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Dietary adherence to whole grain and refined grain rich diets in a randomized controlled trial

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Thesis

**DIETARY ADHERENCE TO WHOLE GRAIN AND REFINED GRAIN RICH
DIETS IN A RANDOMIZED CONTROLLED TRIAL**

by

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B.S., Northeastern University, 2013

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**DIETARY ADHERENCE TO WHOLE GRAIN AND REFINED GRAIN RICH
DIETS IN A RANDOMIZED CONTROLLED TRIAL**

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ABSTRACT

Dietary adherence is the degree to which participants follow prescribed dietary protocol. Without measuring adherence, it is not possible to validly measure the effect of the intervention. Assessing adherence allows the investigator to better determine whether the results are due to the diet itself. The overall goal of the analyses presented in this thesis was to assess if dietary adherence was higher on a whole grain versus refined grain provided food protocol with specific prescription for calorie consumption.

Eighty-two men and women between the ages of 40-65 were assigned to either a refined or whole grain feeding protocol, using a 3-day rotating menu for 6 weeks. Daily food logs were used to assess adherence to the prescribed diets and calculate total energy consumed and macronutrient content.

The first objective was to determine the caloric and macronutrient content of the assigned diets, and to compare whether the reported nutrient content was the same as the provided nutrient content. Overall, the median whole grain group consumption was 45.0 kcal per day more than they were assigned to, and the median refined grain group consumption was 10.5 kcal per day less than assignment. The refined grain diet's macronutrient composition was 52.1% carbohydrate, 19.9% protein, and 28.1% fat, whereas the whole grain group's macronutrient composition was 54.4% carbohydrate, 18.0% protein, and 27.6% fat. Both diets were within the average daily macronutrient

recommendations of 50-55% carbohydrate, 15-20% protein, and 25-30% fat. There was a statistically significant difference in the percentage of carbohydrate and protein between groups.

The second objective was to determine if two different diets had any effect on deviation from the protocol. Overall, there was an 8.9 kcal/day difference in deviation between the two groups throughout the study. When stratifying by diet level, there was no consistent pattern of deviations from the assigned protocol. On the 2000 kcal diet, those in the refined grain group consumed 184.5 kcals/day more than those in the whole grain group. In contrast on the 2500 kcal diet, the whole grain group consumed 105.0 kcal/day more than the refined grain group, while on the 3000 kcal/day diet, those in the refined grain group consumed slightly more kcals/day on average (12.5kcal/day) than the whole grain group.

The study found no consistent difference in caloric consumption between the whole and refined grain groups, as well as no consistent difference in deviations from the assigned diet protocol. These results imply that dietary adherence can be achieved in a provided food whole grains study.

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LIST OF ABBREVIATIONS

BMI.....	Body Mass Index
CM	Centimeter
D.....	Day
G.....	Gram
KCAL.....	Kilocalorie
KG.....	Kilogram
M.....	Meter
NDS	Nutrition Data System
SD	Standard Deviation
VS	Versus

INTRODUCTION

Dietary Adherence

Adherence is defined as “the degree to which a patient’s behaviors coincide with the recommendations of healthcare providers” and in a scientific study, it is the degree to which the subject adheres to the assigned study protocol. Without a measure of adherence how does one know if the estimated effect is due to the intervention itself? Poor adherence may mask the actual effect of the intervention being tested.¹ Although many measures of adherence have been studied, whether it be food records or the measure of a biomarker through serum, there is no gold standard for measuring adherence¹⁻³ or what constitutes adequate or poor levels of adherence.¹

When a feeding study is carried out, there has to be a way to measure if the person is consuming the provided food. Having participants stay in the clinic for the whole study is expensive, thus necessitating self-reports of the intervention, in this case dietary records. Self-reports are cost efficient, easy to follow, and direct, but they rely on memory, tend to underestimate or lead to intentional misreporting to give the appearance of adherence. Biomarkers, which are a measured substance from an organism that may indicate the presence of state or condition, are not always indicative of what is being measured. Plasma Alkylresorcinols have a correlation with whole grain and fiber intake, but are not a direct indicator of whole grain consumption.⁴ With there being no gold standard, it is suggested that multiple measures are used to assess adherences, ie. self-

report data and a measure of a biomarker associated with the outcome, in this case plasma alkylresorcinols.⁵⁻⁶ There is also no measurement to validate adherence against.⁷⁻⁸

Adherence Difficulties in Research

Adherence may be difficult for many reasons, but it is thought the three most difficult instances are in which a behavior has to be altered, when non-adherence does not have extreme consequences (ie RCT for cancer treatment versus calcium study), and when the motivation for the study is financial gain. Age and gender do not consistently affect adherence.⁹⁻¹² With these issues there are many reasons why non-adherence is common, ranging from lack of determination¹³ or support or motivation¹⁴. Participants could also misinterpret or forget the instructions that are provided, simply just ignore the protocol that they are to follow, or join just for financial gain from the study.¹⁵ A participant's uncertainty or lack of knowledge about an intervention may increase the drop out rates in a trial due to inability to adhere to protocol requirements.¹⁶

Food has certain social, cultural, and religious meanings that may be hard to overcome when adhering to a protocol. Social change in most cases is slow, and may act as a barrier to the person to overcome. Due to this issue dietary adherence will be harder to follow than other types of interventions, such as taking a vitamin supplement daily. Along with social change there are perceptions that may hinder adherence. The perceptions they may form can be their own or from outside sources, such as social media, pop culture, or the news.² These perceptions may cause judgment of the diet and lead to food added or subtracted. In clinical trials participants may give the healthy

response and “adhere” to everything they are prescribed to.¹⁷ Suggestions to improve dietary adherence, prevent perceptions, and giving healthy responses include education provided to the individuals, this education will convey the importance that adherence has in regards to the research.² Education combined with motivation is key for optimum adherence. In the end, multiple methods for measuring adherence should be used rather than less to capture the true consumption of the participants.^{9,13,18-22}

Whole Grains

Whole grains or foods containing whole grains contain the entire grain seed and the naturally occurring nutrients of that grain seed. Americans should be consuming 6 servings of grains per day of which half of these sources should be whole grains. Less than 10% of the population meets the recommendation by the USDA. The main sources of whole grains come from whole grain breads and breakfast cereals. Consumption of whole grains is linked to a high socioeconomic status.²³ Whole grains provide dietary fiber, resistant starch, minerals, and vitamins that are missing in refined grains.²⁴ Most of these nutrients are found in the bran and the germ, which are removed when grains are refined.^{22,25} Fiber, resistant starch, and the vitamins and minerals have the ability to be beneficial in regards to weight, glucose homeostasis, and body composition.²⁶⁻²⁷

Whole grain diets have been shown to decrease cardiovascular diseases, type 2 diabetes, cancers, and all-cause mortality.^{24,28} There has been an inverse relationship between whole grains and cardiovascular diseases in epidemiological studies.²³ The reduced risk of cardiovascular diseases is thought to be due to the fiber content of whole

grains compared with refined grains.^{30,31} Cross-sectional studies have shown an inverse association between whole grains and waist circumference, and cohort studies have shown that whole grain consumption reduces obesity risk in individuals.^{28,31-34}

Previous studies have not shown a significant difference in weight loss with the consumption of whole grains vs refined grains.³⁵ The lack of strict dietary control in these studies of whole versus refined grain may explain the null results. Therefore studies are needed to address this issue.^{29,36-37} Katcher et al examined the effect of whole grains on weight loss but found only a 1 kg weight loss overall. This low weight loss may have been due to the participants in the whole-grain group increasing their caloric intake to consume their recommended number of whole-grain servings or to the fact that they ate refined grains in addition to the recommended number of whole-grain servings. Thus, subjects may be adding whole grains to their diets rather than substituting whole grains for refined grains. In fact, many studies have added whole grains rather than substituting whole grains for refined grain sources.^{36,38} As a result, a carefully controlled intervention was needed to prevent this from occurring.

Without assessing compliance, it is difficult to assess the internal validity of a study. Looking at adherence is insightful in regards to this study because of the design. Most whole grain feeding studies have participants add whole grains into their diet, instead of having them on a strict provided food controlled diet. The study aims to determine whether the previous mentioned issues arise when all food is provided or whether providing foods is a better design for a whole grain diet study.

Study Objectives

The overall goal of this thesis is to assess dietary adherence to a provided food protocol consisting of whole grains or refined grains. Specifically, I calculated calorie and nutrient content of provided food regimens, and compared actual intakes with the prescribed intakes by adjusting total intake for provided foods not consumed and foods that were consumed in addition to what was provided. I compared the caloric and nutrient intake of the provided food regimen with actual consumption. Further, I evaluated whether the diet randomization arm had an effect on deviation from protocol. I hypothesized that the refined grain group would not adhere as tightly to the protocol as the whole grain group due to the lower fiber content of the refined grain diet.

METHODS

Subjects and Recruitment

The goal of the parent study for these analyses was to determine if healthy adults consuming diets rich in whole grains vs. diets rich in refined grains have improved markers of immune, digestive, and cardiovascular health, energy metabolism, and body composition. For that study, 103 generally healthy men and postmenopausal women, ages 40 to 65 years, were enrolled and 82 completed the trial. Participants were included who had a body mass index (BMI) between 20 kg/m² and 35 kg/m². Exclusion criteria included the following: smoking or using nicotine containing products over the past 6 months, weight change greater than 4 kg or participation in a weight loss program during the past 3 months, weight loss surgery, medication interfering with energy metabolism, not willing to discontinue dietary supplementation, and not willing to reduce fiber intake prior to enrollment to the national average. The participants were recruited by the Jean Mayer Human Nutrition Research Center on Aging at Tufts University and provided written consent prior to participation and IRB approval.

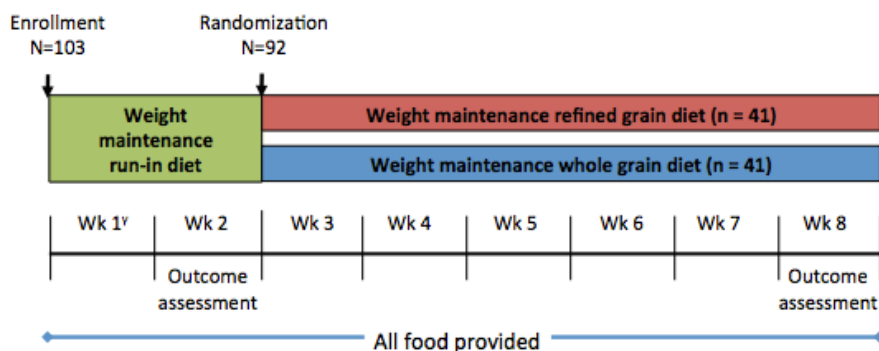
Study Design

The study was an 8-week randomized controlled, single-blind, clinical trial. Throughout the study all food was provided to the participants. They were instructed to consume all provided food, and not to consume food from outside sources. Daily food logs were used to track dietary adherence. Food logs were distributed to participants when they receive their food.

Prior to randomization, all eligible participants were asked to complete a 2-week run-in period during which they consumed a 3-day rotating diet, which contained no whole grains: the diet was used as a run-in period, as well as a way to determine energy requirements in order to ensure that the amount of food provided matched energy requirements for weight maintenance. The run-in period also helped to eliminate anyone that might lose motivation or interest in the study prior to randomization, which can help to increase adherence to the intervention. Diet was assessed with daily food logs similar to the intervention food logs. After two weeks, 92 participants were randomized to either a whole grain diet or a refined grain diet for a 40-day period.

Figure 1. The study design is shown below; 103 participants were eligible for enrollment. Of the 103, 92 participants completed the weight maintenance run-in diet and were randomized, and 82 completed the intervention after being randomized.

Figure 1. Study Design



^{*}Compliance measurements include:
 - food intake log (daily)
 - body weight (3x/wk)

Diet Composition

After the run in period the participants (n=92) were randomized to either a whole grain or refined grain diet for the 6 week intervention stage of the study. The study dietitian assigned participants to one of three calorie levels: 2000 kcal, 2500 kcal, or 3000 kcal on a 3-day rotating menu diet, based on their weight maintenance energy requirements. The diet composition for the two diets was as follows: (a) 70 g of whole grains/1000 kcal/day (menu average=83.5 g of whole grains/1000 kcal/day) and 16 g fiber/1000kcal/day for the whole grain group and (b) 0 g of whole grains/1000kcal/day and 8g fiber/1000kcal/day for the refined grain group. The whole grain diet did contain some refined grains in it, whereas the refined grain diet contained no whole grain sources. The differentiation in the diets was achieved by replacing refined grain sources with similar whole grain sources (i.e. whole grain pasta for refined grain pasta). The macronutrient composition goals were the same for both diets, at 50-55% of calories from carbohydrate, 15-20% of calories from protein, and 25-30% of calories from fat.

Dietary Assessment

Participants are expected to completely adhere to the prescribed diet, and were told not to eat any other food besides the food provided. Their daily consumption was tracked via daily food log (see figure 2). The participants were trained by the study dietitian on how to record the provided food, and how to measure left over portions. The record consisted of the foods provided to them, and a checklist in which they reported

whether they ate all, some, or none of the food provided. If participants ate any part of the items provided they were told to write the portion size next to the checklist. There was also a section for added foods and the portion size of the added foods, if they consumed outside food sources.

Figure 2. Daily Food Log

2720 Meal Check List: ID _____ **Date** _____
 Please indicate what you ATE from the HNRC Metabolic Nutrition Laboratory by completing the following table. Please eat all foods given to you for the study. Remember to return this form to the study staff for in person review. Thank you for your cooperation.

Breakfast								
Diet Tech Initials	Food Item	Food item Amount	How much of this food did you eat? (check one box)					Description of remainder food
			0	1/4	1/2	3/4	All	

Lunch & Snack								
Diet Tech Initials	Food Item	Food Item Amount	How much of this food did you eat? (check one box)					Description of remainder food
			0	1/4	1/2	3/4	All	

Dinner								
Diet Tech Initials	Food Item	Food Item Amount	How much of this food did you eat? (check one box)					Description of remainder food
			0	1/4	1/2	3/4	All	

Please list any other foods you ate today (what, amount, when, why)

Reviewed with (staff initials): _____

Statistical Analysis

Analyses were performed using Statistical Analysis Systems (SAS) software, version 9.4 (SAS Institute, Cary, NC, USA). Normality was assessed via the Shapiro-Wilk test with the cut off for normality being $p < .05$. When normality was met, t-tests were used to compare between groups, if one or both did not meet it, the Wilcoxon test was used for comparison between groups. Wilcoxon rank sum 2-tailed tests were used when comparing between group differences for total calories, weight change, change in fiber, percentage of carbohydrates, and difference in calories between the 2500kcal group (the other groups were analyzed with t-tests). The rest of the tests used a 2-tailed independent t-test due to the normality of the data, assessed by the Shapiro Wilk test. Spearman correlation was used to assess any association between weight change and average daily caloric deviation. A p-value of less than 0.05 was considered statistically significant for t-tests and the Wilcoxon rank sum test.

RESULTS

Table 1. Baseline Characteristics

	Whole Grains		Refined Grains		p-value
	N=41		N=41		
	Mean	SD	Mean	SD	
Age (years)	56.7	6.2	54.9	4.9	.148
BMI (kg/m ²)	25.7	3.9	26.0	3.2	.729
Height (cm)	170.5	9.6	170.8	8.9	.878
Weight (kg)	74.7	12.4	75.9	11.6	.654
Weight Change (kg)	-0.1	1.7	-0.4	1.9	.593
Female n [%]	17 [41.5]		16 [39.0]		

Forty-one participants per grain group completed the study. The whole grain group was 41.5% female (n=17), with an average age of 56.7 years (SD=6.2 years). The refined grain group was 39.0% female (n=16), and was on average 1.8 years younger at 54.9 years (sd=4.9 years). There was no significant difference between the two groups in regard to age (p=.15). The whole grain group had a mean height of 170.5 cm and mean weight of 74.7 kg, and a BMI of 25.7kg/m² compared with the refined grain group which had a mean height of 170.8 cm, mean weight of 75.9kg, and a BMI of 26.5 kg/m². There was no difference between the two groups as far as BMI (p=.73), height (p=.88), and weight (p=.65). Throughout the 40 days of the intervention there was no statistically significant difference in weight change between the groups. The whole grain group lost 0.1kg compared to 0.4kg for the refined grain group (p=.59).

Table 2. Diet Composition

Diet Profile					
	Whole Grains		Refined Grains		
	N=41		N=41		
	Mean	SD	Mean	SD	p-value
Carbohydrate (%)	54.4	1.6	52.1	1.7	0.0001
Protein (%)	18.0	0.9	19.9	1.1	0.0001
Fat (%)	27.6	1.5	28.1	1.2	0.13
Fiber (g/1000kcal/d)	15.7	1.3	8.2	1.1	0.0001
Fiber (g/d)	39.9	4.8	20.7	3.5	0.0001
Whole Grains (g)/1000kcal/d	81.1	9.7	0	0	0.0001

The average percentage of calories from each macronutrient was determined from daily dietary logs. Both groups were within the prescribed ranges for dietary percentages for each macronutrient. The whole grain group on average consumed 54.4% (sd=1.6) of calories from carbohydrate, 18.0% (sd =0.9) of calories from protein, and 27.6% (sd=1.5) of calories from fat. The refined grain group consumed 52.1% (sd=1.7) of calories from carbohydrate, 19.9% (sd=1.1) of calories from protein, and 28.1% (sd=1.2) of calories from fat. The percentage of calories from fat was similar in both groups, with the refined group consuming 0.5% more calories from fat (p-value=0.13). There was a statistically significant difference in percentage of calories from carbohydrates and from protein between the groups. The whole grain group consumed 2.3% more calories from carbohydrate (p-value= 0.0001), whereas the refined grain group consumed 1.9% more calories from protein (p-value= 0.0001). The fiber intake was different between the groups, with the refined grain group consuming 19.2 g/d less than the whole grain group,

(p-value =0.0001). Actual fiber consumption was similar to assignment of 8g/1000kcal/day at 8.2 g/1000kcal/day for the refined grain group and the assignment of 16g/1000kcal/day at 15.7 g/1000kcal/day for the whole grain group. The whole grain group on average consumed 81.1g of whole grains per 1000kcal daily, compared to 0g of whole grains per 1000kcal daily for those in the refined grain group.

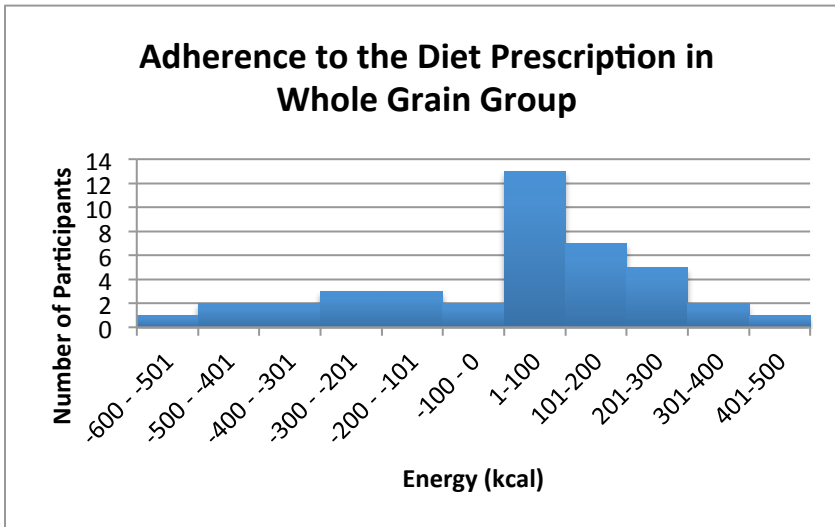
Table 3. Adherence to the Diet Prescription

	Whole Grain				Refined Grain			
	Mean	SD	Median	Range	Mean	SD	Median	Range
Difference in Calories # (kcal/day)	17.6	231.8	45	-506, 476	26.5	268.0	-10.5	-450, 835
Difference in Fiber (g/day)	-0.1	6.5	-0.6	-8.4, 6.4	0.5	2.64	0.8	-7.9, 5.4

Calculated as the difference between average daily consumption and the prescribed diet

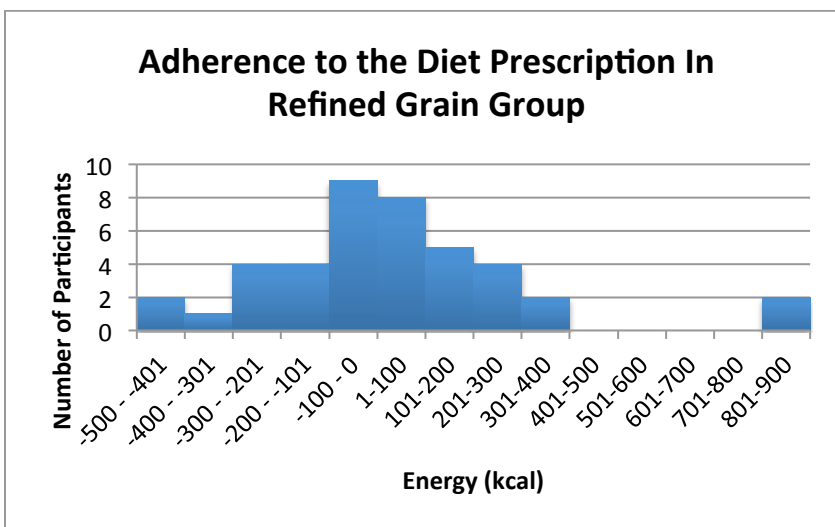
Both the groups consumed more calories than were assigned. Neither of the average daily differences were significantly different from 0 (p=.63) for whole and p=.53 for refined). There was no significant difference between the two groups as far as deviation from assignment (p=.53). The whole grain group consumed 17.6 kcals/day more than assigned, compared to the refined grain group who consumed 26.5 kcal/day more than the study dietitian assigned them to, an 8.9 kcal/day difference in deviation between the two groups. The whole grain group overall consumed 0.1 g less of fiber than they were prescribed to, whereas the refined grain group overall consumed 0.5 g of fiber per day more than prescribed. There was a significant difference between the two groups in regards to fiber deviation from the protocol (p=.01).

Figure 3. Adherence to the Diet Prescription in Whole Grain Group (kcal/day)



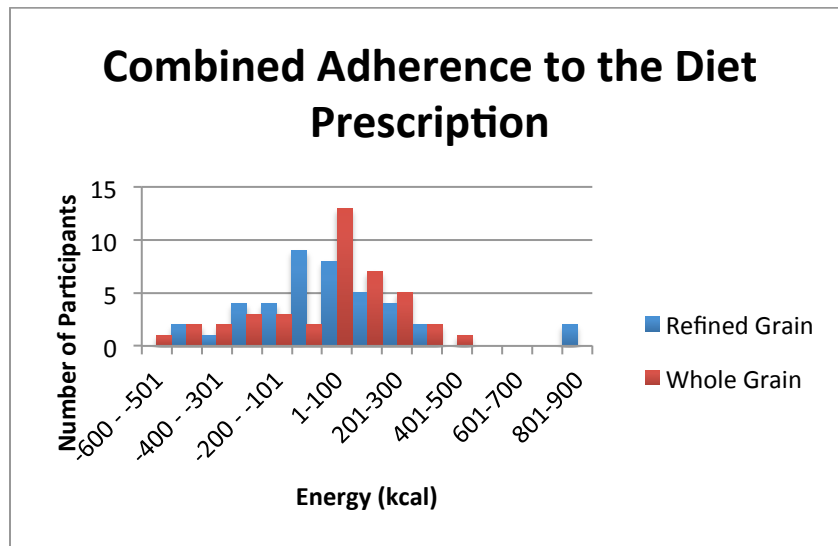
15 of the 41 of the whole grain participants consumed with-in 100 kcal/day of what they were assigned to. The difference ranged from 506kcal/day less than assigned to 476 kcal/day more.

Figure 4. Adherence to the Diet Prescription in Refined Grain Group (kcal/day)



17 participants in the refined grain group were within 100 kcal/day of their assigned daily values. There was a greater spread in the data evidenced by two participants eating an excess of 800 kcal/day.

Figure 5. Combined Calorie Difference of both groups (kcal/day)



Deviation from energy assignment was not normally distributed. However, the right skewed distribution of the refined grains group was due to two extreme outliers who consumed 800 kcals/day more than their assigned diet. The distribution of intake in the whole grains group was slightly left skewed.

Table 4. Difference in Prescribed vs. Actual Calorie Consumption, Stratifying by Calorie Assignment Level

Diet Assignment	Whole Grains					Refined Grains					p-value
	N	Mean	SD	Median	Range	N	Mean	SD	Median	Range	
2000 kcal	6	82.3	155.4	74.5	-154, 269	6	275.5	320.5	259.0	-98, 835	0.213
2500 kcal	25	22.0	228.8	45.0	-506, 476	27	-38.9	264.9	-60.0	-450, 831	0.144
3000 kcal	10	-32.1	283.0	46.5	-482, 384	8	60.3	74.6	59.0	-48, 149	0.344

The deviation from protocol was not different between groups overall. Stratification into the three-calorie levels for each diet was performed and differences in calorie intake between the groups at all three levels were compared. The whole grain group at 2000 kcal level consumed 2082.3 kcal/day, which was 82.3 kcal/day more than assignment. The median diet deviation, from 2000 kcal in the whole grain group, was 74.5 kcal/day. In comparison, the refined grain group ate 193.2 kcal/day (p=0.21) more on average than the whole grain group (median difference of 184.5 kcal/day). In the 2500 kcal group assignment, the whole grain group consumed on average 22.0 kcal/day more than they were assigned, compared with the refined grain group who consumed an average of 38.9 kcal/day less than assigned. The median deviation for both groups was within 25 kcal/day of the mean. There was no significant difference between the two 2500 kcal groups (p=.144). The 3000 kcal group had no significant difference between groups in regards to deviation from the protocol. (p=.344). The whole grain group consumed 32.1 kcal/day less than protocol, whereas the refined grain group consumed 60.3 kcal /day more than protocol.

Figure 6. Energy Intake and Weight Change in participants in the Refined Grains group.

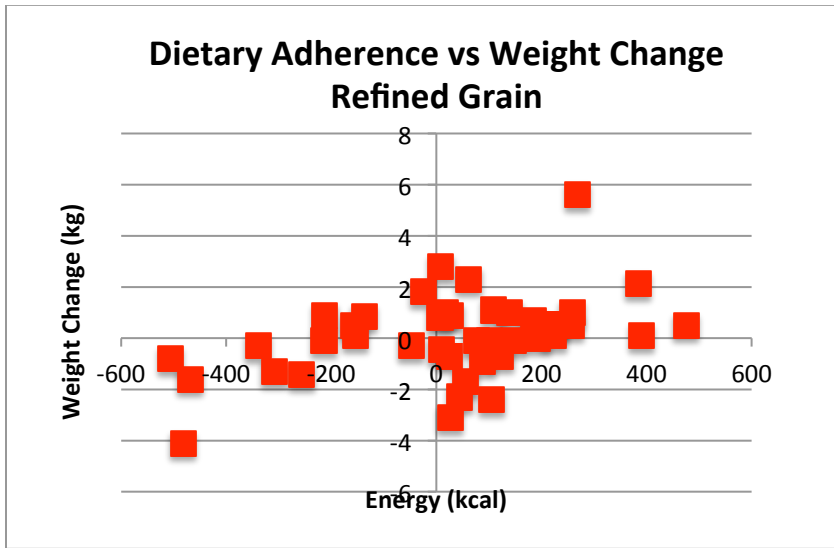


Figure 7. Energy Intake and Weight Change in participants in the Whole Grains group.

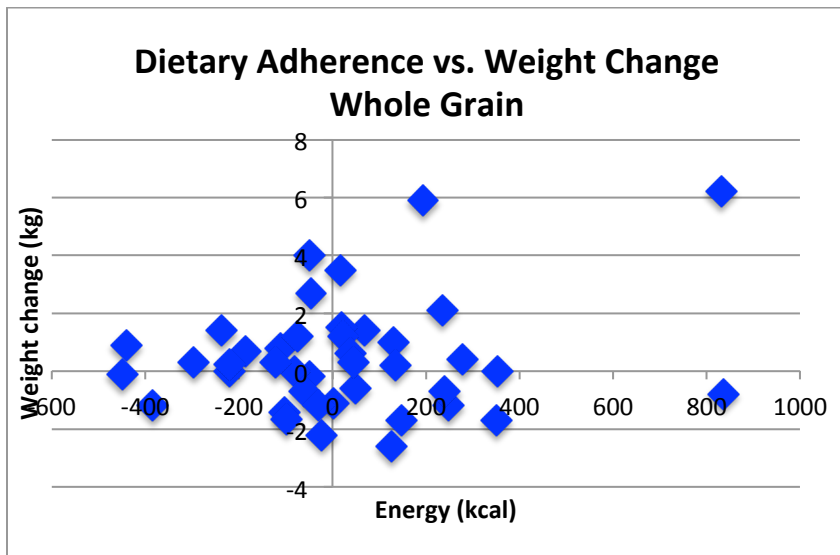
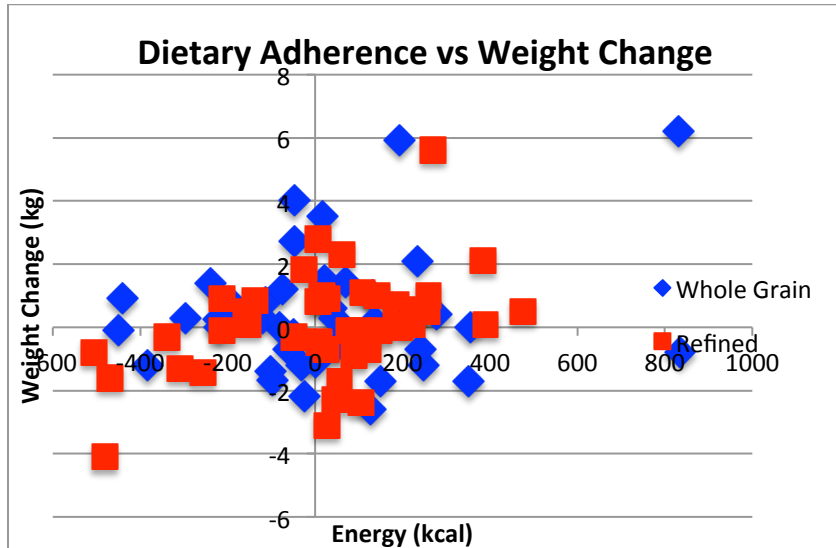


Figure 8. Combined Effects of Energy Intake on Weight



The deviation from prescribed calories versus weight change for the refined grains group is shown in Figure 6 and whole Grains group in Figure 7. There was no statistically significant correlation between the whole grain group's average daily calorie difference and weight change ($r=.001$ $p=.99$) or when combining the whole and refined grain participants ($r=.16$ $p=.14$). However, there was a modest correlation ($r=.36$ $p=.02$) between the refined grain group's average daily caloric difference and weight change throughout the study. The whole grain group lost 0.1kg (median of 0.71 kg weight loss) compared to 0.4kg for the refined grain group (median of 0.28 kg weight gain).

DISCUSSION

The study provided all foods to be consumed as part of a whole grain versus refined grains protocol. I evaluated whether there were any systematic differences in dietary adherence associated with group assignment in this study. Overall, there was no difference between groups in calorie intakes and no difference in caloric deviation from the prescribed diets. Both the refined and whole grain groups adhered to their dietary assignments.

There was no difference in caloric compliance between the grain groups. This lack of difference may be explained by the fiber intake in the two groups. The generally good dietary adherence levels in this study may be due to increases in fiber intake in both groups. Dietary fiber, regardless of type, has been associated with post meal satiety and decreases subsequent hunger postmeal.²² The mechanisms that fiber increases satiety is through hormonal and metabolic effects: reduced insulin secretion, increased fat oxidation, and decreased fat storage. Insoluble fiber increases transit time and fecal bulking in the digestive tract, leading to feeling satiated.²⁵ The whole grain group ate on average 39.9 g/day of fiber, over two times greater than the national average, and 10g higher than the average requirements for American adults.²⁴ The refined grain group on average consumed 20.7 g of fiber per day. Although, this is lower than the daily recommendation, 20.7 g is still higher than the national average, which may have resulted in improved adherence to the protocol in both groups.²⁴

Overall there was no caloric difference in adherence to the prescribed diet for various calorie levels between the groups. As mentioned above, the actual fiber intakes

were greater than the national average, regardless of calorie level.²⁴ The 2000 kcal group has the lowest fiber assignment at 16g/day. This group saw the greatest deviation from the protocol, which may have been due to the lower fiber assignment/intake.

There was no difference in whole grain consumption from the prescribed diet. Given the amount of whole grains being consumed by the whole grain group, a slight difference in consumption is not worrisome. It is recommended that Americans eat 3-5 servings (16 g each) of whole grains per day²⁴ for a total of 48 g to 80 g per day. The participants in the whole grain group consumed 81.1g of whole grains/1000 kcal/day and on average 207.3 g of whole grains per day, a 2.5 to 4-fold higher intake than current recommendations. This generally good dietary adherence in this study suggest that it is feasible for Americans to eat the recommended 3-5 servings of whole grains per day.³⁶

One major limitation of this study is the amount of fiber that each group received. The refined group received 20.7 g/day on average, which is higher than the national average of 15 g/day, and close to the recommended dietary allowance. It is likely that most of the individuals, had a lower intake of fiber prior to participating in the study, and the relative increases in both groups may have improved satiety.^{22,25} This could explain the similar energy intakes between the refined and whole grain groups. It would be insightful to have the refined grain group consume fiber close to the national average, and the whole grain group to consume the recommended dietary allowance. In doing so we can see the effect of the recommendation and assess whether it has a benefit in comparison to what Americans are eating. A limitation is that self reports were used to measure adherence and no verification using objective biomarkers of dietary fiber intake

such as plasma alkylresorcinols were used,⁴ as a way to access dietary adherence. It is suggested that multiple methods for measuring adherence is the best approach.^{9,13,18-22} By using the combination of the two, it will better capture the actual adherence of the participants in the study.

The adherence as whole had no significant difference from the protocol, although some participants did deviate greatly from the protocol, implying that not everyone will adhere. The adherence across the groups could be primarily due to the effects of fiber, and the relative increases in dietary fiber compared with pre-study intakes. This study suggests that it is feasible to replace refined grains with whole grains in future studies.

REFERENCES

- (1) Vitolins MZ, Rand CS, Rapp SR, Ribisl PM, Sevick MA. Measuring Adherence to Behavioral and Medical Interventions. *Controlled Clinical Trials*. 2000;21:188-194.
- (2) Sherman AM, Bowen DJ, Vitolins M, Perri MG, Rosal MC, Sevick MA, Ockene JK. Dietary Adherence: Characteristics and Interventions. *Controlled Clinical Trials*. 2000;21:206-211.
- (3) Farmer KC. Methods for Monitoring Medication Regimen Adherence in Clinical Trials and Clinical Practice. *Clinical Therapeutics*. 1999;21;1074-1089.
- (4) Larsson SC. Plasma Alkylrescorcinols as a Biomarker for Whole-Grain Intake and Association With Colorectal Cancer. *Journal of the National Cancer Institute*. 2014;106:1.
- (5) Hebert JR, Yunsheng M, Ebbeling CB, et al. Self-report data. In: Burke LE, Ockene IS, eds. *Compliance in Healthcare and Research*. Armonk, NY: Futura; 2001:163–179.
- (6) Funder DC. On seeing ourselves as others see us: self–other agreement and discrepancy in personality ratings. *Journal of Personality Assessment*. 1980;48:473–493.
- (7) Hays RD, DiMatteo MR. Key issues and suggestions, sources of information, focus of measures, and nature of response options. *Journal of Compliance in Health Care*. 1987;2:37–53.
- (8) Dunbar-Jacob J. , Sereika SM. Conceptual and methodological problems. In Burke LE, Ockene IS, eds. *Compliance in Healthcare and Research*. Armonk, NY: Futura; 2001:93–104.
- (9) Conrad P. The meaning of medications: another look at compliance. *Social Science and Medicine*. 1985;20:29–37.
- (10) Lambert BL, Street RL, Cegala DJ, et al. Provider-patient communication, patient-centered care, and the mangle of practice. *Health Communications*. 1997;9:27–43.
- (11) Kleinman A. *The Illness Narratives: Suffering, Healing, and the Human Condition*. New York: Basic Books; 1988.

- (12) Kleinman A, Seeman D. Personal experience of illness. In: Albrecht GL, Fitzpatrick R, Scrimshaw SC, eds. *Handbook of Social Studies in Health & Medicine*. Thousand Oaks, CA: Sage; 2000:230–242.
- (13) Sieber WJ, Kaplan RM. Informed adherence: the need for shared medical decision making. *Control Clinical Trials*. 2000;21:233S–240S
- (14) DiMatteo MR. Social support and patient adherence to medical treatment: a meta-analysis. *Health Psychology*. 2003;3:In Press.
- (15) Shine KI. Health care quality and how to achieve it. *Academic Medicine*. 2002;77:91–99.
- (16) Dodd S, White IR, Williamson P. Nonadherence to treatment protocol in published randomized controlled trials: a review. *Trials*. 2012; 13:84.
- (17) Yao CK, Gibson PR, Shepherd SJ. Design of Clinical Trials Evaluating Dietary Interventions in Patients With Functional Gastrointestinal Disorders. *American Journal of Gastroenterol*, 2013;108(5):748–758.
- (18) Trostle JA. Patient compliance as an ideology. In: Gochman DS, ed. *Handbook of Health Behavior Research II: Provider Determinants*. New York: Plenum; 1997:109–122.
- (19) Rogers A, Day JC, Williams B, et al. The meaning and management of neuroleptic medication: a study of patients with a diagnosis of schizophrenia. *Social Science and Medicine*. 1998;47:1313–1323.
- (20) Adams S, Pill R, Jones A. Medication, chronic illness and identity: the perspectives of people with asthma. *Social Science and Medicine*. 1997;45:189–201.
- (21) Karp D. The meanings of medications. In: Karp D, ed. *Speaking of Sadness*. New York: Oxford; 1996:79–103.
- (22) Okarter N, Liu RH. Health benefits of whole grain phytochemicals. *Critical reviews in food science and nutrition*. 2010;50:193-208.
- (23) Lang R, Jebb SA. Who consumes whole grains, and how much? *Proceedings of the Nutrition Society*. 2003;62:123-127.
- (24) U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th edition, Washington, DC: U.S. Government Printing Office, December 2010.

- (25) Fardet A. New hypotheses for the health-protective mechanisms of whole-grain cereals: What is beyond fibre? *Nutrition research reviews*. 2010;23:65-134.
- (26) Wanders AJ, van den Borne JJ, de Graaf C, Hulshof T, Jonathan MC, Kristensen M, Mars M, Schols HA, Feskens EJ. Effects of dietary fibre on subjective appetite, energy intake and body weight: A systematic review of randomized controlled trials. *Obesity Reviews*. 2011;12:724-39.
- (27) Howarth NC, Saltzman E, Roberts SB. Dietary fiber and weight regulation. *Nutrition Reviews*. 2001;59:129-39.
- (28) Harland JI, Garton LE. Whole-grain intake as a marker of healthy body weight and adiposity. *Public Health Nutrition*. 2008;11:554-63.
- (29) Karl JP, Saltzman E. The role of whole grains in body weight regulation. *Advances in Nutrition*. 2012;3:697-707.
- (30) McKeown NM, Hruby A, Saltzman E, Choumenkovitch SF, Jacques PF. Weighing in on whole grains: A review of evidence linking whole grains to body weight. *Cereal Foods World*. 2012;57:20-7.
- (31) Bazzano LA, Song Y, Bubes V, Good CK, Manson JE, Liu S. Dietary intake of whole and refined grain breakfast cereals and weight gain in men. *Obesity Reviews*. 2005;13:1952-60.
- (32) Koh-Banerjee P, Franz M, Sampson L, Liu S, Jacobs DR, Jr., Spiegelman D, Willett W, Rimm E. Changes in whole-grain, bran, and cereal fiber consumption in relation to 8-y weight gain among men. *American Journal of Clinical Nutrition*. 2004;80:1237-45.
- (33) Liu S, Willett WC, Manson JE, Hu FB, Rosner B, Colditz G. Relation between changes in intakes of dietary fiber and grain products and changes in weight and development of obesity among middle-aged women. *American Journal of Clinical Nutrition*. 2003;78:920-7.
- (34) Mozaffarian D, Hao T, Rimm EB, Willett WC, Hu FB. Changes in diet and lifestyle and long-term weight gain in women and men. *New England Journal of Medicine*. 2011;364:2392-404.
- (35) Ye EQ, Chacko SA, Chou EL, Kugizaki M, Liu S. Greater whole-grain intake is associated with lower risk of type 2 diabetes, cardiovascular disease, and weight gain. *Journal of Nutrition*. 2012;142:1304-13.

- (36) Katcher HI, Legro RS, Kunselman AR, Gillies PJ, Demers LM, Bagshaw DM, Kris-Etherton PM. The effects of a whole grain-enriched hypocaloric diet on cardiovascular disease risk factors in men and women with metabolic syndrome. *American Journal of Clinical Nutrition*. 2008;87:79-90. 23
- (37) Kristensen M, Toubro S, Jensen MG, Ross AB, Riboldi G, Petronio M, Bugel S, Tetens I, Astrup A. Whole grain compared with refined wheat decreases the percentage of body fat following a 12-week, energy-restricted dietary intervention in postmenopausal women. *Journal of Nutrition*. 2012;142:710-6.
- (38) Brownlee IA, Moore C, Chatfield M, Richardson DP, Ashby P, Kuznesof SA, Jebb SA, Seal CJ. Markers of cardiovascular risk are not changed by increased whole-grain intake: The wholeheart study, a randomised, controlled dietary intervention. *British Journal of Nutrition*. 2010;104:125-34.

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