EFFECT OF CALCIUM-FORTIFIED CEREAL BARS ON DIETARY CALCIUM INTAKE IN WOMEN

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DEDICATION

For my mom,
thank you for your never-ending love and support.

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ABSTRACT

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This study aimed to determine if consuming calcium-fortified whole grain cereal bars will improve dietary calcium intake in women, and decrease risk of osteoporosis development. In this randomized controlled crossover study, 35 healthy women above age 18 in Houston, Texas, in either Group I or II received two Kellogg's Nutri-Grain® cereal bars daily during a 3-week intervention period and ate their usual diet for three weeks (control) after a 3-week baseline period. Dietary intakes were estimated from 3-day diet and supplemental diaries. Wilcoxon signed-rank test was used for within group and Mann Whitney U test for between group comparisons. Dietary calcium intake was significantly higher during intervention (1071 mg per day) than baseline (720 mg per day, $p<0.0001$) or control (775 mg per day, $p=0.0001$). No previous studies have used this study bar. Findings may advance current research on feasible ways to obtain adequate calcium intake to improve bone health.

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CHAPTER I

INTRODUCTION

Osteoporosis is a skeletal disorder pertaining to the deterioration of bone mass and tissues, leading to increased bone fragility and risk of fracture. According to the National Osteoporosis Foundation (NOF), it is a major public health issue affecting about 57 million Americans, where 9 million individuals are estimated to have the disease and about 48 million individuals are at risk with low bone density (NOF, 2013). The progression of osteoporosis can be controlled through changeable factors such as diet and exercise (Villareal et al., 2003). While exercising may help alleviate the burden on bones through muscle development, consuming an adequate amount of dietary calcium had been shown to have a beneficial effect on bone growth and maintenance (Chapuy et al., 1992). Even with high consumption of milk and dairy products, most individuals have an inadequate calcium intake (Albertson, Tobelmann, & Marquart, 1997). As a result, non-dairy products that may potentially increase calcium intake have become the focus of recent research. This study aimed to determine the effect of calcium-fortified whole grain cereal bars on dietary calcium intake.

Purpose of the Study

The purpose of this study is to determine if consumption of the calcium-fortified whole grain cereal bars will increase dietary calcium intake in women and be a potential way to help prevent osteoporosis. This study hypothesized that consuming the Kellogg's Nutri-Grain® cereal bars will increase calcium intake in healthy women above age 18.

Null Hypothesis

The null hypothesis is that the consumption of calcium-fortified cereal bars, Kellogg's Nutri-Grain® cereal bars, by healthy women will not increase daily calcium intake.

Definitions

Osteoporosis – bone mass density of ≥2.5 standard deviations (SD) below the average value for young healthy women (World Health Organization [WHO], 2007).

Osteopenia – t-score at the femoral neck of between –1.0 SD and –2.5 SD below the young female adult mean (WHO, 2007).

Body mass index (BMI) – a measure of weight in kilograms divided by height in meters squared (kg/m^2); used to classify individuals into the following categories:

Underweight: BMI ≤18.5

Normal Weight: BMI 18.6 to 24.9

Overweight: BMI 25 to 29.9

Obesity: BMI ≥30.0

(Centers for Disease Control and Prevention [CDC], 2014).

Estimated Average Requirements (EAR) – average daily nutrient intake level estimated to meet the requirements of half of the healthy individuals in a group (Institute of Medicine [IOM], 2006).

Recommended Dietary Allowance (RDA) – the average daily dietary nutrient intake that is sufficient to meet the nutrient requirement of most (97-98%) healthy individuals in a particular life stage and gender group (IOM, 2006).

Adequate Intake (AI) – used when an RDA cannot be determined; recommended average daily intake based on approximations or estimates that is assumed to be adequate to cover the needs of all healthy individuals in the groups (IOM, 2006).

Tolerable Upper Intake Level (UL) – highest average daily nutrient intake level not likely to pose potential risk of adverse health effects to almost all individuals in the general population (IOM, 2006).

Dietary Reference Intakes (DRI) – nutrition reference values intended to serve as a guide for good nutrition in the US and Canada; comprise of the EAR, RDA, AI, and Tolerable Upper Intake Level (UL) (IOM, 2006).

Daily Value (DV) – a reference value to report the amount of nutrients present in a food based on a caloric intake of 2,000 calories (kcal), for adults and children four or more years of age. (U.S. Food and Drug Administration [FDA], 2013)

Whole grain – contain all of the essential parts and naturally-occurring nutrients of the entire grain seed in their original proportions (Whole Grains Council, 2004).

Dietary fiber – consist of non-digestible carbohydrates and lignin that are intrinsic and intact in plants (National Research Council [NRC], 2001).

Fortified – contain ≥10% DV (FDA, 2013)

Excellent Source – contains ≥20% DV (FDA, 2013)

Good Source – contain 10 to 19% DV (FDA, 2013)

Assumptions

1. All participants knew how to speak, read, and write in English.

2. All participants were able to comprehend and complete 3-day diet and supplement diaries.
3. All participants were not pregnant or planning on becoming pregnant during the course of the study.
4. All participants were able to consume Kellogg's Nutri-Grain® cereal bars.
5. All participants were not regularly consuming two Kellogg's Nutri-Grain® cereal bars per month, or not taking calcium supplements or calcium-containing medications.
6. All participants were healthy women who did not have liver disease, kidney disease, gastrointestinal disease (celiac disease, ulcerative colitis, or Crohn's disease), a history of bariatric surgery, or have had a major cardiovascular event (stroke or myocardial infarction)
7. All participants were not undergoing cancer treatment with the exception of non-melanoma cancer, following a weight-controlled diet, a disease specific diet, or a vegan diet, having a diagnosed eating disorder, or being allergic to any of the ingredients in the study bar.

Limitations

1. Participants may not be representative of all females.
2. Diet assessed using 3-day diet and supplement diaries may not be representative of normal food intake.
3. This study did not control participants' the usual diet intake.
4. This study did not assess bone mass density status or calcium absorption.

5. The Nutrition Data System for Research 2011 used to analyze the dietary records may not provide complete and accurate nutrition information.
6. This 9-week feeding study does not assess long-term habitual change in diet.

Significance of the Study

This study evaluated whether the intake of calcium-fortified whole grain cereal bars will increase dietary calcium intake in healthy women. Consuming Kellogg's Nutri-Grain® cereal bars may be a feasible way to obtain additional calcium sources in the daily intake. The findings from this study may help further current investigation on ways to obtain adequate calcium intake and potentially prevent osteoporosis.

CHAPTER II

LITERATURE REVIEW

Prevalence of Osteoporosis

Osteoporosis is a major public health concern. According to the NOF (2013), osteoporosis affects over 57 million individuals. Approximately 9 million of these individuals currently have the disease and about 48 million are at risk with low bone density (NOF, 2013). Osteoporosis is a symptomless "silent disease" where the bone loss often went undetected until a fracture occurs. It has the literal meaning of "porous bone." The minerals and proteins that make up the inner structure of the bone is progressively loss overtime. The bones become thin and porous as bone mineral density decreased. This leads to increased bone fragility and risk of fracture.

Risk Factors

Osteoporosis is defined in terms of bone mass density (BMD) and skeletal deterioration of bone tissues. The WHO classified osteoporosis as more than 2.5 SD below the mean peak BMD of healthy 30-year old women as assessed by standardized BMD measurements (WHO, 2007). Low BMD is a risk factor of osteoporotic fractures. Studies showed that decreased BMD results in increased risk of fracture (Bauer et al., 1999; Marshall, Johnell, & Wedel, 1996). Regular BMD measurement may help evaluate strength of bones, determine risk of fracture, and allow early detection of osteoporosis.

Total BMD is only one component in assessing fracture risk. All factors that contribute to risk of osteoporotic fracture should be taken into consideration in order to

accurately assess the development of osteoporosis. There are both changeable and unchangeable risk factors. Unchangeable risk factors include age, gender, bone frame size, ethnicity, family history, certain medical conditions and medications. Changeable risk factors largely pertain to diet and physical activity. Research had been focused on identifying changeable risk factors that could help decrease individual's risk of fractures.

Dietary Calcium

Calcium is an important component of the skeletal system in maintaining bone health and preventing osteoporosis. However, most adult women do not consume an adequate amount of this nutrient (Bailey et al., 2010). The current recommendation for calcium intake is the amount required to maintain an adequate rate of calcium retention in bones of healthy individuals based on gender and age. While the RDA established by the Food and Nutrition Board of the IOM is 1000 milligrams (mg) of calcium per day for women between the ages 19 to 50, and 1200 mg per day for women above age 50, most women in this category fail to reach this level (IOM, 2006; NRC, 2011). In general, women are more susceptible to bone loss and have a lower calcium intake compared to men. Based on the dietary data from the National Health and Nutrition Examination Survey (NHANES) 2003-2006, Bailey et al. (2010) found that over 70% of women between the ages of 18 and 50 without supplement use had a total dietary calcium intake below the recommended amount. Maintaining an adequate calcium intake is especially important for women in this category for osteoporosis prevention. This proposed study will target women over the age of 18 years without calcium supplement use.

Dairy products have been well established in providing abundant amounts of dietary calcium. Fleming and Heimbach (1994) demonstrated that dairy products supplied at least 50% of the total dietary calcium intake. This included milk, yogurt, cheese, and any milk-based products such as ice cream and puddings. However, even when the predominant sources of dietary calcium are dairy products, the total dietary calcium intake can be inadequate (Alaimo et al., 1994; Albertson et al., 1997). Dietary calcium from non-dairy sources, such as those from natural sources and products fortified with calcium, has gained much attention as a possible means to increase calcium intake.

Calcium can be obtained from non-dairy products. They are naturally found in sardines, spinach, kale, and some fruits. In addition, there had also been an increased in the availability of calcium-fortified foods (Forshee, Anderson, & Storey, 2006). Many fruit juice beverages, soy products, margarines, ready-to-eat cereals, snack bars, and pasta products are now commonly fortified with calcium (Olson, Chung, Reckase, & Schoemer, 2009). Fleming and Heimbach (1994) also found that about 12% of the total dietary calcium intake was contributed by grain products, about 6% was obtained from fruits and vegetables, and the remainder from meat, legumes, and other sources. With the growing awareness of the importance of calcium in osteoporosis prevention, studies that seek to improve dietary calcium intake through consuming non-dairy products are being conducted.

Since a wide variety of calcium-fortified food products are currently available for the convenience of the public, studies have examined the effect of the various calcium-fortified food products as ways to increase daily calcium intake. Ho et al. (2005)

demonstrated that the consumption of calcium-fortified soymilk providing 600 mg per day by adolescent girls resulted in increased dietary calcium intake, bone mineral density, and bone mineral content at the hip. They found that the average calcium intake increased from about 500 to 550 mg per day at baseline to close to the recommended level. Zemel, Richards, Mathis, Milstead, Gebhardt, and Silva (2005) reported a significant increase in average daily calcium intake from about 500 to 1100 mg per day when participants consumed three servings of calcium-fortified yogurt daily, providing 600 mg per day of calcium, for twelve weeks. In addition, consumption of beverages fortified with calcium, such as fruit juice, resulted in greater calcium absorption compared to a similar intake of calcium from dairy products (Miller et al., 1988; Smith, Heaney, Flora, & Hinders, 1987). Furthermore, Haub et al. (2005) demonstrated that the consumption of calcium-fortified beverages for 12 months increased the calcium to protein ratio by two fold; an increase of this level may be protective against osteoporosis and other diseases. The current proposed study will help further elucidate the effect of consuming the calcium-fortified food product, Kellogg's Nutri-Grain® cereal bars, on dietary calcium intake.

Vitamin D

Vitamin D plays an important role in osteoporosis prevention. This contributes to its functions of promoting calcium absorption and maintaining adequate serum calcium and phosphorous concentration in the body (Pettifor & Prentice, 2011). Adequate vitamin D may help preserve BMD and bone strength. The body absorbs about 10% of calcium consumed when vitamin D is limited, compared to about 30-40% when vitamin

D is available (Wagner & Greer, 2008). A low vitamin D level in the body may result in low calcium even with adequate intake. As a result, research studies often examine vitamin D conjointly with calcium.

Vitamin D can be obtained through the diet or synthesized by the body when exposed to ultraviolet light from sunlight. However, it is generally challenging to quantify the amount of vitamin D that could be produced by the skin. Also, since there is an increased risk for skin cancer with prolonged exposure to the sun, the preferred method would be to obtain vitamin D from diet. The RDA of vitamin D for women between ages 19 to 70 is 15 micrograms (mcg) daily, and the DV is 10 mcg per day (NRC, 2011; FDA, 2013). Dietary sources of vitamin D include fatty fish such as salmon, tuna, and mackerel, and fish liver oil. The majority of dietary vitamin D is obtained from fortified diary, yogurt, orange juice, and some ready-to-eat cereals. Egg yolk, beef liver, and cheese also contain small amounts. Although Kellogg's Nutri-Grain® cereal bars does not contain dietary vitamin D, it is important to also assess participants' overall dietary vitamin D intake for a comprehensive overview of this intervention in osteoporosis prevention.

Whole Grain

Interest has been shown in regards to increasing dietary calcium intake through consumption of whole grain products since some grain products provide a source of bioavailable calcium. A study by Ahmed, Anjum, Rehman, Randhawa, and Farooq (2008) demonstrated that the added calcium in whole wheat chapattis was more bioavailable than that in unfortified products. Also, Weaver, Heaney, Martin, and

Fitzsimmons (1991) reported significantly higher calcium absorption (59 to 64%) from whole wheat bread (0.817 millimole) compared to milk (0.589 millimole) at a comparable calcium load, and concluded that the phytate and fiber in whole-wheat products did not reduce calcium absorbability relative to milk. The results suggested that whole grain products provide a good amount of dietary calcium that may help individuals reach the calcium requirement.

While some studies found whole grain products to be a promising source of calcium, other studies showed phytate in whole grain products to be an inhibitor of mineral absorption (Gibson, 1994; Gibson, Perlas, & Hotz, 2006; Pallauf, Pietsch, & Rimbach, 1998). Phytate may form insoluble complexes with certain minerals such as zinc, iron, and calcium (Wise, 1995). In general, the molar ratio of phytate-to-mineral is often used to estimate the mineral bioavailability in diet (Morris & Ellis, 1989). While a phytate-to-calcium molar ratio of 0.2 or higher is considered to have a negative impact on calcium balance, Adeyeye, Arogundade, Akintayo, Aisida, and Alao (2000) found that whole wheat cereal has a ratio of about 1.7. However, Weaver et al. (1991) found that this ratio decreased from 1.22 to 0.14 when wheat bran cereal is consumed with other food items, suggesting that the calcium bioavailability may depend on the total phytate contents of the entire meal. Also, it has been pointed out that the phytate:calcium molar ratio may not accurately predict the calcium bioavailability because the formation of the insoluble complexes may depend on many conditions such as pH, temperature, ion charges, food processing, and cooking methods (Dendougui & Schwedt, 2004; Ma et al., 2005). Furthermore, Davidsson et al. (1996) found that the calcium absorption for infants

remained high, at about 60%, even though the phytate content in their cereal-based foods is high. This suggested that the calcium deficiency observed in adults may be due to low intake rather than poor absorption (Hurrell, 2003). Cleveland, Moshfegh, Albertson, and Goldman (2000) found significantly higher ($p<0.05$) calcium intake in those who consumed ≥3 servings (422 mg per 1000 kcal) and >0 servings (398 mg per 1000 kcal) of whole grains per day compared to non-whole grain consumers (344 mg per 1000 kcal). This proposed study will focus on increasing calcium intake through consumption of a whole grain product. Particularly, this study will use the calcium-fortified whole grain cereal bars that may potentially increase the total calcium intake in adult women.

Dietary Fiber

Mixed results had been reported regarding the effect of fiber on calcium absorption. Vermorel et al. (2004) reported an increase in calcium absorption when given with a high-dose wheat dextrin supplement. Moreover, Bosscher, Van Caillie-Bertrand, Van Cauwenbergh, and Deelstra (2003) and Scholz-Ahrens and Schrezenmeir, (2002) found that consuming soluble fiber enhanced calcium absorption. However, other studies found inconsistent results (Coudray et al., 1997; Tahiri et al., 2001; van den Heuvel, Schaafsma, Muys, & van Dokkum, 1998). Knox et al. (1991) suggested that high fiber intake decreased calcium absorption in the elderly population. Several studies also reported decreased calcium absorption when consuming fiber from wheat bran, but not from green leafy vegetables such as kale, broccoli, and bok choy (Heaney, Weaver, Hinders, Martin, & Packard, 1993; Weaver et al., 1991; Weaver, Heaney, Teegarden, & Hinders, 1996).

The inconsistent results may largely pertain to the various types of fiber in different foods. Fiber is categorized into either soluble or insoluble based on its dissolubility in water. Insoluble fiber such as cellulose and wheat bran can pass through the intestine without being digested. This may result in decreased calcium absorption by speeding up transit time of intestinal content and forming insoluble complexes with calcium (Heaney, 2001; Weaver et al., 1996). On the other hand, bacteria in the colon may breakdown soluble fiber such as wheat dextrin, pectin, fructo-oligosaccharides, and psyllium. This subsequently stimulates epithelial cell growth and decreases pH in stomach, leading to increased food breakdown and calcium availability for absorption (Cummings, Rombeau, & Sakata, 1995; Demigne, Levrat, Younes, & Remesy, 1995; Park & Floch, 2007; Scholz-Ahrens & Schrezenmeir, 2007; Tahiri et al., 2003; Wong, de Souza, Kendall, Emam, & Jenkins, 2006).

It has been speculated that foods with higher fiber content are more likely to be a poor source of calcium compared to foods with less fiber. However, dietary fiber at the recommended intake as part of a balanced diet has not been found to adversely affect the calcium status of healthy individuals (Trumbo, Schlicker, Yates, & Poos, 2002). The recommended daily intake of fiber for women between ages 19 and 50 is about 25 grams (g) per day. On average, Americans only eat about 15 g per day (Slavin, 2008). Less than 5% of Americans consume dietary fiber at the AI (Alaimo et al., 1994). Kellogg's Nutri-Grain® whole grain cereal bar provides a good source of fiber (3 g per bar, 10% DV). An adequate fiber intake may have health benefits without having to compromise calcium absorption. This study will also examine participants' dietary fiber intake.

Calcium Fortification

Several studies explored the possibility of consuming whole grain products with added calcium to increase dietary calcium intake, particularly cereal products (Abrams, Griffin, Davila, & Liang, 2001; Ekbote et al., 2011; Gao, Wilde, Lichtenstein, & Tucker, 2006; Zemel, 2002). Typically, one slice of whole wheat bread can provide about 2% of the DV for calcium (20 mg), whereas one serving of calcium-fortified breakfast cereal product may provide up to 100% (1000 mg) of the DV for calcium. Ekbote et al. (2011) reported an increase in dietary calcium intake in children consuming calcium-fortified cereal based snacks. In addition, Abrams et al. (2001) suggested that the use of these products may be a practical way to increase calcium intake in children between the ages 6 and 9 years. The present study aims to further the current research by determining whether Kellogg's Nutri-Grain® cereal bars, a calcium-fortified whole grain product, will increase dietary calcium intake. Kellogg's Nutri-Grain® cereal bars provides 200 mg of calcium per serving. Consumption of this product may be a possible convenient and practical solution to increase daily calcium intake. To the best of the author's knowledge, this study has not been conducted before.

CHAPTER III

METHODS

Participants

Forty participants were recruited through flyers posted on bulletin boards in the building of Texas Woman's University, Houston Center, and several shuttle stops in the Texas Medical Center in Houston, and through *ClinicalTrials.gov* of the U.S. National Institutes of Health (NIH). Inclusion criteria were healthy women above age 18 years, able to speak, read, and understand English, and able to consume Kellogg's Nutri-Grain® cereal bars. Exclusion criteria were consumption of calcium supplements or calcium-containing medications, regular consumption of two Kellogg's Nutri-Grain® cereal bars per month, pregnant or planning to become pregnant during the course of the study, having liver disease, kidney disease, gastrointestinal disease (celiac disease, ulcerative colitis, or Crohn's disease), or a history of bariatric surgery, having had a major cardiovascular event (stroke or myocardial infarction), undergoing treatment of cancer with the exception of non-melanoma cancer, following a weight-controlled diet, a disease specific diet, or a vegan diet, having a diagnosed eating disorder, or being allergic to any of the ingredients in the study bar.

Potential participants who showed an interest were asked if they were willing to meet with the researcher once every three weeks during this nine-week study. An informed consent form was given to each potential participant to notify her of the purpose,

as well as the potential risks and benefits of the study. The principal investigator kept the original completed consent form, and a copy was given to the participant.

Study Design

This study used a randomized controlled crossover design. During the first meeting (T_1) after completion of the informed consent, the participants were randomly assigned into either Group I or II by a random draw from a hat. Twenty people maximum were allowed in each group. All participants were told to consume their usual diet for three weeks to determine baseline intake. The second meeting was held after the baseline period. During the second meeting (T_2), each participant in Group I was provided with 42 Kellogg's Nutri-Grain® cereal bars and was asked to consume 2 bars per day for the following three weeks. This provides an additional of about 40% of the DV of calcium (200 mg per bar) per day for women aged 18 and above. Table 1 shows the energy, calcium, vitamin D, and fiber content in a study bar.

Table 1
Energy, Calcium, Vitamin D, and Fiber Content of Kellogg's Nutri-Grain® Cereal Bar

	Content per bar[b]	% DV
Energy	120 kcal	-
Calcium	200 mg	20
Vitamin D[a]	-	-
Fiber	3 g	10

Notes: [a]Study bar contains an insignificant amount of dietary vitamin D, [b]values based on the manufacturer information.

The participants in Group II were asked to continue consuming their usual diet during the second three-week period. The diets of the two groups were switched for the last three-week period. During the third meeting (T_3) held after the second three-week period, participants in Group I were asked to consume their usual diet, while participants

in Group II were provided with 42 bars each and were asked to consume 2 bars per day during the last three-week period. The fourth and last meeting (T_4) was held after the last three-week period. Figure 1 shows the flowchart of participants' progress through this study.

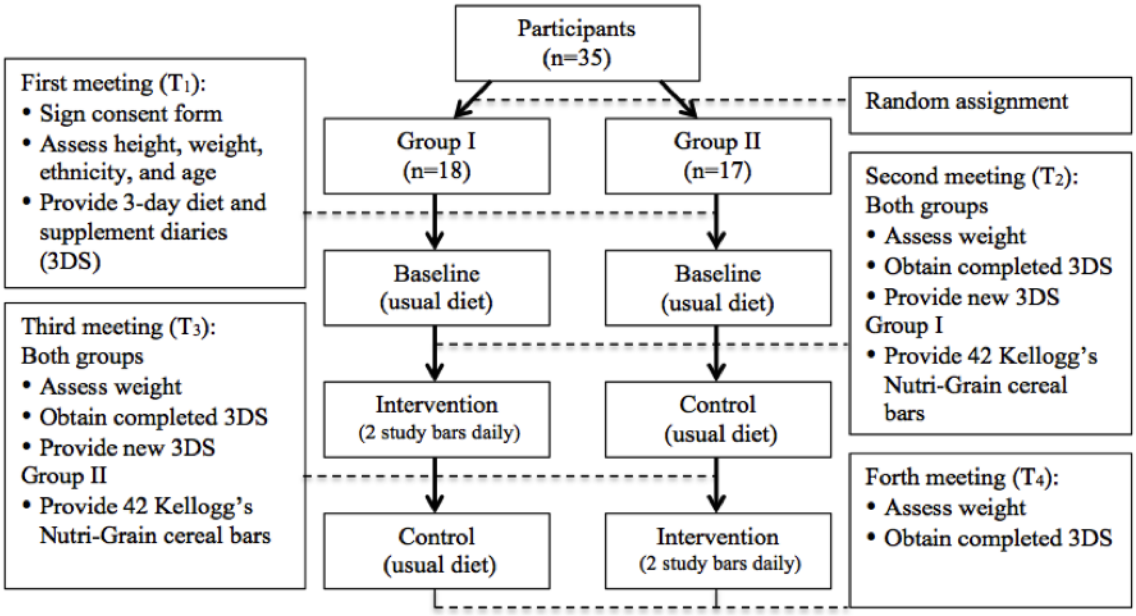

Figure 1. Flowchart of participants' progress through the study

Switching diets between the groups allowed each participant to serve as her own control. This could be used to counterbalance the order effect. Data on age, ethnicity, height, and weight were recorded at T_1, and weight will be measured again at T_2, T_3, and T_4. A $20 gift certificate was given to participants who completed the study.

Dietary Records

Dietary records were kept as three-day diet and supplement diaries (3DS). The 3DS consisted of two nonconsecutive weekdays and one weekend day. Each participant completed one form during weeks 2, 5, and 8 of the study. Empty forms were provided

during each meeting, and the completed forms were returned to the principal investigator during the subsequent meeting. The forms asked for the specific brand name, amount, type of content, and the time when each food item or supplement was consumed. Participants kept a checklist of the numbered bars consumed during the period when they are provided with the bars. The completed checklist form was also returned to the principal investigator during the subsequent meeting along with any uneaten bars. The principal investigator periodically made phone calls and emails to the participants to ensure the adherence to the diets and to answer any questions or concerns the participants may have had regarding the study.

Dietary Analysis

The completed 3DS were analyzed using the Nutrition Data System for Research (NDSR) program developed by the University of Minnesota (Nutrition Coordinating Center, 2011). This program provided data on the intake of energy and various nutrients. This study analyzed participants' dietary intake of energy, and calcium, vitamin D, and fiber.

Statistical Analysis

Data were analyzed using statistical software, Stata® version 11.2. The Shapiro-Wilk test was used to test normality of the data. This is a common test used for checking normality of data, and it is useful for data from a small sample size. The data of this study were not normally distributed. Therefore, the Wilcoxon signed-rank test was used for within group comparisons and the Mann Whitney U test was used for between group comparisons. The Wilcoxon signed-rank test is a statistical nonparametric hypothesis test

equivalent to the dependent or paired t-test for normally distributed data. This test does not assume normality and is used for comparing two sets of related data from the same participants. The Mann Whitney U test is a statistical hypothesis test for nonparametric independent data. It is equivalent to the unpaired t-test for two independent samples. The Chi-squared test was used to analyze categorical data. The data are considered statistically significant if $p<0.05$.

CHAPTER IV

RESULTS

Demographic Characteristics

A total of 40 individuals signed the consent form to participate in this study, but only 35 participants completed the study. Five individuals dropped out (12.5%) due to reasons unrelated to the study design. The age, ethnicity, height, and initial weight were not significantly different between dropouts and participants who completed the study.

Participants identified themselves as non-Hispanic White (34%), Asian (46%), non-Hispanic Black (14%), or Hispanic (6%). The average age was 27.8 years; age ranged between 21 and 58 years. The average weight (kg) at initial, baseline, end of intervention, and end of control was 57.5, 57.4, 58.2, and 57.7, respectively. The average BMI (kg/m^2) at initial, baseline, end of intervention, and end of control was 22.1, 22.1, 22.4, and 22.2, respectively. No significant changes in weight and BMI were found during the course of this study. The compliance was 98.6% in consuming the study bars.

Participants were randomly distributed into Group I (n=18) or Group II (n=17) at the beginning of the study. No significant differences were found in ethnicity, age, height, weight, and BMI between the two groups. The average age (28.2 years) and range (22 to 58 years) of participants in Group I was not significantly different compared to the average age (27.3 years) and range (21 to 49 years) of participants in Group II. The average weight (kg) at initial, baseline, intervention, and control in Group I was 55.9, 55.7, 56.7, and 56.2, respectively; while in Group II was 59.1, 59.1, 59.6, and 59.1,

respectively. Participants were compliant to consuming the study bars in Group I (98.1%) and Group II (99%). Table 2 shows the baseline characteristics of participants who dropped out of the study, all participants, and participants in Group I and Group II.

Table 2
Demographic Characteristics of All Study Participants, Drop-outs, and Participants in Group I and Group II.

	Drop-outs	Combined[a]	Group I	Group II	*p*[b]
Participants (n)	5	35	18	17	
Drop-out (n)	5	5	2	3	
Age (years)	25.0±2.3	27.8±7.9	28.2±8.6	27.3±7.4	*0.5717*
Height (cm)	157.5±3.7	161.3±5.7	160.1±4.2	162.5±6.9	*0.1790*
Averaged Weight (kg)					
Initial	53.8±4.4	57.5±10.7	55.9±9.8	59.1±11.8	*0.4476*
Baseline	-	57.4±10.7	55.7±9.8	59.1±11.6	*0.3907*
Intervention	-	58.1±10.7	55.9±7.1	59.1±11.5	*0.4476*
Control	-	57.6±10.6	56.2±9.5	59.1±11.7	*0.5413*
BMI (kg/m^2)					
Initial	21.7±1.6	22.0±3.6	21.8±3.1	22.4±4.1	*0.4476*
Baseline	-	22.0±3.6	21.7±3.1	22.4±4.1	*0.3907*
Intervention	-	22.3±3.5	22.1±3.2	22.6±3.9	*0.4985*
Control	-	22.1±3.5	21.9±3.0	22.4±4.1	*0.5413*
Ethnicity (n), (%)					*0.5370*
Non-Hispanic White[c]	0 (0)	12 (34)	6 (33)	6 (35)	*0.9030*
Non-Hispanic Black	1 (20)	5 (14)	2 (11)	3 (18)	*0.5810*
Hispanics	2 (20)	2 (6)	2 (11)	0 (0)	*0.1570*
Asians	3 (60)	16 (46)	8 (44)	8 (47)	*0.8770*
Taking Supplements (n, %)	-	6 (17.1)	3 (16.7)	3 (17.6)	*0.9390*
Compliance (%)	-	98.57±6.2	98.2±7.9	99.0±4.0	*0.9673*

Notes: Unit±SD; [a]participants in Group I and Group II combined, [b]*p*-value shows statistical significance between Group I and Group II by Mann Whitney U test for quantitative data and Chi-squared test for categorical data, [c]Lebanese is considered as Non-Hispanic White

Table 3 shows the number and percentage of all participants, and participants in Group I and Group II classified as underweight, normal weight, overweight, and obese. Participants in Group I showed no weight category changes throughout the study. Two

participants in Group II showed changed in weight category. One participant experienced an increase in weight from being underweight at initial measurement (48.4 kg, BMI 18.3) to normal weight (49.3 kg, BMI 18.7) in control. Another participant experienced weight increased slightly from normal weight at initial measurement (52.9 kg, BMI 24.8) to overweight (53.18 kg, BMI 25.0) at baseline, then returned to normal weight (52.27 kg, BMI 24.5) at the end of study. No significant difference ($p>0.05$) was found in weight and BMI within each group during the study.

Table 3
All Study Participants, and Participants in Group I and Group II Classified as Underweight, Normal Weight, Overweight, and Obese.

	Underweight[a]	Normal Weight[b]	Overweight[c]	Obese[d]
Combined (n=35)				
Initial	5 (14)	24 (69)	5 (14)	1 (3)
Baseline	4 (11)	25 (71)	5 (14)	1 (3)
Intervention	4 (11)	25 (71)	5 (14)	1 (3)
Control	4 (11)	24 (69)	6 (17)	1 (3)
Group I (n=18)				
Initial	2 (11)	13 (72)	3 (17)	0 (0)
Baseline	2 (11)	13 (72)	3 (17)	0 (0)
Intervention	2 (11)	13 (72)	3 (17)	0 (0)
Control	2 (11)	13 (72)	3 (17)	0 (0)
Group II (n=17)				
Initial	3 (18)	11 (65)	2 (12)	1 (6)
Baseline	2 (12)	11 (65)	3 (18)	1 (6)
Intervention	2 (12)	12 (71)	2 (12)	1 (6)
Control	2 (12)	11 (65)	3 (18)	1 (6)

Notes: Unit in n (%); body mass index (kg/m^2) [a]<18.5, [b]18.5-24.9, [c]25-29.9, or [d]≥30

Dietary Intake

This study examined the average energy, calcium, vitamin D, and fiber intake of participants at baseline, intervention, and control (Table 4). The average daily energy

(kcal) intake of all participants at baseline, intervention, and control were 1734, 1789, and 1789, respectively. No significant difference was found in the average daily energy intake between baseline, intervention, and control. The average daily calcium intake during intervention (1071 mg per day) was significantly higher compared to baseline (720 mg per day, *p<0.0001*) and control (775 mg per day, *p=0.0001*). However, calcium intake was not significantly different (*p=0.4915*) between baseline and control. Daily dietary fiber intake was also significantly higher at intervention (23 g per day) compared to baseline (19 g per day, *p=0.0007*) and control (19 g per day, *p=0.0056*). Daily vitamin D intake at intervention (3.3mcg per day) was significantly lower compared to baseline (4.78 mcg per day, *p=0.0122*) and control (4.39 mcg per day, *p=0.0134*). No statistical significance (*p=0.9217*) was found in vitamin D intake between baseline and control.

Table 4
Average Energy, Calcium, Vitamin D and Fiber Intake of All Study Participants, Participants Not Accounted for Study Bars, and Participants in Group I and Group II at Baseline, Intervention, and Control Not Accounted for Supplementation.

	Baseline	Intervention	Control
Energy (kcal/d)			
Combined[a] (n=35)	1740±531	1789±492	1789±579
Excluded[b] (n=35)	-	1550±490	-
Group I (n=18)	1639±445	1726±441	1742±552
Group II (n=17)	1842±616	1852±543	1817±606
p1[e]	*0.2618*	*0.3908*	*0.8689*
p2[f]	-	*0.0139*	-
Calcium (mg/d)			
Combined[a] (n=35)	720±256	1070±369	775±347
Excluded[b] (n=35)	-	675±363	-
Group I (n=18)	714±296	1044±321[cd]	768±339
Group II (n=17)	725±216	1097±417[cd]	783±355
p1[e]	*0.6921*	*0.9737*	*0.8173*
p2[f]	-	*<0.0001*	-

Table 4.
Continued.

Vitamin D (mcg/d)			
Combined[a] (n=35)	4.8±3.6	3.3±2.7	4.4±3.0
Excluded[b] (n=35)	-	3.3±2.7	-
Group I (n=18)	5.0±4.2	3.3±2.8	4.3±3.0
Group II (n=17)	4.6±3.0	3.3±2.7	4.5±3.0
p1[e]	*1.0000*	*0.8045*	*0.5974*
p2[f]	-	*1.0000*	-
Fiber (g/d)			
Combined[a] (n=35)	18.7±9.6	22.7±8.0	19.3±9.2
Excluded[b] (n=35)	-	16.8±8.7	-
Group I (n=18)	16.7±7.1	20.4±4.7[cd]	16.9±6.4
Group II (n=17)	20.8±12.0	25.0±11.3[c]	21.6±11.9
p1[e]	*0.4000*	*0.4478*	*0.4283*
p2[f]	-	*0.0001*	-

Notes: Data written as mean±SD; [a]participants in Group I and Group II combined, [b]participants' intake not accounted for study bars, [c]statically significant ($p<0.05$) between baseline and intervention by Wilcoxon signed-rank test, [d]statistically significant ($p<0.05$) between intervention and control by Wilcoxon signed-rank test, [e]statistical significance between Group I and Group II by Mann Whitney U test, [f]statistical significance between Excluded and Combined by Mann Whitney U test.

In Group I, no significant differences ($p>0.05$) were found in the daily energy intake between baseline (1639 kcal), intervention (1726 kcal), and control (1742 kcal). Dietary calcium intake was significantly higher in intervention (1044 mg per day) compared to baseline (714 mg per day, $p=0.0003$) and control (768 mg per day, $p=0.0156$), but no significant difference ($p=0.7439$) was reported between baseline and control. The dietary fiber intake at intervention (20.4 g per day) is also significantly higher than at baseline (16.7 g per day, $p=0.0156$) and control (16.9 g per day, $p=0.0198$), but not between baseline and control ($p=0.8107$). Dietary vitamin D intake was not

significantly different ($p>0.05$) between baseline (5 mcg per day), intervention (3.33 mcg per day), and control (4.29 mcg per day).

In Group II, the average energy intake was not significantly different ($p>0.05$) between baseline (1842 kcal), intervention (1852 kcal), and control (1817 kcal). The calcium intake at intervention (1097 mg per day) was significantly higher compared to baseline (725 mg per day, $p=0.0003$) and control (783 mg per day, $p=0.0005$), but not ($p=0.5862$) between baseline and control. No significant differences ($p>0.05$) were found in vitamin D intake between baseline (4.55 mcg per day), intervention (3.26 mcg per day), and control (4.49 mcg per day). Finally, dietary fiber intake in intervention (25g per day) was significantly higher ($p=0.0168$) compared to baseline (20.8 g per day), but not ($p=0.0929$) control (21.6 g per day). No significant difference ($p=0.3812$) was also shown in dietary fiber intake between baseline and control. Table 5 shows the p-value in the average energy, calcium, vitamin D, and fiber intake of participants between baseline, intervention, and control.

Table 5.
p-value of Average Energy, Calcium, Vitamin D, and Fiber Intake in All Study Participants, Participants Not Accounted for Study Bars, and Participants in Group I and Group II between Baseline, Intervention, and Control.

	Intervention vs Baseline	Baseline vs Control	Intervention vs Control
Energy			
Combined[a]	*0.2797*	*0.6116*	*0.8957*
Group I	*0.1989*	*0.3958*	*0.7771*
Group II	*0.7226*	*0.8684*	*0.7583*
Excluded[b]	*0.0161* [c]	*0.6116*	*0.0030* [c]
Calcium			
Combined[a]	*<0.0001*[c]	*0.4915*	*0.0001* [c]
Group I	*0.0003* [c]	*0.7439*	*0.0156* [c]
Group II	*0.0003* [c]	*0.5862*	*0.0005* [c]
Excluded[b]	*0.1404*	*0.4915*	*0.1318*
Vitamin D			
Combined[a]	*0.0122* [c]	*0.9217*	*0.0134* [c]
Group I	*0.1024*	*0.7439*	*0.0936*
Group II	*0.0615*	*0.7946*	*0.0615*
Excluded[b]	*0.0122* [c]	*0.9217*	*0.0134* [c]
Fiber			
Combined[a]	*0.0007* [c]	*0.4035*	*0.0056* [c]
Group I	*0.0156* [c]	*0.8107*	*0.0198* [c]
Group II	*0.0168* [c]	*0.3812*	*0.0929*
Excluded[b]	*0.1178*	*0.4035*	*0.0654*

Notes: [a]Participants in Group I (n=18) and Group II (n=17) combined (n=35), [b]participants' intake not accounted for study bars (n=35), [c]statistically significant (*p<0.05*) by Wilcoxon signed-rank test.

The percentage of participants in each group with energy, calcium, vitamin D, and fiber intake meeting the EAR, and RDA or AI is shown in Table 6. No significant differences (*p>0.05*) in energy, calcium, vitamin D, and fiber intake were found between the two groups at baseline, intervention, and control. Figures 2, 3, 4, and 5 shows the energy, calcium, vitamin D, and fiber intake at baseline, intervention, and control of the

two groups in respect to each other. The average daily energy intake was about 200 kcal lower in Group I than Group II at baseline. Then, it increased in Group I and decreased in Group II through intervention and control. Dietary fiber intake in Group I was consistently lower by about 5 g per day compared to Group II in the study. Finally, calcium, vitamin D, and fiber intake followed a similar trend between the two groups in the study.

Table 6
Participants Meeting EAR, RDA/AI in Baseline, Intervention, and Control in All Participants, and Participants in Group I and Group II Not Accounted for Supplementation, and All Participants Accounted for Supplementation.

	Total[c] (n=35)		Combined (n=35)		Group I (n=18)		Group II (n=17)	
	EAR	RDA/ AI	EAR	RDA/ AI	EAR	RDA/ AI	EAR	RDA/ AI
Calcium[a]								
Baseline	12 (34.2)	4 (11.4)	12 (34.2)	4 (11.4)	7 (38.9)	2 (11.1)	5 (29.4)	2 (11.8)
Intervention	28 (79.9)	15[d] (42.9)	28 (79.9)	14 (40.0)	15 (83.3)	7 (38.9)	13 (76.5)	7 (41.2)
Control	14 (40.0)	11[d] (31.4)	14 (40.0)	9 (25.7)	7 (38.9)	5 (27.8)	7 (41.2)	4 (23.5)
Vitamin D[a]								
Baseline	6[d] (17.1)	0 (0)	5 (14.2)	0 (0)	3 (16.7)	0 (0)	2 (11.8)	0 (0)
Intervention	4[d] (11.4)	1[d] (2.9)	2 (5.9)	0 (0)	0 (0)	0 (0)	2 (11.8)	0 (0)
Control	3[d] (8.6)	0 (0)	2 (5.7)	0 (0)	1 (5.6)	0 (0)	1 (5.9)	0 (0)

Table 6
Continued.

Fiber[b]								
Baseline	-	6 (17.3)	-	6 (17.3)	-	2 (11.1)	-	4 (23.5)
Intervention	-	8 (22.9)	-	8 (22.9)	-	4 (22.2)	-	4 (23.5)
Control	-	7 (20.3)	-	7 (20.3)	-	2 (11.1)	-	5 (29.4)

Notes: Unit in n (%), EAR = estimated averaged requirement for calcium (800 mg per day) and vitamin D (10 mcg per day), [a]RDA = recommended dietary allowance used for calcium (1000 mg per day) and vitamin D (15 mcg per day), [b]AI = adequate Intake used for dietary fiber (25 g per day), [c]all participants with intake accounted for supplementation, [d]values that are different compared to Combined.

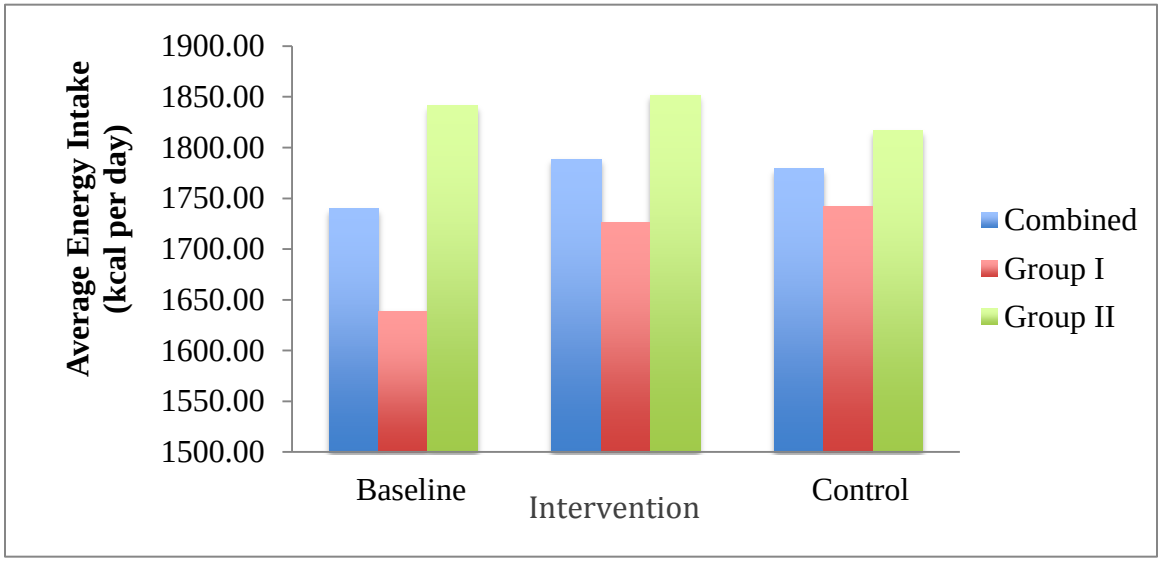

Figure 2. Average energy intake in all participants, and participants in group I, and group II at baseline, intervention, and control

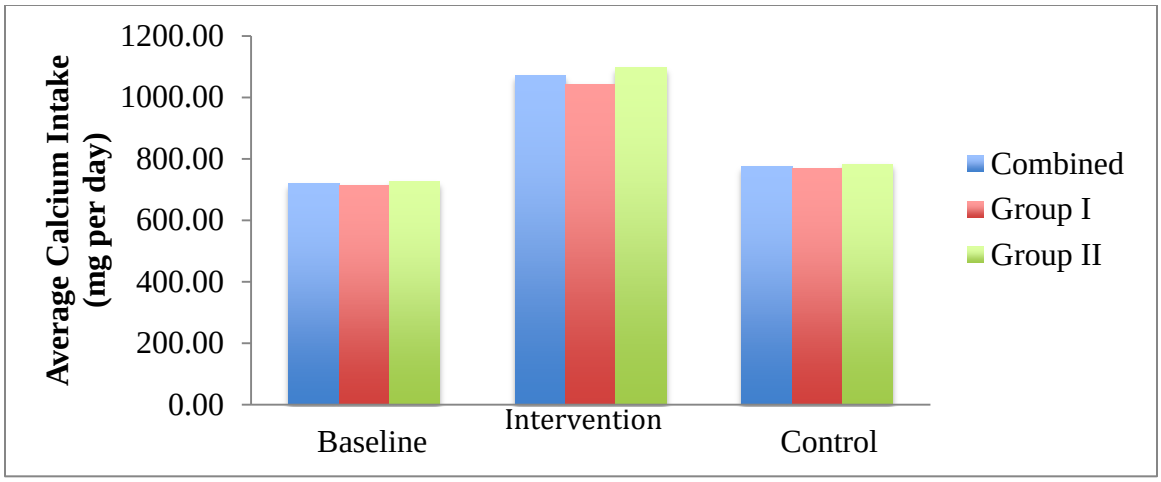

Figure 3. Daily average calcium intake not accounted for supplementation in all participants, and participants in Group I, and Group II at baseline, intervention, and control.

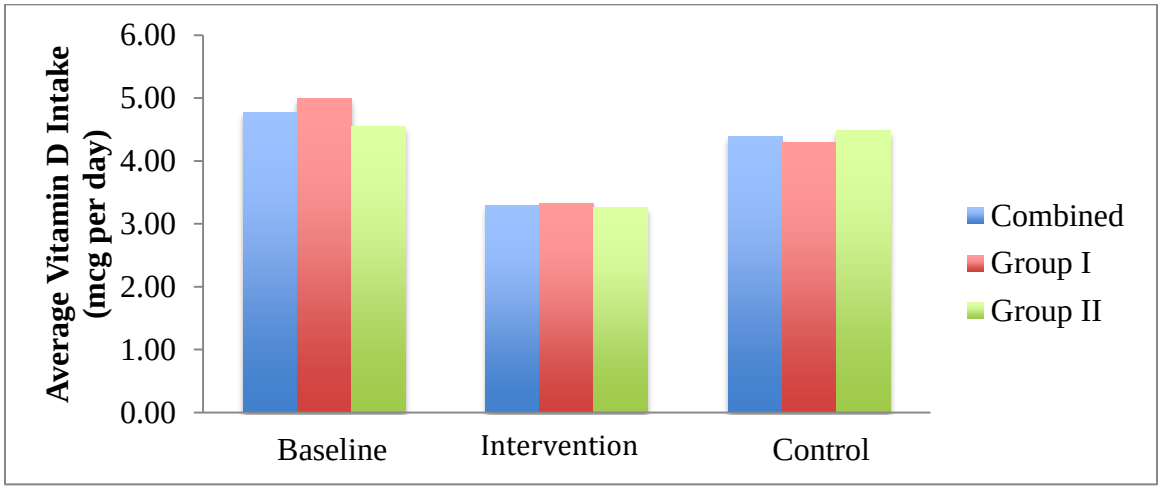

Figure 4. Daily average vitamin D intake not accounted for supplementation in all participants, and participants in Group I, and Group II at baseline, intervention, and control.

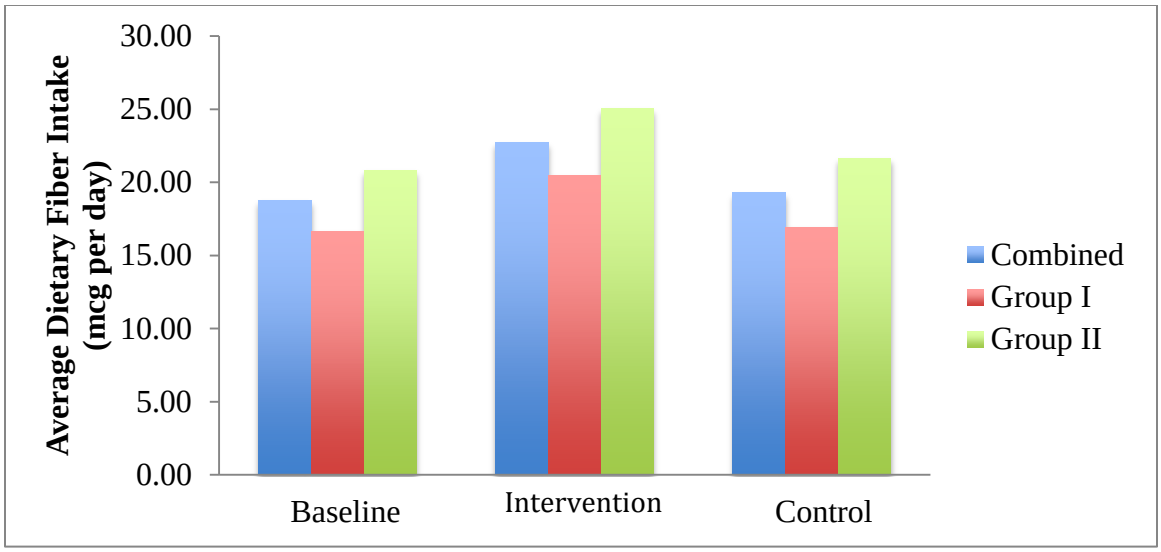

Figure 5. Daily average dietary fiber intake in all participants, and participants in Group I, and Group II at baseline, intervention, and control.

Supplementation

Of the six (17%) participants who took supplements during the study, three were taking calcium-containing multi-supplements. Table 7 shows the calcium and vitamin D content in supplements taken by the participants during the study. No changes in statistical significance were detected in calcium intake between baseline, intervention, and control when supplementation is accounted for. Dietary calcium intake at intervention (1092 mg per day) was significantly higher compared to baseline (732 mg per day, $p<0.0001$) and control (801 mg per day, $p=0.0001$), but not ($p=0.3177$) between baseline and control. However, the average dietary vitamin D intake of all participants between baseline and intervention became not significantly different ($p=0.1449$) when supplementation is accounted for. Table 8 shows the *p*-value for calcium and vitamin D

intake between baseline, intervention and control for all participants when including supplementation.

Table 7
Calcium and Vitamin D Content in Participants' Supplementation[a]

	Calcium (mg/serving)	Vitamin D (mcg/serving)
Women's Multivitamin	450	10
Centrum	200	10

Notes: [a]Two participants took Women's Multivitamin, one participant took Centrum; other supplements include vitamin B12, vitamin C, iron, and magnesium; participants did not take the same serving per day in 3-day diet and supplement record.

Table 8
p-value of Average Calcium and Vitamin D Intake of All Study Participants between Baseline, Intervention, and Control Accounted for Supplementation.

	Baseline vs Intervention	Baseline vs Control	Intervention vs Control
Calcium	*<0.0001*[a]	*0.3177*	*0.0001*[a]
Vitamin D	*0.1449*	*0.8699*	*0.0228*[a]

Notes: [a]Statistically significant ($p<0.05$) by Wilcoxon signed-rank test

Table 9 shows the average calcium and vitamin D intakes of all participants accounted for supplementation (n=35), supplement takers (n=6), and non-supplement takers (n=29) at baseline, intervention, and control. No significant difference was found between supplement takers and non-supplement takers, and between non-supplement takers and all participants accounted for supplements at baseline, intervention, and control.

Table 9

Average Calcium and Vitamin D Intake of All Study Participants Accounted for Supplementation, and Participants Who Took and Did Not Take Supplements at Baseline, Intervention, and Control.

	Baseline	Intervention	Control
Calcium (mg/d)			
Combined[a]	720±256	1070±369	775±347
Total[b]	732±275	1092±377	801±373
Supp[c]	806±506	1153±455	819±516
Non-Supp[d]	716±211	1080±367	797±348
p1[e]	*0.8268*	*0.6936*	*0.6616*
p2[f]	*0.8536*	*0.7398*	*0.7122*
Vitamin D (mcg/d)			
Combined[a]	4.8±3.6	3.3±2.7	4.4±3.0
Total[b]	5.2±3.9	4.1±3.7	5.0±3.7
Supp[c]	7.3±5.4	7.9±5.7	8.3±5.4
Non-Supp[d]	4.7±3.5	3.3±2.6	4.3±3.0
p1[e]	*0.2935*	*0.0838*	*0.0418*
p2[f]	*0.3759*	*0.1450*	*0.0862*

Notes: Data written as mean±SD; [a]participants in Group I and Group II combined not accounted for supplementation (n=35), [b]participants in Group I and Group II combined accounted for supplementation (n=35), [c]participants who are supplement takers (n=6), [d]participants who are not supplement takers (n=29), [e]statistically significant ($p<0.05$) between Non-Supp and Supp by Mann Whitney U test, [f]statistically significant ($p<0.05$) between Non-Supp and Total by Mann Whitney U test.

CHAPTER V

DISCUSSION

The results of this study support the hypothesis that consuming Kellogg's Nutri-Grain® cereal bars will increase dietary calcium intake in healthy women over the age of 18 years. This study found a significantly higher dietary calcium intake during intervention compared to baseline and control. The estimated calcium intake at baseline (714 mg per day) was lower than the NHANES 2005-2006 average intake (836 mg per day) for women above age 19 years (Bailey et al., 2010). Participants in this study were given two Kellogg's Nutri-Grain® cereal bars per day for three weeks. This provides an additional 400 mg of calcium per day (which is about 40% RDA, 50% EAR, or 20% DV) to increase the intake close to the recommended level. Consuming this calcium-fortified whole grain cereal bar may be a feasible way to increase dietary calcium intake as a potential mean to prevent osteoporosis development.

The calcium used in most previous intervention studies to increase dietary calcium intake mainly comes from dairy sources (Chan, Hoffman, & McMurry, 1995; Cadogan, Eastell, Jones, & Barker, 1997; Kristinsson, Valdimarsson, Steingrimsdottir, & Sigurdsson, 1994; Park, Heo, & Park, 2011; Renner, Hermes, & Stracke, 1998; Tenta, Moschonis, Koutsilieris, & Manios, 2011), both dairy products and calcium supplements (Liu, Qiu, Chen, & Su, 2011; Matkovic, Fontana, Tominac, Goel, & Chesnut, 1990), or calcium supplements alone (Kristinsson et al., 1994; Lee et al., 1995; Nowson et al., 1997; Tang, Eslick, Nowson, Smith, & Bensoussan, 2007; Winzenberg, Shaw, Fryer, & Jones, 2006). Chan et al. (1995) found a significantly higher calcium ($p=0.0001$), phosphate,

vitamin D, and protein intake, and BMD status when 48 adolescent girls were supplemented with dairy products such as milk, cheese, and yogurt to provide at least 1200 mg of calcium per day. Another intervention by Liu et al. (2011) on BMD and dietary calcium intake provided pregnant Chinese women between ages 24 and 31 with milk (350 mg per day), and milk with calcium supplement (600 mg per day) from gestational age of 20 weeks to 6 weeks post-partum. This study also found a significantly higher dietary calcium intake in the milk only (840 to 960 mg per day) and milk plus calcium supplementation (1320 to 1440 mg per day) groups compared to the control group (480 to 560 mg per day). Only a few intervention studies that looked at dietary calcium intake used calcium-fortified products.

The finding is consistent with previous studies using calcium-fortified products to increase calcium intake. However, most studies do not solely examine changes in dietary calcium intake, but also their effect on other factors such as body composition, BMD, and glycemic control, etc. (Ferrar et al., 2011; Haub et al., 2005; Ho et al., 2005; Nikooyeh et al., 2011; Martini & Wood, 2002; Schroder, Griffin, Specker, & Abrams, 2005; Zemel et al., 2005). Nikooyeh et al. (2011) reported an increased dietary calcium intake and improved glycemic control in type 2 diabetic patients when they were given yogurts fortified with calcium (300 mg and 500 mg) and vitamin D (25 mcg) daily for 12 weeks. A study by Haub et al. (2005) examining body composition observed a significant increase in dietary calcium intake in older women when they were supplemented with calcium-fortified beverage (600 mg) daily. In addition, Ho et al. (2005) found an increased in dietary calcium intake and improved BMD status when provided 600 mg

calcium per day in the form of calcium-fortified soymilk to 104 adolescent girls aged 14 to 16 years old for a year. Table 10 shows the details of other intervention studies using calcium-fortified products (on the next page).

Similar to this study, several previous clinical trials on calcium-fortified products excluded those with chronic disease, and those taking supplements and medication that may affect bone health (Ferrar et al., 2011; Haub et al., 2005; Ho et al., 2005; Martini & Wood, 2002). Others also excluded potential participants if they were using insulin, smoking, drinking alcohol regularly, or exercising excessively (Ferrar et al., 2011; Haub et al., 2005; Nikooyeh et al., 2011; Martini & Wood, 2002; Zemel et al., 2005). Also similar to this study, participants in Ferrar et al. (2011) were mostly premenopausal women with an average age of 29.5 years and BMI 24.1. However, it is a part of their inclusion criteria to include women between ages 20 to 39 and has a BMI between 18 and 30. In addition, several previous studies did not provide information on the ethnicity of their participants (Haub et al., 2005; Martini & Wood, 2002; Schroder et al., 2005; Zemel et al., 2005).

Table 10

Details on Previous Interventions Using Calcium-Fortified Food Product.

Author(s)	Year	Purpose	Inclusion/Exclusion Criteria	Participants Characteristics	Study Design	Intervention (INT)	Mean Body Weight (kg) [BMI (kg/m^2)]	Calcium Intake (mg per day)	Percent Drop-out	Percent Compliance
Ferrar, L., Hee, R. M., Berry, M., Watson, C., Miret, S., Wilkinson, J., . . . Eastell, R.	2011	To determine if calcium-fortified ice cream would produce significant and sustainable changes in bone turnover markers and parathyroid hormone in premenopausal women with calcium intake below recommended UK levels.	Inclusion: female between ages 20 to 39 years with habitual dietary calcium intake <750 mg per day, serum 25-hydroxy vitamin D >50 nmol per liter; willing and able to consume one ice cream per day for 28 days; BMI 18 to 30; have regular menses (11 to 12 periods per year); women taking oral contraceptives included if continuous usage for >2 years. Exclusion: take bisphosphonates in any dose within previous 2 years; take medications (within the previous 6 months) or have chronic conditions known to affect calcium metabolism or bone health; have malabsorption syndromes such as coeliac or Crohn's disease, hyperthyroidism, hyperparathyroidism, hypo- or hypercalcaemia, osteomalacia, Paget's disease, diabetes, history of cancer within previous 5 years (except for non-melanoma skin cancer), any fracture within the previous 12 months, and clinically significant organic disease that could limit ability to complete the study; alcohol intake >21 units per week or >4 units the day before screening visit; use of illicit drugs; serum calcium <2.2 mmol per liter; abnormal clinical biochemistry results; participate in clinical trial of active therapy within 3 months pre-randomization; attempt to conceive; pregnant, or breast feeding; excessive exercise (>4 strenuous exercise sessions per week); contraceptive injections within the previous year.	Premenopausal women (n=80). Ethnicity Caucasian (n=72) Asian (n=2) Mixed race (n=1) Other (n=1) Average age (years) INT: (1) 29.5±7.1 (2) 29.6±4.5 (3) 29.5±6.1 Control: 29.8±6.8	Single-centre randomized, double-blinded, controlled study. Participants randomly assigned to 1 of 4 groups, stratified by age to have 10 women ages 20 to 29, and 10 women ages 30 to 39 in each group; after a 7 days baseline period, participants consume 1 serving of ice cream per day for 28 days. Dietary intakes were assessed using the 4-day food diaries at day 1, 7, and 28.	Participants consume 1 serving of lower saturated fat/sugar ice cream (<90 kcal per serving) daily for 28 days to provide (mg calcium per day): INT: (1) 244 (2) 459 (3) 676 Control: 96	Overall: Baseline 65.6 (24.09) Post- 65.8 (24.1) INT: Baseline (1) 64.1±9.0 (24.1±2.8) (2) 70.8±9.9 (25.7±2.8) (3) 63.8±7.3 (23.4±2.3) Control: 64.1±10.1 (23.5±2.7)	INT: (1) Baseline 735±167 Post- 948.4±242.7 (2) Baseline 663±282 Post- 1171.2±327.0 (3) Baseline 754±256 Post- 1440.0±284.8 Control: Baseline 714±236 Post- 873.5±442.3	2 participants withdrew after day 1 and replaced. 80 women completed the study.	95% overall compliance by day 28; 4 women with <80% compliance by end of study excluded as non-compliant for per-protocol analyses.
Haub, M., Simons, T., Cook, C., Remig, V., Al-Tamimi, E., & Holcomb, C.	2005	To examined the effect of calcium-fortified beverage on body composition in postmenopausal women.	Inclusion: female between age 45 to 75 years, and postmenopausal. Exclusion: current diagnosis of chronic disease; smoking; fracture within past year; beginning or ending hormone replacement therapy within 6 months; taking medications known to affect bone metabolism (bisphosphonates, thiazides, corticosteroids, calcitonin, or tamoxifen).	Healthy postmenopausal women (n=37). Average age (years) Overall: 60±7	Randomized controlled intervention study. Participants were randomly assigned with stratification according to body composition to either intervention (n=17) or control (n=20); participants in INT consumed 2 servings of study drink per day (half in the morning and half in the evening) for 12 months. Dietary intakes assessed by 3-day diet records (2 weekdays and 1 weekend day) at baseline and at 12 months.	INT: 591 mL per day of drink (provides 1125 mg per day) containing milk (7%) and fruit juice (15%) for 12 months. Control: usual diet	Overall: Baseline 69.5±9.9 (BMI 26.1±3.7) INT: Baseline 69.6±11.5 Post- 70.2±12.6 Control: Baseline 69.3±8.7 Post- 69.3±8.3	INT: Baseline 919±435 Post- 2201±763 Control: Baseline 1244±734 Post- 1153±647	4 dropped out in INT: 2 unwilling to take supplement daily, and 2 due to personal reasons not related to the study. 41 recruited, 37 completed the study.	97% compliant by weekly consumption reports; Reasons for missing include: gastrointestinal discomfort, forgetfulness, flu, family emergency, and surgery.
Ho, S., Guldan, G., Woo, J., Yu, R., Tse, M., Sham, A., & Cheng, J.	2005	To examine the effect of calcium-fortified soymilk on bone mineral density and content in Chinese adolescent girls aged 14 to 16 years.	Inclusion: Chinese adolescent girls between ages 14 to 16 from 6 secondary schools of comparable academic status. Exclusion: participants with disease conditions, medications that may affect bone mineral density, or soy allergy.	Adolescent girls (n=199) Average age (years) Overall: 14.5±0. 6 INT: 14.47±0.75 Control: 14.5±0.39	Six schools assigned to either intervention or control to obtain equal numbers of participants in each group; participants in INT consumed 375 mL of soymilk per day for 12 months. Dietary intakes were assessed using 3-day diet records at baseline and at 12 months.	INT: 375 mL of calcium-fortified soymilk (142.5 kcal, 600 mg calcium) daily for 12 months. Control: usual diet	INT: Baseline 48.75±7.13 (19.39±2.59) Post- 50.20±6.90 (19.90±2.62) Control: Baseline 48.70±8.74 (19.24±2.73) Post- 49.90±8.71 (19.6±2.69)	INT: Baseline 511.03±215.94 Post- 496.1±211.0 Control: Baseline 513.68±217.99 Post- 558.7±224.7 Extra calcium intake provided by the fortified soymilk is not included.	5 from control and 6 from intervention refused to participate in follow-up. Reasons for drop-out: change of school, overseas study, bulky feeling after drinking soymilk. 210 enrolled, 199 completed the study.	N/A

Table 10
Continued

Nikooyeh, B., Neyestani, T. R., Farvid, M., Alavi-Majd, H., Houshiarrad, A., Kalayi, A., . . . Zahedirad, M	2011	To examine effects of daily vitamin D or vitamin D plus calcium-fortified yogurt intake on glycemic status in type 2 diabetic patients	Inclusion: between age 30 to 60 years and fasting blood glucose ≥126 mg/dL. Exclusion: inability or unwilling to participate; taking vitamin D, calcium, or omega-3 supplementation within the past 3 months; taking medications that may influence vitamin D metabolism such as for renal, hepatic, other endocrinologic disorder, and malignancies); using insulin or changing in dosage or type of current hypoglycemic medications during the study period.	Diabetic patients (n=90), 55 women and 35 men, who registered at the Iranian Diabetes Society. Average age (years) Overall: 50.7±6.1 (1): 50.8±6.6 (2): 51.4±5.4 (3): 49.9±6.2	Participants were randomly assigned to 1 of 3 groups; after a 2-week run-in (following a weight-maintenance diabetic diet), participants consumed 2 servings per day of yogurt (1 serving during the day and 1 serving at night) for 12 weeks. Dietary intake was assessed pre- and post-intervention via 24-hour recall for 2 days.	(1) Plain yogurt (PY; 150 mg calcium per 250 mL, no detectable vitamin D_3) (2) Vitamin D-fortified (DY; 500 IU vitamin D_3 and 150 mg calcium per 250 mL) (3) Vitamin D plus calcium-fortified yogurt (DCY; 500 IU vitamin D_3 and 250 mg calcium per 250 mL).	(1) pre-77.4±16.7; post- 77.3±16.9 (2): pre- 75.0±14.1; post-72.9±14.3 (3): pre-75.7±11.9; post-74.6±12.0	(1) pre-668.9±277.3 post-693.5±269.3 (2): pre-738.8±304.8 post-714.1±306.7 (3) pre-667.3±257.8 post-689.4±279.2 Extra calcium intake provided by the fortified yogurt drink is not included.	0% (All participants completed the study).	Estimated 100%
Zemel, M. B., Richards, J., Mathis, S., Milstead, A., Gebhardt, L., & Silva, E.	2005	To determine if the utilization of a single dairy product (yogourt) in a highly structured (calorie-reduced) diet would accelerate body weight and fat loss, similar to that observed with a mixture of dairy products.	Exclusion: >3 kg weight change over the preceding 12 weeks; changes in exercise frequency or intensity within 12 weeks of study entry; those requiring the use of oral antidiabetic agents or insulin; use of anti-obesity agents (prescription or herbal); use of calcium supplements; reported adverse effects to dairy products; a history of significant endocrine, hepatic or renal disease; pregnancy or lactation; or suffering from any form of malabsorption syndrome	Healthy obese adults n=34 (female n=27, male n=7) Average age (years) Yogurt: 39±10 Control: 42±6	Randomized, controlled clinical study; after a 2-week lead-in period, participants were randomly assigned to either control or INT; participants on yogurt diet consumes 3 servings of yogurt per day for 12 weeks.	INT: 3 daily 6-oz servings of fat free yogurt (provides 600 mg calcium per day), total intake 1100 mg calcium per day; 500 kcal deficit daily. Control: 0-1 serving per day of dairy, 400 to 500 mg calcium per day	BMI: Baseline: 30 to 39.9 INT: 32.1±0.4 Control: 33.2±0.9	Baseline: 500 to 600 INT: 1077±22 Control: 495±28	4 dropped out; reasons include: scheduling conflicts (n=3) or relocating out of state (n=1); no significant difference between completers and non-completers; 38 recruited, 34 completed the study.	N/A
Schroder, B. G., Griffin, I. J., Specker, B. L., & Abrams, S. A.	2005	To compare calcium absorption of dairy soft drink, fat-free milk, and calcium-fortified orange juice.	Inclusion: currently consuming milk or milk products, not currently taking calcium supplements or other medication that might impact calcium absorption, and be in general good health. Exclusion: had gastrointestinal problems, such as nausea, vomiting, or diarrhea, within 48 hours were not allowed to participate.	Data include n=33 women. Average age 43 (ranged 22-72 years) 25 women on hormone replacement therapy, 7 women estrogen depleted, 1 unknown.	Randomized, crossover study; participants supplement 400 IU vitamin D starting at 30 days prior to first visit; participants were randomly assigned to 2 groups. Dietary intake assessed by 3-day diet diary prior to the visit.	Participants were provided dairy soft drink (109 mg calcium per day), fat free milk (367 mg calcium per day), and orange juice (456 and 512 mg calcium per day) consumed in order of: (1) milk, orange juice, then dairy soft drink (2) dairy soft drink, orange juice, then milk	Overall: 71.4±17.5 kg (BMI 25.8±6.0).	Overall: 759±279 Extra calcium intake provided by the INT is not included.	34 women enrolled, 31 completed all three arms of the study; one completed only 1 of 3 arms (excluded), two completed 2 of 3 arms (included in data analysis).	N/A

Previous studies showed an overall compliance of around 95 to 100% (Ferrar et al., 2011; Haub et al., 2005; Nikooyeh et al., 2011). Some studies did not provide information on compliance (Ho et al., 2005; Martini & Wood, 2002; Zemel et al., 2005). Reasons for noncompliance included discomfort, forgetfulness, flu, family emergency, and surgery (Haub et al., 2005). In the study by Schroder et al. (2005), data of one participant who only completed 1 of 3 parts of the study was excluded, and the data of another two participants who only completed 2 of 3 parts of the study were included in analysis. Data for four participants in Ferrar et al. (2011) showed less than 80% compliance by the end of the study was excluded from the analysis, but the reasons for the noncompliance were not described. This study showed 98.6% compliance, and reasons for noncompliance included forgetfulness and undesirable taste.

Five participants dropped out from this study due to scheduling conflicts (n=4) and relocation to out of state (n=1). Four out of 38 participants also dropped out due to the same reasons in Zemel et al. (2005). Reasons for dropouts in Ho et al. (2005) include change of school, overseas study, and feeling discomfort after drinking soymilk. Four participants dropped out from the intervention group in Haub et al. (2005) due to unwilling to participate and personal reason reasons unrelated to the study. Nikooyeh et al. (2011) had a 0% drop-out rate. Some studies did not describe the reasons for dropping out (Ferrar et al., 2011; Schroder et al., 2005).

This study used a randomized control crossover design. The studies by Schroder et al. (2005) and Martini and Wood (2002) also used a crossover design on calcium-fortified orange juice. In addition, random assignment was used in studies by Ferrar et al.

(2011), Haub et al. (2005), Nikooyeh et al. (2011), Schroder et al. (2005), and Zemel et al. (2005). However, participants were stratified based on body composition in Haub et al. (2005), and based on age in Ferrar et al. (2011). Ho et al. (2005) assigned 6 schools to obtain an equal number of participants in the intervention and control group.

Similar to this study, most previous interventions also assessed dietary intake using dietary records (Ferrar et al., 2011; Haub et al., 2005; Ho et al., 2005; Martini & Wood, 2002; Schroder et al., 2005). In addition, the duration of most previous interventions were longer than this study (Ferrer et al., 2011; Haub et al., 2005; Ho et al., 2005; Nikooyeh et al., 2011; Zemel et al., 2005). This study provided calcium-fortified cereal bars for 3 weeks during a 9-week period. This is similar to Ferrar et al. (2011), which provided the calcium-fortified ice cream for 28 days after a 7-day baseline period.

Previous intervention studies examined various calcium-fortified products. Ferrar et al. (2011) examined the effect of consuming calcium-fortified ice cream on bone markers and did not find significant change in calcium intake over the course of the study when given an additional 96, 244, 459, and 676 mg calcium per day. However, they suggested that even supplementing with a small amount of calcium per day could help individuals meet the recommended calcium intake. In addition, Nikooyeh et al. (2011) found that consuming calcium-fortified yogurts (providing an additional 500 mg of calcium per day) for 12 weeks would improve glycemic control and significantly increase calcium intake in type 2 diabetic patients. Calcium-fortified orange juice was used in Schroder et al. (2005) and Martini and Wood (2002). Martini and Wood (2002) provided 1300 mg of calcium per day for 3 out of 6 weeks of the study and suggested that

consuming any supplemental sources with calcium may help the individual to achieve optimal dietary calcium intake. To the best of the author's knowledge, no studies had been done to determine whether consuming Kellogg's Nutri-Grain® cereal bars could improve calcium status in in healthy women above age 18 years.

Another finding of this study is that Kellogg's Nutri-Grain® cereal bars may help improve daily dietary fiber intake. Consuming adequate dietary fiber may be beneficial for the gastrointestinal and heart health, glycemic control, weight management, metabolic risk factors, and more (Liu et al., 1999; Liu et al., 2000; McKeown, Meigs, Liu, Wilson, & Jacques, 2002; Schatzkin et al., 2007; Schulze et al., 2004). The fiber intake at baseline (18.7 g per day) was higher than the average fiber intake of women above age 20 years (15 g per day) in the United States, but it has not yet reached the recommended level of 25 g per day for women aged 19 to 50 years, and 21 g per day for women above 50 years (Slavin, 2008). Consuming two Kellogg's Nutri-Grain® cereal bars per day will provide a total of 6 g (20% DV) of dietary fiber daily, which increases the fiber intake close to the recommended level. Participants' daily average dietary fiber intake was significantly ($p<0.05$) higher during the intervention (22.7 g per day) compared to baseline (18.7 g per day) and control (19.3 g per day). Eating this bar could be a practical method to obtain adequate fiber intake.

This study found a significantly lower daily dietary vitamin D intake at intervention (3.3 mcg per day) compared to baseline (4.78 mcg per day, $p=0.0122$) and control (4.39 mcg per day, $p=0.0134$). Vitamin D could be found in fatty fish and fish liver oil. However, fortified diary, yogurt, orange juice, and some ready-to-eat cereals

provide the majority in the diet. The Kellogg's Nutri-Grain® cereal bar does not provide dietary vitamin D. The decrease in intake may be due to a lower consumption of these foods containing vitamin D in the intervention group, as they were receiving the study bars.

The average vitamin D intake between baseline and intervention are not significantly different (*p=0.1449*) when supplementation is accounted for. Three of the 35 participants (8.6%) took supplements that contain calcium and vitamin D. However, only some participants reported taking the supplements on certain, but not all, days. Supplementation increased vitamin D intake during the intervention but not during baseline.

The study participants were not a good representation of the general population in terms of ethnicity. Most participants in this study reported to be Asian (46%) and White (34%). However, the Asian population only consists of less than 5% of the general population in most places in the United States. There may be sample selection bias in the sense that Participants in this study may mostly be students and staffs at Texas Woman's University, Houston Center, and residents in the Texas Medical Center in Houston.

The length of the study may not be long enough to facilitate a sustainable long-term behavior change. Participants received the Kellogg's Nutri-Grain® cereal bars for only 3 weeks during this 9-week study. This study found a small but not significant increase in the calcium intake between baseline and control in all study participants, as well as participant in Group I and II. In particular, participants in Group I consumed their normal diet after the intervention period. A slight increase in calcium intake was

reported between baseline (714 mg per day) and control (767 mg per day), but the change was not significantly different (*p=0.3958*).

This study did not control participants' usual diet intake. However, controlling their usual diet was impractical since participants were free-living adults. Also, by not controlling their usual diet, the measured intake is more likely to reflect habitual intake and feasibility of the intervention, and to enhance compliance in consuming the study bars.

This study also did not assess participants' BMD status or calcium absorption. Previous studies showed an improved BMD status from increased calcium intake (Chan et al., 1995; Ho et al., 2005; Liu et al., 2011). However, intestinal calcium absorption may vary depending on factors such as intake, age, and gender (Ensrud et al., 2000; Heaney, 2008). Future studies will be needed to assess the effect of Kellogg's Nutri-Grain® cereal bars consumption on BMD status and bone health in this population.

The food record assessed by the 3DS may not accurately reflect the usual diet of the participants. Participants were required to keep a 3DS for a total of 9 days in this study. However, most have not had the experience prior to this study. This may limit the generalizability and accuracy of the findings. Research showed a decrease in validity of the diet record in later days of a 7-day recording period compared to earlier days (Gersovitz, Madden, & Smiciklas-Wright, 1978). The work required to keep a diet record may affect their food choices and amounts consumed (Andersen, Johansson, & Solvoll, 2002; Kristjansdottir, Andersen, Haraldsdottir, de Almeida, & Thorsdottir, 2006; Rebro, Patterson, Kristal, & Cheney, 1998). The average energy intake was reported

lower in Group I than Group II at baseline. Then, it trended up in Group I and trended down in Group II at intervention and control (Graph 1). This may potential be due to over- or under-estimation of the 3DS.

Overall, the calcium, vitamin D, and fiber intake followed a similar trend between the groups. Although not significantly different, the average dietary fiber intake in Group I was consistently about 5 grams lower than in Group II during the study. No apparent order effect was shown between the two groups.

CHAPTER VI

CONCLUSION

The results of this study showed a significantly higher average dietary calcium and fiber intake when healthy women above age 19 years were provided with two Kellogg's Nutri-Grain® cereal bars daily for three weeks. The study also reported a significant decrease in the daily average dietary vitamin D intake when the study bars were given, and no significant changes in energy intake. No other studies have examined the consumption of this calcium-fortified whole grain cereal bar on dietary calcium intake. The findings from this study may help further future research on feasible ways to obtain adequate calcium intake as means to improve bone health and prevent osteoporosis development.

Recommendations

It is recommended for future studies to have a larger sample size and longer length of study. Future studies should perform a more comprehensive assessment on the participants. Information such as socioeconomic status and perception on dietary health could be assessed. Future studies should examine the long-term effect of consuming Kellogg's Nutri-Grain® cereal bars on BMD status and calcium absorption. Studies should also examine whether eating the study bars could improve gastrointestinal health as a potential mean to protect against colorectal cancer.

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APPENDIX A

IRB Approval Letter

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

November 16, 2011

Ms. Jennifer Lee
Nutrition and Food Sciences
6700 Fannin Street
Houston, TX 77030

Dear Ms. Lee:

Re: "Effect of Calcium-fortified Cereal Bars on Dietary Calcium Intake in Women" (Protocol #: 16802)

Your application to the IRB has been reviewed and approved.

This approval lasts for one (1) year. The study may not continue after the approval period without additional IRB review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

The signed consent forms, as applicable, and final report must be filed with the Institutional Review Board in the Office of Research, IHS 10110, at the completion of the study.

Sincerely,

Carolyn Kelley, PT, DSc, NCS
Institutional Review Board - Houston

APPENDIX B

Informed Consent Form

TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: Effect of Calcium-fortified Cereal Bars on Dietary Calcium Intake in Women

Investigator: Jennifer Lee ..... jlee9@twu.edu 281/782-8789
Advisor: John Radcliffe, PhD, RD ..... jradcliffe@twu.edu 713/794-2375

Explanation and Purpose of the Research

You are being asked to participate in the research study for Ms. Lee's thesis at Texas Woman's University (TWU), Houston Center. The intake of calcium from the diet for adult women in the United States is below the recommended level, which increases their risk of developing osteoporosis. The purpose of this study is to determine whether eating Kellogg's Nutri-Grain® cereal bars, providing approximately 40% of the daily need for calcium, will increase calcium intake in healthy adult women.

Your calcium intake will be calculated from information from your diet diaries that you will be asked to keep. A nutrient analysis program will be used. Your intake of energy (as calories), fat, protein, carbohydrates, vitamins, and minerals will also be determined to help describe the effect of consuming cereal bars on your nutritional status.

In order to take part in this study, you must be over the age of 18 years, be able to speak, read, and understand English, be able to keep three-day diet diaries, and be able to eat Kellogg's Nutri-Grain® cereal bars and not be allergic to any of the ingredients (oats, wheat flour, wheat bran, wheat gluten, corn fiber, cornstarch, corn syrup, whey, soybean oil, soy lecithin, sugar, red #40, strawberries, blueberries, apples, and cinnamon). You should not be regularly consuming more than two Kellogg's Nutri-Grain® cereal bars per month. You must not be pregnant or plan to become pregnant during this nine-week study. You must not be taking any calcium-containing medication. You must not have kidney disease, liver disease, gastrointestinal disease (celiac disease, ulcerative colitis, and Crohn's disease), a history of bariatric surgery, have had a major cardiovascular event (stroke or myocardial infarction), be undergoing treatment for cancer with the exception of non-melanoma skin cancer, be following a weight control diet or a disease specific diet, be following a vegan diet, or have a diagnosed eating disorder.

Description of Procedures

You will be one of 40 participants in this nine-week study. As participants, you will be placed into either Group I or Group II by drawing numbers from a hat. If you are assigned to Group I, you will be asked to eat your usual diet for the first three weeks of the study, then you will be given 42 cereal bars to be consumed for the following three weeks, with two bars being available each day; after this, you will be asked to eat your usual diet again for the next three weeks. If you are assigned to Group II, you will be asked to eat your usual diet for the first six weeks of the study, and then you will be given 42 cereal bars to be consumed for the following three weeks. You will be asked to consume 2 bars per day for three weeks. You will be asked

Participant Initials

to keep a three-day diet and supplement diary on weeks 2, 5, and 8 of the study. You will be asked to keep a daily check list of cereal bars consumed during the three weeks when the cereal bars are made available to you. You will be asked to have four visits to the Department of Nutrition and Food Sciences at TWU, Houston Center. Cereal bars will be given to you as necessary during these visits. You will be asked to return any uneaten cereal bars.

During your first visit, after completing the consent form, you will be assigned to either Group I or Group II. You will be assigned a code number. You will have your height and weight taken, and you will be asked to give your age and ethnicity. You will have your height and weight taken using an instrument called a Health-O-Meter. You will be given a schedule with dates and times for your next meeting session, blank pages of the diet diaries with your code number, and instructions how to keep a three-day diet and supplement diary. You will need to keep a three-day diet and supplement diary during weeks 2, 5, and 8 of the study, each with two nonconsecutive (not next to each other) weekdays and one weekend day. However, you may choose to have a weekday next to a weekend day (for example, a Friday next to a Saturday or a Sunday next to a Monday). You will be asked to write down the brand name, type of food, amount consumed, and the time it was consumed (for example, HEB, Milk, 2% fat, 1 glass [8 oz], 8 am), as well as the names of any supplements (for example, Centrum). You will be provided with measuring cups that will enable you to estimate the amounts of foods and drinks that you consume. However, you may record commonly used items without using the measuring cups (for example, one can of Sprite). Also, you may only need to measure the amount(s) of the food item(s) consumed once if you eat similar amount(s) each day. You will be asked to complete a check list during each of the weeks when you are given the cereal bars.

During the second, third, and fourth meeting sessions (after the third, sixth, and ninth week of the study), you will return the completed three-day diet and supplement diaries to the researcher and you will have your diet and supplement diary reviewed with the researcher. You will be given blank diet and supplement diaries during the meeting sessions at the third and sixth weeks of the study. If you are in Group I, you will be given 42 cereal bars during the second meeting (after the third week of the study). If you are in Group II, you will be given 42 cereal bars during the third meeting session (after the sixth week of the study). You will be asked to have your weight measured again at the end of weeks 3, 6, and 9.

It is estimated that your total time commitment for the study will be no more than 3 hours. It will take no more than 3 minutes to have your height and weight taken on your first visit and no more than 6 minutes to have your weight taken at three subsequent visits (3x2 minutes); it will take no more than 15 minutes to receive instructions on how to keep a diet and supplement diary; it should take no more than 10 minutes per day, 30 minutes per week, or a total of 1 hour and 30 minutes for weeks 2, 5, 8 of the study to keep your diet and supplement diaries; it should take you no more than 1 minute per day, 7 minutes per week, or 21 minutes per 3 weeks to keep a check list during the period when you are given cereal bars; it should take no more than 15 minutes per session, and 45 minutes per 3 sessions to have your diet diaries reviewed at the end of weeks 3, 6, and 9.

You will receive cash reimbursement if you park at TWU at the day of your visit.

Participant Initials

Potential Risks

You will be asked to consume two Kellogg's Nutri-Grain® cereal bars per day, providing approximately 240 kilocalories per day, so a potential risk for this study is weight gain. However, the potential for weight gain may be reduced, as you will most likely eat less of other food items that you normally eat, and your weight should not change.

Another risk in this study is loss of confidentiality. However, every effort will be made to maintain the confidentiality of the study records. Confidentiality will be maintained by using codes rather than names. The data will be stored in a locked filing cabinet in Room 10132B. Only the researcher and the advisor of this study will have access to the filing cabinet. All data will be destroyed by shredding before September 1st, 2021. All meeting sessions will be held in Room 10132B at TWU, Houston Center or at a private setting agreed upon by you and the researcher. The data and results of the study may be reported in scientific magazines or journals but your name or any other identifying information will not be included. Confidentiality will be protected to the extent allowed by law.

There is a risk that your normal schedule may be disrupted by coming to TWU, Houston Center. To minimize this risk, the meeting sessions can be scheduled within an 8-hour period (from 9 am to 5 pm) during week days.

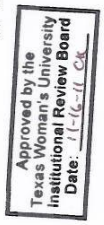
The researchers will try to prevent any problem that could happen because of this study. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Your involvement in this study is completely voluntary and you may withdraw from the study at any time. Following the completion of the study, you will receive a $20 gift card for your participation. Another benefit is that you will receive free food in the form of 42 Kellogg's Nutri-Grain® cereal bars valued at $1 per bar. This study may also provide you with knowledge of the potential health benefits of consuming cereal bars fortified with calcium. If you would like to know the results of this study, we will mail them to you.*

Questions Regarding the Study

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study you could ask the researchers at any time during the entire course of the study; their phone numbers are at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman's University Office of Research at 713-794-2480 or via e-mail at IRB@twu.edu.



_____ _____

Signature of Participant Date

*If you would like to know the results of this study tell us the address of where you want them to be sent:

E-mail: _____

Or address: _____

_____

APPENDIX C

Announcement for the Study Flyer

PARTICIPANTS NEEDED!!

Texas Woman's Univeristy - Houston Center

9 WEEKS FEEDING STUDY

The purpose of this study is to determine if eating calcium-fortified cereal bars will result in higher intakes of calcium.

IF YOU ARE:

- Healthy woman
- Between the ages of 18 and 50
- Not taking calcium-containing medication or calcium supplements
- Not allergic to dairy, soy, wheat
- Not pregnant nor plan to become pregnant during the course of the study

YOU WILL BE ASKED TO:

- Visit the Texas Woman's University, Houston Center for 4 times
- Either consume your usual diet for 6 weeks then receive cereal bars for the next 3 weeks or consume your usual diet for 3 weeks, receive cereal bars for 3 weeks, then consume your usual diet again for 3 weeks
- Have your height taken on one occasion and weight taken on four occasions
- Eat **2 Kellogg's Nutri-Grain® cereal bars per day for FREE!**

COST $1 EACH!

Participants will be compensated upon completion of this study.

For More Information, Please Contact:
Jennifer Lee
281-782-8789

Jennifer Lee 281 782 8789 JLEE9@TWU.EDU

APPENDIX D

Announcement for the Study Schedule

Code Number: _____ Date: _____

GROUP I SCHEDULE

Purpose of Visit:									
Visits	**Date**	**Instruction/ Consent to Participate**	**Group Assignment**	**Height Taken**	**Weight Taken**	**Pick up Cereal Bars**	**Pick up Blank Diaries**	**Return & Review Previous Diaries**	**Additional Comments**
1		√	√	√	√		√		
2					√	√	√	√	
3					√		√	√	
4					√			√	

Code Number: _____ Date: _____

GROUP II SCHEDULE

Purpose of Visit:									
Visits	**Date**	**Instruction/ Consent to Participate**	**Group Assignment**	**Height Taken**	**Weight Taken**	**Pick up Cereal Bars**	**Pick up Blank Diaries**	**Return & Review Previous Diaries**	**Additional Comments**
1		√	√	√	√		√		
2					√		√	√	
3					√	√	√	√	
4					√			√	

APPENDIX E

Raw Data

Appendix E

Raw Data.

Group I (n=18)	Initial Measurement				Baseline Intake				Intervention Intake				Control Intake			
Participant ID	Ethnicity	Age (years)	Height (in)	Weight Initial (lbs)	Energy (kcal)	Calcium (mg)	Fiber (g)	Weight Baseline (lbs)	Energy (kcal)	Calcium (mg)	Fiber (g)	Weight Intervention (lbs)	Energy (kcal)	Calcium (mg)	Fiber (g)	Weight Control (lbs)
1	W	22	64.25	130.00	1628	866	18	130.50	1639	811	27	131.00	2108	1002	20	130.00
5	A	24	62.50	112.00	1748	317	8	112.00	1742	876	17	113.00	2722	589	20	110.00
8	A	25	60.50	108.00	1342	752	14	109.00	1707	1081	21	110.00	1717	494	11	110.00
9	A	25	62.25	111.50	1205	362	16	109.50	1303	808	23	108.00	1362	376	21	106.50
14	W	23	62.50	121.50	1239	766	12	121.00	1447	1303	20	120.50	2060	1014	21	121.50
15	A	25	62.50	102.50	1276	525	13	100.00	1751	610	15	102.00	804	432	8	102.50
16	B	30	61.00	138.00	1788	424	22	137.50	2190	661	23	140.50	2419	953	18	137.00
20	H	32	62.50	112.00	2540	977	14	111.00	2355	980	23	111.50	1427	591	13	111.75
22	W	58	64.25	148.50	1500	530	12	147.50	1489	872	18	149.25	1395	519	10	148.00
23	A	23	61.00	86.02	2729	727	16	83.60	2718	898	17	84.48	2529	1721	13	85.80
26	W	25	63.50	137.00	1426	1164	37	139.00	1282	1303	28	141.00	1170	927	20	140.60
27	A	25	64.00	110.00	2032	878	17	113.00	1211	976	14	113.00	1467	1164	12	112.00
28	A	28	60.50	106.00	1459	404	9	104.50	1712	675	16	104.00	1593	640	20	105.00
31	W	34	65.50	145.00	1900	1416	25	144.00	2266	1696	22	145.00	2262	1056	32	144.00
33	H	22	64.00	130.50	1856	882	25	131.00	1734	1496	26	131.00	1860	661	27	128.00
34	B	37	65.94	180.00	1238	828	17	178.00	1028	1539	17	180.00	954	569	13	174.50
37	A	27	63.00	113.30	1266	415	9	111.54	1477	912	13	133.74	2163	509	10	133.30
38	W	23	65.00	123.50	1328	621	14	124.50	2012	1286	25	125.50	1349	603	18	125.00
Group II (n=17)	Initial Measurement				Baseline Intake				Control Intake				Intervention			
Participant ID	Ethnicity	Age (years)	Height (in)	Weight Initial (lbs)	Energy (kcal)	Calcium (mg)	Fiber (g)	Weight Baseline (lbs)	Energy (kcal)	Calcium (mg)	Fiber (g)	Weight Control (lbs)	Energy (kcal)	Calcium (mg)	Fiber (g)	Weight Intervention (lbs)
2	W	49	62.00	174.00	921	586	15	176.00	1426	883	19	172.50	1061	769	25	170.00
3	A	23	66.50	110.00	2764	717	19	110.00	1767	826	16	107.00	1789	949	16	108.00
10	W	24	67.50	156.00	2158	1015	46	152.00	2054	891	32	155.50	2139	1438	49	155.00
11	L	22	61.00	112.00	2348	684	30	113.00	2081	696	39	114.00	1802	963	33	116.50
12	A	23	61.50	103.00	1671	557	16	103.00	2121	659	19	103.00	1764	675	20	104.00
13	B	21	63.50	162.00	1410	439	19	156.00	1149	385	13	158.00	1411	832	17	159.00
17	W	41	65.50	143.00	1831	771	13	143.00	1998	725	17	140.00	1793	1227	19	144.00
18	A	24	62.50	111.50	1312	791	13	111.00	1918	1018	23	110.00	1683	1282	16	110.50
19	A	27	62.50	124.00	1991	609	11	126.30	1797	445	10	125.00	1909	897	21	127.00
21	B	28	65.50	119.00	894	429	5	123.00	954	385	10	120.50	1284	834	13	120.50
24	A	27	57.50	116.50	1762	964	15	117.00	1232	673	10	117.50	1671	1132	21	115.00
29	A	23	66.50	150.00	2416	688	25	151.00	1778	456	13	151.00	1588	696	18	152.00
30	A	25	64.00	106.48	1269	880	13	108.47	1597	788	20	110.01	1789	941	23	111.60
32	B	23	66.50	125.00	3100	1213	46	125.00	3643	1726	52	124.50	3278	1908	42	128.00
35	W	24	65.25	131.00	1790	666	22	131.00	1597	1229	28	129.50	1588	1250	19	130.00
36	A	26	62.50	89.00	1414	448	11	88.00	1397	393	12	90.00	1972	708	24	94.25
40	W	34	67.50	176.00	2255	872	34	178.00	2377	1134	35	181.00	2960	2144	49	183.00

Notes: W = Non-Hispanic White, B = Non-Hispanic Black, H = Mexican-American/Hispanic, A = Asian, L = Lebanese

APPENDIX F

Nutrient Content of Study Bar in Nutrition Data System for Research 2011

UNIVERSITY OF MINNESOTA
NDSR
NUTRITION DATA SYSTEM FOR RESEARCH

NDSR 2011 Recommended Dietary Allowances/Adequate Intake Report

Project Abbreviation: CBStudy
Participant ID: 00 Date of Intake: 01/01/2012
Life Stage Group: Females, Age 31-50 y

Nutrient	Amount Reported	RDA	%RDA	AI
Vitamin A	225 mcg RAE	700 mcg RAE	32 %	
Vitamin C	0.030 mg	75 mg	0 %	
Vitamin D	0.000 mcg	15 mcg	0 %	
Vitamin E	1.184 mg	15 mg	8 %	
Vitamin K	0.273 mcg			90 mcg
Thiamin	0.375 mg	1.1 mg	34 %	
Riboflavin	0.425 mg	1.1 mg	39 %	
Niacin	5.263 mg NE	14 mg NE	38 %	
Vitamin B6	0.500 mg	1.3 mg	38 %	
Folate	66 mcg DFE	400 mcg DFE	16 %	
Vitamin B12	0.000 mcg	2.4 mcg	0 %	
Pantothenic Acid	0.082 mg			5 mg
Choline	2.685 mg			425 mg
Calcium	200 mg	1000 mg	20 %	
Copper	31 mcg	900 mcg	3 %	
Iron	1.800 mg	18 mg	10 %	
Magnesium	11 mg	320 mg	3 %	
Manganese	0.252 mg			1.8 mg
Phosphorus	28 mg	700 mg	4 %	
Selenium	4.194 mcg	55 mcg	8 %	
Zinc	1.499 mg	8 mg	19 %	
Potassium	0 g			4.7 g
Sodium	0 g			1.5 g
Total Fiber	0.855 g			25 g
Total Water	0.007 l			2.7 l

RDA/AI values based on the Dietary Reference Intakes provided by the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (1997-2011).

UNIVERSITY OF MINNESOTA
NDSR
NUTRITION DATA SYSTEM FOR RESEARCH

NDSR 2011 Recommended Dietary Allowances/Adequate Intake Report

Project Abbreviation: CBStudy
Participant ID: 00 Date of Intake: 01/01/2012
Life Stage Group: Females, Age 31-50 y

Additional Recommendations

Nutrient	Amount Reported	% of Energy	Recommended Intake
Energy	131 kcal		
Fat	3.165 g	21.148 %	20-35% [2]
Carbohydrate	25.691 g	75.588 %	45-65% [2]
Protein	1.172 g	3.236 %	10-35% [2]
Alcohol	0.000 g	0.000 %	
Cholesterol	0 mg		< 300 mg [1]
Saturated Fatty Acids	0.345 g	2.316 %	< 10% [1]
Trans-Fatty Acids	0.013 g	0.090 %	
Linoleic Acid	1.961 g	13.519 %	5-10% [2]
Alpha-Linolenic Acid	0.006 g	0.041 %	0.6-1.2% [2]
Added Sugars	18.213 g	55.804 %	< 25% [2]

Note: DSAM nutrients are not included in these totals. Nutrient totals may not equal the sum of their parts. Alpha-linolenic acid values are represented as undifferentiated 18:3. (Refer to the NDSR User Manual.)

[1] Dietary Guidelines for Americans, 2010.
[2] Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (2002/2005).

APPENDIX G

Nutrient Content of Study Bar in USDA National Nutrient Database for Standard Reference Release 26

USDA National Nutrient Database for Standard ReferenceRelease 26

Basic Report 19441, Snacks, KELLOGG'S, NUTRI-GRAIN Cereal Bars, fruit

Report Date:March 04, 2014 14:19 EST

Nutrient values and weights are for edible portion

Nutrient	Unit	1 Value Per100 g	1.0 bar 37g	1.0 bar 37g
Proximates				
Water	g	15.29	5.66	5.66
Energy	kcal	324	120	120
Protein	g	4.69	1.74	1.74
Total lipid (fat)	g	8.76	3.24	3.24
Carbohydrate, by difference	g	69.54	25.73	25.73
Fiber, total dietary	g	6.9	2.6	2.6
Sugars, total	g	30.84	11.41	11.41
Minerals				
Calcium, Ca	mg	541	200	200
Iron, Fe	mg	4.90	1.81	1.81
Magnesium, Mg	mg	41	15	15
Phosphorus, P	mg	115	43	43
Potassium, K	mg	222	82	82
Sodium, Na	mg	315	117	117
Zinc, Zn	mg	4.10	1.52	1.52
Vitamins				
Vitamin C, total ascorbic acid	mg	7.8	2.9	2.9
Thiamin	mg	0.610	0.226	0.226
Riboflavin	mg	1.150	0.426	0.426
Niacin	mg	13.500	4.995	4.995
Vitamin B-6	mg	1.350	0.500	0.500
Folate, DFE	µg	24	9	9
Vitamin B-12	µg	0.00	0.00	0.00
Vitamin A, RAE	µg	604	223	223
Vitamin A, IU	IU	2027	750	750
Vitamin E (alpha-tocopherol)	mg	0.00	0.00	0.00
Vitamin D (D2 + D3)	µg	0.8	0.3	0.3

Nutrient	Unit	1 Value Per100 g	1.0 bar 37g	1.0 bar 37g
Vitamin D	IU	32	12	12
Vitamin K (phylloquinone)	µg	15.3	5.7	5.7
Lipids				
Fatty acids, total saturated	g	1.600	0.592	0.592
Fatty acids, total monounsaturated	g	2.200	0.814	0.814
Fatty acids, total polyunsaturated	g	4.800	1.776	1.776
Fatty acids, total trans	g	0.100	0.037	0.037
Cholesterol	mg	1	0	0
Other				
Caffeine	mg	0	0	0

APPENDIX H

American Institute for Cancer Research 2013 Poster

TEXAS WOMAN'S UNIVERSITY
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Effect of consuming calcium-fortified whole-grain bars on calcium and fiber intake: Implications for the prevention of colon cancer

Jennifer Lee and John Radcliffe, PhD, RD
Nutrition and Food Sciences

Abstract

Background: Epidemiological studies suggest that calcium and dietary fiber may be protective against colon cancer, but the national intakes of both are below recommended levels. Consumption of good dietary sources of both calcium and fiber, such as calcium-fortified whole-grain bars, may decrease the risk of colon cancer.

Methods: In a randomized controlled cross-over study, 15 women received 2 calcium-fortified whole-grain cereal bars (Kellogg's Nutri-Grain cereal bars) a day (intervention) providing 400 mg of calcium and 6 g of fiber daily and ate their usual diet (control) after a baseline period (all periods were 3 weeks). Dietary intakes were estimated from 3-day diet diaries analyzed using the Nutrition Data System for Research program.

Results: Mean calcium intake during baseline, intervention, and control periods was 633, 910, and 699 mg per day, respectively; mean fiber intake during these three periods was 18.08, 22.73, and 18.93 g per day, respectively.

Conclusions: Consumption of calcium-fortified whole-grain bars is a useful way to increase the intake of calcium and dietary fiber, and this increased consumption may be protective against colon cancer.

Background

- Dietary calcium and fiber may be protective against colon cancer.
- Intakes of dietary calcium and fiber are below the recommended levels.
- Calcium-fortified whole-grain bars, such as Kellogg's Nutri-Grain cereal bars, provide good dietary sources of both calcium and fiber (Each bar provides 200 mg of calcium and 3 g of fiber).
- Consuming these bars may improve dietary calcium and fiber, and may decrease the risk of colon cancer.

Purpose

To determine whether consumption of Kellogg's Nutri-Grain cereal bars increases dietary calcium and fiber intake in women

Participants

- 15 healthy women age 18 years or older residing in Houston, Texas
- Inclusion criteria: Able to read, write, speak, and understand English
- Exclusion criteria: Allergic to ingredients in the bar, taking calcium-containing medication or calcium supplement, pregnant or plan to become pregnant during the course of study, or eating more than 2 Kellogg's Nutri-Grain cereal bars per month.

Methods

- 9-week randomized controlled cross-over study
- Each participant received 2 bars a day (intervention) and ate usual diet (control) after a baseline period (all periods were 3 weeks).
- Dietary intakes were estimated from 3-day diet diaries analyzed using the Nutrition Data System for Research program.

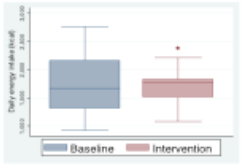
Results

Average age, height, and weight at baseline in Group I and Group II

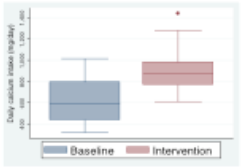
Variables	Group I	Group II
Age (years)	30.9	28.4
Height (in)	62.8	65.0
Weight at baseline (lbs)	122.1	134.2
Weight after intervention (lbs)	122.2	133.4

Average energy, calcium, and fiber intake for baseline, intervention, and control periods

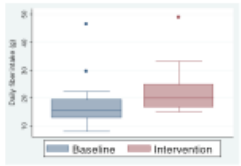
Periods	Energy (kcal/d)	Calcium (mg/d)	Fiber (g/d)
Baseline	1736	633	18.1
Intervention	1720	910	22.7
Control	1725	699	18.9
Daily value	2000	1000	25



Boxplot distribution of energy intake for baseline, and intervention periods



Boxplot distribution of calcium intake for baseline, and intervention periods



Boxplot distribution of fiber intake for baseline, and intervention periods

Conclusion

- Consuming these cereal bars significantly increased the intakes of both calcium (by 44%) and dietary fiber (25%).
- Consuming these cereal bars did not effect energy intake (1% decrease).
- Consuming these cereal bars had no effect on body weight (0.4% decrease).
- Consumption of these calcium-fortified whole-grain fiber-containing bars is a useful way to increase the dietary intake of both calcium and fiber, neither affecting energy intake or body weight and thus may be protective against colon cancer.

National Clinical Trial (NCT) #01508689