Almond Consumption And Weight Loss

In Obese And Overweight Adults

by

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ABSTRACT

Nut consumption, specifically almonds, have been shown to help maintain weight and influence disease risk factors in adult populations. Limited studies have been conducted examining the effect of a small dose of almonds on energy intake and body weight. The objective of this study was to determine the influence of pre-meal almond consumption on energy intake and weight in overweight and obese adults. In this study included 21, overweight or obese, participants who were considered healthy or had a controlled (>3 month) disease state. This 8-week parallel arm study, participants were randomized to consume an isocaloric amount of almonds, (1 oz) serving, or two (2 oz) cheese stick serving, 30 minutes before the dinner meal, 5 times per week. Anthropometric measurements including weight, waist circumference, and body fat percentage were recorded at baseline, week 1, 4, and 8. Measurement of energy intake was self-reported for two consecutive days at week 1, 4 and 8 using the ASA24 automated dietary program. The energy intake after 8 weeks of almond consumption was not significantly different when compared to the control group ($p=0.965$). In addition, body weight was not significantly reduced after 8 weeks of the almond intervention ($p=0.562$). Other parameters measured in this 8-week trial did not differ between the intervention and the control group. These data presented are underpowered and therefore inconclusive on the effects that 1 oz of almonds, in the diet, 5 per week has on energy intake and bodyweight.

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Chapter 1

INTRODUCTION

The prevalence of individuals who are overweight or obese in the United States has greatly increased over the last two decades (90). The health consequences of being overweight and obese include cardiovascular disease, stroke, type 2 diabetes, respiratory disease, and some types of cancer (90). Recommendations for weight loss often require major changes to diet and physical activity levels, which many individuals find difficult to sustain. The lack of success with current weight loss strategies indicates a need for simple and effective dietary approaches. Recently the Joint Task Force of the American Nutrition Society, Institute of Food Technologist, and International Food Information Council has endorsed a small step approach to weight loss (56). In searching for a simple, dietary change, individuals would be able to make, interest in the affect of almond consumption on body weight has developed. Present research has demonstrated a beneficial effect of almonds consumption on weight maintenance (7, 58). It is thought that the protein, fat, and fiber content of the almonds leads to a satiating effect, which may help reduce total calorie intake (7, 79).

The majority of research conducted has examined the effects almond consumption on blood cholesterol, maintenance of body weight, insulin resistance, and blood glucose levels (45, 50, 61). Few studies, however, have directly measured the effect of almond consumption on weight loss.

Most research on almond consumption and body weight has focused primarily on weight gain and weight maintenance. Recent studies in which participant's ingested large amounts of almonds, 2-3 oz per day, contributing between 300-630 calories per day did not result in weight gain (45, 61, 103). Weight maintenance is thought to come from a compensatory mechanism, where participants consume fewer than expected calories to compensate for the almond servings ingested. Cross sectional studies have focused on the eating habits of populations with lower body mass indexes (BMI). Interestingly, these studies consistently demonstrate an inverse relationship between BMI and almond consumption (7, 8, 45).

When considering research that examined almond consumption and body weight, it may be plausible that the dosage of almonds previously given was too high to see a reduction of weight. A lower dose, such as 1 oz, provides protective benefits (62) but may also promote weight loss. In addition, most studies did not control when or how the participants were supposed to consume the almonds. Providing the almonds before the evening meal may encourage a small calorie deficit in the evening meal that could potentially lead to weight loss.

Although Healthy People 2010 has recognized the importance of reducing the portion of adults who are overweight or obese as one of its main goals, little progress has been made in reversing this trend.

The health implications and economic cost related to being overweight and obese continues to make it a key concern of Americans and nations worldwide. In 2000, the Surgeon General stated the United States had spent an estimated total of 117 billion dollars treating obesity, associated morbidity and an estimated 300,000 deaths occur each year that can be related to obesity (87). Even modest weight loss (5% of body weight) can reduce a person's risk for cardiovascular disease, type 2 diabetes and other chronic diseases (87). Effective and sustainable strategies, geared toward compliance, resulting in successful weight loss are needed. Redefining recommendations for weight loss that include a small step approach may be able to bring the desired results, as well as long term compliance, that is required for success.

Purpose

The primary intent of this randomized parallel arm experiment was to determine the effect of almond consumption on weight loss in 126 overweight and obese adults, ages 20-75, from the Phoenix, metropolitan area. The study consisted of two groups. The first group consumed 1 ounce of almonds before the evening meal 5x per week and the second group consumed two, 2oz cheese sticks before the evening meal 5x per week. Changes in the dependant variables energy intake, weight, body composition, BMI, and waist circumference, were assessed at 0, 4 and 8 weeks.

Hypotheses

1. Overweight and obese adults consuming 1 oz of almonds before the evening meal will consume, on average, fewer calories, compared to pre-trial values. Overweight and obese adults consuming an equal caloric portion of control product before the evening meal will consume, on average, similar calories as compared to pre-trial values.

2. Overweight and obese adults consuming 1 oz almond servings before the evening meal will lose a moderate but significant amount of body weight after 8 weeks. Overweight and obese adults consuming an equal caloric portion of control product before the evening meal will not experience a change in body weight after 8 weeks.

Definition of Terms

Body composition: the relative proportions of protein, fat, water, and mineral components in the body.

Hemoglobin A1C: a test that measures the amount of hemoglobin bound to glucose. It is a measure of how much glucose has been in the blood during the past two to four months.

Insulin resistance: is the condition in which normal amounts of insulin are inadequate to produce a normal insulin response from fat, muscle and liver tissue.

Overweight: An adult who has a BMI Between 25 and 29.9 is considered overweight.

Obese: An adult who has a BMI of 30 or higher is considered obese.

Delimitations

Subjects were recruited from the Phoenix, metropolitan area. Subjects were sedentary adults 20-75 years of age, who were not be pregnant or lactating. In addition subjects were not taking steroidal medication and were not allergic or intolerant to any nuts, peanuts, or dairy products. Subjects were also expected to have regular access to a computer to complete 24-hour dietary recalls. Due to these restrictions the results of this study may not be generalizable to all population groups.

Limitations

There are several limitations that should be discussed regarding this study. The first limitation is that participants may not adhere to the protocol of the study. Subjects may also experience circumstances within their lives that impact their dietary behaviors and overall food intake during the course of this study. Secondly this study will use the 24hour dietary recalls that rely on participant's memory and knowledge of portion sizes. An automated dietary program ASA24 was used to administer the 24-hour dietary recalls. Participants received emails to help ensure compliance to dietary protocol.

Chapter 2

Review of Literature

Obesity

Trends and Prevalence's

Since the 1980's the United States has seen a rise in the rate of overweight and obese individuals that has increased to epidemic proportions (18). To date, approximately 35% of American adults are defined as overweight and another 30% are considered obese (88, 117). Based on data from the 1970's a dramatic increase can be seen when comparing these to recent data. In 1970's, about 32% and 15% of the US adult population was considered overweight and obese (19). Compared to the Third National Health and Nutrition Examination Survey (NHANES III 1999-2000), which reported 59.3% of men and 49.6% of women, aged 20-74 years, were considered overweight (17).

Reported body weight has increased across age, sex, socio-economic classes, ethic groups, and geographical regions in the United States. However, disparities are shown between race, ethnicity, gender, age and socioeconomic status. A meta-regression analysis examined the current disparities as well as observed prevalence's (119). This analysis looked at data compiled by all NHANES surveys, examining over 900 articles, with over 80 journal publications that assessed obesity and overweight in the United States.

Women demonstrate the largest disparities shown between racial and ethnic differences. Minority groups (except for Asians) have a higher rate ($\geq$ 10%) of obesity compared to White women.

This is particularly noticeable among Non-Hispanic blacks, where 80% of women over 40 years of age are considered overweight or obese (119). However, most large databases examined did not have adequate number of other minorities besides Non-Hispanic Blacks and Mexican Americans. The Add Health Study showed that Asian women were less likely to be obese, but that disparities between Asian groups do exist. Native Hawaiians and Samoans experience the highest prevalence of overweight and obese women compared to other Asian groups (54). When looking at the current obesity trends, increases among Mexican-American women have been slower then White and Non-Hispanic Black women (118).

Health disparities have long been observed between different socioeconomic status groups. Socioeconomic status is a complex variable that does not always accurately reflect risk because of variances in gender, race and education level. Individuals who have received less than a high school diploma (or equivalent) have a higher prevalence of obesity, compared to those with more education, with the exception of black women (17).

Geographical differences are also noted for obesity trends. In 2005 only Colorado, Hawaii, Vermont, and Connecticut had obesity rates less than 20 %. In contrast three states; Louisiana, Mississippi and West Virginia had an obesity rate of 30% or higher (118).

Currently southeastern states have higher rates of obesity compared to the West Coast, Midwest and Northeast coast (118).

Body Mass Index

Overweight and obesity definitions have been determined based on an increased risk of mortality and chronic disease (85, 122). Overweight and obesity are defined by body mass index (BMI), a calculation derived from height and weight measurements (kg/m^2). Based on these categories, overweight is defined as an adult who has a BMI between 25.0 and 29.9, while obese is defined as an adult who has a BMI of over 30.0 (119) (See Table 1). Obesity is further broken down into three subcategories: Obese I (BMI 30-34.9), Obese II (BMI 35-40) and Obese III (BMI >40). BMI has been well established and is used by many different organizations including the Center for Disease Control (CDC) and the World Health Organization (WHO) as a leading measurement for health risk (41).

TABLE 1

Standard Body Mass Index Chart

	Under Weight	Healthy Weight	Overweight	Obese
Adult > 18 yrs	<18.5	18.5-24.9	25.0-29.9	> 30.0

Several studies have supported the use of BMI as a predictor of health risk. A study by Brown et al. examined data from NHANES III and measured parameters known to increase risk of chronic disease including blood pressure, total cholesterol and high density lipoprotein levels (HDL-C) levels.

Results from this study showed that blood pressure was higher in men (131 vs. 121 mmHg) and women (127 vs. 116 mmHg), than adults who were categorized as having a normal BMI (<25).

Total cholesterol levels were also increased with a rise in BMI. High levels of blood cholesterol in women increased from 13% among the lowest BMI category to 30% at higher BMI categories.

Among men a similar trend was found, where 13% of men had high cholesterol in the lowest BMI category compared to 22% at the highest BMI category. This study also reported HDL-C being inversely related to BMI status in both men and women across different races. Low HDL-C was reported in 17% of women with a BMI less then 25, and rose to 41% when BMI was greater than 30. Men with low levels of HDL-C and a BMI <25 was 9%, where as, in men with BMI >30 the percentage of low HDL-C was 31% (14).

In the prospective study, The Nurses' Health Study, relationships between BMI and overall mortality and specific mortality in middle-aged women were examined. Self reported heights and weights were recorded at baseline in 1976 and BMI's were assigned. After a 16-year follow-up, mortality was the lowest in women with BMI of 19-26.9, and after a multivariate adjustment for smoking and other risk factors, the association between obesity and mortality strengthened (77). Manson et al. stated that, "53 percent of deaths among the women with a body-mass index 29.9 or higher could be attributed to their obesity", even when controlling for hypertension, high cholesterol and diabetes.

Michels et al. examined the sole use of BMI as an indicator of risk for elevated blood pressure in adolescent girls. This study analyzed 3,543 13 year-old, white girls who did not demonstrate a difference in gender, race or age. Data was analyzed to determine the impact of each variable, including height, weight and BMI, on blood pressure. This study reported that BMI alone ($p < 0.001$) was not an adequate predictor of risk for high blood pressure (80).

The sole use of BMI as an indicator of risk is controversial for many reasons. For example, BMI does not take into account body composition and may under identify individuals who are obese and overweight (89). In addition, a calculated BMI cannot distinguish whether the body weight is derived from bone, muscle or fat, which may result in inaccurate identification of risk for individuals. This is especially true for the elderly and for individuals who are very muscular (36). Body composition often changes with age and certain medical conditions, which in turn can alter the associated health risks. These factors suggest that BMI classifications may not be applicable across all populations (36,89).

Waist Circumference

An increased amount of abdominal adipose, especially intra-abdominal fat is commonly associated with obesity. As the prevalence of overweight and obesity has risen in the American population, so has waist circumference (36). The use of waist circumference as a measurement of risk for heart disease and diabetes is gaining support.

Waist circumference measurements are thought to be a better indicator of metabolic disturbances and disease risk than BMI, even for individuals who fall into normal BMI categories (60, 82).

Janssen et al. examined data from NHANES III, which compared waist circumference to BMI as a predictor of health risk that are commonly associated with obesity. In the 14,924 adults examined, this study demonstrated that waist circumference alone, significantly predicted the risk of co-morbidities ($p<0.05$) in overweight and obese participants compared to normal weight adults. The use of BMI alone also significantly predicted the risk of co-morbidities ($P<0.05$) in participants who were overweight or obese compared to subjects with normal weights. When waist circumference with the addition of BMI was examined, waist circumference still predicted co-morbities except for increased LDL-C in men, where as BMI predicted only one co-morbity, hypertension, for male participants. This study suggests that waist circumference alone may be better at predicting health risk than BMI and waist circumference used in conjunction (60).

Waist circumference is not a flawless measure as it lacks specificity between intra-abdominal (visceral) adipose and subcutaneous abdominal adipose tissue (36). Further more, waist circumference measurements are weakened due to the lack of standardized measurement procedures. The American Heart Association recommends measuring just above the navel, but most federal researchers favor the superior mark of the iliac crest, which puts the measurement around navel level.

However, it is sometimes difficult to find physical landmarks in obese adults to determine the start point for waist measurements, which may weaken the reliability between measurements.

Waist–to-Hip Ratio

Waist-to-Hip Ratio (WHR) is calculated by dividing the waist circumference by the hip circumference and is used to measure the distribution of adipose in the body (96). Waist measurements are normally taken around the smallest part of the waist, and the hips are measured around the widest part of the buttocks (82). WHR measurements have been replaced by waist circumference measurements, in part, because waist circumference has been strongly correlated to visceral fat and is simpler to obtain (82). An advantage of WHR is that waist circumferences are not always the stronger predictor of cardiovascular disease or diabetes (42). Since a higher WHR can be a result of a larger waist and smaller hips, which represents lower fat or muscle mass at the hip area, it may show an association of smaller hips in determining increases in risk (27,42,82).

Factors Affecting Weight Regulation

There are three main components that make up body weight regulation: energy storage, energy intake and energy expenditure. Weight gain reflects a state of increased energy intake and energy storage, or a decrease in energy expenditures (56). Factors that influence weight regulation are complex and often wide reaching.

These factors can include biological, behavioral and environmental influences that often interact and contribute to increase energy balance and overall body weight.

Biological

Over 100 genes have been recognized to effect body weight. These genes help regulate adipose stores by impacting rates of energy expenditure and regulating food intake (25, 83). Three ways that genes can influence weight are by single gene mutations, multi-gene mutations and single nucleotide polymorphisim's (SNP's). Single gene mutations are rare and typically very severe. The consequences of this type of mutation can be seen in syndromes such as Prader-Willi, Cohen and Bardet-Biedl, in which patients are known to have high rates of obesity and difficulty controlling energy intake (21). The type of mutations generally diagnosed in childhood (39). Multi-gene mutations are more indirect and often interact with the environment. It is thought that these types of genes if expressed on their own, without the influence of an, 'at risk' environment, would likely have a slight impact on body weight. Lastly, single nucleotide polymorphisms can develop that affect a variety of genes and have been associated with weight regulation (25).

The Mauritian Family Study examined the role of 78 SNP's, within the gene SH3-comain GRB2-like-interacting protein 1 (SGIP1), in 400 Indo-Mauritians adults. SGIP1 is found exclusively in the central nervous system of the hypothalamus and has been shown to promote energy intake and weight gain.

The SNP's in this study were chosen based on their potential impact on energy balance by the role it plays in the nervous system. SNP rs2146905 showed the strongest association to fat mass (p=0.0005), and demonstrated an association to increased BMI (p=0.037) (25).

These abnormalities may affect several factors that play important functions in pathways that contribute to weight regulation. For example, mutations in the melanocortin 4 receptor (MC4R) impair the melanocortin pathway. Normal expression of this pathway uses the hormone leptin to signal to the hypothalamus, which helps to suppress food intake by reducing hunger cues and increasing energy expenditure (71). A defect in this gene helps account for an increase in energy intake and lowered energy expenditures. The defect in this passageway, however, is only seen in about 3 to 5 % of the severely obese population (71).

Behavioral

Individual as well societal behaviors have attributed to the obesity epidemic (57). Two significant changes made in the past several decades are changes in dietary habits and physical activity. Dietary habits have drastically changed in the recent decades. As the dynamics of family and work have changed, more Americans are choosing meals based on convenience and low prices. In addition, meals purchased away from home are usually given to a consumer in much larger portions then would be typically served at the home (123). This may account for an increase in intake during these types of meals. Studies have found that larger serving sizes do influence eating behavior.

One study examining how food portions influenced energy intake in a natural setting, found that portion size significantly increases the amount of food consumed. A 50% increase in portion size of a pasta dish was associated with a 43% increase in energy intake (29).

Physical activity is known to help lower risks of obesity, hypertension, heart disease and diabetes (87). In 2009, The Behavioral Risk Factor Surveillance System (BRFSS) examined the amount of adults who reported engaging in physical activities at the recommended levels for states and the overall U.S. (20). A total of 50.6 % of adults reported the recommended 30 minutes or more of moderate physical activity 5 or more days per week or at least 20 minutes of vigorous physical activity, 3 or more days per week. This report indicates that half of the American population does not get the required amount of physical activity needed to promote health (20).

Donnelly et al. examined the effect of exercise on body weight and body composition in overweight and moderately obese adults. Seventy-four participants were randomized into a supervised exercise group or a control group. Energy expenditure from physical exercise was measured using doubly labeled water DLW. Men in the physically active group demonstrated significant decreases in body weight ($p=0.01$) compared to the control group. Women in the physically active group did not lose weight, however, they were able to remain weight stable compared to an increase in weight shown by women in the control group ($p=0.03$) (31). The amount of exercise recommended for modest weight loss is thought to be between 150-250 minutes per week of moderately intense physical activity and has been shown to increase weight loss in interventions with moderate but no severe caloric restrictions. This recommendations equals roughly 22 minutes per day of moderately intense physical activity (32).

Recording physical activities in participants are typically done through the use of questionnaires that range from simple to very detailed. The use of validated physical questionnaires is useful to determine the type of physical activity, the intensity and the amount of time participants spend on these activities to accurately determine the amount of energy expended. In a study conducted by Jacobs et al., the validity of 10 different physical activity questionnaires was examined. Jabcobs et al. concluded that none of the questionnaires completely covered all dimensions of physical activity, and that account for recent compared to usual physical activity (59). This study demonstrated the complexity of capturing an accurate estimation of energy expenditure by the use of physical activity questionnaires that are frequently used in research for weight loss.

Food Environment

Several studies have looked at specific foods that are responsible for the increase in weight gain throughout the population. Bray et al. examined the relationship between high fructose corn syrup beverages and their role in obesity. This study evaluated a 13-year span of food consumption patterns with the U.S Department of Agriculture's food tables.

It reported that intake of high fructose corn syrup increased a 1000% between 1970 and 1990, exceeding increases shown by any other foods, or food groups (75). Bray et al. concluded that a pattern of increased consumption of high fructose corn might be associated with increased body weight.

It is more plausible, however, to approach this with a much broader focus then determining a specific food. The changes in our food supply have lead to large, inexpensive portions of food that are high in fat, sugar, and calorically dense, which is know to negatively influence our food environments (57). Drewnowski's article on obesity, diets and social inequalities highlights this negative influence in relation to the energy cost of food production of vegetables, which can be up to ten times higher than that of oil and sugar (35). This increase in production cost, in turn, raises the cost to the consumer when choosing healthier food options. As the cost of calorically dense, high fat foods have decreased; consumption of these foods has increased in the Western diet. Not only has the main nutrients of our food supply changed and portion sizes have dramatically increased, but also the distribution of food is extensive.

Food is not only heavily advertised on television, but also readily available, making food accessible everywhere (57, 70). Moreover, access to food outlets that serve calorically dense food, such as fast food and sit down restaurants are higher in low-income neighborhoods and super markets with healthy foods options tend to be less prominent (63, 91).

French et al. analyzed data obtained from the Pound of Prevention study, which looked at the frequency of fast food restaurants use in 891 women over a three-year period. Participants were administered a survey about the frequency of fast food use, and usual dietary intake was reported using a food frequency questionnaire. Changes in the frequency of fast food consumption were statistically significant for total energy intake ($p=0.01$), and weight ($p=0.01$) (48). French et al. concluded that frequent fast food restaurant used could be indentified as a risk factor for excess weight gain over time.

One study, by Jennings et al., examined the relationship between weight status and dietary intake, and neighborhood food outlets for 1669 children ages 9-10 years old. Data was analyzed from Sports, Physical activity and Eating behavior: Environmental Determinants in Young People study (SPEEDY). Food outlets where categorized as supermarkets, fruit and vegetable stores, fast food outlets, restaurants and other food outlets. Each type of food outlet was then counted from individual neighborhoods using the Ordnance Survey “Points of Interest” data. Food outlets were also rated as BMI-healthy, BMI-intermediate, and BMI-unhealthy, that is described in Rundle et al. (63).

Body weight was significantly lower ($p=0.03$) by 1.3 kg for children who had availability of BMI-healthy food outlets compared to children who did not. A lower BMI was also demonstrated ($p=0.02$) for children who had higher access to BMI-healthy food outlets compared to their counterparts.

Physical Environments

The physical environment, also known as the built environment, has demonstrated an impact on physical activity and body weight (94). The advancement of transportation and employment conditions that require little physical labor has decreased the demands to be physically active (57). In 1970 the US census showed that roughly 78% of the populations used vehicles to travel to work, compared to 88% in 2000. In addition there has been a decline of walking as a means of transportation (44). Land use and patterns in urban environments have been associated with decreased physical activity, especially walking (44). The central business and commercial districts are often separated from residential neighborhoods by large roads and infrastructure that may make it dangerous to reach destinations by walking (6).

Walkability is determined in an area by the accessibility and safety of walkways in an environment. Frank et al. analyzed data from adults who were at least 25 years of age and participated in the Strategies for Metropolitan Atlanta's Regional Transportation and Air Quality (SMARTRAQ) survey. In this study, high residential density was demonstrated to be the strongest predictor of walking ($p<0.001$) and those in high density residential areas were significantly more likely to walk if the road ways were well connected ($p<0.001$)(44). In addition low residential density was associated with overweight status for male participants ($p<0.001$).

Interestingly, Frank et al. found that, for non-white female participants, increased street connectivity was related to higher rates of overweight ($P<0.001$). This study concluded that walkability characteristics of neighborhoods, such as residential density and road connectivity were associated with the weight status of participants (44).

Rundle et al. examined the relationship between urban form and body size in a densely settled city (New York, NY). Data was analyzed from the New York Cancer Project (NYCP), which included 18,187 participants from across the five boroughs of New York City. The built environment was measured using mixed land use, access to public transit and population density. Mixed land use was determined by calculating the ratio of building areas that were specified for commercial or residential use. This study reported mixed land ($p=0.05$), public transit density ($p=0.01$), and population density ($p=0.001$) to be inversely associated to BMI while controlling for individual income level and soci-demographics. The availability and increased mixture of commercial areas, which provide goods and services within walking distance from residential areas, may play an advantageous role in lowering BMI (94).

Health and Economic Cost of Obesity

The health impacts of overweight and obesity can be clearly seen in related mortalities and morbidities. As the prevalence of overweight and obesity has climbed, so has the incidence of cardiovascular disease, some types of cancers and type 2 diabetes (40).

The link between obesity, especially abdominal adiposity, and cardiovascular disease is well documented (60). Cardiovascular disease is the leading cause of death and a major cause of disability in the United States (96). As of 2000, it is estimated that an annual 400,000 death per year can be related to obesity (81).

The economic cost of overweight and obesity is a substantial burden to America's health care system. The direct consequences can be related to preventive measures and treatment services that the obese and overweight receive. The treatment costs are staggering for related morbidities such as hypertension, cardiovascular disease and type 2 diabetes (121). In addition, studies have shown that health care spending is increased by 36% for obese adults who are under 65 years of age (107) In 2000, the CDC estimated the total cost linked to overweight and obesity to be 117 billion dollars, with 61 billion dollars direct cost and 56 billion dollars related to indirect cost. Indirectly, the cost can be seen through lost wages, disabilities, and lost future income due to premature death (121).

The Chicago Heart Association (CHA) study examined Medicare spending over a 19-year span, related to overweight and obesity in young adult hood and middle age. Data for Medicare fee-for-service calms were obtained between 1984 through 2002 for participants who were eligible for Medicare benefits.

The CHA study concluded that an increase in weight for both men and women in young adulthood or middle age was significantly associated ($p<0.01$) with total Medicare health care spending in older age, while adjusting for years of Medicare eligibility, race, education, smoking, cholesterol levels, blood pressure and vital status (26).

Using data from 1987 Medical Expenditure Survey (NMES) and the 2001 Medical Expenditure Panel Survey (MEPS), Thorpe et al. estimated the spending in health care cost attributed to changes in obesity among obese people. Medical conditions were self reported and BMI was calculated for each participant using self reported heights and weights. An increase in the number of treated cases for diabetes (+79 %), and hypertension (+29%) was noted between the 1987 NMES and the 2001 MEPS, which may indicate a higher portion of spending attributed to these diseases. Per capita spending was predicted for each participant within the 3 categories of BMI of normal, overweight and obese. Trends in obesity showed a calculated 41% increase in spending for heart disease, 38% increase for diabetes, followed by 22% increase for hyperlipidemia (110).

Weight Loss Strategies and Diet Recommendations

As the prevalence of overweight and obese populations has increased, several weight loss strategies have been developed to meet this challenge. An analysis of the 1998 National Health Interview Survey was conducted in 2004.

These face-to-face interviews were conducted among 32, 440 adults in the U.S with 24% of men and 38% of women trying to lose weight. Among adults interviewed, eating fewer calories was cited at the most common technique, with 58% men and 63% of women mentioned using this strategy (67). In addition, 49% men and 56% women reported eating less fat and, 52% of men and 54% of women, increased physical activity as preferred methods for weight loss (67). The most widely used treatment for obesity is physiological or behavioral treatment, including a change in diet or physical activity habits (15). These diets often range from low calorie, low fat, low carbohydrate-high protein diets or diets that are based on different guidelines than the USDA dietary guidelines (Mediterranean diet) and interventions that include an exercise component. An increasing amount of support has also been growing for a small step, individualized approach to weight loss.

Low Calorie Diet

Low calorie diets are a weight loss strategy that includes lowering energy between 15-60% usual caloric intake (116). A reduction of energy intake can lead to an overall negative energy balance and in turn cause weight loss. The American Heart Association guidelines recommends a diet that is low in calories, high in fruits, vegetables, fish and unrefined grains. An exercise component of at least 30 minutes of exercise everyday is also suggested.

The effectiveness of low calorie diets and weight loss have been well documented (114), however, long-term weight maintenance and compliance to low calorie diets have not been demonstrated as effective in influencing the occurrences of overweight and obesity in the United States.

Tapsell et al. examined the short-term effects of energy restriction and fat sub type on weight loss for 3 months in 150 overweight and obese adults. Participants were randomized into four groups who received isocaloric diets and dietary advice pertaining to participants group. Group 1 was a low fat (LF) group with a pattern of 50% carbohydrates, 20% protein and 30% fat, comprised of 5% poly unsaturated fat (PUFA), 15% monounsaturated fat (MUFA) and 10% saturated fat (SFA). Group 2 was a low fat PUFA group same macronutrient distributions as LF but with advice on inclusive foods high in PUFA, comprised of 10% PUFA, 10% MUFA and 10% SFA. Group 3 was a low fat-low calorie LC that received advice to consume the same macronutrient distributions as group 1 and a calorie restriction. Group 4 was a low fat-PUFA-low calorie group that received the same dietary advice as group 2 and an additional calorie restriction requirement. After three months all groups reported weight loss, however the low calorie groups 3 and 4 lost more weight (p=0.026) compared to groups 1 and 2 who did not have an additional calorie restriction (109).

A systematic review of 16 studies was completed, researching the effects of low calorie or calorie-restricted diets. Douketis et al. researched studies that where greater then 1 year in length and had more than 100 participants, without pharmacological intervention. After 2-3 years, weight loss was usually reported to be 5 kg less then baseline weight and within a 4-7 year, weight was 3.6±2.6 kg below participant's baseline (33).

Low Fat Diet

Low fat diets are often used as a means of reducing body weight and are closely in line with current recommendations from the 2010 Dietary Guidelines for Americans. The role of dietary fat and regulation of energy intake was examined by Lissner et al. in 24 adult women. Each subject participated in three, 2-week ad libitum diets that contained low 15-20%, medium 30-35% and high 45-50% of dietary fat. All foods were provided and participants were given a choice of 20 food items with each category that had similar fat content. No significant difference ($p>0.05$) in energy intake was noted between the three, 2-week periods, which suggested that participants had not adjusted their caloric intake based on the percentage of fat intake (72).

A study by Bradley et al. examined the relationship between energy dense of foods and energy intake across multiple levels of fat content. In this study 36 women who were considered lean or obese participated in 6 experimental sessions in which participants consumed breakfast, lunch, dinner and a snack ad-libitum.

The main entrees for these meals were manipulated in content of fat, ranging from low fat (~25%), medium fat (~35%) and high fat (~45%) and serving portions were similar throughout each range. Total intake of entrees, for all women did not demonstrate a significant change ($p<0,05$) for manipulated entrees. An adjustment for energy density of fat content was not made by either group of participants (10).

Brinkworth et al. examined the long-term effects of a very low carbohydrate diet versus an isocaloric low fat diet on weight loss over a 12-month period. A total of 69 adults with abdominal obesity and at least one risk factor for metabolic syndrome participated in this study. The low carbohydate diet consisted of 4% carbohydrates, 35% protein and 61% fat and the isocaloric low fat diet consisted of 46% carbohydrates, 24% protein and 30% fat. At the end of the 12-month period both groups had lost similar amounts of weight ($p=0.14$) and body fat ($p=0.30$). Brinkworth also reported that the low carbohydrate diet participants demonstrated an increase in HDL cholesterol ($p=018$) and an increase in LDL cholesterol ($p=0.001$) compared to the isocalorie low fat diet independent of energy intake or weight loss (13).

Low Carbohydrate and High Protein Diet

The use of low carbohydrate, high protein diets, for weight loss has received on going attention. In contrast, the current American Dietary Guidelines and the American Dietetic Association recommends a diet high in complex carbohydrates and low in fat (114).

Low carbohydrate, high protein diets can be higher in total and saturated fat, which has the potential to raise triacylgylcrol's and LDL cholesterols and the risk of heart disease.

Skov et al. examined protein versus carbohydrates in an ad libitum, reduced fat diet on body weight. This study was conducted over a 6-month period with 65 health overweight and obese adults.

All participants were randomly assigned to a the high protein (HP) diet which consisted of energy from 25% protein and 45% carbohydrates, a high carbohydrate diet which derived energy from 12% protein and 58% carbohydrates or a control group that was advised to not make any dietary changes. After six months, the HP group intervention group demonstrated significant weight loss (p=0.0002) of 8.7 kg compared to 5.0 kg in the HC intervention group (100).

Noakes et al., examined the effect of energy-restriction, high protein, low fat diets compared to a high carbohydrate, low fat diets on weight loss, body composition and nutritional status. One hundred overweight and obese adults were assigned into two isocaloric diet groups. The first group consisted of a high-protein, low saturated fat (HP) group with energy coming from 34% from protein, 20% fat (<10% saturated fat) and 46% from carbohydrates. The second group was a high-carbohydrate, low saturated fat (HC) group with energy coming from 17% protein, 20% fat (<10% saturated fat) and 64% from carbohydrate.

After 12 weeks, a significant difference ($p= 0.29$) for weight loss was not noted between the HP and the HC group. But decrease in triacylglycerols ($p=0.007$) was demonstrated for participants in the HP compared to the HC groups (84).

A study by Treyzon et al. examined the effects of a high protein meal replacement with in a standard high protein diet compared to a control meal replacement in a standard protein diet. Participants were advised to avoid heavy physical resistance exercises. At the end of 12 weeks both groups had lost significant amounts of weight ($p<0.0001$).
BMI was also shown to be significantly lower than baseline but did not show statistical significant between groups. Participants that were given the high protein meal replacements lost a significant amount of fat at 12 weeks ($p<0.001$) compared to baseline. The high protein group also lost significantly more fat compared to the control group ($p=0.05$). Treyzon et al. concluded that compliance was an important factor in the studies meal replacement regimen, even more so than protein content (112).

As with any diet that focuses on redistribution of macronutrients, a low carbohydrate diet invariably increases intakes of protein and fat. Although these diets report a high level of satiety and in some cases, increased compliance, there can be several disadvantages to a low carbohydrate diet. Subjects on low carbohydrate diets have noted side effects that include headaches, diarrhea, muscle cramps and lack of concentration (43). Long-term low carbohydrate diets need to be further researched to assess potential impact.

Mediterranean Diet

The Mediterranean diet has increased in popularity in the last decade due in part to its positive effect on cardiovascular disease. The Mediterranean diet is often rich in vegetables and tends to favor fish, seafood and poultry, while being lower in some types of meat such as beef, lamb, and pork (97). Emphasis is put on the consumption of nuts and olive oil resulting in a moderate fat diet that is high in monounsaturated fat (114). The high levels of monounsaturated fat commonly found in this diet are thought to lead to the protective benefit seen in the cardiovascular system (93).

The impact that the Mediterranean diet has on weight loss has only been examined in a few studies. Shea et al. conducted a study that looked at the difference of weight loss between the Mediterranean diet, low carbohydrate diets and low fat diets. In this 2-year trial, 322 moderately obese participants were randomized to three different diets. The Mediterranean diet restricted calorie intake to 1500 for women and 1800 for men with less than 35 % of calories coming from fat. The low carbohydrate diet was a non-restrictive-calorie diet that aimed for 20 grams of carbohydrates per day for a 2-month introduction and increased up to 120 grams per day for the duration of the study. In this study the low fat diet was based on the American Heart Association recommendations. The low fat diet was calorie restricted and given similar recommendation for the Mediterranean diet with 1500 calories for women and 1800 calories for men.

Intake of cholesterol was limited to 300mg/day and total fat intake was restricted to <30%/day with <10% coming from saturated fat. The results of this study showed that the Mediterranean-diet and the low-carbohydrate diet achieved the greater weight loss ($p<0.0001$) for interaction between diet group and time compared to the low fat diet group (97).

One study reported the effects of the Mediterranean diet with or without calorie restriction and a conventional diet on weight loss. A total of 192 men were assigned to either a Mediterranean dietary pattern, or a calorie restricted Mediterranean dietary pattern, with a physical activity component, or the two perspective control groups. A significant weight loss 14 kg ($p<0.001$) from baseline was observed for participants in the Mediterranean dietary pattern regardless of caloric restriction compared to only 2.0 kg weight loss from baseline in the control groups (38).

Meal Replacement

Weight loss strategies often use shakes or other products that are controlled for calories and nutritional content for meal replacements (112). Meal replacements typically contribute one or two meals of daily energy intake. Concerns have been raised over the nutritional adequacy of prepackaged foods, however, most meal replacement are fortified with vitamins and minerals to prevent long-term deficiencies (52).

Ashley et al. conducted a one-year long study to examine the nutritional adequacy of meal replacements compared to traditional food group interventions during weight loss.

A total of 96 over weight and obese women were assigned to a Meal Replacement Group (MRG) or a Traditional Food Group (TFG) with a 1200 kcal per day restriction. Both groups were to attend 18 classes within the first 6 months of the study and received education developed by a registered dietitian. Participants also received a LEARN Program for weight control with the MRG receiving the Meal Replacement Edition of the manual. The TFG group was educated on a diet plan based on the USDA Food Guide Pyramid and received grocery store gift certificates for healthy food selections. Participants in the MRG were instructed on a diet plan that included commercially available meal replacements to be used for two out the three main meals. Mean weight loss was not significantly different ($p>0.05$) between the MRG and the TFG groups at one year (3).

The effect of meal replacements on weight loss was examined in an 8-week conducted by Hannum et al. Sixty overweight and obese women were divided into a self-selected diet group, that was advised to consume a diet based on recommendations given from the USDA Food Guide Pyramid, or a portion-controlled group instructed to consume entrees that were provided for lunch and dinner. Both groups were advised to eat two servings from nonfat diary foods, two serving of fruit and eight cups of water per day. Participant who received the meal replacements lost significantly more weight, 6.5% compared to 4.2% for participants in the self-selected diet group ($p<0.01$) (53).

Small Step Approach

The small step approach was examined to provided the needed dietary and behavioral changes that were achievable and maintainable to promote weight loss and decrease disease risk (56). A council, The Joint Task Force of the American Society For Nutrition, Institute of Food Technologists, and International Food Information Council, convened to determine if the small step approach would be useful in addressing global obesity. One study conducted by Stroeble et al. examined the effects of a small change approach for weight maintenance on 100 American families with at least one child. Families were randomly assigned into a control group that was asked to record their physical activity and dietary intake with out change or the America on the Move (AOM) group that advised an additional of 2000 steps per day from baseline and to switch form regular dietary sugar to a non-caloric sweetener, providing a reduction of about 250 kcals from the combined behavior changes. After 6 months both groups demonstrated significant decrease in BMI for age, however significantly more AMO children demonstrated a reduction of BMI for age ($p<0.05$) and fewer demonstrated an increase in BMI for age ($p<0.05$) compared to the control (105).

In addition, the food industry has also made progress supporting the small step approach by offering single serving packages of small snack portions for a variety of products. The impact of this packaging has been controversial on the effect it has on consumers' body weight and overall consumption.

Using an individualized small step approach to weight loss may be able to prevent usual weight gain typically seen overtime in the American population (8, 7, 56) and be able to provide a sustainable mechanism for weight loss in overweight and obese adults.

Surgery

As Americans continue to trend towards morbidly obese proportions, the use of surgical procedures, as well as the use medications for treatment have increased. Surgical procedures often include gastric bypass surgery and gastric banding. These procedures typically lead to a weight loss of 30-35 kg (50-60%) (86).

Gastric bypass is a surgical procedure that removes or resections part of the stomach making the pouch significantly smaller and attaching the resection portion of the stomach to the small intestine (86). Surgical intervention cause changes to the intestinal tract that are permanent and can lead to significant decreased absorption of lipids and fat soluble vitamins such as A, E, K and D. Protein malnutrition can occur, and deficiencies in calcium, vitamin B12 and folate without appropriate supplementation can be problematic (49). Another risk includes the resection size of the remaining stomach, which can be made too small and may lead to the inability to digest foods and liquids, which can results in recurring vomiting (49).

A study by Dixon et al. examined the effects of gastric banding versus conventional therapy for type 2 diabetes.

Sixty obese adults, who were newly diagnosed with type 2 diabetes, were given conventional diabetes therapy and assigned to either to a group that focused on weight loss by lifestyle interventions or a group that received laparoscopic adjustable gastric banding. After a two year follow up, the group who received a surgical intervention achieved a 20% weight loss from baseline compared to a 1.4% weight loss ($p<0.001$) from baseline, for participants who did not receive the gastric banding (30). Dixon et al. stated that no serious complications were reported either participation group.

Sjostrom et al. conducted a ten-year follow up study to The Swedish Obese Subjects (SOS) Study to examine the long-term effects of gastric surgery on weight loss in obese adults. Participants were split into gastric surgery groups that included gastric bypass, vertical banded gastroplasty, gastric banding and a control group. Ten years after the initial start of the study, participants in the control group reported an increase of weight by 0.1% compared to the gastric by pass group that sustained a 25±11 % weight loss, a 16.5±11 % sustained weight loss for vertical banded gastroplasty, and a 13.2±13 % sustained weight loss for the gastric banding group. Groups assigned to a surgical intervention demonstrated a significant maintained weight loss ($p<0.001$) from baseline compared to the control group (99). Although this procedure allows individuals to decrease food intake, and achieve significant weight loss, changes to individual lifelong dietary patterns and supplements are required for long-term success.

Medications

Currently several medications are approved by the US Food and Drug Administration for the pharmacological treatment of obesity. Orlistat and Sibutramine are the two most popular methods of long-term treatment options. Orlistat acts in the intestinal track by blocking pancreatic lipase, inhibiting the body's ability to absorb fat (12). In addition, glucagon-like peptide 1 (GLP-1) is released from the intestines and signals the pancreas and brain to decrease food intake. The use of Orlistat, because of it ability to decrease fat absorption, can lead to a decline in fat-soluble vitamins over time (55). For this reason, a multivitamin is recommend while taking the medication. Rare occurrences of liver damage have also been reported with long-term use of this medication (113).

Sibutramine works by blocking the reuptake of serotonin and norepinephrine. This treatment method is effective because serotonin 5-HT_{2c} helps the body regulate fat and energy intake (75). However, concerns have been raised by Sibutramine's ability to increase blood pressure levels, even in normotensive individuals, or to dull the lowering of blood pressure effect that is typically seen in weight loss (11). The Food and Drug Administration (FDA) recently pulled Sibutramine off of the market due to an increase risk of cardiovascular events for individuals taking the drug (75).

Torgerson et al. conducted a four-year study with 3304 overweight participants, 21% with impaired glucose tolerance.

Participants were randomized into groups who received orlistat doses and advice on lifestyle changes, or a control group who only received advice for lifestyle changes. Initial weight loss within the first year was the highest for the orlistate group being 11% below base line compared to the placebo group at 6% below baseline. After four year, participants receiving orlistat demonstrated a weight loss of 5.8 kg compared to 3.0 kg for the control group ($p<0.001$). A significant reduction ($p=0.03$) of diabetes was also noted with in the incidence of diabetes 9% for the control group and 6.2% for the group who received orlistat (111).

A European study demonstrated the effectiveness of orlistat on weight loss. A total of 743 obese participants were assigned to a group that received orlistat and followed a calorie-restricted diet with 30% intake from fat or to a group that followed a calorie-restricted diet with 30% intake from fat. After 1 year, the group who received orlistat and a calorie-restricted diet achieved significantly greater weight loss ($p<0.001$) than diet alone. Participants with orlistat and diet after 2 years of treatment were able to maintain a 10% decrease in baseline body weight compared to the control group ($p<0.05$) (99).

One study examined the short-term effects of Sibutramine on energy intake. Thirty-six obese adults were randomized into two groups. Groups received either Sibutramine or a placebo for two, 14-day periods. After a 2-week washout period participants were then placed in alternate groups for an additional 14-day period.

Food intake was reduced by 16% ($p<0.001$) at day 14 for participant receiving Sibutramine, compared to those receiving the placebo. A significant decrease in weight ($p<0.01$) was also reported for participants receiving Sibutramine versus placebo (5).

Almonds

Several epidemiological studies have noted a trend of high nut consumption in lean populations. The California Seventh-day Adventists cohort study included 34,192 California Seventh-day Adventists, examining the associations between diet, cancer, ischemic heart disease, and all-cause mortality. Many Seventh-day Adventist consume a vegetarian diet that is high in fruits, vegetables and nuts. In this study participants were categorized as vegetarian, semi vegetarian or non-vegetarians. Based on these predetermined categories, mean BMI was calculated as 24.3 for men and 23.7 for women who were considered vegetarians compared to non-vegetarians with a mean BMI of 26.2 for men and 25.9 for women (45).

In another study Bes-Rastrolo et al. examined nut consumption, long-term weight change and obesity risk in women. This prospective study used 51,1888 participants from the Nurses' Health Study II (ages 20-46) and evaluated dietary intake of nuts and weight changes that occurred over an eight year period. Participants who regularly ate nuts 2x per week or greater had a lower risk of weight gain ($p<0.001$) and a lower risk of obesity ($p<0.003$).

These findings supported the assumption that populations who consume nuts, frequently are leaner then those who do not (95).

Overview

The use of almonds dates back to 1400 BC and was associated mainly with religious and social activities. The Romans frequently showered newlyweds with nuts and almonds as a fertility charm. In 1700's the almond tree was introduced to the North American continent by what is now considered California. Although the crops did poorly until moved farther inland, almonds are ranked as the largest export in the U.S. for specialty crops (1).

Almonds provide a rich array of nutrients. In comparison to other nuts, almonds have more protein, dietary fiber, riboflavin, niacin, alpha-tocopherol and calcium than other nuts (1)(See Appendix G for nutrient composition for almonds). The composition of nutrients in almonds have led researchers to study the health benefits of almonds on several topics including cardiovascular disease (CAD), type 2 diabetes and weight maintenance.

Health Benefits

Cardiovascular Disease

The association between nut consumption and reduced risk factors associated with heart disease has been well documented (62, 92, 103). It is thought that the vitamin E (alpha-tocopherol) in nuts assists in reducing cardiovascular disease by three main mechanisms.

These mechanisms are thought to be; the prevention of oxidation of LDL cholesterol, the prevention of platelet aggregation, and the inhibition of proliferation of smooth muscle cells (45).

In the Adventist Health Study, high nut consumption (5x per week) was associated with a 50% reduction of CAD risk for subjects regardless of BMI. In a randomized crossover trial, Jenkins et al. examined the benefits almonds on blood lipids and low-density lipoproteins. Fourteen participants were given 3 different supplements. These supplements included whole raw unbalanced almonds, muffins and half the portions of almonds, or only almonds. Calorie intakes for the supplements were based on the subject's daily energy requirement. The results of this study showed that a high to moderate intake of almonds (73 grams per day) produced a reduction in LDL cholesterol by 9.4%. As smaller does of almonds (37 grams day) also showed a reduction of LDL by 4.4% (62). This study demonstrates even small dosages of almonds can provide a beneficial physiologic improvement in reducing the risk of cardiovascular disease.

Another study examined the effect of almonds on serum lipids in adults who were diagnosed with type 2 diabetics. In the first study, 20 free-living healthy subjects received 100 grams of almonds per day for four weeks. Researchers noted a slight but statistically significant increase in weight gain, (p=0.006) for participants who had a normal BMI, a significant decrease in LDL-C and total cholesterol was demonstrated (74).

Lovejoy et al. also found a reduction in HDL-C for healthy participants in Study 1 (p<0.05). The second study randomly assigned 30 men and women, with type 2 diabetes, into four different groups. Group 1 was considered the high-fat, high almond group with 37% total fat and 10% from almonds. Group 2 was a low-fat, high-almond group with 25% total fat and 10% almonds. Group 3 was a high fat control group where total fat accounted for 37% and 10% came from either olive or canola oil. The last group, Group 4, was a low fat control group with 25% total fat and 10% from either olive or canola oil. Participants were provided between 57-113 grams of almonds per day depending on estimated energy level. This study demonstrated that total cholesterol was significantly lower in diabetic participants assigned to a high fat diet with almonds (p<0.0004); however, the decrease was attributed to a significant reduction in HDL-C (p=0.002). A trending of lowered LDL-C (p=0.06) in study 2 was also observed (74).

Type 2 Diabetes

The same nutrient rich properties of almonds that have lead researchers to examine the possible positive effects of almonds consumption on CVD has generated interest on the effect of nut intake on type 2 diabetes. Almonds are high in antioxidants and provide an array of other compounds including plant sterols, and phenols that may be beneficial (34). Almonds are also a good source of magnesium, with 84 mg of magnesium provided in one ounce (1). Magnesium intakes may be inversely related to the risk of diabetes (73).

A prospective cohort study that examined nut consumption and risk of type 2 diabetes in women, found that frequent nut intake (> 5x/week) had a 30% reduction in risk compared to individuals who rarely eat nuts (64).

In a study done by Jenkins et al., the effect of adding almonds to a carbohydrate rich meal on postprandial glycemia and insulinemia was assessed. Fifteen healthy adults completed the study in which subjects ate two bread control meals and three test meals containing bread and almonds. Results showed that the meals containing almonds were associated with lower insulin peaks (224± 24 mmol/L) and increased in protein thiol concentrations (15± 14mmol/L) compared to the potato meal (388± 30 mmol/L, -10± 8 mmol/L) or control meal (white bread). An increase in protein thiol concentrations suggests less protein damage was shown in the participants (61).

A 24-week intervention, using 65 overweight participants was conducted to determine the effect of a low calorie almond diet on insulin resistance (119). Out of the participating subjects, 70% of subjects had been diagnosed with type 2 diabetes, while 30% of the subjects reported insulin resistance. After a two-week washout period, groups were randomized into a low calorie diet containing either almonds (84 grams per day) or complex carbohydrates (equal calories) for the remainder of the 24-week trial. Results from the almond group showed an overall 54% reduction of fasting insulin levels and improved beta cell functions.

Medication use was either reduced or sustain in 96% of participants in the almond group (119). These observations associate a positive impact on insulin sensitivity from almond or nut consumption.

The Nurses Health Study, a prospective cohort study, examined nut consumption in 83,818 women and the risk of developing type-2 diabetes. This study found that individuals who had frequent nut intake (as defined intake as > 5x per week) had a 30% reduction in risk compared to those that rarely consume nuts (64). This reduction of risk was found to be independent of age, obesity, physical activity, dietary factors, smoking and family history.

Weight Maintenance

Several studies have been done to examine the relationship between almond consumption and body weight. Fraser et al. conducted a randomized crossover study where 81 adults subjects were supplied 320 daily calories from almonds over a six-month period.
The results showed a non-significant weight gain of less than a pound between the almond feeding and the control group. Considering that the subjects consumed approximately 57,500 extra calories over the course of the study, the predicted weight gain of 6.4 kg was not noted in the participants (46).

Wien et al. examined almonds vs. complex carbohydrates for weight reduction using 65 adults, with BMI ranging from 27 to 55 kg/m^2.

Subjects were placed on low calorie diets that received either 1012 calories per day of almonds or 1015 calories per day from self selected carbohydrate. The outcome of the study determined that the almond group had experienced a greater weight reduction for the 24-wk intervention. Wien et al. reported a 62% greater reduction in weight and BMI, a 50 % greater reduction in waist circumference and a 56% greater reduction in fat mass in the almond group compared to the carbohydrate group intervention (119).

The SUN Study was a prospective cohort study that examined diet and the occurrence of disease and obesity. Subjects were sent self-administered questionnaires every two years. The questionnaire asked questions pertaining to nut consumption including almond intake. Subjects who consumed nuts 2x per week or more were 30% less likely to gain weight compared to subjects who rarely consumed nuts (7). Since almonds are high in monounsaturated fats (MUFA) (89), it is not surprising that the almond group showed increased MUFA levels at the halfway mark and at twelve-weeks ($p<0.01$) compared to baseline levels. During this study's 16 year follow-up, weight again across defined categories of nut consumption did not differ significantly, however women who ate nuts >5x/week had a lower BMI compared to women who reported eating nuts never or almost never (7).

Another study explored the effect of chronic almond consumption on body weight in healthy humans. In this 23-week study, Hollis et al. measured the effect of 1440 kJ (about 333 kcals) of almonds per day for a period of ten weeks. A control group was provided with no almonds and advised to follow normal diet and activity patterns. This study found that there was no significant changes in body weight, percent fat, fat mass, fat free mass or total body weight in the almond group compared to the control (58).

Recently Zaveri et al. conducted a study examining the effect of a conventional snack (cereal bar) and almonds had on hunger, eating frequency, dietary intake and body weight. Forty-five men (25-50 years, BMI 25-35) were recruited for this twelve-week intervention study. Participants were randomly placed into 3 groups, with participants receiving an almond snack, a cereal bar or the control. All groups were given the same advice on healthy eating. In this study the subjects were allowed to eat treatment food at anytime during the day, and the control group was asked to continue habitual diet. Results of this study showed the almond group reported a significant statistical increase in eating frequency compared to the control group ($p<0.05$) and the cereal bar group ($p<0.01$)(124).

In contrast, Ceohlo et al. conducted a parallel-arm long term feeding study that studied the effect of peanut oil loads on body composition in forty-eight adults who were considered either lean or overweight.

Participants who were categorized as overweight gained a significant amount of body weight 2.35 kg ($p<0.05$), compared to baseline weight. Since the participants of this study were given peanut oil and the differences between peanut oil and whole nuts were not determined, Ceohlo et al. concluded that it maybe other properties within nuts that have a strong compensatory response than compared to nut oil alone (22).

Suggested Mechanisms of Weight Loss

Mechanisms of weight maintenance could be explained by nutrient content of almonds, the bioavailability of nutrients and effect of mastication, and the influence nuts may have metabolic rates.

Fiber

Foods that contain a high fiber and protein content are thought to have a satiating effect (78, 101). About 1 oz of almonds is a good source of fiber, containing 3.5 g of fiber, 2.4g from insoluble fiber (1). Meals and foods that contain high amounts of fiber are processed slowly in the intestine with nutrients absorbed over a longer period of time (78). In addition, high fiber foods are usually less energy dense and greater in volume, which may help to decrease unplanned energy intake and increase sensation of fullness. This sensation of fullness may due to the fact that fiber causes distention of the stomach, indicating that volume of food consumed may exert a modulatory effect over hunger signals (66), and suppress hunger.

The type of fiber found in almonds may also positively influence satiety. Willis et al. looked at the effects of four different types of fiber and a low fiber treatment in 20 healthy adults. Results of this trial showed that resistant fiber might increase satiety compared to polydextrose (120). The fiber contained in nuts is thought to slow the release of glucose entry into the blood and reduce insulin secretion (78). Another theory suggests that the fatty acid content of nuts helps to increase insulin sensitivity.

A diet high in mono and poly-unsaturated fats in nuts are thought to influence the fatty acid composition of phospholipids in the cells membrane, a phenomenon highly connected to insulin sensitivity (9). It is thought that specific fatty acids compositions can influence ion permeability, cell signaling and modulate insulin action (64).

Protein

Almonds, as compared to other nuts, contain larger amounts of protein, which can increase feelings of fullness after a meal (76, 106). Concerns for weight loss strategies that have increased protein intakes because of the potential lasting effect high protein exerts on kidney function. The amount of protein to have a satiety effect, however, does not appear to have a negative effect on kidney function (84, 100).

Luecine

The restricted energy intakes that are typically required in treatment of obesity lead to favorable fat loss but are often accompanied by a loss of desirable lean muscle mass (4).

The branched chained amino acid, luecine, has demonstrated the ability to promote muscle protein synthesis even when energy intake is restricted (24,28). Almonds are known to be high in luecine, 1.37 g per ounce, (1) which may have an impact on body composition even during desirable weight loss.

Studies conducted in mammals have associated luecine with decreased energy intakes through the activation of mTOR, in the hypothalamus (24). The activation of mTOR stimulates the synthesis of leptin in adipose tissue (98). Leptin secretion helps regulate body weight by promoting satiety signals (69). Blood levels have been shown to be comparable to individual dietary intakes of luecine, which may allow skeletal muscles to receive an amount proportional to intakes (69).

Bioavailability of Nutrients

Bioavailability refers the amount of the nutrient that is readily available for absorption in the intestinal track (104). Studies have suggested that the fat content found in nuts, and almonds, is not fully absorbed during digestion and an estimated 10-20% is lost in the stool (16). Several factors influence the availability of nutrients released from plant matter, including the structure of the cell wall (37). The fat composition of almonds has been measured and is shown to make up 50% of the total weight of almonds, which is not surprising as fat is considered the main storage component found within the cell walls (37). Studies have shown that the cells walls of almonds are left mostly intact after mastication's (16).

Mandalari et al. examined the release of protein, lipids and vitamin E from almonds during digestion. In this study four different forms of almonds were tested: natural almonds, blanched almonds, finely ground almonds and defatted finely ground almonds. These test foods were digested under simulated in vitro gastric and duodenal conditions. Total fat loss during digestion for all four of the test foods resulted in a 54.9% loss compared to the original amount present. The finely ground almonds showed to have the highest rate of fat breakdown (39%) with defatted almonds at 34% breakdown. This study suggests that consumption of almonds in their whole form, compared to other forms, provides less dietary fat then previously thought due to lower bioavailability (76).

Mastication and Satiety

Mastication is the breakdown of food into smaller particles that allow foods to be swallowed. This break down also assists in increasing the surface area that is accessible to enzymes (47). The release of nutrients and other substances contribute to gut signaling, transit times and the absorption process. Studies using gastric infusions compared to oral feedings have shown that mastication optimizes perceptions of satiety (68). This may be due to the fact that mastication induces sensory stimulation that can cause the release of hormones, such as leptin, that influences appetite (102).

Cassady et al. conducted a study that examined the effects of almond mastication on lipid bio-accessibility, appetite and hormone response. In this randomized, 3- arm crossover study, 13 adults with healthy BMI's were given a standardized amount of almonds to chew either 10, 25 or 40 times. Two hours after almond consumption, fullness levels where shown to be significantly lower than at baseline. The mastication intervention, where participant chewed the almonds 40 times, was associated with a longer duration of fullness compared to other frequency amounts of mastication ($p = 0.041$). These results indicate that mastication could significantly influence absorption and appetite responses, but that the two factors did not seem related (16). However, in a study looking at the effect of almond mastication on BMI in obese and lean participants, Frecka et al. found no significant difference ($p < 0.05$) in BMI between groups (47).

Metabolism

Almonds are considered to have a high protein and unsaturated fat content compared to other nuts. The high protein and unsaturated fat content found in almonds may cause an increase in resting energy expenditure, which could result in a reduction in the accumulation of fat (108, 115). Several studies have demonstrated that a high polyunsaturated to saturated fatty acid ratio could increase resting energy expenditure (65, 115).

Jones et al. examined the effect of dietary fat, polyunstaruated to saturated ratio on energy utilization in obesity. In total, fifteen obese and lean participants underwent two 14-day intervention dietary periods with a week washout period in between. Dietary intake of fat was targeted at 45%, 40% and 15% of total energy intake. Supervision was given to participants, during interventions, for self-selected foods items that contained either a high, or low ratio of polyunstaturated to saturated fat. This study demonstrated that obese participants who consumed a meal high in polyunsaturated fat oxidized more fat than when consuming a diet high in saturated fat ($p<0.01$) (65).

Alper et al. conducted a study looking at the effects of chronic peanut consumption on energy balance and energy expenditure. Fifteen healthy adults with normal weights were assigned into 3 intervention groups with a 4-week wash out period between each group.

One group consisted of free feeding that consumed 50% of fat intake was from peanuts at any given time for 8 weeks. Another group, considered the addition group, had 50% of fat intake from peanuts and participants were placed on an isocaloric diet for 3 weeks. The last group was considered the substitution group, where participants decreased fat intake by 50% and this amount was replaced by peanut intake for 8 weeks.

The results of this study demonstrated an 11% increase in resting energy expenditure (REE) ($p<0.01$) after 19 weeks of peanut consumption compared to participant's baseline REE (2).

The influence of almond consumption on weight maintenance and health risk factors has been widely researched. This study examines the influence of almond consumption on energy intake and body weight in healthy or disease-controlled participants. Using a small step approach, the addition of 1 ounce of almonds in the dietary intake of adults may result in a sustainable lifestyle change that leads to weight loss and a decrease health risks associated with overweight and obesity.

Chapter 3

METHODOLOGY

Subjects

Participants were recruited from advertisements posted in Arizona State University Tempe campus publications, online, at local retail stores, senior citizen community centers and on the Arizona State University Polytechnic campus. Thirty-five participants were recruited from the Phoenix, metropolitan area. All participants were screened for age, BMI, level of exercise, gender, and disease states via telephone using a standardized script (Appendix A). On site screening included measured height, weight and a medical questionnaire and assessment of current physical activity (Appendix B). Subjects were classified as overweight (25-29.9) or obese (>30) according to BMI (kg/m2) standard categories. Participants were screened for willingness to consume the required test foods at the requested time, share information on current medication use, complete randomized 24-dietary recalls, and participate in anthropometric data collection.

Subjects were excluded if they did not consume a dinner meal, currently consumed nuts greater than 2x per week or used medications that may influence weight (Appendix C). Subjects who were not considered sedentary (exercise > 2x week) or currently had an uncontrolled disease condition (treated < 3 months) were also excluded. In addition, subjects were not considered if they were pregnant, less than six months post-partum, or anticipated being pregnant.

Participants did not have a known aversion to consuming almonds, and did not have any known nut and/or milk allergies or intolerances. All subjects provided written informed consent (Appendix D) prior to participation in the study. The Arizona State University Institutional Review Board, Human Subjects Committee approved this research prior to initiation of recruitment.

Sample Size

Power analysis calculations (Appendix E) indicated that 108 subjects were needed to detect a treatment difference between groups. We anticipated a small but significant difference in weight loss for individuals consuming 1 oz almonds (170kcal) as compared to the control treatment. To detect a 3 kg difference, assuming that the SD for body weight is 5.5kg and that the attrition will be 20%, we anticipated enrolling 126 participants or 63 per group. The alpha level was set at .05 and the beta error level is at .2 resulting in a power of 80%.

Study Design and Test Food

This study utilized a randomized, parallel arm, placebo-controlled research design. Subjects were stratified and randomized into groups by age, gender, BMI and body composition and assigned to either consume 1 oz of blanched almonds 5x per week (ALM) group or to the control (CON) group, consuming two, 1 oz cheese sticks 5x per week. Subjects were instructed to be hydrated and refrain from moderate or heavy physical activity for 24 hours prior to collection of anthropometric measurements.

On the day of data collection anthropometric measurements, height, weight, body composition and waist circumference, were obtained. After anthropometric measurements were taken participants received pre-weighed packages of blanched, unsalted blanched almonds or Frigo brand cheese sticks for the initial period. Participants who received the almonds were instructed to consume a 1 oz almond serving before the evening meal 5x per week. Participants in the control group were instructed to consume two, 1 oz cheese sticks before the evening meal 5x per week. (See Appendix F, Table 3 for nutrition composition of the almonds and control cheese stick). (See Appendix G, Table 4, 5, 6, and 7 for specific nutrient content of almonds).

Subjects were trained to complete 24-hour dietary recalls through the National Cancer Institute (NCI) automated web-based application ASA 24 (ASA 24 Bethesda, MD). Anthropometric measurements were repeated at baseline, week 1, 4 and week 8. Additional food was provided to the participants at week 4 of the study. The subjects were instructed not change dietary habits, physical activity behavior, or consume more than two additional nut product servings per week during the eight-week study.

Anthropometric and Physical Activity Measurements

Body weight and body composition were measured using a bio-impedance electrical scale (Tanita Corporation of America, Inc. Arlington Heights, Illinois) with the subjects wearing light clothing and no shoes or socks. Height was measured using a statiometer and BMI was calculated from measured weight and height data.

Height is reported in centimeters (cm), weight in kilograms (kg) and BMI is reported as kg/m^2. Waist circumference was measured by locating the middle of the umbilicus using a spring adjusted Gulick II measuring tape (Country Tech, Inc. Gays Mills, WI) and is reported in centimeters (cm). Physical activity was administered at screening using a modified, validated physical activities questionnaire from Godin et al. and was reported in METs (50). This short questionnaire measures the weekly average frequency of light (minimal effort), moderate (not to point of exhaustion), and strenuous exertion of exercise; average frequencies were multiplied by 3 (light), 5 (moderate), and 9 (strenuous) metabolic equivalents, respectively, to estimate weekly MET's (h/week).

Dietary Recall

All subjects were expected to complete 8, 24-hour dietary recalls, using the ASA 24 three- step automated dietary program through the NIC. This program guided participant through a 24-hour dietary recall using a version of the USDA's Automated Multiple-Pass Method (AMPM, Beltsville, Maryland). Participants were first prompted to record time, location and general items consumed. Next further detail was asked about each meal and items contained within the meal including serving method, size and container. Lastly a review of the recall was provided and subjects were prompted to add any additional foods or drinks not recorded.

Statistical Analysis

All data was statically analyzed using The Statistical Package for the Social Sciences (SPSS 17.0 for Windows, SPSS Inc., Chicago, IL).

Data are presented with a mean ± standard deviation (±SEM). Outcomes were checked for normality and transformed if necessary. ANOVA and Independent t-test was used to examine repeated measures for energy intake, body weight, body composition, and waist circumference.

Chapter 4

RESULTS

Descriptive Statistics

Thirty-five individuals were screened for this study, 28 of these participants were enrolled, and 21 subjects completed the 8-week study with an attrition rate of 40%. Of the 35 individuals originally screened, 7 participants were unable to meet during the required trial times to receive test foods and were disqualified from the study. Three participants were dropped from research, stating reason as inability to eat the specified amount of string cheese 5x per week. Two participants were unresponsive in attempts to contact them during the study and two were disqualified for new medication usage and uncontrolled illness. In total, 13 participants in the almond group and 8 participants in the cheese group completed all data collection for the study. Data was obtained for 21 participants at week 4 and 20 participants completed all 8-weeks of the parallel-arm study.

TABLE 8
Basic Descriptives for Completed Participants

	Almonds (n=13)	Cheese (n=8)	*P*
Gender			
Men/Women	3/10	1/7	
Ethnicity			
Caucasian/Hispanic	13/0	7/1	
Weight (kg)	96.1±21.5	95.0±3.3	.891
Age (Years)	43±3.1	48±3.6	.319
BMI (kg/m^2)	33.9±1.9	35.0±1.5	.425
Waist Circumference (cm)	106.2±4.3	104.7± 1.3	.750
Body Fat %	39.9±2.5	42.0±2.1	.425
Height (cm)	166.3±1.9	165.7±2.6	.858
METS (hours/week)	29.9±7.9	17.9±4.5	.270
Activity Level			
Not Active	1	4	
Active	5	2	
Somewhat Active	6	2	
Very Active	0	0	

P values are derived from the independent t-test

Mean participant weight was 96.1± 21.5 kg for subjects who participated in the ALM group and 95.0±3.3 for CHE group. Mean age was 43±3.1 for participants in the ALM group and was 48±3.6 for CHE participants. Mean body fat percentage was 39.9±2.5 and 42.0±2.1 in participants selected for the ALM group and CHE group respectively. The mean waist circumference was 106.2±4.3 cm for ALM participants compared to 104.7±1.3 cm for CHE participants. The mean BMI values were 33.9±1.9 cm and 35.0±1.5 cm for ALM and CHE participants respectively. BMI values are reflective of the standard classifications used for obesity.

Age, body fat percentage, waist circumference, BMI or body weight did not differ significantly between participants selected for the ALM group and participants in the CHE group. Descriptive characteristics for the completed 21 participants are presented in Table 8.

Demographics for completed participants showed three men and ten women completed the ALM group, while one man and seven women completed in the CHE group. Statistical significance was not shown between genders for weight, BMI, waist circumference and body fat percentage. The entire ALM group and seven of the CHE group considered themselves Caucasian while only one CHE participant reported being Hispanic. When reporting on activity level participants, the ALM group reported one for not active, five active, six somewhat active and zero very active. The CHE group reported four not active, two active, two somewhat active and zero very active. Chi Square was unable to run an analysis of this data due to cells having less then five. A summary of this information is displayed in Table 8.

Participant Energy Intake

Energy intake was measured at week 1, week 4 and week 8. Mean energy intake from screening for participant in ALM group was 1858±215 kcal and 2107±145 kcal for CHE participants. At week 1, the mean energy intakes for both groups were, 1832±156 kcal and 1857±194 kcal for the ALM and CHE respectively. Week 4 mean energy intake for the ALM was 1716±156 kcal and 1958±194 kcal for the CHE group.

Energy intakes measures at week 8 were 1642±156 kcal and 1610±194 kcal for the ALM and CHE groups respectively. Data received for energy intakes were normally distributed. Table 9 summarizes mean energy intake for completed participants. Analysis of data in repeated measures ANOVA did not demonstrate a statistical significant reduction in energy intake after almond consumption compared to the control group between week 1 and week 8 ($p=0.519$). Summary information is displayed in Table 5. Statistical significance was not demonstrated when kcal intake was divided by weight in kg for participants, to control for weight differences between groups.

TABLE 9
Mean Energy Intake For Completed Participants

	Almond (n=13)	Cheese (n=8)	*P*
Energy Intake week 0 (kcal)	1857±215	2107±145	.502
Energy Intake week 1 (kcal)	1832±156	1857±194	.833
Energy Intake week 4 (kcal)	1716±156	1958±194	.324
Energy Intake week 8 (kcal)	1642±156	1610±194	.600

*Data are mean± SEM
*P values are derived from the independent t-test

TABLE 10
Changes in Weight, Energy Intake, Body Fat %, BMI and Waist Circumference for Week 4 and Week 8 in Completed Participants

	Pre Week 1	Post Week 4	Δ Wk 4-1	Post Week 8	Δ Wk 8-1
Weight (kg)					
Almond	96.1±6.0	96.9±6.1	0.5±0.2	96.6±6.1	0.2± 0.3
Cheese	95.0±3.3	94.4±3.7	0.7±0.5	95.4±3.4	0.5±0.5
Kcal					
Almond	1832±154	1716±118	-114.8±121.1	1642± 156	-182.7±172.4
Cheese	1857±215	1958±194	-70.3±308.6	1610± 194	-98.3±291.8
Body Fat %					
Almond	39.4±3.3	40.9±2.7	1.1±1.3	40.3±2.7	0.4±0.4
Cheese	42.0±2.6	41.9±2.9	0.4±0.5	41.8±2.5	- 0.2±0.07
BMI (kg/m²)					
Almond	35.1±2.4	35.0±2.0	0.2±0.1	34.9±2.1	0.1±0.1
Cheese	34.7±1.4	34.2±1.5	0.3±0.2	34.9±1.5	0.2±0.2
Waist (cm)					
Almond	108.1±4.3	108.2±4.3	0.0±1.7	107.6±4.1	-0.5±1.2
Cheese	1.05.1±1.8	105.8±2.4	0.7±1.3	105.8±1.6	0.6±0.8

*Data are mean± SEM n=21
*There are no significant differences between groups

Changes in Weight

Body weight was measured at baseline, week 0, week 4, and week 8. Twenty-one participants completed all measurements for weight, including 13 participants from the ALM group and 8 participants from the CHE group. Data for week 1 was normally distributed; however data for week 8 required being transformed using log10 to achieve normality. Weight change for week 1 to week 4 was a gain of 0.5±0.2 kg for the ALM group and a gain of 0.7±0.5 kg. Weight change for participants of the ALM group between week 1 and week 8 was a gain of 0.2±0.3 kg and a gain of 0.5±0.5 kg for the participants in the CHE group.

Analysis of weight change between weeks 1, week 8 and week using independent t-test did not demonstrate a significant change of weight for participant or differences between genders in the ALM or CHE group (p=0.562). See Table 10 and Figure 1. for details.

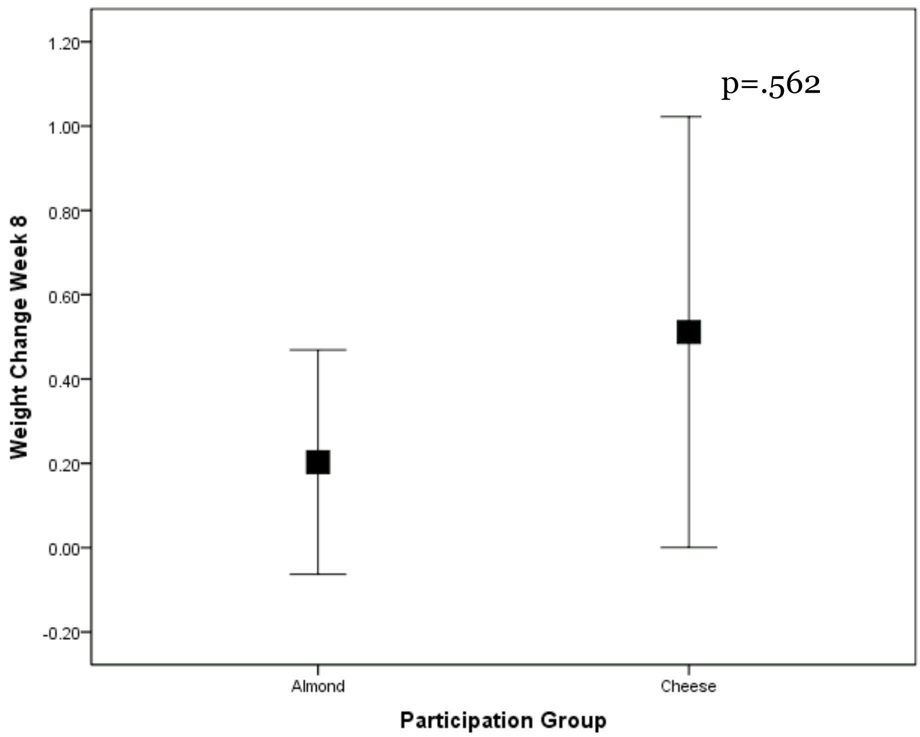

FIGURE 1. Mean Weight Change for Completed Participants for Week 8

Changes in Kcal Intake

Energy intake was recorded at week 1, week 4 and week 8 of the study. For week 1 to week 4, a change in energy intake for the ALM group was a decrease of -114.8±121.1 kcal and a decrease of -70.3±308.6 kcal for the CHE group.

Week 1 to week 8 change of energy intake showed that the ALM group had decreased by -182.7±172.4 kcal and the CHE group had decreased by -98.3±291.8 kcal. An analysis of the changes in energy intake between week 1 and week 4, and weeks 1 to week 8 was completed using an independent t test, however, no statistical significance was reached for either time frame. A summary of this information can be found in Table 10 and Figure 2.

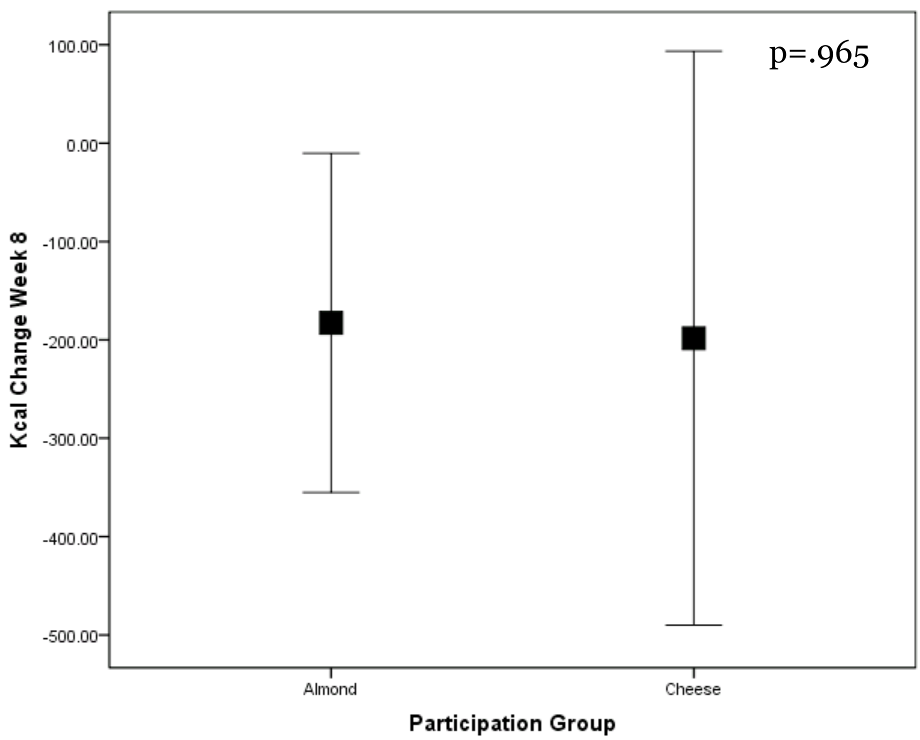

FIGURE 2. Mean Kcal Intake Change Week 8

Changes in Body Fat Percentage

Body fat percentage was recorded for all participants at baseline, week 1, week 4 and week 8. The mean change in body fat percentage, for week 1 to week 4 was an increase of 1.1±1.3 or the ALM group and an increase of 0.4±0.5 for the CHE group. For week 1 to week 8 the mean change in body fat percentage was an increase of 0.4±0.4 for participants in the ALM group and a decrease of -0.2±0.1 in the CHE group. There was no statistical significance shown for changes in body fat percentage between week 1 to week 4 or week 1 to week 8. Results are shown in Table 10, Figure 3.

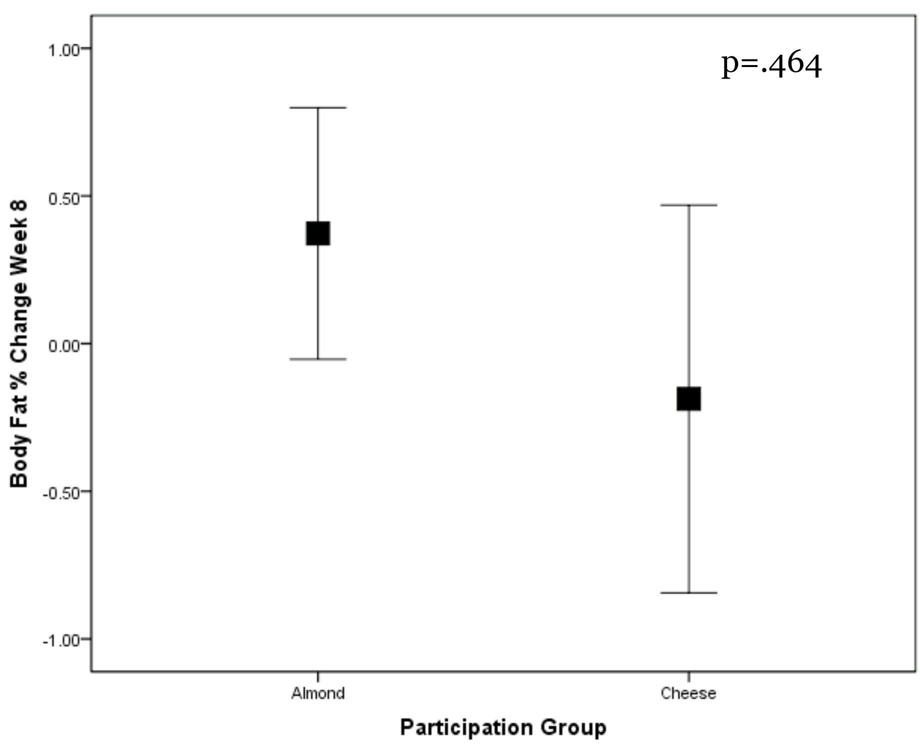

FIGURE 3. Mean Body Fat Percentage Change Week 8

Changes in Body Mass Index

The change in BMI for completed participants was calculated between week 1, week 4 and week 8. The mean changes in BMI for the ALM group for week 1 to week 4 was an increase of 0.2±0.1 and an increase of 0.3±0.2 for the CHE group. The mean change of BMI for week 1 to week 8 was an increase of 0.1±0.1 for the ALM group and 0.2±0.2 for the participants in the CHE group. No statistical significances were found in changes of BMI with an independent t test analysis. See Table 10, Figure 4 for details.

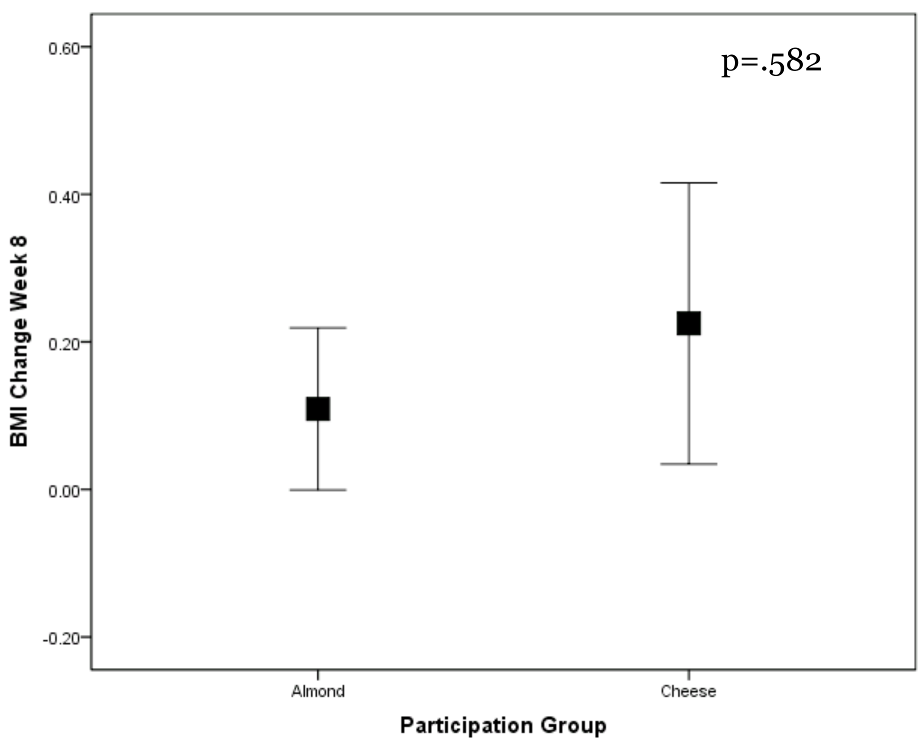

FIGURE 4. Mean Body Mass Index Change Week 8

Changes in Waist Circumference

Waist circumference was recorded from participants screening, week 1, week 4 and week 8. Mean weight circumference change for week 1 to week 4 was an increase of 0.0±1.7 cm for ALM participants and 0.7±1.3 cm for CHE participants. For baseline to week 8 the mean weight circumference change was a decrease of -0.5±1.2 cm for the ALM group and an increase of 0.6±0.8 cm for the CHE group. Analysis was done using an independent t- test. No statistical significant was found for either time frame. A summary of this information can be found in Table 10, Figure 5.

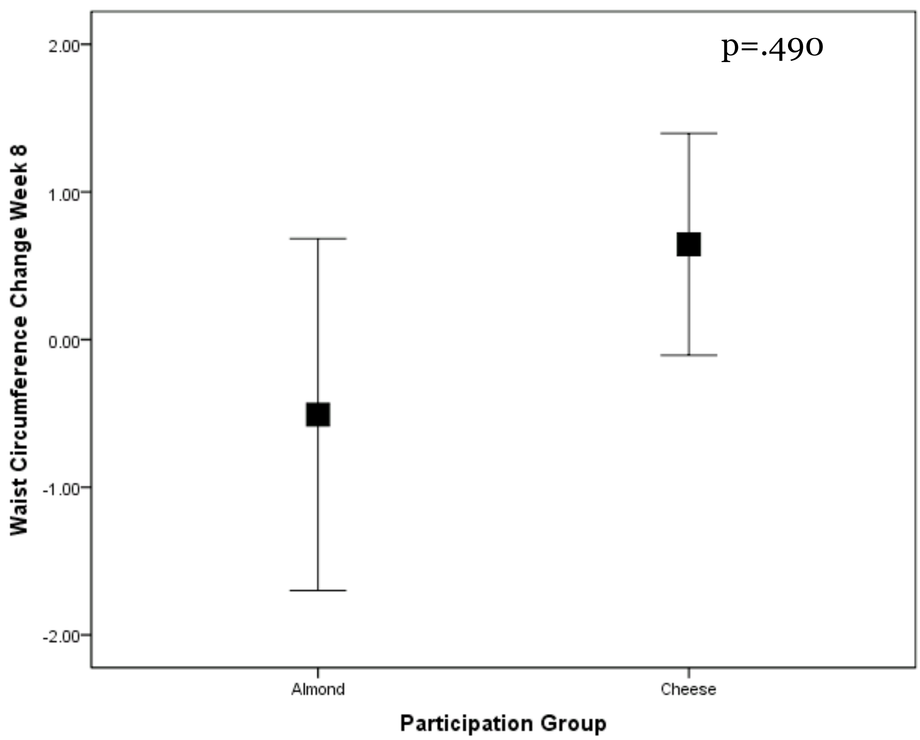

FIGURE 5. Mean Waist Circumference Change Week 8

CHAPTER 5

DISCUSSION

Excess body weight increases risk for several chronic diseases including cardiovascular disease and diabetes. Treatment for obesity often includes surgical, pharmaceutical options, as well as lifestyle modifications to diet and physical activity. However, maintenance of weight loss resulting from gastric surgery or medications still requires a change in dietary intake and or physical activity. Studies have debated the best course for dietary intake to achieve long-term weight loss. This study examined the ingestion of 1 oz of almonds 5x per week for 8 weeks to determine the effect of almond consumption on energy intake and weight loss.

The effects of nut consumption on energy intake and body weight have been examined in a number of studies; however, a majority of these studies were conducted with nuts other than almonds or with multiple daily servings of almonds. Fraser et al. demonstrated no significant change in body weight after ingestion 2 oz of almond (46). Hollis et al. reported no changes in body weight when a similar amount of almonds were consumed (58). Lovejoy et al. showed a slight but significant weight gain for normal weight subjects after including 100g of almonds to daily intake (74). Several cross sectional studies have also examined the effect of overall nut consumption on body weight. Bes-Rastrollo et al. conducted a study that reported nut consumption greater than 2x week resulted in a reduced risk of obesity over an 8 year follow up (8).

The almond trial reported here included overweight or obese participants who were considered healthy or with controlled (>3 months) disease states. At baseline there was no significant difference between age, weight, waist circumference, BMI or body fat percentage, MET's/week for participants in the ALM or CHE groups. Criteria for overweight and obese participants were based on standard BMI classifications.

There was no significant change in energy intake at week 4 or at week 8 of the study for participants consuming either 1 oz of almonds or two, 2 oz cheese sticks prior to the evening meal. However, the participants in the ALM group did consume 156.6 ± 114.3 kcals less at week 8 compared to baseline. Although this did not reach statistical significance, this deficit could theoretically lead to a meaningful weight loss over time. Small amounts of weight loss up to 5% have been shown beneficial to decrease health risks (87).

A change in energy intake may not have been shown in ALM participants because the dose of almond given may not have been high enough to produce a significant compensatory effect. The compensatory effect of nuts on energy intake has been examined. Foods high in fiber and protein are thought to produce a satiating effect (78, 120). Almonds contain 3.5 grams of fiber and are considerably higher in protein compared to other nuts (1).

Body weight for overweight and obese participants was not altered by the intake of almonds. Other studies have demonstrated a significant reduction in weight after almond consumption.

In a study conducted by Wien et al., significant weight loss was demonstrated in overweight and obese adults after an intervention of 84g of raw, unsalted almonds with safflower oil and self-selected carbohydrates (119). In the present study, the intervention was 1 oz, approximately 28 g, of almonds, which is roughly one-third the amount consumed in Wien et al. study. In another study, Bes-Rastrollo et al. conducted a 5-year follow up, that examined the effect nut consumption on body weight. Rastrollo et al. concluded that frequent nut consumption of greater than 2x week was associated with reduced risk of weight gain up to 5 kg (7). In each study, Wien et al. used a large portion of almonds and Bes-Rastrollo examined all nut consumption.

The results from this study suggest that 1 oz almond consumed prior to the evening meal over an 8-week period did not significantly effect energy intake or body weight, however this study was underpowered therefore the true effect of almonds on energy intake and body weight remains inconclusive. If sample size were increased, it would further increase power that may demonstrate a greater effect of almonds on energy intake and body weight. Another factor to considerer is the load of almond given in this trial. Participants were also advised to consume the 1 ounce almonds before the dinner meal 5x per week. It may be that a serving of 1 ounce almonds would need to be consumed 7 days per week to differ results.

The attrition of participants was higher than anticipated, at 40%, which could have impacted the results of the study's intervention. Several factors for the high attrition rate have already been accounted for. However, participant in the control group had the burden of consuming the cheese products that required refrigeration and may not have been palatable in taste. It may also be that the unsalted, blanched almonds used in this study were not what participants were accustomed to eating, as most commercial nuts have added salt and flavors added. These factors could have attributed to a lack of compliance for consuming the assigned foods.

Chapter 6

CONCLUSION

Drastic lifestyle changes, pharmaceutical, and surgical options are available for treatment of obesity. However, maintainable lifestyle changes that improve dietary intake and physical activity provide the most effective long-term outcome. Previous studies have demonstrated that almond consumption can decrease energy intake and help to maintain or promote weight loss. The results of this study suggest that 8 weeks of almond consumption (1 oz/day, 5x per week) does not lead to significant changes in energy intake. Therefore the null hypothesis is accepted. A significant change in body weight was not indicated when 1 ounce of almonds was compared to cheese intake in this study, the lack of effect also suggest that the second null hypotheses should be rejected. The addition of almonds to a daily diet has demonstrated several health benefits in other studies with participants who were overweight, obese or considered lean. It is suggested that properties within almonds, such as fiber and protein, have a satiating effect and benefit individuals during weight loss. Research that is adequately powered is required to understand the potential benefits of almonds and nut consumption on energy intake and body weight.

References

1. Almond Board of California. Nutrient Dense page. Available at: http://www.almondboard.com/Consumer/Pages.html. Accessed October 15, 2010.

2. Alper CM, Mattes RD. Effects of chronic peanut consumption on energy balance and hedonics. *Int J Obes Relat Metab Disord*. 2002;26(8):1129-1137.

3. Ashley JM, Herzog H, Clodfelter S, Bovee V, Schrage J, Pritsos C. Nutrient adequacy during weight loss interventions: A randomized study in women comparing the dietary intake in a meal replacement group with a traditional food group. *Nutr J*. 2007;6:12.

4. Balage M, Dardevet D. Long-term effects of leucine supplementation on body composition. *Curr Opin Clin Nutr Metab Care*. 2010;13(3):265-270.

5. Barkeling B, Elfhag K, Rooth P, Rossner S. Short-term effects of sibutramine (reductil) on appetite and eating behaviour and the long-term therapeutic outcome. *Int J Obes Relat Metab Disord*. 2003;27(6):693-700.

6. Berrigan D, Dodd K, Troiano RP, Krebs-Smith SM, Barbash RB. Patterns of health behavior in U.S. adults. *Prev Med*. 2003;36(5):615-623.

7. Bes-Rastrollo M, Sabate J, Gomez-Gracia E, Alonso A, Martinez JA, Martinez-Gonzalez MA. Nut consumption and weight gain in a mediterranean cohort: The SUN study. *Obesity (Silver Spring)*. 2007;15(1):107-116.

8. Bes-Rastrollo M, Wedick NM, Martinez-Gonzalez MA, Li TY, Sampson L, Hu FB. Prospective study of nut consumption, long-term weight change, and obesity risk in women. *Am J Clin Nutr*. 2009;89(6):1913-1919.

9. Borkman M, Campbell LV. Non insulin dependent diabetes mellitus. rational approach to management. *Aust Fam Physician*. 1993;22(9):1549-51, 1554-7, 1560.

10. Bradley U, Spence M, Courtney CH, McKinley MC, Ennis CN, McCance DR, McEneny J, Bell PM, Young IS, Hunter SJ. Low-fat versus low-carbohydrate weight reduction diets: Effects on weight loss, insulin resistance, and cardiovascular risk: A randomized control trial. *Diabetes*. 2009;58(12):2741-2748.

11. Bray GA. Soft drink consumption and obesity: It is all about fructose. *Curr Opin Lipidol*. 2010;21(1):51-57.

12. Bray GA, Greenway FL. Pharmacological treatment of the overweight patient. *Pharmacol Rev*. 2007;59(2):151-184.

13. Brinkworth GD, Buckley JD, Noakes M, Clifton PM, Wilson CJ. Long-term effects of a very low-carbohydrate diet and a low-fat diet on mood and cognitive function. *Arch Intern Med*. 2009;169(20):1873-1880.

14. Brown CD, Higgins M, Donato KA, Rohde FC, Garrison R, Obarzanek E, Ernst ND, Horan M. Body mass index and the prevalence of hypertension and dyslipidemia. *Obes Res*. 2000;8(9):605-619.

15. Byrne SM, Cooper Z, Fairburn CG. Psychological predictors of weight regain in obesity. *Behav Res Ther*. 2004;42(11):1341-1356.

16. Cassady BA, Hollis JH, Fulford AD, Considine RV, Mattes RD. Mastication of almonds: Effects of lipid bioaccessibility, appetite, and hormone response. *Am J Clin Nutr*. 2009;89(3):794-800.

17. Center for Disease Control. National Health and Nutrition Examination Survey III, 1999-2000. Available at: http://www.cdc.gov/nchs/nhanes/nh3data.html. Accessed September 7, 2010.

18. Center for Disease Control. National Health and Nutrition Examination Survey III, 1976-1998. Available at: http://www.cdc.gov/nchs/nhanes/nh2data.html. Accessed September 7, 2010.

19. Center for Disease Control: National Health and Nutritional Examination, 1971-1975.Available at: http://www.cdc.gov/nchs/nhanes.html. Accessed September 7, 2010.

20. Center for Disease Control: Behavioral risk factor surveillance system, 2009. Availiable at: http://www.cdc.gov/brfss.html. Accessed March 25, 2011.

21. Center for Disease Control: Pradar Willie Syndrome page. Availiable at:http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002572.html. Accessed February 12, 2011.

22. Coelho SB, de Sales RL, Iyer SS, Bressan J, Costa NM, Lokko P, Mattes R. Effects of peanut oil load on energy expenditure, body composition, lipid profile, and appetite in lean and overweight adults. *Nutrition*. 2006;22(6):585-592.

23. Cota D, Barrera JG, Seeley RJ. Leptin in energy balance and reward: Two faces of the same coin? *Neuron*. 2006;51(6):678-680.

24. Crozier SJ, Kimball SR, Emmert SW, Anthony JC, Jefferson LS. Oral leucine administration stimulates protein synthesis in rat skeletal muscle. *J Nutr*. 2005;135(3):376-382.

25. Cummings N, Shields KA, Curran JE, Bozaoglu K, Trevaskis J, Gluschenko K, Cai G, Comuzzie AG, Dyer TD, Walder KR, Zimmet P, Collier GR, Blangero J, Jowett JB. Genetic variation in SH3-domain GRB2-like (endophilin)-interacting protein 1 has a major impact on fat mass. *Int J Obes (Lond)*. 2011.

26. Daviglus ML. Health care costs in old age are related to overweight and obesity earlier in life. *Health Aff (Millwood)*. 2005;24 Suppl 2:W5R97-100.

27. de Vegt F, Dekker JM, Jager A, Hienkens E, Kostense PJ, Stehouwer CD, Nijpels G, Bouter LM, Heine RJ. Relation of impaired fasting and postload glucose with incident type 2 diabetes in a dutch population: The hoorn study. *JAMA*. 2001;285(16):2109-2113.

28. Devkota S, Layman DK. Protein metabolic roles in treatment of obesity. *Curr Opin Clin Nutr Metab Care*. 2010;13(4):403-407.

29. Diliberti N, Bordi PL, Conklin MT, Roe LS, Rolls BJ. Increased portion size leads to increased energy intake in a restaurant meal. *Obes Res*. 2004;12(3):562-568.

30. Dixon JB, O'Brien PE, Playfair J, Chapman L, Schachter LM, Skinner S, Proietto J, Bailey M, Anderson M. Adjustable gastric banding and conventional therapy for type 2 diabetes: A randomized controlled trial. *JAMA*. 2008;299(3):316-323.

31. Donnelly JE, Hill JO, Jacobsen DJ, Potteiger J, Sullivan DK, Johnson SL, Heelan K, Hise M, Fennessey PV, Sonko B, Sharp T, Jakicic JM, Blair SN, Tran ZV, Mayo M, Gibson C, Washburn RA. Effects of a 16-month randomized controlled exercise trial on body weight and composition in young, overweight men and women: The midwest exercise trial. *Arch Intern Med*. 2003;163(11):1343-1350.

32. Donnelly JE, Blair SN, Jakicic JM, Manore MM, Rankin JW, Smith BK, American College of Sports Medicine. American college of sports medicine position stand. appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. *Med Sci Sports Exerc*. 2009;41(2):459-471.

33. Douketis JD, Macie C, Thabane L, Williamson DF. Systematic review of long-term weight loss studies in obese adults: Clinical significance and applicability to clinical practice. *Int J Obes (Lond)*. 2005;29(10):1153-1167.

34. Dourado F, Barros A, Mota M, Coimbra MA, Gama FM. Anatomy and cell wall polysaccharides of almond (prunus dulcis D. A. webb) seeds. *J Agric Food Chem*. 2004;52(5):1364-1370.

35. Drewnowski A. Obesity, diets, and social inequalities. *Nutr Rev*. 2009;67 Suppl 1:S36-9.

36. Duren DL, Sherwood RJ, Czerwinski SA, Lee M, Choh AC, Siervogel RM, Cameron Chumlea W. Body composition methods: Comparisons and interpretation. *J Diabetes Sci Technol*. 2008;2(6):1139-1146.

37. Ellis PR, Kendall CW, Ren Y, Parker C, Pacy JF, Waldron KW, Jenkins DJ. Role of cell walls in the bioaccessibility of lipids in almond seeds. *Am J Clin Nutr*. 2004;80(3):604-613.

38. Esposito K, Di Palo C, Maiorino MI, Petrizzo M, Bellastella G, Siniscalchi I, Giugliano D. Long-term effect of mediterranean-style diet and calorie restriction on biomarkers of longevity and oxidative stress in overweight men. *Cardiol Res Pract*. 2010;2011:293916.

39. Farooqi IS, O'Rahilly S. Monogenic obesity in humans. *Annu Rev Med*. 2005;56:443-458.

40. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: Payer-and service-specific estimates. *Health Aff (Millwood)*. 2009;28(5):w822-31.

41. Flegal KM, Shepherd JA, Looker AC, Graubard BI, Borrud LG, Ogden CL, Harris TB, Everhart JE, Schenker N. Comparisons of percentage body fat, body mass index, waist circumference, and waist-stature ratio in adults. *Am J Clin Nutr*. 2009;89(2):500-508.

42. Folsom AR, Kushi LH, Anderson KE, Mink PJ, Olson JE, Hong CP, Sellers TA, Lazovich D, Prineas RJ. Associations of general and abdominal obesity with multiple health outcomes in older women: The iowa women's health study. *Arch Intern Med*. 2000;160(14):2117-2128.

43. Foreyt JP, Salas-Salvado J, Caballero B, Bullo M, Gifford KD, Bautista I, Serra-Majem L. Weight-reducing diets: Are there any differences? *Nutr Rev*. 2009;67 Suppl 1:S99-101.

44. Frank LD, Kerr J, Sallis JF, Miles R, Chapman J. A hierarchy of sociodemographic and environmental correlates of walking and obesity. *Prev Med*. 2008;47(2):172-178.

45. Fraser GE. Associations between diet and cancer, ischemic heart disease, and all-cause mortality in non-hispanic white california seventh-day adventists. *Am J Clin Nutr*. 1999;70(3 Suppl):532S-538S.

46. Fraser GE, Bennett HW, Jaceldo KB, Sabate J. Effect on body weight of a free 76 kilojoule (320 calorie) daily supplement of almonds for six months. *J Am Coll Nutr*. 2002;21(3):275-283.

47. Frecka JM, Hollis JH, Mattes RD. Effects of appetite, BMI, food form and flavor on mastication: Almonds as a test food. *Eur J Clin Nutr*. 2008;62(10):1231-1238.

48. French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the pound of prevention study: Dietary, behavioral and demographic correlates. *Int J Obes Relat Metab Disord*. 2000;24(10):1353-1359.

49. Furtado LC. Nutritional management after roux-en-Y gastric bypass. *Br J Nurs*. 2010;19(7):428-436.

50. Godin G, Shephard RJ. A simple method to assess exercise behavior in the community. *Can J Appl Sport Sci*. 1985 Sep;10(3):141-6

51. Garcia-Lorda P, Megias Rangil I, Salas-Salvado J. Nut consumption, body weight and insulin resistance. *Eur J Clin Nutr*. 2003;57 Suppl 1:S8-11.

52. Hamdy O, Zwiefelhofer D. Weight management using a meal replacement strategy in type 2 diabetes. *Curr Diab Rep*. 2010;10(2):159-164.

53. Hannum SM, Carson L, Evans EM, Canene KA, Petr EL, Bui L, Erdman JW,Jr. Use of portion-controlled entrees enhances weight loss in women. *Obes Res*. 2004;12(3):538-546.

54. Harris KM, Gordon-Larsen P, Chantala K, Udry JR. Longitudinal trends in race/ethnic disparities in leading health indicators from adolescence to young adulthood. *Arch Pediatr Adolesc Med*. 2006;160(1):74-81.

55. Hauptman J. Orlistat: Selective inhibition of caloric absorption can affect long-term body weight. *Endocrine*. 2000;13(2):201-206.

56. Hill JO. Can a small-changes approach help address the obesity epidemic? A report of the joint task force of the american society for nutrition, institute of food technologists, and international food information council. *Am J Clin Nutr*. 2009;89(2):477-484.

57. Hill JO. Understanding and addressing the epidemic of obesity: An energy balance perspective. *Endocr Rev*. 2006;27(7):750-761.

58. Hollis J, Mattes R. Effect of chronic consumption of almonds on body weight in healthy humans. *Br J Nutr*. 2007;98(3):651-656.

59. Jacobs DR,Jr, Ainsworth BE, Hartman TJ, Leon AS. A simultaneous evaluation of 10 commonly used physical activity questionnaires. *Med Sci Sports Exerc*. 1993;25(1):81-91

60. Janssen I, Katzmarzyk PT, Ross R. Waist circumference and not body mass index explains obesity-related health risk. *Am J Clin Nutr*. 2004;79(3):379-384.

61. Jenkins DJ, Kendall CW, Josse AR, Salvatore S, Brighenti F, Augustin LS, Ellis PR, Vidgen E, Rao AV. Almonds decrease postprandial glycemia, insulinemia, and oxidative damage in healthy individuals. *J Nutr*. 2006;136(12):2987-2992.

62. Jenkins DJ, Kendall CW, Marchie A, Parker TL, Connelly PW, Qian W, Haight JS, Faulkner D, Vidgen E, Lapsley KG, Spiller GA. Dose response of almonds on coronary heart disease risk factors: Blood lipids, oxidized low-density lipoproteins, lipoprotein(a), homocysteine, and pulmonary nitric oxide: A randomized, controlled, crossover trial. *Circulation*. 2002;106(11):1327-1332.

63. Jennings A, Welch A, Jones AP, Harrison F, Bentham G, van Sluijs EM, Griffin SJ, Cassidy A. Local food outlets, weight status, and dietary intake associations in children aged 9-10 years. *Am J Prev Med*. 2011;40(4):405-410.

64. Jiang R, Manson JE, Stampfer MJ, Liu S, Willett WC, Hu FB. Nut and peanut butter consumption and risk of type 2 diabetes in women. *JAMA*. 2002;288(20):2554-2560.

65. Jones PJ, Ridgen JE, Phang PT, Birmingham CL. Influence of dietary fat polyunsaturated to saturated ratio on energy substrate utilization in obesity. *Metabolism*. 1992;41(4):396-401.

66. Kirkmeyer SV, Mattes RD. Effects of food attributes on hunger and food intake. *Int J Obes Relat Metab Disord*. 2000;24(9):1167-1175.

67. Kruger J, Galuska DA, Serdula MK, Jones DA. Attempting to lose weight: Specific practices among U.S. adults. *Am J Prev Med*. 2004;26(5):402-406.

68. Lavin JH, French SJ, Read NW. Comparison of oral and gastric administration of sucrose and maltose on gastric emptying rate and appetite. *Int J Obes Relat Metab Disord*. 2002;26(1):80-86.

69. Layman DK, Walker DA. Potential importance of leucine in treatment of obesity and the metabolic syndrome. *J Nutr*. 2006;136(1 Suppl):319S-23S.

70. Ledikwe JH, Ello-Martin JA, Rolls BJ. Portion sizes and the obesity epidemic. *J Nutr*. 2005;135(4):905-909.

71. Leibel RL. Energy in, energy out, and the effects of obesity-related genes. *N Engl J Med*. 2008;359(24):2603-2604.

72. Lissner L, Levitsky DA, Strupp BJ, Kalkwarf HJ, Roe DA. Dietary fat and the regulation of energy intake in human subjects. *Am J Clin Nutr*. 1987;46(6):886-892.

73. Lopez-Ridaura R, Willett WC, Rimm EB, Liu S, Stampfer MJ, Manson JE, Hu FB. Magnesium intake and risk of type 2 diabetes in men and women. *Diabetes Care*. 2004;27(1):134-140.

74. Lovejoy JC, Most MM, Lefevre M, Greenway FL, Rood JC. Effect of diets enriched in almonds on insulin action and serum lipids in adults with normal glucose tolerance or type 2 diabetes. *Am J Clin Nutr*. 2002;76(5):1000-1006.

75. Malik VS, Popkin BM, Bray GA, Despres JP, Willett WC, Hu FB. Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: A meta-analysis. *Diabetes Care*. 2010;33(11):2477-2483.

76. Mandalari G, Faulks RM, Rich GT, Lo Turco V, Picout DR, Lo Curto RB, Bisignano G, Dugo P, Dugo G, Waldron KW, Ellis PR, Wickham MS. Release of protein, lipid, and vitamin E from almond seeds during digestion. *J Agric Food Chem*. 2008;56(9):3409-3416.

77. Manson JE, Willett WC, Stampfer MJ, Colditz GA, Hunter DJ, Hankinson SE, Hennekens CH, Speizer FE. Body weight and mortality among women. *N Engl J Med*. 1995;333(11):677-685.

78. Marlett JA, McBurney MI, Slavin JL, American Dietetic Association. Position of the american dietetic association: Health implications of dietary fiber. *J Am Diet Assoc*. 2002;102(7):993-1000.

79. Mattes RD, Kris-Etherton PM, Foster GD. Impact of peanuts and tree nuts on body weight and healthy weight loss in adults. *J Nutr*. 2008;138(9):1741S-1745S.

80. Michels KB, Greenland S, Rosner BA. Does body mass index adequately capture the relation of body composition and body size to health outcomes? *Am J Epidemiol*. 1998;147(2):167-172.

81. Mokdad AH, Serdula MK, Dietz WH, Bowman BA, Marks JS, Koplan JP. The continuing epidemic of obesity in the united states. *JAMA*. 2000;284(13):1650-1651.

82. Mukuddem-Petersen J, Snijder MB, van Dam RM, Dekker JM, Bouter LM, Stehouwer CD, Heine RJ, Nijpels G, Seidell JC. Sagittal abdominal diameter: No advantage compared with other anthropometric measures as a correlate of components of the metabolic syndrome in elderly from the hoorn study. *Am J Clin Nutr*. 2006;84(5):995-1002.

83. Mutch DM, Clement K. Unraveling the genetics of human obesity. *PLoS Genet*. 2006;2(12):e188.

84. Noakes M, Keogh JB, Foster PR, Clifton PM. Effect of an energy-restricted, high-protein, low-fat diet relative to a conventional high-carbohydrate, low-fat diet on weight loss, body composition, nutritional status, and markers of cardiovascular health in obese women. *Am J Clin Nutr*. 2005;81(6):1298-1306.

85. Nooyens AC, Visscher TL, Schuit AJ, van Rossum CT, Verschuren WM, van Mechelen W, Seidell JC. Effects of retirement on lifestyle in relation to changes in weight and waist circumference in dutch men: A prospective study. *Public Health Nutr*. 2005;8(8):1266-1274.

86. O'Brien PE. Bariatric surgery: Mechanisms, indications and outcomes. *J Gastroenterol Hepatol*. 2010;25(8):1358-1365.

87. Office of the Surgeon General: PHS:The surgeon general's call to action to prevent and decrease overweight and obesity, 2001. Availaible at: http://www.surgeongeneral.gov/topics/obesity.html. Accessed on September 17, 2010.

88. Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the united states, 1999-2004. *JAMA*. 2006;295(13):1549-1555.

89. Piers LS, Soares MJ, Frandsen SL, O'Dea K. Indirect estimates of body composition are useful for groups but unreliable in individuals. *Int J Obes Relat Metab Disord*. 2000;24(9):1145-1152.

90. Pi-Sunyer FX. Medical hazards of obesity. *Ann Intern Med*. 1993;119(7 Pt 2):655-660.

91. Powell LM, Chaloupka FJ, Bao Y. The availability of fast-food and full-service restaurants in the united states: Associations with neighborhood characteristics. *Am J Prev Med*. 2007;33(4 Suppl):S240-5.

92. Rajaram S, Sabate J. Nuts, body weight and insulin resistance. *Br J Nutr*. 2006;96 Suppl 2:S79-86.

93. Romaguera D, Norat T, Mouw T, May AM, Bamia C, Slimani N, Travier N, Besson H, Luan J, Wareham N, Rinaldi S, Couto E, Clavel-Chapelon F, Boutron-Ruault MC, Cottet V, Palli D, Agnoli C, Panico S, Tumino R, Vineis P, Agudo A, Rodriguez L, Sanchez MJ, Amiano P, Barricarte A, Huerta JM, Key TJ, Spencer EA, Bueno-de-Mesquita HB, Buchner FL, Orfanos P, Naska A, Trichopoulou A, Rohrmann S, Kaaks R, Bergmann M, Boeing H, Johansson I, Hellstrom V, Manjer J, Wirfalt E, Uhre Jacobsen M, Overvad K, Tjonneland A, Halkjaer J, Lund E, Braaten T, Engeset D, Odysseos A, Riboli E, Peeters PH. Adherence to the mediterranean diet is associated with lower abdominal adiposity in european men and women. *J Nutr*. 2009;139(9):1728-1737.

94. Rundle A, Roux AV, Free LM, Miller D, Neckerman KM, Weiss CC. The urban built environment and obesity in new york city: A multilevel analysis. *Am J Health Promot*. 2007;21(4 Suppl):326-334.

95. Sabate J. Nut consumption and body weight. *Am J Clin Nutr*. 2003;78(3 Suppl):647S-650S.

96. Seidell JC, Nooyens AJ, Visscher TL. Cost-effective measures to prevent obesity: Epidemiological basis and appropriate target groups. *Proc Nutr Soc*. 2005;64(1):1-5.

97. Shai I, Schwarzfuchs D, Henkin Y, Shahar DR, Witkow S, Greenberg I, Golan R, Fraser D, Bolotin A, Vardi H, Tangi-Rozental O, Zuk-Ramot R, Sarusi B, Brickner D, Schwartz Z, Sheiner E, Marko R, Katorza E, Thiery J, Fiedler GM, Bluher M, Stumvoll M, Stampfer MJ, Dietary Intervention Randomized Controlled Trial (DIRECT) Group. Weight loss with a low-carbohydrate, mediterranean, or low-fat diet. *N Engl J Med*. 2008;359(3):229-241.

98. She P, Van Horn C, Reid T, Hutson SM, Cooney RN, Lynch CJ. Obesity-related elevations in plasma leucine are associated with alterations in enzymes involved in branched-chain amino acid metabolism. *Am J Physiol Endocrinol Metab*. 2007;293(6):E1552-63.

99. Sjostrom L, Rissanen A, Andersen T, Boldrin M, Golay A, Koppeschaar HP, Krempf M. Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. european multicentre orlistat study group. *Lancet*. 1998;352(9123):167-172.

100. Skov AR, Toubro S, Ronn B, Holm L, Astrup A. Randomized trial on protein vs carbohydrate in ad libitum fat reduced diet for the treatment of obesity. *Int J Obes Relat Metab Disord*. 1999;23(5):528-536.

101. Slavin JL. Position of the american dietetic association: Health implications of dietary fiber. *J Am Diet Assoc*. 2008;108(10):1716-1731.

102. Sobhani I, Buyse M, Goiot H, Weber N, Laigneau JP, Henin D, Soul JC, Bado A. Vagal stimulation rapidly increases leptin secretion in human stomach. *Gastroenterology*. 2002;122(2):259-263.

103. Spiller GA, Jenkins DA, Bosello O, Gates JE, Cragen LN, Bruce B. Nuts and plasma lipids: An almond-based diet lowers LDL-C while preserving HDL-C. *J Am Coll Nutr*. 1998;17(3):285-290.

104. Stahl W, van den Berg H, Arthur J, Bast A, Dainty J, Faulks RM, Gartner C, Haenen G, Hollman P, Holst B, Kelly FJ, Polidori MC, Rice-Evans C, Southon S, van Vliet T, Vina-Ribes J, Williamson G, Astley SB. Bioavailability and metabolism. *Mol Aspects Med*. 2002;23(1-3):39-100.

105. Stroebele N, Rodearmel SJ, Wyatt HR,Smith SM, Ogden LG, Hill JO. Small changes in dietary sugar and physical activity as an approach to preventing excessive weight gain: The america on the move family study. *Pediatrics*. 2007;120(4):e869-79.

106. Stubbs RJ, Ritz P, Coward WA, Prentice AM. Covert manipulation of the ratio of dietary fat to carbohydrate and energy density: Effect on food intake and energy balance in free-living men eating ad libitum. *Am J Clin Nutr*. 1995;62(2):330-337.

107. Sturm R. The effects of obesity, smoking, and drinking on medical problems and costs. *Health Aff (Millwood)*. 2002;21(2):245-253.

108. Swaminathan R, King RF, Holmfield J, Siwek RA, Baker M, Wales JK. Thermic effect of feeding carbohydrate, fat, protein and mixed meal in lean and obese subjects. *Am J Clin Nutr*. 1985;42(2):177-181.

109. Tapsell L, Batterham M, Huang XF, Tan SY, Teuss G, Charlton K, Oshea J, Warensjo E. Short term effects of energy restriction and dietary fat sub-type on weight loss and disease risk factors. *Nutr Metab Cardiovasc Dis*. 2010;20(5):317-325.

110. Thorpe KE, Florence CS, Howard DH, Joski P. The impact of obesity on rising medical spending. *Health Aff (Millwood)*. 2004;Suppl Web Exclusives:W4-480-6.

111. Torgerson JS, Hauptman J, Boldrin MN, Sjostrom L. XENical in the prevention of diabetes in obese subjects (XENDOS) study: A randomized study of orlistat as an adjunct to lifestyle changes for the prevention of type 2 diabetes in obese patients. *Diabetes Care*. 2004;27(1):155-161.

112. Treyzon L, Chen S, Hong K, Yan E, Carpenter CL, Thames G, Bowerman S, Wang HJ, Elashoff R, Li Z. A controlled trial of protein enrichment of meal replacements for weight reduction with retention of lean body mass. *Nutr J*. 2008;7:23.

113. United States Federal Drug Administration. Questions and Answers: Orlistat and Severe Liver Injury. Available at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders.html. Accessed March 20, 2011.

114. United States Agricultural Department: Dietary Guidelines for Americans, 2010. Available at: http://www.cnpp.usda.gov/dietaryguidelines.html. Accessed March 11, 2011.

115. van Marken Lichtenbelt WD, Mensink RP, Westerterp KR. The effect of fat composition of the diet on energy metabolism. *Z Ernahrungswiss*. 1997;36(4):303-305.

116. Varady KA. Intermittent versus daily calorie restriction: Which diet regimen is more effective for weight loss? *Obes Rev*. 2011.

117. Visscher TL, Seidell JC. The public health impact of obesity. *Annu Rev Public Health*. 2001;22:355-375.

118. Wang Y, Beydoun MA. The obesity epidemic in the united states--gender, age, socioeconomic, racial/ethnic, and geographic characteristics: A systematic review and meta-regression analysis. *Epidemiol Rev*. 2007;29:6-28.

119. Wien MA, Sabate JM, Ikle DN, Cole SE, Kandeel FR. Almonds vs complex carbohydrates in a weight reduction program. *Int J Obes Relat Metab Disord*. 2003;27(11):1365-1372.

120. Willis HJ, Eldridge AL, Beiseigel J, Thomas W, Slavin JL. Greater satiety response with resistant starch and corn bran in human subjects. *Nutr Res*. 2009;29(2):100-105.

121. Wolf AM, Colditz GA. Current estimates of the economic cost of obesity in the united states. *Obes Res*. 1998;6(2):97-106.

122. World Health Organization. Obesity and overweight page. Available at: http://www.who.int/mediacentre/factsheets/fs311/en/index.html. Accessed October 3, 2010.

123. Young LR, Nestle M. The contribution of expanding portion sizes to the US obesity epidemic. *Am J Public Health*. 2002;92(2):246-249.

124. Zaveri S, Drummond S. The effect of including a conventional snack (cereal bar) and a nonconventional snack (almonds) on hunger, eating frequency, dietary intake and body weight. *J Hum Nutr Diet*. 2009;22(5):461-468.

APPENDIX A

STANDARDIZED PHONE SCRIPT

Date: ____________________ Time: _________________
Interviewer:_________________
Thank you for your interest in our study. Before I can enroll you in this study, I will need to ask you a few simple questions that will allow me to determine if you qualify to participate.

Participant

Name:____

Contact

information:____

Gender: M F

Weight______________ Age________________

Height_______________ Calculated BMI________________

How often do you usually exercise? Days________________ Minutes _____________

What would you considered the intensity of your exercise to be:

Mild **Moderate** **Intense**

Are you currently Pregnant/Lactating/Anticipating being pregnant? Y N

Have you recently been pregnant in the last 6 months? Y N

Are you currently taking any medications? Y N
If so, what medications do you currently take?
Medication Time on Medication

____ ________________________

____ ________________________

Are you currently being treated for any medical condition? Y N

Are you currently being treated for a chronic disease? Y N

Do you have any known allergies or intolerances to any nuts/dairy products?
Y N

This study is expected to last 8 weeks in length, is there any reason that may prevent you from completing this study?

____

____

APPENDIX B

HEALTH HISTORY/QUESTIONAIRE

ID#____________________

1. Gender: M F

2. Age: ___________

3. Have you lost or gained <u>more than</u> 5 lbs in the last 12 months? Yes No
If yes, how much lost or gained? __________
How long ago? ____________

4. Ethnicity: (please circle) Native American African-American Caucasian Hispanic Asian Other

5. Do you smoke? No, never _________
Yes ________ # Cigarettes per day = _________
I used to, but I quit ________ months/years (circle) ago

7. Do you take any medications regularly? Yes No
If yes, list type and date you started:

Medication Date

____

____

____

____

8. Do you currently take supplements (vitamins, minerals, herbs, etc.) ? Yes No

If yes, list type and frequency:

<u>Supplement</u> <u>Dosage</u> <u>Frequency</u>

____

____

9. Have you ever been hospitalized? _______

If yes, please explain?

____

10. Please ANSWER (YES/NO) if **<u>you</u> currently have** or if **<u>you</u> have <u>ever</u>** been diagnosed with any of the following diseases or symptoms:

	YES	NO		YES	NO
Coronary Heart Disease			Chest Pain		
High Blood Pressure			Shortness of Breath		
Heart Murmur			Heart Palpitations		
Rheumatic Fever			Any Heart Problems		
Irregular Heart Beat			Coughing of Blood		
Varicose Veins			Feeling Faint or Dizzy		
Stroke			Lung Disease		
Diabetes			Liver Disease		
Low Blood Sugar			Kidney Disease		
Bronchial Asthma			Thyroid Disease		
Hay Fever			Anemia		
Leg or Ankle Swelling			Hormone Imbalances		
Eating Disorders			Emotional Problems		

Please elaborate on any condition listed

above.____

____

11. How would you rate your lifestyle?
Not active ___________ Active ___________
Somewhat active __________ Very Active ___________

12. Please circle the total time you spend <u>in each category</u> for an average **week.**

Light activities such as:
Slow walking, golf, slow cycling, doubles tennis, easy swimming, gardening
Hours per week: 0 1 2 3 4 5 6 7 8 9 10+

Moderate activities such as:
Mod. Walking, mod. cycling, singles tennis, mod. swimming, mod. weight lifting
Hours per week: 0 1 2 3 4 5 6 7 8 9 10+

Vigorous activities such as:
Fast walking/jogging, fast cycling, court sports, fast swimming, heavy/intense
weight lifting
Hours per week: 0 1 2 3 4 5 6 7 8 9 10+

13. How much alcohol do you drink? (average drinks per day)
____

14. Do you have any food allergies/intolerances? Yes No If yes, explain:____

15. Do you follow a special diet? (weight gain/loss, vegetarian, low-fat, etc.) Yes No

If yes, explain:

____

____

16. How often do you *usually* consume nuts or nut products including peanuts?

____

APPENDIX C

EXCLUEDED MEDICATIONS

TABLE 2
Exclusion List of Medications that Influence Weight

Used in the Treatment of:	***Generic Name***	***Brand Names***
Psychiatric Disorders	Olanzapine	Zyprexa
	Clozapine	Clozaril
	Lithium	Eskalith,
	Ziprasidone	Lithobid
		Geodon
Depression	Amitriptyline	Elavil
	Paroxetine	Paxil
	Phenelzine	Nardil
	Tranylcypromine	Parnate
	Nefazadone	Serzone
	Bupropion	Wellbutrin SR
Epilepsy	Valproate	Depakene
	Gabapentin	Neurontin
	Carbamazepine	Tegretol
	Topiramate	Topamax
Inflammatory Disorders	Corticosteroids	Deltasone
		Prednisone
Diabetes	Insulin	Glucotrol,
	Sulfonylureas	Diabeta
	Thiazolidinediones	Avandia, Actos
	Biguanide metformin	Glucophage
Hypertension	Propranolol	Inderal

APPENDIX D

CONSENT FORM

Almond and Dairy Consumption on Body Composition

INTRODUCTON

The purposes of this form are (1) to provide you with information that may affect your decision as to whether or not to participate in this research study, and (2) to record your consent if you choose to be involved in this study.

RESEARCHERS

Dr. Carol Johnston a Nutrition professor, and Lindsey Wood, a nutrition masters student, have requested your participation in a research study.

STUDY PURPOSE

The purpose of the research is to examine the health benefits of moderate almond consumption or dairy products on body composition in overweight and obese individuals.

DESCRIPTION OF RESEARCH STUDY

You have indicated that you are willing to participate in five randomized 24-hr dietary recalls, adhere to diet and activity restrictions, and consume almonds or cheese sticks as required in this study. Initially you will come to the test site in a rested state, with no moderate/intense activities for 24 hours prior to data collection. You will complete a brief medical history questionnaire to demonstrate the absence of medical conditions that may impact the study and provide the first 24-hr dietary recall. Your weight and height will be measured; your waist circumference will be measured, as well as your body composition at this time. This first meeting will take about 2 hours. At this visit you will be scheduled for appointments at week 4 of this study. In addition, you will be receiving weekly follow-up phone calls by researchers.

This study will last about 2 months. At week four, your anthropometric measurements will be taken and you will be provided either the amount of almonds or cheese sticks to be consumed over the next four weeks. You will agree to eat the specified amount of almonds or cheese sticks at the time indicated each day. Randomly you will be asked to provide an automated 24-hr dietary recall. During the study you will be instructed to consume almonds (1 oz serving) or cheese sticks (2, 2oz servings) five days per week based on a randomization scheme over the two trials. During the 8-week trial, you will consume your normal diet and maintain you current physical activity. If you begin taking medications at any time between trials, you are to notify the investigators of the study. The testing will take place at the specified trial sites and will include 128 participants.

RISKS
The experimental supplements are common food items and ingredients; yet some participants may be allergic or intolerant to nut and diary consumption, or to other things that are often manufactured with these items. Individuals will be carefully screened to exclude individuals with these conditions/situations.

BENEFITS
This study will provide information regarding the effect of moderate almond consumption and/or dairy products on body composition in overweight or obese individuals. There are no direct benefits to you if you participate in this study.

NEW INFORMATION
If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

CONFIDENTIALITY
All information obtained in this study is strictly confidential unless law requires the disclosure. The results of this research study may be used in reports, presentations, and publications, but your name or identity will not be revealed. In order to maintain confidentiality of your records, Dr. Johnston will use subject codes on all data collected, maintain a master list separate and secure from all data collected, and limit access to all confidential information to the study investigators.

WITHDRAWAL PRIVILEGE
You may withdraw from the study at any time for any reason without penalty or prejudice toward you. Your decision will not affect you in any manner.

COSTS AND PAYMENTS
You will receive two $10.00 gift certificates for full participation in this study. The first gift card will be received at week 4 and the second will be given at the time of trial completion.

COMPENSATION FOR ILLNESS AND INJURY
If you agree to participate in the study, then your consent does not waive any of your legal rights. However, in the event of harm, injury, or illness arising from this study, neither Arizona State University nor the researchers are able to give you any money, insurance coverage, free medical care, or any compensation for such injury. Major injury is not likely but if necessary, a call to 911 will be placed.

VOLUNTARY CONSENT
Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by Dr. Carol Johnston; 7001 E. Williams Field Rd., Mesa, AZ 85212; 480-727-1713.

If you have questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at 480-965 6788.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given to you.

Your signature below indicates that you consent to participate in the above study.

____________________________	____________________________
Subject's Signature	Printed Name
____________________________	
Date	
____________________________	____________________________
Contact phone number	Email

INVESTIGATOR'S STATEMENT

"I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided the subject/participant a copy of this signed consent document."

Signature of Investigator_______________________________________

Date______________

APPENDIX E

POWER CALCULATIONS

A total of 125 patients were calculated to enter this two-treatment parallel-design study. The power analysis calculations indicated that 108 subjects are needed to detect a difference between treatment groups. We anticipated a small but significant difference in weight loss for individuals consuming 1 oz of almonds (170 kcals) as compared to the control treatment. To detect a 3 kg difference, assuming that the SD for body weight for body weight is 5.5kg and accounting for a 20% attrition rate, we aimed to enroll 126 participants or 63 per group. The alpha level would have been set at .05 and the beta error level is at .2 resulting in a power of 80%.

APPENDIX F
NUTRIENT COMPARISON OF FOOD

TABLE 3
Macronutrient Content for Almonds and Cheese Sticks

	Almonds (1 oz)	Cheese Stick (2, 2 oz)
Calories	170.0	160.0
Protein	6.0g	12.0g
Carbohydrates	6.0g	0.0g
Total Fat	15.0g	12.0g
Saturated Fat	1.5g	7.0g
Fiber	3.0g	0.0g

APPENDIX G

ALMOND NUTRIENT COMPOSITION

TABLE 4
Fat Composition Single Serving (1 ounce) of Almonds

Fat	
Cholesterol	0 mg
Mono	10.0g
Poly	3.0g
Saturated	1.5g

TABLE 5
Carbohydrates Composition Single Serving (1 ounce) of Almonds

Carbohydrate	
Dietary fiber	3.5g
Soluble fiber	.06g
Insoluble fiber	2.4g
Sugar	2.0g

TABLE 6
Vitamins Composition Single Serving (1 ounce) of Almonds

Vitamin	
Vitamin A	.0IU
Vitamin E	10.0 IU
Vitamin C	.0mg
Niacin	.95mg
Thiamin	.06mg
Biotin	6.0mcg
Folate	17.0mcg
Vitamin B_6	.03mg
Vitamin D	0.0IU

TABLE 7
Minerals Composition Single Serving (1 ounce) of Almonds

Mineral	
Sodium	.0mg
Potassium	207mg
Iron	1.0mg
Calcium	75mg
Magnesium	84mg
Phosphorus	147mg
Zinc	1.0mg
Copper	.27mg