36627	0.39943
Gramineae	0.11050	0.04702	0.00568
Vitaceae	0.14527	0.00280	0.00460
Actinidiaceae	0.05222	0.00011	0.00058
Caricaceae	0.00007	0.00008	0.00022
Ebenaceae	0.00009	.	.
Bromeliaceae	0.00223	0.00308	0.00213
Polygonaceae	0.00014	0.00015	.
Leguminosae	1.11438	0.34978	0.45208
Chenopodiaceae	0.26483	0.14022	0.14694
Cruciferae	1.28356	0.18341	0.19059
Umbelliferae	0.73919	0.32724	0.35781
Mixed	0.00350	0.00157	0.00150
Cucurbitaceae	0.10075	0.07014	0.01933

[1] The 2 intervention diets are averaged over 4 weeks; run in is averaged over 2 weeks

Table 3 Average Daily Servings of Fruit & Vegetables by Botanical Family			
Botanical Family	**FV[1]**	**GR**	**RUN IN**
Total Daily Servings	9.29	3.60	3.01
Min	0.75	0	0.02
Max	25.55	15.43	11.95
SD	3.12	1.36	1.94

Descriptive Statistics by Group

The study participants were predominantly white (95%) and well-educated(73% had at least 4 years of college). Their median age was 49 years. Nearly 40% were overweight (BMI between 25 and 30) and 22% were obese (BMI at least 30); median BMI was 26.5. There were *no significant differences* in age, BMI or self-reported daily servings of fruits and vegetables between randomization groups. A complete listing of the items from the Lifestyle Questionnaire is in Appendix A, clinical values and baseline measures of the outcome variables appear in Appendix B. Differences in categorical variables at baseline across randomization groups were tested using a chi-square test for independence of proportions. Continuous data were tested for differences in means using a two-group two-sided t-test.

Self-reported average number of daily servings of Fruits and Vegetables was slightly higher in the subjects randomized to the high fruit & vegetable arm of the study. Distribution among the stages of change was uneven, so the data were collapsed into 2 components – fewer than 5 servings daily and greater than 5 servings daily. The group difference for daily servings collapsed in this way is just significant:

Table 4

Daily Average Consumption (self-report)

Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
0 to 4	66 28.57 45.21 56.90	80 34.63 54.79 69.57	146 63.20
5 or more	50 21.65 58.82 43.10	35 15.15 41.18 30.43	85 36.80
Total	116 50.22	115 49.78	231 100.00

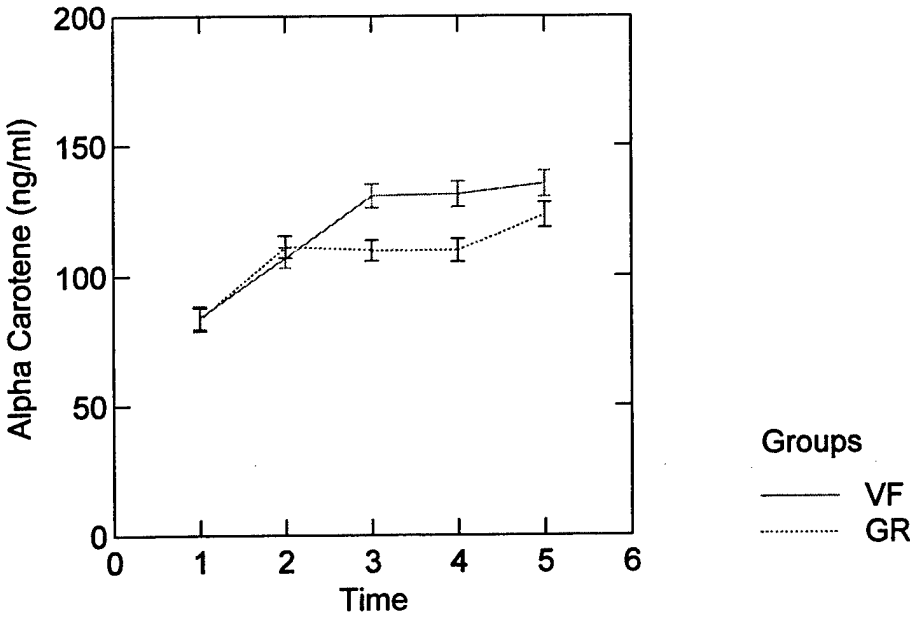
Frequency Missing = 7

Statistic	DF	Value	Prob
Likelihood Ratio Chi-Square	1	4.0012	0.0455

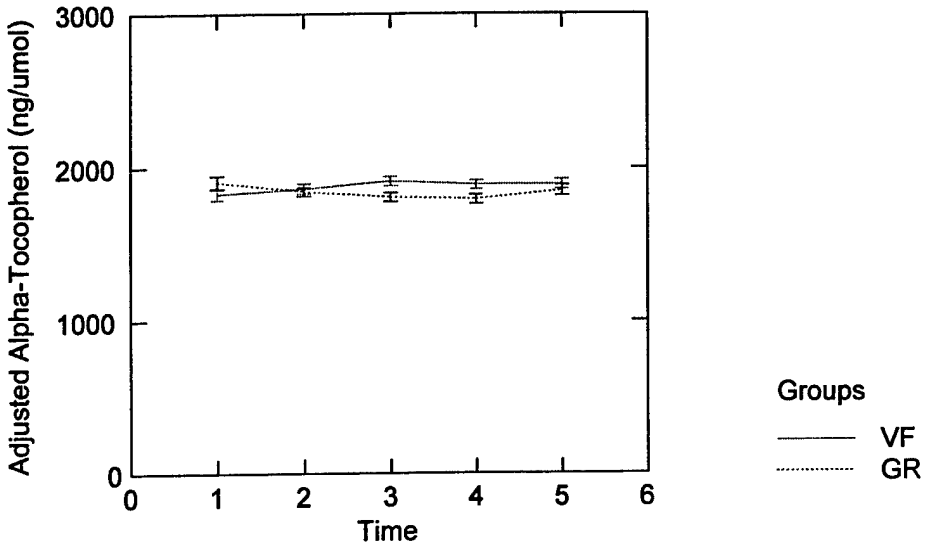
Although the mean number of self-reported servings based on the single question is not different by group, daily servings estimated by compiling the responses in the food frequency questions, which usually gives a higher estimate of daily servings, is different by group. The response to 'How Many Servings for Good Health?' is different between groups as well:

Table 5			
Mean by Group	High F&V ((N=120)	Grain (N=118)	p-value
NaDay (Single Item)	4.33	3.99	0.09
NaDay (7 item Food Frequency)	4.73	4.06	0.02
Knowledge (How many Servings for Good Health)	6.87	6.24	0.01

Compliance Self-reported compliance was 85%. Plasma alpha-carotene data also are consistent with a high level of compliance (see figure). Alpha carotene increased on the run-in diet suggesting that participants probably over estimated their intake of vegetables and fruit at baseline. Alpha carotene plateaued after 2-weeks on the high VF diet. Participants randomized to the grain diet had plasma alpha-carotene levels similar to those observed on the run-in diet. When individuals on the grain diet were crossed over to the VF diet, plasma alpha carotene increased.



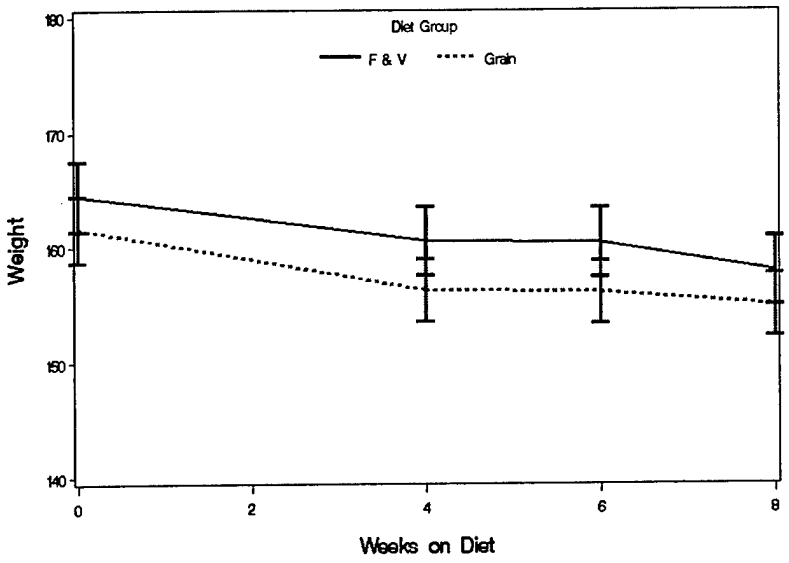
Of interest was the observation that plasma alpha tocopherol levels were unaffected by the dietary interventions.


Adjusted Alpha-Tocopherol (ng/umol)
3000
2000
1000
0
0
1
2
3
4
5
6
Time
Groups
VF
GR

Weight Loss

Weight loss was not a research objective, and in fact every effort was made to match each participants' normal caloric intake during the study. Nonetheless, it became evident that some reduction in caloric intake was inevitable, probably because many of the participants were very interested in losing weight. Only 39% of women were within the limits of normal BMI (18.5 to 25); the average weight loss over the 6 weeks on the research diets was 6.5 pounds. In this sample of the population, overweight is correlated with age and activity level, and inversely correlated with self-reported consumption of fruits and vegetables. Initial mean weight was marginally higher in the grain diet group (164.5 lb) than the F & V diet group (161.6 lb), and weight loss was not different by group.

Figure 1 WEIGHT LOSS (error bars are 1SD)



The slope between weeks 0 and 4 is –2.11 (average weight loss was 2 pounds/week) and after week 4 it is –0.98 (about a pound a week). The piecewise linear model has a knot at week 4 to allow a change in the rate of weight loss. The model has a random slope and a random intercept, and these random effects are negatively correlated. That is, women who are heavier initially tend to lose weight faster. This is not particularly surprising, and it indicates the model is reasonable. The distribution of BMI by self-reported level of activity is shown in Table 6.

Table 6				
Self-Reported Physical Activity	BMI			
Frequency Percent Row Pct Col Pct	Normal	Overweight	Obese	Total
Sedentary	1 0.53 10.00 1.41	5 2.63 50.00 6.41	4 2.11 40.00 9.76	10 5.26
Light	17 8.95 29.82 23.94	19 10.00 33.33 24.36	21 11.05 36.84 51.22	57 30.00
Moderate	40 21.05 40.40 56.34	43 22.63 43.43 55.13	16 8.42 16.16 39.02	99 52.11
Heavy	13 6.84 54.17 18.31	11 5.79 45.83 14.10	0 0.00 0.00 0.00	24 12.63
Total	71 37.37	78 41.05	41 21.58	190 100.00

Statistic	DF	Value	Prob
Likelihood Ratio Chi-Square	6	25.0807	0.0003
Mantel-Haenszel Chi-Square	1	15.6130	<.0001

Follow Up Questionnaire

The follow up questions addressed knowledge and confidence, the process of getting entrees from the two purveyors (Wild Oats for challenge 1 and 2, Spinelli's for challenge 3,4 and 5), specific biological changes that might be associated with a change in diet, and the participants' intentions to change their diet in the future. Frequencies of responses to each item are listed in appendix C.

Intervention Results

Maximum likelihood (ML) estimates of a multivariate repeated measures model using all available data was used for the analysis of the primary outcomes (levels of lymphocyte 8-OHdG and urinary 8-EPG). This approach is conceptually identical to multivariate analysis of variance (MANOVA) but avoids the case-wise deletion of subjects with missing assessments, and relaxes the assumption that missing data are missing completely at random (MCAR). The model provides unbiased estimates under the less restrictive assumption that missing data are missing at random

(MAR)[2]. Both measures were statistically significantly lower in the high fruit and vegetable group after 2 weeks on the study diets.

The ML estimates are based on a piecewise linear model with knots at 2 weeks, 4 weeks and 6 weeks to allow the slopes to change at the end of the run-in period and at crossover. The knot at 4 weeks was placed to model the possibility that the full effect of the high F & V diet would be evident after two weeks. This knot was retained in the model for 8-epg but was not significant in the model for 8-OHdG, and was therefore dropped. The fully parameterized model with 3 knots is:

$$y_{ij} = \beta_0 + \beta_1 t + \beta_2 k_1 G + \beta_3 k_1 F + \beta_4 k_2 G + \beta_5 k_2 F + \beta_6 k_3 G + \beta_7 k_3 F$$

where y_{ij} is the outcome measure for the *i*th subject in the *j*th randomization group; j={1,2}; t ={0, 1, 2, 3, 4}; k_1 ={max (0, t -1)}; k_2 ={max (0, t -2)}; k_3 ={max (0, t -3)}; F=1 if the subject is in the High F&V group, 0 otherwise; G=1 if the subject is in the whole grain group, 0 otherwise.

Table 7 Unadjusted Means

Outcome Measure	Treatment Group	Measurements at Two-Week Intervals (mean±SD)				
		Baseline	2[a]	4	6	8[b]
8EPG (ng/mg Creatinine)	F n V	0.82±0.71	0.55±0.36	0.45 ±0.24	0.46±0.23	0.43±0.19
	Grain			0.55±0.36	0.56±0.44	0.49±0.36
8OHdG (residues/ million dG)	FnV	17.50±5.60	18.91±6.84	18.06±6.15	18.14±6.23	17.03±4.59
	Grain			18.93±6.82	18.73±6.06	17.89±5.05

[a] During the first two weeks all subjects were on the Run-In diet
[b] During the last two weeks all subjects were on the high F & V diet

Both diet regimens and the run-in diet lowered 8EPG; the high F&V diet had a larger effect than the whole grain diet, and the difference in group means for 8EPG at the end of four weeks on the two diets is almost significant (p=0.08). The difference between 8-EPG levels at 6 weeks and at 2 weeks is statistically significant (p=0.0002). All subjects were on the high F & V diet for the last two weeks, and 8-EPG declined significantly in the crossover group (grain to F&V) with p=0.02. See Table 8a. The log of 8-EPG was used in the model, and the coefficients back transformed for the table; this gives a geometric mean, and the data will not match the unadjusted means in table 7.

In contrast, levels of lymphocyte 8-OHdG rose during the two-week run-in period (1.5 residues/ million dG, p=0.0003), and subsequently dropped in the High F&V diet group but not the Grain diet group. The difference in group means for 8-OHdG at the end of four weeks on the two diets is not significant (0.38, p=0.59). The crossover group showed lower 8OHdG at the end of the two-week crossover to high F& V, but the drop in the group mean between the fourth (6 weeks) and fifth (8 weeks) measures was not significant (p=0.27). See Table 8b.

[2] A missing value for an outcome measure, $Y^{(m)}$, is MCAR if its missingness is independent of the value of both missing and observed measures, $Y^{(m)}$ and $Y^{(o)}$; it is MAR if the missingness is independent of the value of the missing outcome measure, $Y^{(m)}$. When the missingness is not independent of the missing value, $Y^{(m)}$ the data are not missing at random (NMAR).

Table 8a ML Estimates for 8EPG

	Exp{ML Estimate ±SE}	*p*-value
Baseline	0.67±1.04	
Two Week Run-in	0.48±1.04	
Run in effect (2 weeks – Baseline)	0.72±1.03	<0.0001
Gr (4 weeks)	0.48±1.04	
High F&V (4 weeks)	0.42±1.04	
Gr (6 weeks)	0.47±1.04	
High F & V (6 weeks)	0.43±1.04	
Difference (Gr – F&V at 6weeks[3]	0.04±1.05	0.0758
High F&V (crossover from grain 8 weeks)	0.43±1.05	
High F&V (8Weeks)	0.41±1.04	
FV (8 weeks – 2 weeks)	0.07±1.04	0.0002
FV (crossover from grain 8 weeks-6weeks)	0.04±1.04	0.0186

Table 8b ML Estimates for 8OHdG

	ML Estimate ±SE	*p*-value
Baseline	17.43 ±0.40	
Two Week Run-in (Start)	18.94 ±0.39	
Start – Baseline	1.51 ±0.42	0.0003
Whole Grain (4 weeks)	18.73 ±0.37	
High F&V (4 weeks)	18.54 ±0.37	
Whole Grain (6 weeks)	18.53 ±0.55	
High F & V (6 weeks)	18.14 ±0.54	
Difference (Gr – F&V) at 6 weeks	-0.38 ± 0.72	0.5918
High FV (crossover from grain 8 weeks)	17.82 ±0.58	
High F&V (8 Weeks)	17.21 ±0.56	
FV (6 weeks – 2 weeks)	-1.73 ±0.56	0.0022
FV (crossover 6 weeks-4weeks)	-0.71 ±0.64	0.2674

Other Analyses

The run-in diet reduced mean 8-EPG by 33%, and after 2 weeks on the two intervention diets, mean levels were further reduced by VF, but the difference between the two diet groups was not statistically significant. Our working hypothesis for this result was that the response to the dietary intervention was dependent on the baseline level of oxidative stress. Baseline levels of 8-EPG ranged from 0.16 to 7.67 ng/ mg creatinine. The population was divided into quartiles (EPG<0.45, 0.45≤EPG<0.64, 640≤ EPG<0.94, and EPG>0.94 ng/mg creatinine) and the response of women in each quartile to the dietary interventions was assessed. A dramatic difference in response was

[3] The primary hypothesis was that the 2 diet groups would be statistically different after 4 weeks on the study diets.

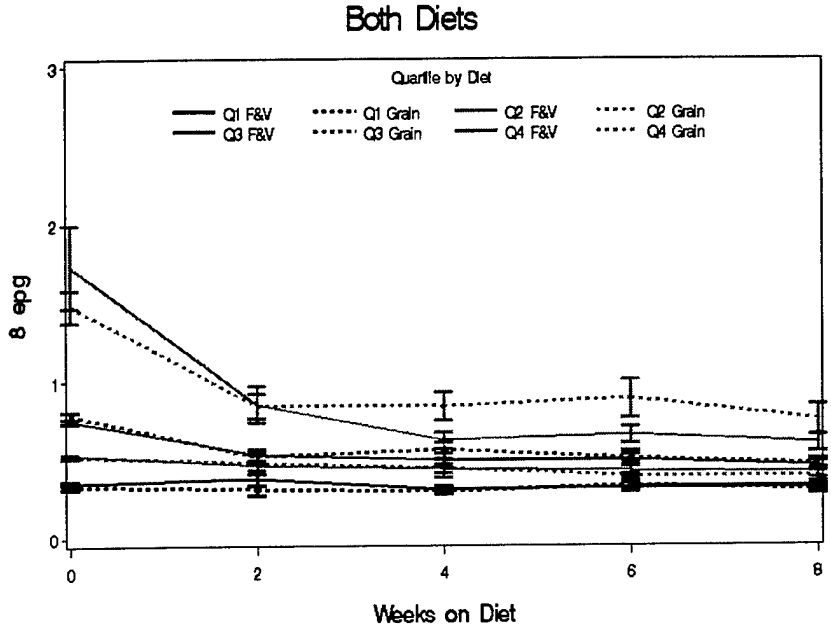
observed depending on baseline quartile of 8-EPG. See (Figure below). The greatest reductions in urinary 8-EPG were observed among individuals with the highest baseline levels of this analyte. After two weeks on the run-in diet, the mean 8-EPG in the highest quartile was reduced by 47% ($p<0.001$), and in the lowest three quartiles, only 18% ($p<=0.001$). After 2 weeks on the study diets, the difference in mean 8-EPG between diet groups in the highest quartile was 0.22 ng/mg, $p=0.03$. P-values are based on contrasts estimated in the repeated measures mixed-effects model described above,using the log transform of 8-EPG, with an additional indicator variable for baseline quartile of 8-EPG. No significant change in urinary excretion of 8-EPG was observed in individuals in the lowest quartile of baseline 8-EPG (up 3% after two weeks on the run in diet, and down by 17% and 11 % respectively in the low and high F&V intervention groups after two weeks on the study diets). The beneficial effect of the high VF diet seen after two weeks was maintained at the same levels thereafter. Interestingly, individuals in the highest baseline quartile of 8-EPG, despite experiencing dramatic reductions in the urinary excretion of this analyte, still remained higher in 8-EPG excretion than individuals in the lower three quartiles irrespective of the diets to which they were assigned throughout the 8-week intervention. This pattern is similar to that observed in a previous study where both interventions were high in fruits and vegetables but only 5 botanical families were represented in one arm of the intervention and 17 were represented in the other.

Table 9 Unadjusted Means for 8EPG by Quartile, diet, and time

Quartile	Treatment Group	Measurements at Two-Week Intervals (mean±SD)				
		Baseline	2[a]	4	6	8[b]
1st	F n V	0.34±0.07	0.35±0.21	0.31±0.13	0.32±0.18	0.33±0.16
	Grain			0.29±0.05	0.33±0.14	0.30±0.10
2nd	F n V	0.53±0.05	0.47±0.26	0.45±0.27	0.45±0.20	0.42±0.13
	Grain			0.44±0.15	0.38±0.09	0.39±0.24
3rd	F n V	0.77±0.09	0.53±0.19	0.50±0.25	0.50±09.1	0.46±0.16
	Grain			0.56±0.26	0.51±0.24	0.47±0.21
4th	F n V	1.59±1.03	0.85±0.50	0.63±0.25	0.66±0.24	0.60±0.23
	Grain			0.84±0.49	0.89±0.65	0.75±0.51

[a] During the first two weeks all subjects were on the Run-In diet
[b] During the last two weeks all subjects were on the high F & V diet

Figure 2 Change in EPG by baseline quartile of EPG
(Error Bars are 1SD)



The obvious question now is whether there are any variables in the database that will explain the dramatic differences in baseline EPG. We checked age, BMI, weight, overall weight loss, baseline servings of fruits and vegetables, any use of supplements prior to baseline, breast cancer survivor (yes/no), the ratio of alpha to gamma tocopherol in baseline plasma[4] for any relationship to baseline 8-epg and found the following significant relationships in multiple regression of log 8-epg:

Table 9 Predictors of 8-EPG level

variable	Standardized $\hat{\beta}$	SE $\hat{\beta}$	*p*-value
intercept	0	0.169	<.0001
BMI	0.216	0.006	<.0001
SUPPTOC (αTOC/γTOC)	-0.166	0.0001	0.0014
NADAY	-0.102	0.016	0.0402
Change in epg (time2-time1)	-0.627	0.069	<.0001

We also examined the medications and supplements records of the 4 subjects whose 8-EPG rose more than 1SD from their baseline value and found A: dropped out; B: multivitamin, benadryl; C: took no supplements, no medications;
D: Vitamin E, C, Magnesium, Zinc, glucosamine, Lipitor, Voltarin, Estrase, HRT.

[4] This is expected to be a more robust indicator of supplement use than self-report.

Key Research Accomplishments

- A total of 264 women completed the eligibility questionnaire, 264 completed visit 1 and began the study, and 213 completed the study.
- A menu based exchange system of diet selection can be used to increase consumption of vegetables and fruit.
- Urinary 8-EPG was significantly reduced by the dietary intervention, and the degree of reduction was greater in the vegetable and fruit versus grain intervention.
- The effect of the dietary intervention on lipid peroxidation was greatest in individuals who had high levels of lipid peroxidation at baseline.
- Urinary 8-EPG may be a useful indicator that can identify individuals the will or will not respond to a dietary antioxidant intervention
- Levels of the DNA oxidation product 8-hydroxy-2-deoxyguanosine were only marginally affected by the dietary intervention
- Carotenoid data provide evidence of excellent compliance with the research diets
- Plasma Vitamin E was not affected by the intervention
- Plasma triglycerides and cholesterol were reduced during the intervention; the levels of reduction were similar irrespective of dietary assignment

Data evaluation is ongoing.

Reportable Outcomes (cumulative)

- Cookbooks were developed and tested .
- Supporting intervention materials were developed and tested.
- An alternative method of analysis of a urinary product of DNA oxidation was identified.
- Results have been/will be reported at 2 national meetings.

Meeting Presentations/Publications

Thompson, H.J., Heimendinger, J., Sedlacek, S., Diker,A., O'Neill, C., Haegele, A., Kielman,K., Meinecke,B., Zhu,Z., and Jiang, W. Effects of fruit and vegetable intake on markers of oxidative damage to cellular macromolecules. ERA of Hope Conference, 2002.

Thompson, H.J., Heimendinger, J., Sedlacek, S., Diker,A., O'Neill, C., Haegele, A., Kielman,K., Meinecke,B., Zhu,Z., and Jiang, W. Who is likely to respond to dietary antioxidant phytochemical interventions? Frontiers in Cancer Prevention Research, AACR, 2nd Annual Meeting, October 2003.

Please note that we are just entering the stage of manuscript preparation.

Project Personnel

Henry Thompson	Becky Meinecke	Pamela Wolfe
Jerianne Heimendinger	Ann Diker	Caitlin O'Neill
Albert Haegele	Tamra Kielman	Zongjian Zhu

Conclusions The project was successfully completed. However, the process of data evaluation and manuscript preparation is likely to continue for several years.

Background References (cumulative)

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Appendix A
LifeStyle Questionnaire

The following is the questionnaire that was used.

1. What is the highest level of education you have completed?

   1 ❑ Grade school
   2 ❑ Some high school
   3 θ High school graduate
   4 θ Some college
   5 θ College graduate (4-year degree)
   6 θ Post-graduate

2. Which of these categories best describes you?

   10 ❑ Asian or Pacific Islander
   20 ❑ Black or African American
   30 ❑ Hispanic
   40 θ American Indian or Alaskan Native
   50 θ White, Non-Hispanic
   60 ❑ Other

3. Do you live with a spouse or significant other? 1 ❑ yes 2 ❑ no

4. Do you live with adults other than a spouse or significant other, not including adult children? 1 ❑ yes 2 ❑ no

5. Do you live with children under 18 years of age? 1 ❑ yes 2 ❑ no

6. Do you live with children 18 years of age or older? 1 ❑ yes 2 ❑ no

7. How much responsibility do you have for preparing meals?

   0 ❑ None
   1 ❑ Hardly any
   2 θ Some
   3 θ Most
   4 θ All

8. How many servings of fruits and vegetables do you think a person should eat each day for good health?

0 ❑ None
1 ❑ 1
2 θ 2
3 θ 3
4 ❑ 4
5 ❑ 5
6 ❑ 6
7 ❑ 7
8 ❑ 8
9 ❑ 9
10 ❑ 10
11 ❑ 11 or more

9. It is difficult to get fruits and vegetables when I eat out in restaurants.

1 ❑ Strongly Disagree
2 ❑ Disagree
3 ❑ Neither agree nor disagree
4 ❑ Agree
5 ❑ Strongly Agree

10. I don't know how to prepare fruits and vegetables.

1 ❑ Strongly Disagree
2 ❑ Disagree
3 ❑ Neither agree nor disagree
4 ❑ Agree
5 ❑ Strongly Agree

11. Over the past month, about how often did you drink 100% orange juice or grapefruit juice?

1 ❑ Never (less than once a month)
2 ❑ 1-3 times per month
3θ 1-2 times per week
4 ❑ 3-4 times per week
5 θ 5-6 times per week
6 ❑ 1 time per day
7 ❑ 2 times per day
8 ❑ 3 times per day
9 ❑ 4 times per day
10 θ 5 or more times per day

12. Over the past month, about how often did you drink 100% juice other than orange or grapefruit juices? Do not count fruit juices like Hi-C or Hawaiian Punch that are only part juice.

1 ❑ Never (less than once a month)
2 ❑ 1-3 times per month
3θ 1-2 times per week
4 ❑ 3-4 times per week
5 θ 5-6 times per week
6 ❑ 1 time per day
7 ❑ 2 times per day
8 ❑ 3 times per day
9 ❑ 4 times per day
10 θ 5 or more times per day

13. Over the past month, about how often did you eat green salad with or without other vegetables?

1 ❑ Never (less than once a month)
2 ❑ 1-3 times per month
3θ 1-2 times per week
4 ❑ 3-4 times per week
5 θ 5-6 times per week
6 ❑ 1 time per day
7 ❑ 2 times per day
8 ❑ 3 times per day
9 ❑ 4 times per day
10 θ 5 or more times per day

14. Over the past month, about how often did you eat french fries or fried potatoes?

1 ❑ Never (less than once a month)
2 ❑ 1-3 times per month
3θ 1-2 times per week
4 ❑ 3-4 times per week
5 θ 5-6 times per week
6 ❑ 1 time per day
7 ❑ 2 times per day
8 ❑ 3 times per day
9 ❑ 4 times per day
10 θ 5 or more times per day

15. Over the past month, about how often did you eat baked, boiled, or mashed potatoes?

1 ❑ Never (less than once a month)
2 ❑ 1-3 times per month
3θ 1-2 times per week
4 ❑ 3-4 times per week
5 θ 5-6 times per week
6 ❑ 1 time per day
7 ❑ 2 times per day
8 ❑ 3 times per day
9 ❑ 4 times per day
10 θ 5 or more times per day

For the following questions, a serving is defined as:

- a medium piece of fruit
- ¼ cup of dried fruit or vegetable
- ½ cup cooked or raw fruit or vegetable
- ½ cup dried peas or beans

16. Over the past month, about how many servings of vegetables did you eat not counting salad or potatoes?

1 ❑ None (less than one per month)
2 ❑ 1-3 per month
3θ 1-2 per week
4 ❑ 3-4 per week
5 θ 5-6 per week
6 ❑ 1 per day
7 ❑ 2 per day
8 ❑ 3 per day
9 ❑ 4 per day
10 θ 5 or more per day

17. Over the past month, about how many servings of fruit did you eat, not counting juices?

1 ❑ None (less than one per month)
2 ❑ 1-3 per month
3θ 1-2 per week
4 ❑ 3-4 per week
5 θ 5-6 per week
6 ❑ 1 per day
7 ❑ 2 per day
8 ❑ 3 per day
9 ❑ 4 per day
10 θ 5 or more per day

18. Over the past month, about how many servings of meat, poultry, fish, dry beans, eggs and nuts did you eat? Examples of a serving include 3 ounces of cooked meat, poultry or fish (3 ounces is about the size and thickness of a deck of cards); 1½ cup cooked dried beans; 6 tablespoons peanut butter; 3 eggs; and 1 cup nuts.

1 ❑ None (less than one per month)
2 ❑ 1-3 per month
3θ 1-2 per week
4 ❑ 3-4 per week
5 θ 5-6 per week
6 ❑ 1 per day
7 ❑ 2 per day
8 ❑ 3 per day
9 ❑ 4 per day
10 θ 5 or more per day

19. Over the past month, about how many servings of milk, yogurt and cheese did you eat? Examples of a serving include 1 cup of milk, 1 cup of yogurt, and 1½ ounces of cheese.

1 ❑ None (less than one per month)
2 ❑ 1-3 per month
3θ 1-2 per week
4 ❑ 3-4 per week
5 θ 5-6 per week
6 ❑ 1 per day
7 ❑ 2 per day
8 ❑ 3 per day
9 ❑ 4 per day
10 θ 5 or more per day

20. Over the past month, about how many servings of bread, cereal, rice and pasta did you eat? Examples of a serving include 1 slice of bread; ½ cup cooked cereal, rice, or pasta; 1 cup ready-to-eat cereal; and 1 small roll, biscuit or muffin.

1 ❑ None (less than one per month)
2 ❑ 1-3 per month
3θ 1-2 per week
4 ❑ 3-4 per week
5 θ 5-6 per week
6 ❑ 1-3 per day
7 ❑ 4-6 per day
8 ❑ 7-9 per day
9 ❑ 9-11 per day
10 θ 12 or more per day

21. How confident are you that you can include 2 servings of fruit at breakfast every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident

22. How confident are you that you can include 5 – 9 servings of fruits and vegetables in your diet every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident

23. How confident are you that you could eat more fruits and vegetables every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident
6 θ I already eat enough fruits and vegetables

24. How confident are you that you can include whole grains (brown rice, 100% whole-wheat toast) in your diet every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident

25. How confident are you that you can include leafy greens in your diet every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident

26. How much does your family encourage you to eat fruits and vegetables?

1 ❑ A great deal
2 ❑ Somewhat
3 ❑ Not much
4 ❑ Not at all
997 ❑ Not applicable

27. How much do your friends encourage you to eat fruits and vegetables?

1 ❑ A great deal
2 ❑ Somewhat
3 ❑ Not much
4 ❑ Not at all
997 ❑ Not applicable

28. Does your family plan to follow the study diet while you are participating in the study?

1 ❑ Yes 2 ❑ No 997 ❑ Not applicable

The following summarizes the questionnaire results

Table of education by group			
education	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
High School Grad	5 2.10 41.67 4.17	7 2.94 58.33 5.93	12 5.04
Some College	22 9.24 42.31 18.33	30 12.61 57.69 25.42	52 21.85
College Grad	46 19.33 55.42 38.33	37 15.55 44.58 31.36	83 34.87
Post Grad	47 19.75 51.65 39.17	44 18.49 48.35 37.29	91 38.24
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of edu by group

Statistic	DF	Value	Prob
Chi-Square	3	2.6223	0.4536
Likelihood Ratio Chi-Square	3	2.6305	0.4522
Mantel-Haenszel Chi-Square	1	1.1592	0.2816
Phi Coefficient		0.1050	
Contingency Coefficient		0.1044	
Cramer's V		0.1050	

Sample Size = 238

Table of race by group			
race	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Black	1 0.42 33.33 0.83	2 0.84 66.67 1.69	3 1.26
Hispanic	2 0.84 50.00 1.67	2 0.84 50.00 1.69	4 1.68
White(not Hisp)	115 48.32 50.88 95.83	111 46.64 49.12 94.07	226 94.96
Other	2 0.84 40.00 1.67	3 1.26 60.00 2.54	5 2.10
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of race by group

Statistic	DF	Value	Prob
Chi-Square	3	0.5874	0.8993
Likelihood Ratio Chi-Square	3	0.5951	0.8975
Mantel-Haenszel Chi-Square	1	0.0927	0.7607
Phi Coefficient		0.0497	
Contingency Coefficient		0.0496	
Cramer's V		0.0497	

WARNING: 75% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Appendix A

Table of spouse by group			
spouse(Live with Spouse)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Yes	84 35.29 50.91 70.00	81 34.03 49.09 68.64	165 69.33
No	36 15.13 49.32 30.00	37 15.55 50.68 31.36	73 30.67
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of spouse by group

Statistic	DF	Value	Prob
Chi-Square	1	0.0514	0.8206
Likelihood Ratio Chi-Square	1	0.0514	0.8206
Continuity Adj. Chi-Square	1	0.0074	0.9313
Mantel-Haenszel Chi-Square	1	0.0512	0.8209
Phi Coefficient		0.0147	
Contingency Coefficient		0.0147	
Cramer's V		0.0147	

Sample Size = 238

Table of adult by group			
adult(Live with other Adults)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Yes	8 3.36 50.00 6.67	8 3.36 50.00 6.78	16 6.72
No	112 47.06 50.45 93.33	110 46.22 49.55 93.22	222 93.28
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of adult by group

Statistic	DF	Value	Prob
Chi-Square	1	0.0012	0.9722
Likelihood Ratio Chi-Square	1	0.0012	0.9722
Continuity Adj. Chi-Square	1	0.0000	1.0000
Mantel-Haenszel Chi-Square	1	0.0012	0.9723
Phi Coefficient		-0.0023	
Contingency Coefficient		0.0023	
Cramer's V		-0.0023	

Sample Size = 238

Appendix A

Table of child by group			
child(Live with Children <18)	**group**		
Frequency **Percent** **Row Pct** **Col Pct**	**High F&V**	**Grain**	**Total**
Yes	42 17.65 51.85 35.00	39 16.39 48.15 33.05	81 34.03
No	78 32.77 49.68 65.00	79 33.19 50.32 66.95	157 65.97
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of child by group

Statistic	DF	Value	Prob
Chi-Square	1	0.1007	0.7510
Likelihood Ratio Chi-Square	1	0.1007	0.7510
Continuity Adj. Chi-Square	1	0.0326	0.8568
Mantel-Haenszel Chi-Square	1	0.1003	0.7515
Phi Coefficient		0.0206	
Contingency Coefficient		0.0206	
Cramer's V		0.0206	

Sample Size = 238

Appendix A

Table of child18 by group			
child18(Live with Children >18)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Yes	15 6.33 45.45 12.50	18 7.59 54.55 15.38	33 13.92
No	105 44.30 51.47 87.50	99 41.77 48.53 84.62	204 86.08
Total	120 50.63	117 49.37	237 100.00
Frequency Missing = 1			

Statistics for Table of child18 by group

Statistic	DF	Value	Prob
Chi-Square	1	0.4113	0.5213
Likelihood Ratio Chi-Square	1	0.4116	0.5211
Continuity Adj. Chi-Square	1	0.2058	0.6501
Mantel-Haenszel Chi-Square	1	0.4096	0.5222
Phi Coefficient		-0.0417	
Contingency Coefficient		0.0416	
Cramer's V		-0.0417	

Effective Sample Size = 237
Frequency Missing = 1

Appendix A

Table of cook by group			
cook(Responsibility for Cooking?)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Hardly Any	2 0.84 66.67 1.67	1 0.42 33.33 0.85	3 1.26
Some	12 5.04 40.00 10.00	18 7.56 60.00 15.25	30 12.61
Most	43 18.07 50.00 35.83	43 18.07 50.00 36.44	86 36.13
All	63 26.47 52.94 52.50	56 23.53 47.06 47.46	119 50.00
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of cook by group

Statistic	DF	Value	Prob
Chi-Square	3	1.9284	0.5874
Likelihood Ratio Chi-Square	3	1.9431	0.5843
Mantel-Haenszel Chi-Square	1	0.8005	0.3710
Phi Coefficient		0.0900	
Contingency Coefficient		0.0897	
Cramer's V		0.0900	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Table of conf591 by group			
Conf591(Confident 5 - 9 LSQ)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Not at All	1 0.42 100.00 0.83	0 0.00 0.00 0.00	1 0.42
Not Confident	3 1.26 30.00 2.50	7 2.94 70.00 5.93	10 4.20
Neither	8 3.36 42.11 6.67	11 4.62 57.89 9.32	19 7.98
Confident	61 25.63 53.04 50.83	54 22.69 46.96 45.76	115 48.32
Completely	47 19.75 50.54 39.17	46 19.33 49.46 38.98	93 39.08
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of conf591 by group

Statistic	DF	Value	Prob
Chi-Square	4	3.4940	0.4788
Likelihood Ratio Chi-Square	4	3.9279	0.4158
Mantel-Haenszel Chi-Square	1	0.4875	0.4850
Phi Coefficient		0.1212	
Contingency Coefficient		0.1203	
Cramer's V		0.1212	

WARNING: 30% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Table of confmore1 by group			
confmore1(Confident more F&V LSQ)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Not Confident	0 0.00 0.00 0.00	1 0.42 100.00 0.85	1 0.42
Neither	0 0.00 0.00 0.00	1 0.42 100.00 0.85	1 0.42
Confident	51 21.43 53.13 42.50	45 18.91 46.88 38.14	96 40.34
Completely	66 27.73 48.53 55.00	70 29.41 51.47 59.32	136 57.14
Enough Already	3 1.26 75.00 2.50	1 0.42 25.00 0.85	4 1.68
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of confmore1 by group

Statistic	DF	Value	Prob
Chi-Square	4	3.4761	0.4815
Likelihood Ratio Chi-Square	4	4.2952	0.3675
Mantel-Haenszel Chi-Square	1	0.0447	0.8326
Phi Coefficient		0.1209	
Contingency Coefficient		0.1200	
Cramer's V		0.1209	

WARNING: 60% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Appendix A

Table of conf2F1 by group			
conf2F1(Confident Can Include 2 Fruits at Breakfast)	**group**		
Frequency **Percent** **Row Pct** **Col Pct**	**High F&V**	**Grain**	**Total**
Not at All	2 0.84 40.00 1.67	3 1.26 60.00 2.54	5 2.10
Not Confident	1 0.42 100.00 0.83	0 0.00 0.00 0.00	1 0.42
Neither	2 0.84 28.57 1.67	5 2.10 71.43 4.24	7 2.94
Confident	51 21.43 47.22 42.50	57 23.95 52.78 48.31	108 45.38
Completely	64 26.89 54.70 53.33	53 22.27 45.30 44.92	117 49.16
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of conf2F1 by group

Statistic	DF	Value	Prob
Chi-Square	4	3.8367	0.4286
Likelihood Ratio Chi-Square	4	4.2684	0.3709
Mantel-Haenszel Chi-Square	1	1.4732	0.2248
Phi Coefficient		0.1270	
Contingency Coefficient		0.1260	
Cramer's V		0.1270	

WARNING: 60% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Appendix A

Table of confgr1 by group			
confgr1(Confident Include Whole Grains Daily)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Not at All	0 0.00 0.00 0.00	1 0.42 100.00 0.85	1 0.42
Not Confident	3 1.26 60.00 2.50	2 0.84 40.00 1.69	5 2.10
Neither	3 1.26 75.00 2.50	1 0.42 25.00 0.85	4 1.68
Confident	63 26.47 52.07 52.50	58 24.37 47.93 49.15	121 50.84
Completely	51 21.43 47.66 42.50	56 23.53 52.34 47.46	107 44.96
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of confgr1 by group

Statistic	DF	Value	Prob
Chi-Square	4	2.6236	0.6226
Likelihood Ratio Chi-Square	4	3.0577	0.5482
Mantel-Haenszel Chi-Square	1	0.4290	0.5125
Phi Coefficient		0.1050	
Contingency Coefficient		0.1044	
Cramer's V		0.1050	

WARNING: 60% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Appendix A

Table of confLG1 by group			
confLG1(Confident Include Leafy Greens Daily)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Not Confident	1 0.42 100.00 0.83	0 0.00 0.00 0.00	1 0.42
Neither	5 2.10 50.00 4.17	5 2.10 50.00 4.24	10 4.20
Confident	60 25.21 50.42 50.00	59 24.79 49.58 50.00	119 50.00
Completely	54 22.69 50.00 45.00	54 22.69 50.00 45.76	108 45.38
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of confLG1 by group

Statistic	DF	Value	Prob
Chi-Square	3	0.9917	0.8033
Likelihood Ratio Chi-Square	3	1.3779	0.7107
Mantel-Haenszel Chi-Square	1	0.0942	0.7589
Phi Coefficient		0.0645	
Contingency Coefficient		0.0644	
Cramer's V		0.0645	

WARNING: 38% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 238

Appendix A

Table of stage by group			
stage	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
PreContemplation	1 0.43 100.00 0.86	0 0.00 0.00 0.00	1 0.43
Contemplation	57 24.68 42.86 49.14	76 32.90 57.14 66.09	133 57.58
Action	8 3.46 66.67 6.90	4 1.73 33.33 3.48	12 5.19
Maintenance	50 21.65 58.82 43.10	35 15.15 41.18 30.43	85 36.80
Total	116 50.22	115 49.78	231 100.00
Frequency Missing = 7			

Statistics for Table of stage by group

Statistic	DF	Value	Prob
Chi-Square	3	7.6905	0.0529
Likelihood Ratio Chi-Square	3	8.1257	0.0435
Mantel-Haenszel Chi-Square	1	5.3587	0.0206
Phi Coefficient		0.1825	
Contingency Coefficient		0.1795	
Cramer's V		0.1825	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Effective Sample Size = 231
Frequency Missing = 7

Table of family by group			
family(Family Encourage F&V)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
A Great Deal	28 11.76 58.33 23.33	20 8.40 41.67 16.95	48 20.17
Somewhat	26 10.92 43.33 21.67	34 14.29 56.67 28.81	60 25.21
Not Much	15 6.30 38.46 12.50	24 10.08 61.54 20.34	39 16.39
Not at All	17 7.14 56.67 14.17	13 5.46 43.33 11.02	30 12.61
Not Applicable	34 14.29 55.74 28.33	27 11.34 44.26 22.88	61 25.63
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of family by group

Statistic	DF	Value	Prob
Chi-Square	4	5.7971	0.2148
Likelihood Ratio Chi-Square	4	5.8284	0.2123
Mantel-Haenszel Chi-Square	1	0.5767	0.4476
Phi Coefficient		0.1561	
Contingency Coefficient		0.1542	
Cramer's V		0.1561	

Sample Size = 238

Table of friend by group			
friend(Friends Encourage F&V)	**group**		
Frequency **Percent** **Row Pct** **Col Pct**	**High F&V**	**Grain**	**Total**
A Great Deal	10 4.20 58.82 8.33	7 2.94 41.18 5.93	17 7.14
Somewhat	29 12.18 56.86 24.17	22 9.24 43.14 18.64	51 21.43
Not Much	28 11.76 45.90 23.33	33 13.87 54.10 27.97	61 25.63
Not at All	25 10.50 43.10 20.83	33 13.87 56.90 27.97	58 24.37
Not Applicable	28 11.76 54.90 23.33	23 9.66 45.10 19.49	51 21.43
Total	120 50.42	118 49.58	238 100.00

Statistics for Table of friend by group

Statistic	DF	Value	Prob
Chi-Square	4	3.4771	0.4814
Likelihood Ratio Chi-Square	4	3.4875	0.4798
Mantel-Haenszel Chi-Square	1	0.0262	0.8715
Phi Coefficient		0.1209	
Contingency Coefficient		0.1200	
Cramer's V		0.1209	

Sample Size = 238

Appendix B

Table of famstudy by group			
famstudy(Family Will Do Study Diet?)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Yes	59 25.11 47.20 50.43	66 28.09 52.80 55.93	125 53.19
No	30 12.77 58.82 25.64	21 8.94 41.18 17.80	51 21.70
Not Applicable	28 11.91 47.46 23.93	31 13.19 52.54 26.27	59 25.11
Total	117 49.79	118 50.21	235 100.00
Frequency Missing = 3			

Statistics for Table of famstudy by group

Statistic	DF	Value	Prob
Chi-Square	2	2.1286	0.3450
Likelihood Ratio Chi-Square	2	2.1371	0.3435
Mantel-Haenszel Chi-Square	1	0.0610	0.8049
Phi Coefficient		0.0952	
Contingency Coefficient		0.0947	
Cramer's V		0.0952	

Effective Sample Size = 235
Frequency Missing = 3

Appendix B

group	N Obs	Variable	Label	N	Minimum	Mean	Median	Maximum	Std Dev
High F&V	120	naday1	F&V Svg LSQ	120	1.00	4.33	4.00	9.00	1.56
		nadayff	F&V FFQ LSQ	120	0	4.73[a]	5.00	9.00	2.16
		meat	Daily Svg Meat	120	0.07	1.71	2.00	5.00	1.07
		dairy	Daily Svg Dairy	120	0.07	1.33	1.00	4.00	0.93
		grain	Daily Svg Grain	120	0.21	1.17	1.00	2.00	0.49
		health1	Svg for Health LSQ	120	3.00	6.87[a]	6.00	11.00	2.03
Grain	118	naday1	F&V Svg LSQ	118	1.00	3.99	4.00	8.00	1.54
		nadayff	F&V FFQ LSQ	118	0	4.06[a]	4.00	13.00	2.37
		meat	Daily Svg Meat	118	0.07	1.70	2.00	5.00	1.03
		dairy	Daily Svg Dairy	118	0	1.40	1.00	5.00	0.95
		grain	Daily Svg Grain	118	0.07	1.26	1.00	5.00	0.71
		health1	Svg for Health LSQ	117	2.00	6.24[a]	6.00	11.00	1.87

[a]Difference in Group means statistically significant ($p<0.05$)

Appendix B

Lab data and clinical measures by group at baseline

GROUP	N Obs	Variable	N	Minimum	Mean	Median	Maximum	Std Dev
High F&V	135	age	104	24.0000000	48.1442308	50.0000000	69.0000000	9.8033264
		bmi	108	19.0044696	26.8440525	26.5395092	45.1627427	4.7167241
		naday	100	1.0000000	4.2300000	4.0000000	10.0000000	1.8249395
		ACAR	128	10.7000000	107.2578125	84.5500000	460.5000000	85.3882173
		ALLCAR	128	305.5000000	1050.54	956.4500000	3263.80	464.2692440
		ATOC	128	6066.40	14573.76	12223.65	47476.80	7217.21
		ATOCLIP	128	1031.71	2081.37	1845.07	5556.62	808.3243169
		BCAR	128	45.0000000	334.0882813	259.9500000	1823.00	288.6473086
		CAROTS	128	62.3000000	441.3460938	352.2500000	2276.10	358.8769484
		CHOL	128	2.9816580	5.3752907	5.2460450	8.3217480	1.0608678
		CHOLRSLT	128	1.1530000	2.0764219	2.0255000	3.2180000	0.4102108
		CRYPTO	128	16.2000000	106.9929688	86.2500000	473.6000000	70.8262676
		GTOC	128	0	1548.89	1175.20	8561.50	1437.46
		GTOCLIP	128	0	214.5989200	175.6361447	873.2602519	166.7846311
		LUTEIN	128	40.8000000	141.7125000	131.1500000	480.9000000	75.0378340
		LYCOPENE	128	99.3000000	360.4882813	355.3500000	727.5000000	124.5037068
		PLLIPIDS	128	3.7316580	7.0343705	6.6917650	17.7263500	2.1398411
		TRIG	128	0.3880000	1.6590547	1.3250000	11.8600000	1.6578528
		XANTHO	128	68.2000000	248.7054688	232.2000000	739.4000000	117.9304575
		LYOHDG	114	8.4264227	17.3630150	16.6203103	38.0828454	4.7941145
		UREPGCT	121	0.2200000	0.8171901	0.6400000	7.6700000	0.8428585
		lnepg	121	-1.5141277	-0.4279531	-0.4462871	2.0373166	0.6026311
Grain	130	age	105	24.0000000	47.1142857	47.0000000	67.0000000	10.0807454
		bmi	107	19.6350939	27.2596868	26.6157548	41.5946547	4.9015020
		naday	103	0	4.0388350	4.0000000	10.0000000	1.7485138
		ACAR	121	10.2000000	104.7545455	91.5000000	397.9000000	73.2141027
		ALLCAR	121	408.1000000	1014.34	973.9000000	2343.80	369.7491263
		ATOC	121	5697.60	14561.34	12836.50	46489.70	6496.91
		ATOCLIP	121	1161.98	2118.02	1898.97	4569.38	715.7564885
		BCAR	121	39.4000000	272.5247934	234.6000000	1044.90	177.0547167
		CAROTS	121	49.6000000	377.2793388	330.4000000	1442.80	230.1030407
		CHOL	121	2.9241100	5.2521987	5.2162600	8.4251880	0.9488798
		CHOLRSLT	121	1.1290000	2.0287355	2.0140000	3.2580000	0.3665197
		CRYPTO	121	16.7000000	105.8661157	90.5000000	472.8000000	68.8157680
		GTOC	121	0	1471.91	1171.70	7568.20	1192.50
		GTOCLIP	121	0	217.1341200	185.9574873	943.5387753	167.6695330
		LUTEIN	121	27.0000000	137.6347107	125.2000000	340.8000000	63.7560425
		LYCOPENE	121	121.8000000	393.5586777	374.6000000	798.5000000	146.4260864
		PLLIPIDS	121	3.5801100	6.8159838	6.7342600	12.7826400	1.4821596
		TRIG	121	0.4800000	1.5637851	1.3600000	4.5050000	0.8397221
		XANTHO	121	76.9000000	243.5008264	222.6000000	616.6000000	108.8867948
		LYOHDG	106	8.1072325	17.6393027	16.2731244	46.3113278	6.3702531
		UREPGCT	122	0.1600000	0.8170492	0.6450000	3.2900000	0.5489444
		lnepg	122	-1.8325815	-0.3744698	-0.4385350	1.1908876	0.5748910

Appendix B

Statistics										
Variable	GROUP	N	Lower CL Mean	Mean	Upper CL Mean	Lower CL Std Dev	Std Dev	Upper CL Std Dev	Std Err	Minimum
age	Grain	105	45.163	47.114	49.065	8.8772	10.081	11.665	0.9838	24
age	High F&V	104	46.238	48.144	50.051	8.6279	9.8033	11.352	0.9613	24
age	Diff (1-2)		-3.742	-1.03	1.6821	9.0711	9.9437	11.003	1.3757	
bmi	Grain	107	26.32	27.26	28.199	4.3212	4.9015	5.6633	0.4738	19.635
bmi	High F&V	108	25.944	26.844	27.744	4.1606	4.7167	5.4458	0.4539	19.004
bmi	Diff (1-2)		-0.878	0.4156	1.7088	4.393	4.8096	5.3141	0.656	
naday	Grain	103	3.6971	4.0388	4.3806	1.538	1.7485	2.0264	0.1723	0
naday	High F&V	100	3.8679	4.23	4.5921	1.6023	1.8249	2.12	0.1825	1
naday	Diff (1-2)		-0.686	-0.191	0.3034	1.6277	1.7866	1.9801	0.2508	
ACAR	Grain	121	91.576	104.75	117.93	65.007	73.214	83.811	6.6558	10.2
ACAR	High F&V	128	92.323	107.26	122.19	76.054	85.388	97.354	7.5473	10.7
ACAR	Diff (1-2)		-22.41	-2.503	17.402	73.254	79.706	87.414	10.106	
ALLCAR	Grain	121	947.79	1014.3	1080.9	328.3	369.75	423.27	33.614	408.1
ALLCAR	High F&V	128	969.34	1050.5	1131.7	413.52	464.27	529.33	41.036	305.5
ALLCAR	Diff (1-2)		-141.3	-36.2	68.94	386.93	421.01	461.72	53.382	
ATOC	Grain	121	13392	14561	15731	5768.6	6496.9	7437.3	590.63	5697.6
ATOC	High F&V	128	13311	14574	15836	6428.3	7217.2	8228.6	637.92	6066.4
ATOC	Diff (1-2)		-1730	-12.42	1704.9	6320.1	6876.7	7541.7	871.93	
ATOCLIP	Grain	121	1989.2	2118	2246.9	635.52	715.76	819.36	65.069	1162
ATOCLIP	High F&V	128	1940	2081.4	2222.7	719.96	808.32	921.6	71.446	1031.7
ATOCLIP	Diff (1-2)		-154.3	36.651	227.64	702.85	764.75	838.71	96.967	
BCAR	Grain	121	240.66	272.52	304.39	157.21	177.05	202.68	16.096	39.4
BCAR	High F&V	128	283.6	334.09	384.57	257.09	288.65	329.1	25.513	45
BCAR	Diff (1-2)		-121.7	-61.56	-1.383	221.47	240.98	264.28	30.554	
CAROTS	Grain	121	335.86	377.28	418.7	204.31	230.1	263.41	20.918	49.6
CAROTS	High F&V	128	378.58	441.35	504.12	319.65	358.88	409.17	31.721	62.3
CAROTS	Diff (1-2)		-139.8	-64.07	11.66	278.68	303.22	332.55	38.447	
CHOL	Grain	121	5.0814	5.2522	5.423	0.8425	0.9489	1.0862	0.0863	2.9241
CHOL	High F&V	128	5.1897	5.3753	5.5608	0.9449	1.0609	1.2095	0.0938	2.9817
CHOL	Diff (1-2)		-0.375	-0.123	0.1286	0.9264	1.008	1.1055	0.1278	
CHOLRSLT	Grain	121	1.9628	2.0287	2.0947	0.3254	0.3665	0.4196	0.0333	1.129
CHOLRSLT	High F&V	128	2.0047	2.0764	2.1482	0.3654	0.4102	0.4677	0.0363	1.153
CHOLRSLT	Diff (1-2)		-0.145	-0.048	0.0496	0.3581	0.3896	0.4273	0.0494	
CRYPTO	Grain	121	93.48	105.87	118.25	61.102	68.816	78.776	6.256	16.7
CRYPTO	High F&V	128	94.605	106.99	119.38	63.084	70.826	80.752	6.2602	16.2

Appendix B

Statistics										
Variable	GROUP	N	Lower CL Mean	Mean	Upper CL Mean	Lower CL Std Dev	Std Dev	Upper CL Std Dev	Std Err	Minimum
CRYPTO	Diff (1-2)		-18.57	-1.127	16.319	64.202	69.857	76.612	8.8575	
GTOC	Grain	121	1257.3	1471.9	1686.6	1058.8	1192.5	1365.1	108.41	0
GTOC	High F&V	128	1297.5	1548.9	1800.3	1280.3	1437.5	1638.9	127.05	0
GTOC	Diff (1-2)		-407.7	-76.98	253.7	1216.9	1324.1	1452.2	167.89	
GTOCLIP	Grain	121	186.95	217.13	247.31	148.87	167.67	191.94	15.243	0
GTOCLIP	High F&V	128	185.43	214.6	243.77	148.55	166.78	190.16	14.742	0
GTOCLIP	Diff (1-2)		-39.22	2.5352	44.295	153.68	167.22	183.39	21.202	
LUTEIN	Grain	121	126.16	137.63	149.11	56.609	63.756	72.984	5.796	27
LUTEIN	High F&V	128	128.59	141.71	154.84	66.835	75.038	85.554	6.6325	40.8
LUTEIN	Diff (1-2)		-21.51	-4.078	13.35	64.136	69.785	76.533	8.8484	
LYCOPENE	Grain	121	367.2	393.56	419.91	130.01	146.43	167.62	13.311	121.8
LYCOPENE	High F&V	128	338.71	360.49	382.26	110.89	124.5	141.95	11.005	99.3
LYCOPENE	Diff (1-2)		-0.793	33.07	66.934	124.62	135.6	148.71	17.193	
PLLIPIDS	Grain	121	6.5492	6.816	7.0828	1.316	1.4822	1.6967	0.1347	3.5801
PLLIPIDS	High F&V	128	6.6601	7.0344	7.4086	1.9059	2.1398	2.4397	0.1891	3.7317
PLLIPIDS	Diff (1-2)		-0.68	-0.218	0.2436	1.7	1.8498	2.0286	0.2345	
TRIG	Grain	121	1.4126	1.5638	1.7149	0.7456	0.8397	0.9613	0.0763	0.48
TRIG	High F&V	128	1.3691	1.6591	1.949	1.4766	1.6579	1.8902	0.1465	0.388
TRIG	Diff (1-2)		-0.426	-0.095	0.2356	1.2178	1.3251	1.4532	0.168	
XANTHO	Grain	121	223.9	243.5	263.1	96.681	108.89	124.65	9.8988	76.9
XANTHO	High F&V	128	228.08	248.71	269.33	105.04	117.93	134.46	10.424	68.2
XANTHO	Diff (1-2)		-33.58	-5.205	23.172	104.43	113.63	124.61	14.407	
LYOHDG	Grain	106	16.412	17.639	18.866	5.6129	6.3703	7.3657	0.6187	8.1072
LYOHDG	High F&V	114	16.473	17.363	18.253	4.2423	4.7941	5.5123	0.449	8.4264
LYOHDG	Diff (1-2)		-1.215	0.2763	1.7679	5.1281	5.6088	6.1897	0.7568	
UREPGCT	Grain	122	0.7187	0.817	0.9154	0.4876	0.5489	0.628	0.0497	0.16
UREPGCT	High F&V	121	0.6655	0.8172	0.9689	0.7484	0.8429	0.9649	0.0766	0.22
UREPGCT	Diff (1-2)		-0.18	-14E-5	0.1795	0.6525	0.7107	0.7803	0.0912	
lnepg	Grain	122	-0.478	-0.374	-0.271	0.5107	0.5749	0.6577	0.052	-1.833
lnepg	High F&V	121	-0.536	-0.428	-0.319	0.5351	0.6026	0.6899	0.0548	-1.514
lnepg	Diff (1-2)		-0.095	0.0535	0.2023	0.5407	0.5889	0.6466	0.0756	

Statistics		
Variable	GROUP	Maximum
age	Grain	67

Appendix B

Statistics		
Variable	**GROUP**	**Maximum**
age	**High F&V**	69
age	**Diff (1-2)**	
bmi	**Grain**	41.595
bmi	**High F&V**	45.163
bmi	**Diff (1-2)**	
naday	**Grain**	10
naday	**High F&V**	10
naday	**Diff (1-2)**	
ACAR	**Grain**	397.9
ACAR	**High F&V**	460.5
ACAR	**Diff (1-2)**	
ALLCAR	**Grain**	2343.8
ALLCAR	**High F&V**	3263.8
ALLCAR	**Diff (1-2)**	
ATOC	**Grain**	46490
ATOC	**High F&V**	47477
ATOC	**Diff (1-2)**	
ATOCLIP	**Grain**	4569.4
ATOCLIP	**High F&V**	5556.6
ATOCLIP	**Diff (1-2)**	
BCAR	**Grain**	1044.9
BCAR	**High F&V**	1823
BCAR	**Diff (1-2)**	
CAROTS	**Grain**	1442.8
CAROTS	**High F&V**	2276.1
CAROTS	**Diff (1-2)**	
CHOL	**Grain**	8.4252
CHOL	**High F&V**	8.3217
CHOL	**Diff (1-2)**	
CHOLRSLT	**Grain**	3.258
CHOLRSLT	**High F&V**	3.218

Appendix B

Statistics		
Variable	**GROUP**	**Maximum**
CHOLRSLT	**Diff (1-2)**	
CRYPTO	**Grain**	472.8
CRYPTO	**High F&V**	473.6
CRYPTO	**Diff (1-2)**	
GTOC	**Grain**	7568.2
GTOC	**High F&V**	8561.5
GTOC	**Diff (1-2)**	
GTOCLIP	**Grain**	943.54
GTOCLIP	**High F&V**	873.26
GTOCLIP	**Diff (1-2)**	
LUTEIN	**Grain**	340.8
LUTEIN	**High F&V**	480.9
LUTEIN	**Diff (1-2)**	
LYCOPENE	**Grain**	798.5
LYCOPENE	**High F&V**	727.5
LYCOPENE	**Diff (1-2)**	
PLLIPIDS	**Grain**	12.783
PLLIPIDS	**High F&V**	17.726
PLLIPIDS	**Diff (1-2)**	
TRIG	**Grain**	4.505
TRIG	**High F&V**	11.86
TRIG	**Diff (1-2)**	
XANTHO	**Grain**	616.6
XANTHO	**High F&V**	739.4
XANTHO	**Diff (1-2)**	
LYOHDG	**Grain**	46.311
LYOHDG	**High F&V**	38.083
LYOHDG	**Diff (1-2)**	
UREPGCT	**Grain**	3.29
UREPGCT	**High F&V**	7.67
UREPGCT	**Diff (1-2)**	

Appendix B

Statistics		
Variable	**GROUP**	**Maximum**
lnepg	**Grain**	1.1909
lnepg	**High F&V**	2.0373
lnepg	**Diff (1-2)**	

T-Tests

These results depend on whether the assumption of equal variances holds. SAS does the test both ways, and then produces the test for equality of variances. If the p-value is <0.05, the appropriate p-value for the t-test is the Satterthwaite adjusted value (unequal) otherwise it is the pooled value (equal). The test for equality of variance follows this t-test table.

Variable	Method	Variances	DF	t Value	Pr > |t|
age	**Pooled**	Equal	207	-0.75	0.4549
age	**Satterthwaite**	Unequal	207	-0.75	0.4548
bmi	**Pooled**	Equal	213	0.63	0.5270
bmi	**Satterthwaite**	Unequal	213	0.63	0.5271
naday	**Pooled**	Equal	201	-0.76	0.4468
naday	**Satterthwaite**	Unequal	200	-0.76	0.4471
ACAR	**Pooled**	Equal	247	-0.25	0.8046
ACAR	**Satterthwaite**	Unequal	245	-0.25	0.8038
ALLCAR	**Pooled**	Equal	247	-0.68	0.4983
ALLCAR	**Satterthwaite**	Unequal	240	-0.68	0.4956
ATOC	**Pooled**	Equal	247	-0.01	0.9886
ATOC	**Satterthwaite**	Unequal	246	-0.01	0.9886
ATOCLIP	**Pooled**	Equal	247	0.38	0.7058
ATOCLIP	**Satterthwaite**	Unequal	246	0.38	0.7048
BCAR	**Pooled**	Equal	247	-2.01	0.0450
BCAR	**Satterthwaite**	Unequal	213	-2.04	0.0425
CAROTS	**Pooled**	Equal	247	-1.67	0.0969
CAROTS	**Satterthwaite**	Unequal	218	-1.69	0.0932
CHOL	**Pooled**	Equal	247	-0.96	0.3365
CHOL	**Satterthwaite**	Unequal	246	-0.97	0.3349
CHOLRSLT	**Pooled**	Equal	247	-0.97	0.3353
CHOLRSLT	**Satterthwaite**	Unequal	246	-0.97	0.3338
CRYPTO	**Pooled**	Equal	247	-0.13	0.8989
CRYPTO	**Satterthwaite**	Unequal	247	-0.13	0.8988
GTOC	**Pooled**	Equal	247	-0.46	0.6470
GTOC	**Satterthwaite**	Unequal	243	-0.46	0.6453

T-Tests These results depend on whether the assumption of equal variances holds. SAS does the test both ways, and then produces the test for equality of variances. If the p-value is <0.05, the appropriate p-value for the t-test is the Satterthwaite adjusted value (unequal) otherwise it is the pooled value (eqnal). The test for equality of variance follows this t-test table.					
Variable	**Method**	**Variances**	**DF**	**t Value**	**Pr > |t|**
GTOCLIP	**Pooled**	Equal	247	0.12	0.9049
GTOCLIP	**Satterthwaite**	Unequal	246	0.12	0.9049
LUTEIN	**Pooled**	Equal	247	-0.46	0.6453
LUTEIN	**Satterthwaite**	Unequal	244	-0.46	0.6438
LYCOPENE	**Pooled**	Equal	247	1.92	0.0556
LYCOPENE	**Satterthwaite**	Unequal	236	1.91	0.0567
PLLIPIDS	**Pooled**	Equal	247	-0.93	0.3527
PLLIPIDS	**Satterthwaite**	Unequal	227	-0.94	0.3480
TRIG	**Pooled**	Equal	247	-0.57	0.5712
TRIG	**Satterthwaite**	Unequal	190	-0.58	0.5649
XANTHO	**Pooled**	Equal	247	-0.36	0.7182
XANTHO	**Satterthwaite**	Unequal	247	-0.36	0.7176
LYOHDG	**Pooled**	Equal	218	0.37	0.7154
LYOHDG	**Satterthwaite**	Unequal	195	0.36	0.7182
UREPGCT	**Pooled**	Equal	241	-0.00	0.9988
UREPGCT	**Satterthwaite**	Unequal	206	-0.00	0.9988
lnepg	**Pooled**	Equal	241	0.71	0.4797
lnepg	**Satterthwaite**	Unequal	240	0.71	0.4798

Test for Equality of Variances					
Variable	**Method**	**Num DF**	**Den DF**	**F Value**	**Pr > F**
age	**Folded F**	104	103	1.06	0.7773
bmi	**Folded F**	106	107	1.08	0.6922
naday	**Folded F**	99	102	1.09	0.6681
ACAR	**Folded F**	127	120	1.36	0.0896
ALLCAR	**Folded F**	127	120	1.58	0.0122
ATOC	**Folded F**	127	120	1.23	0.2454
ATOCLIP	**Folded F**	127	120	1.28	0.1791
BCAR	**Folded F**	127	120	2.66	<.0001
CAROTS	**Folded F**	127	120	2.43	<.0001
CHOL	**Folded F**	127	120	1.25	0.2178
CHOLRSLT	**Folded F**	127	120	1.25	0.2134

Test for Equality of Variances					
Variable	Method	Num DF	Den DF	F Value	Pr > F
CRYPTO	Folded F	127	120	1.06	0.7509
GTOC	Folded F	127	120	1.45	0.0394
GTOCLIP	Folded F	120	127	1.01	0.9519
LUTEIN	Folded F	127	120	1.39	0.0722
LYCOPENE	Folded F	120	127	1.38	0.0721
PLLIPIDS	Folded F	127	120	2.08	<.0001
TRIG	Folded F	127	120	3.90	<.0001
XANTHO	Folded F	127	120	1.17	0.3779
LYOHDG	Folded F	105	113	1.77	0.0032
UREPGCT	Folded F	120	121	2.36	<.0001
lnepg	Folded F	120	121	1.10	0.6056

Appendix C Followup Questionnaire

Please feel free to make additional comments on any question.

1. How many servings of fruits and vegetables do you think a person should eat each day for good health?

0	❑	None	6	❑	6
1	❑	1	7	❑	7
2	θ	2	8	❑	8
3	θ	3	9	❑	9
4	❑	4	10	❑	10
5	❑	5	11	❑	11 or more

For questions 2 and 3, a serving is defined as:

- a medium piece of fruit
- ¼ cup of dried fruit or vegetable
- ½ cup cooked or raw fruit or vegetable
- ½ cup dried peas or beans
- 1 cup leafy greens

2. How confident are you that you can include 2 servings of fruit at breakfast every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident

3. How confident are you that you can include 5 – 9 servings of fruits and vegetables in your diet every day?

1 ❑ Not at all confident
2 ❑ Not confident
3θ Neither
4 ❑ Confident
5 ❑ Completely confident

4. How confident are you that you could eat more fruits and vegetables every day?

1 ❑ Not at all confident
2 ❑ Not confident
3 θ Neither
4 ❑ Confident
5 ❑ Completely confident
6 θ I already eat enough fruits and vegetables

5. How confident are you that you can include whole grains (brown rice, 100% whole-wheat toast) in your diet every day?

1 ❑ Not at all confident
2 ❑ Not confident
3 θ Neither
4 ❑ Confident
5 ❑ Completely confident

6. How confident are you that you can include leafy greens in your diet every day?

1 ❑ Not at all confident
2 ❑ Not confident
3 θ Neither
4 ❑ Confident
5 ❑ Completely confident

7. Within your daily routine, how convenient was it to go to Wild Oats to pick up your entrees?

1 ❑ Very inconvenient
2 ❑ Inconvenient
3 θ Neither
4 ❑ Convenient
5 ❑ Very convenient

8. Once you were at the Wild Oats deli, how easy was the pick-up procedure?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

9. How well did the Wild Oats entrees reheat?

1 ❑ Very poorly
2 ❑ Poorly
3 θ Neither
4 ❑ Well
5 ❑ Very well

10.How well did the Wild Oats packaging (containers, lids) remain intact?

1 ❑ Very poorly
2 ❑ Poorly
3 θ Neither
4 ❑ Well
5 ❑ Very well

11. How easy was it for you to store the food from Wild Oats in your freezer/refrigerator?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

12. How easy was it for you to store the food purchased at the grocery store?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

13. Did you go out of town during the study?

1 ❑ Yes
2 ❑ No (go to question 14)

13a. Did you follow the diet or substitute foods while you were out of town?

1 ❑ Followed the diet (answer question 13b, then skip to question 14)
2 ❑ Substituted foods (skip to question 13c)
3 θ Both

13b. How easy was it to follow the diet while you were out of town?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

13c. Did you receive assistance in making substitutions to your diet from the study staff while you were out of town?

1 ❑ Yes
2 ❑ No

13d. How easy was it to make substitutions to your diet while you were out of town?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

14. Did you attend a special event (e.g. wedding, play, banquet) during the study?

1 ❑ Yes
2 ❑ No (go to question 15)

14a. Did you follow the diet or substitute foods when you attended the special event?

1 ❑ Followed the diet (answer question 14b, then skip to question 15)
2 ❑ Substituted foods (skip to question 14c)
3θ Both

14b. How easy was it to follow the diet when you attended the special event?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

14c. Did you receive assistance in making substitutions to your diet from the study staff when you attended the special event?

1 ❑ Yes
2 ❑ No

14d. How easy was it to make substitutions to your diet when you attended the special event?

1 ❑ Very difficult
2 ❑ Difficult
3 θ Neither
4 ❑ Easy
5 ❑ Very easy

15. Could you stay on the intervention diet for 8 weeks?

1 ❑ No
2 ❑ Yes

If you answered no to question 15, what changes could we make that would help you stay on the intervention diet for 8 weeks?

16. If you were allowed 2 non-study meals each week and allowed 1 alcoholic beverage per day could you stay on the intervention diet for 8 weeks?

1 ❑ No
2 ❑ Yes

17. Would holidays falling during the 8 week study prevent you from wanting to participate?

1 ❑ No
2 ❑ Yes

If you answered yes to question 17, which holidays in particular would prevent you from participating?

18. On a scale of 1 to 5, with 1 being "very unlikely" and 5 being "very likely", please indicate how likely you would be to follow the diet for 8 weeks if it included the following foods:

Eggs:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Waffles:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pancakes:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Beef:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Luncheon Meats:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Desserts:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Chocolate/Candy:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Alcohol:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑

Please comment on any additional foods that would help you to follow the diet for 8 weeks:

19. Please tell us things you liked and disliked about the first meeting on March 18.

20. Please tell us what would make the intervention easier for you to follow.

21. Overall, please tell us what you liked about this study.

22. Overall, please tell us what you disliked about this study.

23. Do you plan to make any changes in your dietary habits as a result of participating in this study?

1 ❑ No
2 ❑ Yes

If you answered yes to question 23, what do you plan to do?

If you were in Group A, answer questions 24 and 25. If you were in Group B, answer questions 26 and 27.

24. On a scale of 1 to 5, with 1 being "disliked very much" and 5 being "liked very much", please indicate how you liked the following foods prepared by Wild Oats:

Lycopene Soup:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Broccoli-Mushroom Pasta:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Tofu-Parsley Dressing:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Springtime Vegetable Stew:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Orange-Glazed Sweet Potatoes:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Cauliflower Linguine:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Orange-Poppy Seed Dressing:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Lentil Stew:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Garlic Vegetable Stir Fry:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Vegetarian Chili:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pasta and Beans with Basil:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Mexican Stew:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Steamed Carrot, Cauliflower and Apricots:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑

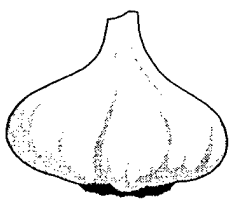
Comments: _____

25.On a scale of 1 to 5, with 1 being "disliked very much" and 5 being "liked very much", please indicate how you liked the following recipes from the cookbook:

Wilted Spinach Pasta Peanut Salad:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Banana-Orange Smoothie:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Teriyaki Chicken:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pasta and Broccoli Salad:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Banana-Raspberry Smoothie:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pepper Crusted Tuna:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Blueberry-Strawberry Smoothie:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Spinach Salad with Mandarin Orange:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Cantaloupe-Banana Smoothie:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Shrimp-Avocado Salad:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Broccoli and Cauliflower Baked Potato:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Cottage Cheese Salad:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Cucumber-Green Pepper Salad:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Tuna Salad Sandwich:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑

Comments: _____

Thank you!



26. On a scale of 1 to 5, with 1 being "disliked very much" and 5 being "liked very much", please indicate how you liked the following foods prepared by Wild Oats:

Lycopene Soup:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Tofu-Broccoli Stir Fry:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pasta with Herb-Cheese Sauce:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Carrots with Cauliflower:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pasta with White Bean Sauce:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Risotto de Napoli:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Macaroni and Cheese a la Moutarde:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Cajun Rice and Red Beans:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑

Comments: _____

27.On a scale of 1 to 5, with 1 being "disliked very much" and 5 being "liked very much", please indicate how you liked the following recipes from the cookbook:

Teriyaki Chicken:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Avocado-Pasta Shrimp Salad:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Broiled Salmon:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Roasted Quesadilla Ole:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Pepper Crusted Tuna:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Spaghetti:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑
Tuna Salad Sandwich:	1 ❑	2 ❑	3 θ	4 ❑	5 ❑

Comments: _____

Thank you!

Results of the questionnaire responses

Confident 5 - 9 FQ				
conf592	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	1	0.52	1	0.52
Not Confident	14	7.33	15	7.85
Neither	10	5.24	25	13.09
Confident	110	57.59	135	70.68
Completely	56	29.32	191	100.00

Confident can eat more F&V FQ				
confmore2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	1	0.53	1	0.53
Not Confident	5	2.63	6	3.16
Neither	5	2.63	11	5.79
Confident	72	37.89	83	43.68
Completely	91	47.89	174	91.58
Enough Already	16	8.42	190	100.00

Frequency Missing = 1

Confident Can Include 2 Fruits at Breakfast FQ				
conf2F2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	2	1.05	2	1.05
Not Confident	9	4.71	11	5.76
Neither	3	1.57	14	7.33
Confident	89	46.60	103	53.93
Completely	88	46.07	191	100.00

Appendix C

Confident Include Leafy Greens Daily FQ				
confLG2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	1	0.52	1	0.52
Not Confident	10	5.24	11	5.76
Neither	7	3.66	18	9.42
Confident	94	49.21	112	58.64
Completely	79	41.36	191	100.00

Confident Include Whole Grains Daily FQ				
confgr2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not Confident	2	1.05	2	1.05
Neither	8	4.19	10	5.24
Confident	82	42.93	92	48.17
Completely	99	51.83	191	100.00

Compliance Self-report				
compSR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
3	1	0.53	1	0.53
4	1	0.53	2	1.05
5	1	0.53	3	1.58
6	2	1.05	5	2.63
7	20	10.53	25	13.16
8	62	32.63	87	45.79
9	82	43.16	169	88.95
10	21	11.05	190	100.00

Frequency Missing = 1

Appendix C

Physical Activity				
phyact	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Sedentary	10	5.29	10	5.29
Light	57	30.16	67	35.45
Moderate	98	51.85	165	87.30
Heavy	24	12.70	189	100.00

Frequency Missing = 2

Notable change in diarrhea				
diar	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	148	77.49	148	77.49
Yes	43	22.51	191	100.00

Notable change in constipation				
constip	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	150	78.53	150	78.53
Yes	41	21.47	191	100.00

Notable change in flatulence				
flat	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	66	34.55	66	34.55
Yes	125	65.45	191	100.00

Notable change in digestive discomfort				
dige	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	138	72.25	138	72.25
Yes	53	27.75	191	100.00

Appendix C

Notable change in headaches				
head	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	168	87.96	168	87.96
Yes	23	12.04	191	100.00

How convenient to go to Wild Oats?				
WOPICKUP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Inconvenient	2	3.08	2	3.08
Inconvenient	15	23.08	17	26.15
Neither	19	29.23	36	55.38
Convenient	19	29.23	55	84.62
Very Convenient	10	15.38	65	100.00

Frequency Missing = 126

How easy was the pick up procedure?				
WOPROCED	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Difficult	1	1.56	1	1.56
Difficult	1	1.56	2	3.13
Neither	2	3.13	4	6.25
Easy	29	45.31	33	51.56
Very Easy	31	48.44	64	100.00

Frequency Missing = 127

How well did the Wild Oats entrees reheat?				
WOREHEAT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Poorly	3	4.69	3	4.69
Poorly	8	12.50	11	17.19
Neither	10	15.63	21	32.81
Well	28	43.75	49	76.56
Very WEll	15	23.44	64	100.00

Frequency Missing = 127

How well did the Wild Oats packaging remain intact?				
WOPACK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Poorly	4	6.15	4	6.15
Neither	8	12.31	12	18.46
Well	33	50.77	45	69.23
Very WEll	20	30.77	65	100.00

Frequency Missing = 126

How was storing the food from Wild Oats?				
WOSTORE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Difficult	5	7.69	5	7.69
Neither	6	9.23	11	16.92
Easy	20	30.77	31	47.69
Very Easy	34	52.31	65	100.00

Frequency Missing = 126

Appendix C

Continue to use WildOats (1 & 2)?				
WildOats	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	16	29.09	16	29.09
Yes	39	70.91	55	100.00

Frequency Missing = 136

How convenient to go to Spinellis?				
SPPICKUP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Inconvenient	8	6.35	8	6.35
Inconvenient	34	26.98	42	33.33
Neither	25	19.84	67	53.17
Convenient	42	33.33	109	86.51
Very Convenient	17	13.49	126	100.00

Frequency Missing = 65

How easy was the pick up procedure?				
SPPROCEED	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Difficult	1	0.81	1	0.81
Neither	1	0.81	2	1.61
Easy	22	17.74	24	19.35
Very Easy	100	80.65	124	100.00

Frequency Missing = 67

Appendix C

How well did the Spinellis entrees reheat?				
SPREHEAT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Poorly	1	0.79	1	0.79
Poorly	13	10.32	14	11.11
Neither	13	10.32	27	21.43
Well	63	50.00	90	71.43
Very WEll	36	28.57	126	100.00

Frequency Missing = 65

How well did the Spinellis packaging remain intact?				
SPPACK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Poorly	3	2.38	3	2.38
Poorly	18	14.29	21	16.67
Neither	3	2.38	24	19.05
Well	43	34.13	67	53.17
Very WEll	59	46.83	126	100.00

Frequency Missing = 65

How was storing the food from Spinellis?				
SPSTORE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Difficult	1	0.79	1	0.79
Difficult	7	5.56	8	6.35
Neither	4	3.17	12	9.52
Easy	46	36.51	58	46.03
Very Easy	68	53.97	126	100.00

Frequency Missing = 65

Appendix C

Continue to use Spinellis (3,4,5)?				
spinell	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	12	10.00	12	10.00
Yes	108	90.00	120	100.00

Frequency Missing = 71

How easy to store food from grocery store?				
FOODPUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Difficult	17	8.95	17	8.95
Neither	15	7.89	32	16.84
Easy	93	48.95	125	65.79
Very Easy	65	34.21	190	100.00

Frequency Missing = 1

Did you go out of town during the study?				
OUTTOWN	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	94	49.47	94	49.47
No	96	50.53	190	100.00

Frequency Missing = 1

Did you follow the diet while out of town?				
SUBORFOL	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Followed	37	38.95	37	38.95
Substituted	16	16.84	53	55.79
Both	42	44.21	95	100.00

Frequency Missing = 96

How easy to follow diet while out of town?				
EASFOL	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Difficult	11	12.94	11	12.94
Difficult	39	45.88	50	58.82
Neither	10	11.76	60	70.59
Easy	19	22.35	79	92.94
Very Easy	6	7.06	85	100.00

Frequency Missing = 106

Assistance in making substitutions to diet from study staff?				
OOTASSIT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	29	35.37	29	35.37
No	53	64.63	82	100.00

Frequency Missing = 109

How easy to make substitutions while out of town?				
EASSUB	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Difficult	5	6.85	5	6.85
Difficult	23	31.51	28	38.36
Neither	17	23.29	45	61.64
Easy	24	32.88	69	94.52
Very Easy	4	5.48	73	100.00

Frequency Missing = 118

Did you ttend a special event during the study?				
SPECEVEN	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	104	55.61	104	55.61
No	83	44.39	187	100.00

Frequency Missing = 4

Did you follow the diet at the special event?				
SUBFOLEVT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Followed	24	23.53	24	23.53
Substituted	46	45.10	70	68.63
Both	32	31.37	102	100.00

Frequency Missing = 89

How easy was it to follow the diet at the special event?				
SEFOL	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Difficult	15	18.52	15	18.52
Difficult	30	37.04	45	55.56
Neither	13	16.05	58	71.60
Easy	20	24.69	78	96.30
Very Easy	3	3.70	81	100.00

Frequency Missing = 110

Assistance in making substitutions for the special event?				
SEASSIST	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	16	17.39	16	17.39
No	76	82.61	92	100.00

Frequency Missing = 99

How easy to make substitutions at the special event?				
SESUB	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Very Difficult	8	9.41	8	9.41
Difficult	21	24.71	29	34.12
Neither	26	30.59	55	64.71
Easy	26	30.59	81	95.29
Very Easy	4	4.71	85	100.00

Frequency Missing = 106

Will Change Diet Due to Participation?				
CHANGE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	2	1.05	2	1.05
Yes	188	98.95	190	100.00

Frequency Missing = 1

Interest in Weight Loss Presentation				
WEIGHT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	4	2.35	4	2.35
2	2	1.18	6	3.53
3	12	7.06	18	10.59
4	32	18.82	50	29.41
Very Much	120	70.59	170	100.00

Frequency Missing = 21

Interest in Soy Presentation				
SOY	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	4	2.31	4	2.31
2	9	5.20	13	7.51
3	25	14.45	38	21.97
4	35	20.23	73	42.20
Very Much	100	57.80	173	100.00

Frequency Missing = 18

Interest in Dietary Guidelines Presentation				
DIETGUIDE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	2	1.12	2	1.12
2	3	1.69	5	2.81
3	25	14.04	30	16.85
4	30	16.85	60	33.71
Very Much	118	66.29	178	100.00

Frequency Missing = 13

Interest in Transition to Real Life Presentation				
transition	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Not at All	1	0.75	1	0.75
2	2	1.49	3	2.24
3	11	8.21	14	10.45
4	25	18.66	39	29.10
Very Much	95	70.90	134	100.00

Frequency Missing = 57

The SAS System

Table of phyact by group			
phyact(Physical Activity)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
Sedentary	5 2.65 50.00 5.32	5 2.65 50.00 5.26	10 5.29
Light	29 15.34 50.88 30.85	28 14.81 49.12 29.47	57 30.16
Moderate	45 23.81 45.92 47.87	53 28.04 54.08 55.79	98 51.85
Heavy	15 7.94 62.50 15.96	9 4.76 37.50 9.47	24 12.70
Total	94 49.74	95 50.26	189 100.00
Frequency Missing = 2			

Statistics for Table of phyact by group

Statistic	DF	Value	Prob
Chi-Square	3	2.1654	0.5388
Likelihood Ratio Chi-Square	3	2.1821	0.5355
Mantel-Haenszel Chi-Square	1	0.2088	0.6477
Phi Coefficient		0.1070	
Contingency Coefficient		0.1064	
Cramer's V		0.1070	

Effective Sample Size = 189
Frequency Missing = 2

Table of diar by group			
diar(Notable change in diarrhea)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
No	68	80	148
	35.60	41.88	77.49
	45.95	54.05	
	72.34	82.47	
Yes	26	17	43
	13.61	8.90	22.51
	60.47	39.53	
	27.66	17.53	
Total	94	97	191
	49.21	50.79	100.00

Statistics for Table of diar by group

Statistic	DF	Value	Prob
Chi-Square	1	2.8103	0.0937
Likelihood Ratio Chi-Square	1	2.8246	0.0928
Continuity Adj. Chi-Square	1	2.2594	0.1328
Mantel-Haenszel Chi-Square	1	2.7956	0.0945
Phi Coefficient		-0.1213	
Contingency Coefficient		0.1204	
Cramer's V		-0.1213	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	68
Left-sided Pr <= F	0.0662
Right-sided Pr >= F	0.9681
Table Probability (P)	0.0343
Two-sided Pr <= P	0.1189

Sample Size = 191

Table of constip by group			
constip(Notable change in constipation)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
No	78 40.84 52.00 82.98	72 37.70 48.00 74.23	150 78.53
Yes	16 8.38 39.02 17.02	25 13.09 60.98 25.77	41 21.47
Total	94 49.21	97 50.79	191 100.00

Statistics for Table of constip by group

Statistic	DF	Value	Prob
Chi-Square	1	2.1690	0.1408
Likelihood Ratio Chi-Square	1	2.1847	0.1394
Continuity Adj. Chi-Square	1	1.6809	0.1948
Mantel-Haenszel Chi-Square	1	2.1577	0.1419
Phi Coefficient		0.1066	
Contingency Coefficient		0.1060	
Cramer's V		0.1066	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	78
Left-sided Pr <= F	0.9509
Right-sided Pr >= F	0.0972
Table Probability (P)	0.0480
Two-sided Pr <= P	0.1607

Sample Size = 191

Table of flat by group			
flat(Notable change in flatulence)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
No	38 19.90 57.58 40.43	28 14.66 42.42 28.87	66 34.55
Yes	56 29.32 44.80 59.57	69 36.13 55.20 71.13	125 65.45
Total	94 49.21	97 50.79	191 100.00

Statistics for Table of flat by group

Statistic	DF	Value	Prob
Chi-Square	1	2.8207	0.0931
Likelihood Ratio Chi-Square	1	2.8283	0.0926
Continuity Adj. Chi-Square	1	2.3327	0.1267
Mantel-Haenszel Chi-Square	1	2.8060	0.0939
Phi Coefficient		0.1215	
Contingency Coefficient		0.1206	
Cramer's V		0.1215	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	38
Left-sided Pr <= F	0.9667
Right-sided Pr >= F	0.0632
Table Probability (P)	0.0299
Two-sided Pr <= P	0.0973

Sample Size = 191

Table of dige by group			
dige(Notable change in digestive discomfort)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
No	65	73	138
	34.03	38.22	72.25
	47.10	52.90	
	69.15	75.26	
Yes	29	24	53
	15.18	12.57	27.75
	54.72	45.28	
	30.85	24.74	
Total	94	97	191
	49.21	50.79	100.00

Statistics for Table of dige by group

Statistic	DF	Value	Prob
Chi-Square	1	0.8886	0.3459
Likelihood Ratio Chi-Square	1	0.8893	0.3457
Continuity Adj. Chi-Square	1	0.6100	0.4348
Mantel-Haenszel Chi-Square	1	0.8839	0.3471
Phi Coefficient		-0.0682	
Contingency Coefficient		0.0680	
Cramer's V		-0.0682	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	65
Left-sided Pr <= F	0.2174
Right-sided Pr >= F	0.8653
Table Probability (P)	0.0827
Two-sided Pr <= P	0.4194

Sample Size = 191

Table of head by group			
head(Notable change in headaches)	group		
Frequency Percent Row Pct Col Pct	High F&V	Grain	Total
No	80 41.88 47.62 85.11	88 46.07 52.38 90.72	168 87.96
Yes	14 7.33 60.87 14.89	9 4.71 39.13 9.28	23 12.04
Total	94 49.21	97 50.79	191 100.00

Statistics for Table of head by group

Statistic	DF	Value	Prob
Chi-Square	1	1.4211	0.2332
Likelihood Ratio Chi-Square	1	1.4297	0.2318
Continuity Adj. Chi-Square	1	0.9404	0.3322
Mantel-Haenszel Chi-Square	1	1.4137	0.2344
Phi Coefficient		-0.0863	
Contingency Coefficient		0.0859	
Cramer's V		-0.0863	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	80
Left-sided Pr <= F	0.1662
Right-sided Pr >= F	0.9218
Table Probability (P)	0.0880
Two-sided Pr <= P	0.2707

Sample Size = 191

group	N Obs	Variable	Label	N	Minimum	Mean	Median	Maximum	Std Dev
High F&V	94	compSR health2	Compliance Self-report	94	4.0000000	8.4574468	9.0000000	10.0000000	1.0017715
			Know Svg FQ	93	2.0000000	8.0215054	8.0000000	11.0000000	2.1109368
Grain	97	compSR health2	Compliance Self-report	96	3.0000000	8.4687500	9.0000000	10.0000000	1.0755965
			Know Svg FQ	96	2.0000000	6.8645833	6.0000000	11.0000000	1.8042044