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Thesis

Pilot Study: Barriers to Whole Grain Consumption Among Diabetics of German Heritage

Living in South Carolina, United States

By: Nicole Erickson

Thesis submitted to the School of Health Sciences at Eastern Michigan University in partial fulfillment of the requirements for the degree of Master of Science in Human Nutrition,

Coordinated Program in Dietetics

(MS-CPD)

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February 1, 2011

Ypsilanti, Michigan

Dedication

To my family, especially my husband, who supported me throughout my degree program and let me talk things through when I needed a sounding board. Without his support I would not be where I am today.

Acknowledgments

I would like to acknowledge the employees at the Carolina Center for Diabetes and Endocrinology at Spartanburg Regional Hospital in South Carolina. In particular I would like to thank Cindy Norris, RN, CDE, for her great contribution to subject recruitment. I would like to acknowledge my thesis committee, Judi Brooks, PhD, RD, and Cindy Norris, RN, CDE for their help, insight, and guidance. I would also like to thank Juergen Guldner, PhD, who contributed greatly to the statistical analysis, and Catherine Cooker, who took the time and effort to thoroughly edit the final version.

Abstract

Whole grains play a cost-effective role in the treatment and prevention of type 2 diabetes, yet consumption remains well below recommendations. This pilot study showed that nonfamilial environmental factors have a strong influence on whole grain consumption among type 2 diabetics of German descent. Dietary records and grain questionnaires were used to probe subjects' knowledge of the benefits of whole grains, reasons for grain preferences, and actual consumption. For this population ($n=18$), mean whole grain consumption ($\bar{x} = 48 \pm 30$ g/d = 3 ± 2 servings/d) was much higher than the national average ($\mu \leq 1$ serving/d).

Misunderstanding of labels negatively influenced whole grain consumption ($z = 1.69$, $P=0.09$) while nutrition education showed a positive influence ($z=1.4$, $P=0.14$). This study provides preliminary evidence that the message about the benefits of whole grains will become more effective when a component on correct product identification is included in standard nutrition education.

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Chapter One: Introduction

The benefits of whole grain consumption for type 2 diabetics are well researched. Eating whole grains is a cost-effective, simple treatment that brings improvements in glucose and insulin metabolism. Whole grains have also been implicated in prevention of type 2 diabetes as well as other common medical complications and causes of death in the diabetic population (1–5). Encouraging whole grain intake in this population is thus vital.

Problem

Despite the known benefits and low cost of whole grains, consumption in the United States remains well below recommendations (6–12). In contrast, consumer reports show that Germans have a preference for whole grain breads (13). When living in the United States, do German descendants maintain that cultural preference, or do environmental and/or other influences prevail? If environmental factors prevail, which ones are the most important—and can we change them?

Objective

This pilot study sought to show that environmental factors other than familial influence are dominating reasons for whole grain consumption. This was achieved by studying a random sample of type 2 diabetic Americans of German descent living in South Carolina in the United States, using dietary records. In addition to recording the whole grain intake, the study probed subjects' knowledge of the benefits of whole grains and reasons for their grain preferences. Correlating the contributing factors to actual intake gave a more accurate picture of the most significant factors and helped verify the hypothesis.

Potential Benefit for the Subjects

By nature of participation in the study, subjects increased their knowledge of both portion control and estimation as well as the benefits of whole grains for diabetics. Subjects were also offered a free class on cooking for diabetics. Such a class is not normally offered, or paid for, under standard medical care and reimbursement.

Potential Benefit for Society and the Dietetics Profession

This pilot study was designed to identify important barriers to whole grain consumption. Its methods are unique as it relates factors positively or negatively affecting whole grain consumption to actual consumption. This method is intended to yield a precise analysis as to which factors are most important and deserve further attention. The study is also designed to serve as a basis for broader follow-up studies investigating environmental factors and whole grain consumption and could thus help increase whole grain intake among diabetics. It could also lead to further investigation into cross-cultural dietary-pattern comparisons that could be extended to include other sub-populations or the general population.

Research Method

The Patient Database of Carolina Center for Diabetes and Endocrinology was accessed, and a simple random sample (SRS) of subjects was chosen. Inclusion criteria were as follows:

1. Age range of 18-65.
2. Type 2 diabetics diagnosed at least one year previously.
3. German heritage. German heritage is defined as having one or more full-blooded

German grandparent/s.

A 3-day dietary record was utilized to record whole grain consumption. It should be noted that this pilot study was designed to be applicable on a larger international front, thus leading to intercultural research of the same design – for example, a larger study with three cohorts: Germans in Germany, Americans of German descent, and average Americans. This method of dietary analysis was chosen to fulfill the following criteria:

1. It must guide the subject without any cultural bias. For example, if a food frequency record is used for a study intended for expansion into an intercultural study, it will present inherent cultural biases. Food frequency questionnaires such as that developed by the Fred Hutchinson Cancer Research Center or the Harvard Food Frequency survey may have the ability to include minority populations such as Asians or Hispanics, but they are still country specific and utilize the databases of the country of origin (14, 15). In fact, current food frequency questionnaires are developed using data from specific populations and thus they all incorporate food choices specific only to these populations. This type of survey would not be useful when trying to identify cultural influences or culturally based food choices.
2. Similarly, it must apply to food markets in several countries. For example, 24-hour dietary recalls are developed for, and focus on, the food market within a given country. This fact remains true for dietary recalls and electronic-based surveys such as the Nutrition Data System for Research developed by the University of Minnesota or the Automated Self-Administered 24-hour Dietary Recall (16, 17). As with food frequency questionnaires, they utilize established food databases that are country and/or population-specific. In order to use these methods for an international study, it

would thus be necessary to use a database for analysis of the recalls made with different criteria for each country, and the results would no longer be comparable. Considering these points, the Principal Investigator (PI) developed an appropriate 3-day dietary record (Appendix A). Dietary records are not synonymous with dietary recalls. To ensure accuracy and reduce error with dietary records, the subjects are required to record foods immediately after consumption. Dietary records kept over multiple days, including a sampling of both weekdays and weekends, are considered by some to be a gold standard for collection of individual dietary data. Generally, at least 3 days of diet data are required for accuracy (18–20).

Suitable subjects were asked to keep a 3-day dietary record, concentrating on grains. The PI gave guidance in person on estimating serving size and amounts consumed. She analyzed these records at both the ingredient and food level in order to obtain the most precise estimate of quantity of grains consumed. The PI separated whole grains from refined grains and calculated the amounts of both consumed.

In addition to the amounts of whole grain consumed in each group, the PI identified significant factors influencing whole grain intake using a grain questionnaire (Appendix B). The PI then correlated these factors to actual whole grain consumption to validate their significance.

Because the purpose of the study was to identify the most significant factors contributing to low and high whole grain consumption, the PI examined positive and negative influences. Figure 1, developed by Seal and Jones, shows various barriers to whole grain consumption and was utilized as a base for examining these factors (21).

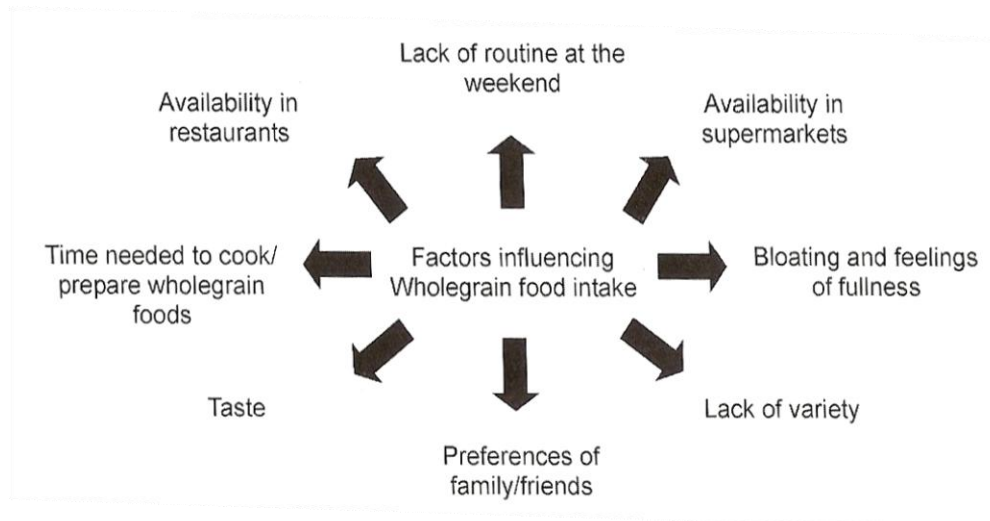


Figure 1: Barriers to Whole Grain Consumption (Source: Seal and Jones [21])

Obvious environmental factors identified by Seal and Jones include cost and availability in supermarkets and restaurants. Familial/cultural preferences may also be considered an environmental factor. In fact, numerous studies addressing food habits and preferences have proven that food choice and habits are greatly influenced by familial, cultural, and socioeconomic factors (22, 23). In this study, familial influence was examined separately to determine exactly how strongly this factor influences whole grain consumption. As friends' preferences tend to play an influential role only during childhood and adolescence, they were not considered in this study (24).

Taste is a less obvious environmental factor that was also mentioned. While one could also categorize taste as a personal factor, taste can be manipulated by the food industry and therefore can also be considered environmental. For example, the recent production and skillful marketing of white whole wheat bread and its wide acceptance is one way the

environment has helped increase consumption and taste acceptance of whole grains (25, 26). A further way the food industry affects environmental factors is through the labeling system and claims about health effects of eating certain foods. A recent investigation of whole grain consumption, using data from the 1999-2004 National Health and Nutrition Examination Survey, found that the inability to correctly identify or purchase whole grain products because of misunderstood health claims or nutrition labels may be a barrier to increased consumption (27).

Education as to the benefits of eating whole grains and/or recommendations from a medical provider may also play a role in the encouragement of whole grain consumption. Education could be viewed as a positive influence on whole grain consumption, and not a barrier, which is perhaps a reason why Seal and Jones did not include it in their diagram (Figure 1). Nevertheless, a lack of the presence of positive factors may also be considered a barrier, and education is a particularly important category to consider when investigating whole grain intake among the diabetic population. Education about whole grains in general may also serve as a positive factor.

Lack of variety, bloating and feelings of fullness, and lack of routine at weekends have not been considered dominating factors in whole grain research. While Seal and Jones include these points in their model (Figure 1), they do not address these factors in their discussion (21). Other researchers have found that an investigation of these barriers is complicated by uncontrollable contributing factors (28, 29). Thus the PI considered these factors secondary when developing the questionnaire for this study.

To better serve the purposes of this study, the PI modified the conceptual diagram created by Seal and Jones (Figure 1) to show an examination of environmental factors that may contribute to whole grain intake (Figure 2).

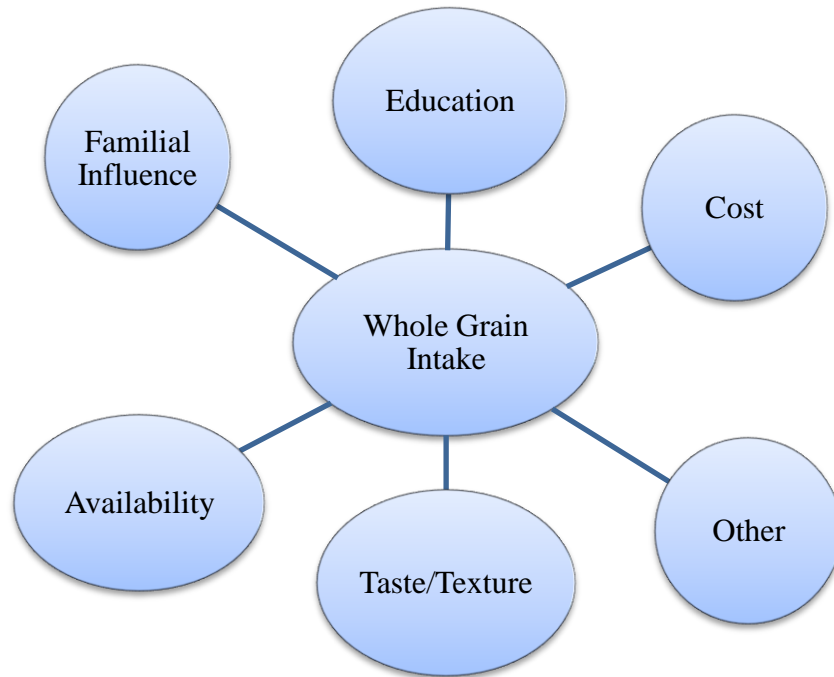


Figure 2: Environmental Factors Contributing to Whole Grain Consumption

Further discussion of known barriers to whole grain consumption follows a comprehensive review of literature examining whole grain foods from past to present, consumption rates in Germany and the United States, and the benefits of whole grains for diabetes prevention and control.

Chapter Two: Review of Literature

Historical Perspective: Whole Grains from Past to Present

Whole grains can be traced back in human history to as early as 8000 B.C. (30). Whole grain consumption and its importance in the human diet have been linked to various ancient civilizations in Africa, Asia, the Americas, and Europe. Evidence shows that grains have contributed a significant proportion of energy to the human diet for 3000-4000 years (31). Grains have contributed not only to the human diet but also to culture. In fact, the cultural transition from a nomadic tribal life to agrarian culture is thought to be directly linked to cultivation of wheat and other grains (30). Myths and legends from around the globe also tell of the importance of grains (32). For example, grain production was so important to the Romans that Ceres, a powerful goddess, was entrusted with grain protection – hence the evolution of the word “cereal” (1). Similarly, early civilizations believed grains were so important that each type of grain was thought to be a gift from the gods. The Aztecs gave thanks to their corn goddess with amaranth grain products, and ancient Chinese writings dating back to 5500 B.C. record millet as an extremely important and revered grain (31).

Traditionally, grains were consumed mostly as whole grains. The first method of preparing grains was to parch them and then boil them whole. Grain milling began by crushing wild grains on rocks, and grinding was done with a mortar and pestle. Evidence of the first grinding stone - called a quern - has been found in ancient Egypt (33). Later, grist mills were used to refine the grain, though they produced limited amounts of purified flour and did not completely separate the bran and the germ. Thus these first grinding methods produced white flour, but it was not as pure as that of today (34). It was with the advent of the roller mill in 1873 that the first efficient removal of the bran and germ from the

endosperm was achieved. Refined flour, which was previously considered to be the “pure flour of the rich and powerful” (34), became increasingly popular and more available. The advancements in the refinement processes also enabled the production of baked goods with a softer texture and extended freshness. Thus, increased consumption and demand for refined grains caused an observed decline in whole grain consumption from about 1870 to 1970 (30).

Definition of Whole Grains

Defining whole grains, especially on an international front, is problematic. Definitions vary widely from country to country, and there is no uniform definition among researchers. Researchers have been called on to create a worldwide definition through an ongoing project supported by the European commission, called HEALTHGRAIN. It published a definition of whole grains in February 2010 (35):

Whole grains shall consist of the intact, ground, cracked or flaked kernel after the removal of inedible parts such as the hull and husk. The principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact kernel. Small losses of components - i.e. less than 2% of the grain/10% of the bran - that occur through processing methods consistent with safety and quality are allowed.

This definition is similar to that of the German food code, which defines a food item as whole grain if it contains the entire grain, including the bran, the germ, and the endosperm. This definition does not change with the addition of any germ, bran, gluten, or starch to a product (36). As in the HEALTHGRAIN definition, the least processed, traditional form of the kernel is required. The German definition also makes clear that similar proportions of these three components cannot be achieved by adding any additional parts (36).

In contrast to these two definitions, the 1999 whole grain definition of the American Association of Cereal Chemists (AACC) reads as follows (37):

Whole grains shall consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact caryopsis.

This definition was adopted by the United States Food and Drug Administration (FDA) and thus could be considered the “official” definition in the United States. Note that this definition is similar to that of the HEALTHGRAIN summit primarily in the last phrase: “are present in the same relative proportions.” The word “relative” allows room for differing interpretations among processors. Such disparity calls for criteria for processing to ensure uniformity, which could be problematic. The HEALTHGRAIN initiative is aware of this problem and has noted it in their forums (38). Nevertheless, the 2004 Whole Grains Council in the United States magnifies this disparity with their definition (39):

Whole grains or foods made from them contain all the essential parts and naturally occurring nutrients of the entire grain seed. If the grain has been processed (i.e. cracked, crushed, rolled, extruded, lightly pearled and/or cooked), the product should deliver **approximately** the same rich balance of nutrients that are found in the original grain seed. (Note: emphasis added.)

Created before the AACC definition, the Whole Grains Council’s definition is one of the more respected definitions in the United States. However, in contrast to all the other definitions, the grain doesn’t have to be a “whole” or “intact” grain; it just has to have all three parts (bran, germ, and endosperm) still present in “approximately” the original

proportions. Again this definition could allow room for different interpretations among processors.

Another respected organization in the United States, the Wheat Foods Council, has a more consumer-friendly definition that is similar to that of the AACC and the HEALTHGRAIN Initiative (40): “If, after milling, they keep all three parts of the original grain – the germ, bran and endosperm – in their original proportions, they still qualify as whole grains.” Due to this disparity, it will be interesting to see if the HEALTHGRAIN project can agree on a single international definition or if it will be necessary to create separate ones for North America and Europe – an option considered less desirable.

Not only do the definitions differ, but discrepancies also exist between countries in the creation of regulations for product labeling. In Germany, bread cannot be considered whole grain unless it consists of $\geq 90\%$ whole grain flour (36). This definition is in strong contrast to that in the United States, where the FDA requires a product to contain $\geq 51\%$ whole grain ingredients by weight to be eligible for the whole grain stamp. This discrepancy is not limited to Germany and the United States, and, as one might expect, it influences how international researchers investigate whole grain consumption. The FDA’s cutoff point of 51% whole grain content may be useful and acceptable for the purposes of food labeling and health claims. It has also been used for some previous analyses of whole grain intake (6, 41). However, The British National Diet and Nutrition Survey of people aged 4-18 years illustrates that defining whole grain foods as those containing $\geq 51\%$ of whole grains could underestimate whole grain intake by as much as 28%. This underestimation is attributed to the fact that the definition excludes foods containing a smaller percentage of whole grains, which, consumed in sufficient amounts, make a significant contribution to total whole grain

intake (42). Jacobs, an American leader in whole grain research, defined whole grains as products containing “at least 25% whole grain or bran by weight” (3). Currently, Jacobs’ definition appears to be the most accepted definition among researchers. Many large multinational epidemiological studies have been conducted using this criterion, including a case-control study in Belgium (43), the Iowa Women’s Health Study (44, 45), the Finnish Mobile Clinic Health Exam Survey (46), The Nurse’s Health Study (7, 8, 47, 48), and the Health Professionals Follow-Up Study (6, 49). Although this definition is less stringent than that of the FDA, Harland and Garton (50) did a systematic review of observational studies published since 1990 that included data from 119,829 male and female subjects aged 13 years and over. They concluded that “lowering the threshold to $\geq 25\%$ content of whole grains to define whole-grain foods reduces underestimation to 15%.” Thus, based on evidence suggesting that it may be a more accurate measure for assessing intake, Jacobs’ definition of whole grain has become more accepted and more commonly used in research over the last decade.

Varying serving size estimates for whole grains further complicates meta-analyses of literature when examining and comparing whole grain intake across cultures. Some researchers report intake in grams, some in ounces, and others in servings per day, according to the United States Department of Agriculture My Pyramid Guidelines (41). Until a uniform definition and system of measurement exists, cross-cultural meta-analyses comparing existing literature will remain challenging. Nevertheless, these discrepancies do not affect studies that utilize established databases capable of separating the products into percent of whole and refined grains by weight proportion, such as those done in Finland (51, 52) and in the United States (9, 53, 54). They also do not affect studies that analyze whole grain content

by product composition, as this will yield specific quantifiable gram amounts and percentage data.

Consumption of Whole Grains

In the United States, low consumption of whole grains has been demonstrated across all ethnic and income groups (10, 12). Data analyzed from the National Health and Nutrition Examination Survey 2001-2002 revealed that whole grains comprised less than 10% of grains consumed (11). The United States Department of Agriculture's Agricultural Research Service conducted a study in 2000 aiming to provide national estimates of whole grain intake in the United States. This study compiled data from the Continuing Survey of Food Intakes by Individuals from 1994-1996 and showed shockingly low consumption of whole grains. According to the results, adults consumed an average of 6.7 servings of grain products per day, and only one of these servings was whole grain. Furthermore, 36% of the survey participants averaged less than one whole grain serving per day, and only 8% met the recommendations of at least three servings per day (12). This study was connected to the 1999 mandate issued by the Food and Drug Administration allowing manufacturers of foods containing at least 51% whole grains to make a label claim in reference to the foods' role in reducing the risk of heart disease and cancer. The goals of this mandate were twofold: "to encourage Americans to increase whole grain consumption and to help consumers identify whole grain foods and recognize their health benefits" (55). Governmental agencies were advised to help increase awareness of whole grains among consumers. On this note, the 2005 Dietary Guidelines for Americans added specific recommendations for whole grain consumption, separate from those for refined grains, recommending 48 g or more of whole grains per day (56). These guidelines remain in the 2010 Dietary Guidelines for Americans,

although this time the guidelines address the point that lacking standards for whole grain foods and measuring whole grain content of foods makes these recommendations difficult to implement (57). Despite implementation difficulties, the success of these FDA objectives was demonstrated by the most recent consumer nutrition trends survey conducted by the American Dietetic Association (ADA). The ADA found that 94% of respondents believe whole grain bread is healthier than white bread. This finding was supported by the fact that 56% of respondents claim they have increased their consumption of whole grain foods (58). While the ADA's findings do not report actual consumption, they demonstrate an increased consumer understanding and desire to switch to whole grain products.

The most recent research addressing whole grain consumption in the United States does, in fact, show improvements. The most accurate reports can be found in research stemming from the University of Minnesota and the Baltimore Longitudinal Study of Aging (9, 49). Both of these organizations have made efforts to create comprehensive whole grain databases, considering various details in the separation of whole and refined grains for a large and varied number of products. The 2009 report from the Baltimore Longitudinal Study of Aging estimates total whole grain intake among older Americans to be between 25.0 and 25.1 g/d for women and between 19.9 and 23.0 g/d for men (9). An earlier study of 17,889 people using the same database but a larger age span (persons 1 year of age and older) had similar findings (59). This level of intake reflects improvements in whole grain consumption in the United States over the last decade; however, whole grain intake still remains at around half of the FDA recommendation.

A similar trend can be seen among the Germans. Since World War II, the consumption of refined grain has doubled. Disappearance data from 2001/2002 shows that

approximately 87% of flour used in Germany was refined (60). However, the Central Marketing Agrar 2006/2007 trend contradicts this, saying that whole grain bread is the preferred bread type, as reported by consumers (12). This preference is significant when one combines this with the fact that the average German ate 86.9 kg of bread products in 2006-2007. In fact, the Central Marketing Agrar reports that, in Germany, 28% of consumers state a preference for the traditional “black bread,” a bread made largely from whole grain; this is a 5% increase since the year 2000. Simultaneously, the preference for white bread also doubled, while rye and mixed-wheat breads lost favor (61). Thus, although white bread is also increasingly favored, it is not having a negative effect on whole grain consumption. It may appear that consumer preference for whole grain products in Germany is much lower than that in the United States (28% versus 56%), but these numbers cannot be fairly compared because the definitions of whole grain products are so different. Furthermore, the German consumer survey included nine types of bread.

Research indicating actual consumption of whole grains in Germany in specific groups is difficult to find. However, a recent study in the state of Schleswig-Holstein reports that 63% of 11- to 13-year-olds eat whole grain bread 3 times a week and 52% of 14- to 17-year-olds consume 3 servings of whole grain breads per week (62). These numbers indicate that consumer preference for whole grain was higher than in the United States and that actual consumption could be more. It should be noted that this study reports intake in children, while the studies in the United States report intakes for a larger age span. It should also be noted that all information obtained on whole grain intake for Germany was limited to bread products. Thus larger, more comprehensive studies comparing whole grain consumption among Germans and Americans could yield different results.

Barriers to Whole Grain Consumption

According to past research, the level of exposure to whole grain foods, combined with family preferences and skillful preparation of whole grain foods, plays a large role in actual consumption (21). Thus, it is important to study each barrier as a separate factor, use a homogeneous group, and try to eliminate as many confounding factors as possible when investigating barriers to whole grain consumption.

Generally, the reasons for consuming whole grain foods are influenced by a multitude of complex factors as well as knowledge of health benefits. A study conducted by Seal and Jones determined that despite the widespread health claims and advertisements on cereal boxes, few individuals cite the ability of whole grain foods to reduce heart disease or provide some kind of other health benefit (21). Thus, it seems that knowledge of health benefits alone does not necessarily increase whole grain consumption. This discovery is supported by studies that examine the relationship between health and taste appraisal and food consumption frequency. Among all food choices, not just whole grain foods, it appears the health messages are not strong enough to overcome predetermined taste ideals and preferences (21). These findings demonstrate that taste is a much stronger influence than health appraisal when it comes to food choice and preferences.

Availability of whole grain foods is another factor that plays a role in consumption patterns. While the past 5 years have seen a considerable increase in whole grain products, and while price is often comparable, restaurants, delis, and food stands rarely include whole grain choices on their menus, and variety is lacking. With the possible exception of health food or vegetarian restaurants, which also tend to be the pricier choices, whole grain

ingredients are rare on menus in the United States, and when they are featured, choice is often very limited.

Insufficient knowledge about health claims and proper interpretation of nutrition labels could also be a barrier to increased consumption. O'Neil and colleagues stress that consumers may misunderstand, or be confused by, nutrition labels. They suggest that a national whole grain campaign similar to the 5-A-Day campaign for fruits and vegetables could help overcome this problem (27). General nutrition education and simplified labels may also be options to overcome this barrier as well.

The last significant influence on whole grain consumption is the influence of family and the social context of eating. According to Smith and colleagues, the dominant factors affecting food choice at the family level are whether the food is acceptable to other family members (63). Studies reveal that consumption is not only influenced by the amount and variety of whole grain products that are brought into the home but also by the attitude of the other family members, including how they present a food to the family, at what age, and whether or not they consume the product alongside the other family members.

Thus, while price and health benefits play a role in the patterns of whole grain consumption, the main barriers seem to be their availability and acceptability among consumers. Education, or lack thereof, may also play a role. It can thus be inferred that an educational campaign designed to increase understanding about whole grains and encouraging positive associations of taste and social acceptability would possibly play a role in a more successful approach to long-term changes in dietary consumption of whole grains.

Whole Grains and Diabetes

The health benefits of whole grains have been recognized for many centuries. Roman wrestlers and gladiators believed coarse whole meal built up their strength (32). Hippocrates advised his men to eat whole grains due to the “salutary effects upon the bowels” (34). From the early 1800s to mid-1900s, physicians and scientists have recommended whole grains to prevent constipation (30) and have also recognized that the milling process rids the grain of essential components necessary for human health (64). Traditional grains such as cereal sprouts (derived from whole grains) have also long been known for their cleansing properties. Various components of grains associated with improved health may include phytoestrogens, lignans, tocotrienols, phenolic compounds, phytic acid, tannins, and enzyme inhibitors (30). Fiber, a component of whole grains, has also been the focus of much research since Trowell and Burkitt published their “fibre hypothesis” in 1972 (65). Much fiber research has been related to a reduced risk of type 2 diabetes. In a unique study carried out in a remote aboriginal population in North America, the researchers concluded that the risk for type 2 diabetes was lowered by up to 39% simply by increasing fiber intake (66). Salmerón and colleagues and McKeon and colleagues take this idea one step further, proposing that cereal fiber contributes more significantly to the reduction of the risk of diabetes than fiber from fruits and vegetables (67, 68). Jacobs and colleagues took a different perspective on the effects of fiber by following 11,040 women from the Iowa Women’s Health Study who ate equal amounts of fiber but differed in the proportion of fiber consumed from whole versus refined grain (45). The study concluded that whole grain fiber confers health benefits that may result in increased longevity. Thus, it appears that fiber has a positive effect on diabetes.

A decrease in dietary fiber is one of the most notable losses resulting from the refining process. Other losses include vitamins, minerals, lignans, phytoestrogens, phenolic compounds, and phytic acid. In addition, refined grains have a higher concentration of starch (30). It is thus no surprise that research spanning from 1970 through the present has turned up epidemiological evidence indicating that whole grains reduce the risks associated with diabetes, certain cancers, coronary heart disease, and all-cause mortality (13, 45). Additionally oats and buckwheat are now recognized as cholesterol-lowering foods (5). In fact the relationship of whole grain consumption and human health is considered so important that the United States Department of Health and Human Services national nutrition objectives for the year 2010 included an objective targeting whole-grain intake: “Increase the proportion of persons aged 2 and older who consume at least 6 daily servings of grain products, with at least 3 being whole grains” (69). As a result of these known health benefits, whole grains are now recommended by the American Diabetes Association, the American Heart Association, the National Institute of Diabetes and Digestive and Kidney Disorders, and even the World Health Organization, among others (70 –73). The established benefits for diabetes prevention and treatment are multiple, with research focusing mainly on the prevention of type 2 diabetes.

Larger epidemiological, long-term studies such as the Nurses’ Health Study (7) and the Iowa Women’s Health Study (74) indicate that an increased intake of whole grain food is associated with significant reductions in the incidence of type 2 diabetes. Further studies correlating whole grain consumption with a diminished risk for type 2 diabetes show a reduced insulin resistance and an improved glucose control (75, 76). In “Whole Grains and Human Health,” Slavin concludes that whole grains affect insulin and gastrointestinal

responses because blood glucose and insulin responses are greatly affected by food structure (30). Slavin goes as far as to assert that “any process that disrupts the physical or botanical structure of food ingredients will increase the plasma glucose and insulin responses.” Supporting evidence for this proposal can be found in the work done by Granfeldt and colleagues in which they show that food structure was more important than gelatinization or the presence of viscous dietary fiber in determining glycemic response (77). Heaton and colleagues also suggest particle size of the grain had the greatest influence on digestion rate and consequent metabolic effects, and they propose that the consumption of finely ground refined grain may be a factor in the etiology of decreased insulin response (4). More recent findings support these earlier findings, also demonstrating that postprandial insulin responses to grain products are determined by the form of food and botanical structure (78).

Other positive links between whole grain intake and insulin metabolism can be found in research showing that refined grain tends to increase glycemic response while whole grains work conversely (79). Pereira and colleagues also significantly correlated whole grain consumption with fasting insulin and glucose levels in a large population of ethnically diverse Americans (80). McKeown and colleagues conducted a similar study showing a strong association between whole grain consumption and a significant decrease in fasting insulin when the highest quintile (13-64 servings/wk) was compared with those with the lowest whole grain consumption (0-1.5 servings/wk) (68).

The benefits of whole grain consumption for diabetics and diabetes prevention extend beyond improvements in glucose and insulin metabolism. Consumption has also been connected to a reduction in the risk of stroke and coronary heart disease, both of which are common medical complications and causes of death in the diabetic population. In fact, in a

randomized controlled clinical trial, Jang and colleagues connect the consumption of whole grains with better outcomes in both diabetes and coronary artery disease by linking intake with both a reduced insulin demand and positive effects on lipid peroxidation (81). This association is so well documented that the FDA has approved the following health claim: “Diets high in plant foods - i.e., fruits, vegetables, legumes, and whole-grain cereals - are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach” (82). It is worthwhile to note that many of these studies also included added bran in their definition of whole grain, which is not consistent with the FDA approved definition and could confound the results. It is also interesting to see the results of studies that go to great lengths to separate out the grains and look at added bran as a separate variable (9, 53, 59, 83). Such diligent work of researchers who take pains to analyze the exact whole grain has only further supported the theory that whole grains may be the single dietary factor associated with these health improvements.

Conclusion

Dietary fiber can be derived from many food sources. Added bran and germ are merely components of whole grains, along with a multitude of other healthful components. However, it is indisputable that whole grains, no matter how we define them, provide many health benefits for diabetics and for disease prevention, as well as for the general population. It is also clear that the German population has a stronger preference for, and thus consumption of, whole grain foods in general. In the United States, whole grain products typically cost as much as their refined alternative and are often offered on the supermarket shelf side by side, and health claims tout the benefits of whole grain products clearly. The literature universally shows that whole grain intakes are well below recommendations (6, 13,

41, 83). Therefore, the questions remain: What interventions are required to remove remaining barriers to whole grain consumption in the United States, and how can these interventions best provide long-term benefits for the population as a whole?

Chapter Three: Research Methodology

The PI conducted a pilot study surveying diabetics of German heritage in upstate South Carolina, United States. The objective of this study was to show that environmental factors other than familial influence are dominating whole grain consumption.

Sample

The PI accessed the Patient Database of the Carolina Center for Diabetes and Endocrinology and selected a simple random sample of 30 subjects ($n = 30$) between the ages of 18 and 65. The age limitation was in place to avoid recruiting members of a more vulnerable population. Only type 2 diabetics were considered. The diagnosis of diabetes was at least 6 months previous to the time of participation. To ensure a homogenous population, the PI limited inclusion criteria for subjects to those of German heritage. German heritage was defined as having at least one full-blooded German grandparent or parent.

Instruments and Methodology

The study was approved by the Internal Review Board at Spartanburg Regional Hospital and also by the Human Subjects Research Committee at Eastern Michigan University. Appendix C contains a summary of human subjects' methodology and data management, and Appendix D contains the approval letters. The CDE identified and contacted potential participants through a scripted telephone call (see Appendix E). Upon agreement to participate, the participants attended a meeting scheduled by the PI to sign the consent forms and receive training on how to complete an accurate diet record (see Appendices C and F). The PI stressed, both in the consent form and in the initial presentation, that participation was voluntary and that the subjects may withdraw at any time with no negative consequences of any kind.

After the PI received consent, she obtained demographic and medical history variables from the medical records and/or self-reports from the subjects. The variables required for this study were age, body mass index (BMI), sex, race, glycosylated hemoglobin levels (A1C), type of diabetes, and identification of German descent.

The PI gave subjects exact instructions in person and asked them to keep a precise 3-day dietary record of all foods eaten (Appendices A and F). In a 45-minute instruction period, subjects learned how to correctly keep a dietary record as well as correctly estimate serving size and record amounts consumed. The PI asked the subjects to weigh their grains whenever possible and to record both the brand and manufacturer information from the label. The PI also requested recipes for homemade dishes. The PI later analyzed these recipes to determine the whole grain content.

Upon completion, the subjects returned their diet records using a postage-paid envelope or by dropping it off at the Carolina Center for Diabetes and Endocrinology. The PI reviewed the diet records and asked the subjects to clarify any unclear entries. The PI entered the diet records into Microsoft® Office Excel 2007 (84). The PI assured accuracy of data entry through random sampling (25%) correlated to the hard copy from the diet records and questionnaire. Next, the PI systematically identified the grain dishes and mixed dishes containing grains (see Appendix G for list of grains considered whole). In order to obtain the most precise estimate of quantities of grains at both the ingredient and food levels, the PI used the following methodology:

1. Fiber, added bran, and added germ content were not considered because the Life Sciences Research Office has determined that these can be confounding factors when determining health benefits of whole grains (85). Furthermore, added bran, added germ,

and fiber are not included in the latest international whole grain definition, nor in the definition recently adopted by the FDA and applied to the MyPyramid Equivalent Database.

2. An exact match for the grain contained in foods consumed by the participants was identified in the MyPyramid Equivalent Database 2.0 (MPED) or in the Harvard School of Public Health database (86, 87).
3. For grain-containing foods composed of more than one ingredient, gram weights of individual ingredients were obtained from the original recipe or manufacturers' input. The grain and whole grain content was calculated based on this information.

After obtaining gram amounts of whole grain content in each food, the PI calculated total whole grain consumption, total grain consumption, total energy intake, and percent of total calories consumed in grain and whole grains for each subject. Thereafter, the PI compiled the questionnaire using the same methods and used the results to identify which factors positively or negatively influenced whole grain consumption (Appendix B).

Data Analysis

The goal of the research was to identify the factors having the most influence on whole grain consumption. The PI then systematically correlated these factors to actual whole grain consumption to validate their significance. Additionally, the PI used box plots to describe the subjects' characteristics and identify possible correlations between A1C and whole grain intake. SAS[®] statistical software version 9.2 assisted in calculations and ensured accuracy of results (88).

The PI used Pareto analyses to visualize the most significant factors leading to higher whole grain consumption by the subjects. To better analyze the strength of the influence of

each factor, the PI divided the subjects into two groups. The first group consisted of those who were affected by the factor, and members of the second group were not affected by the factor. The PI then calculated the mean whole grain intake in grams for each sample and compared the results using the Mann-Whitney-Wilcoxon test (MWW). Subsequently, the PI tested the hypothesis using both the MWW test and a one-sided hypothesis test.

Chapter Four: Presentation and Analysis of Data

Review of Methodology and Conceptual Framework

The main objective of this study was to show that environmental factors other than familial ones are dominating whole grain consumption. To this end, the study focused on a special homogeneous subset of the population. Of candidates listed in the patient database at the Carolina Center for Diabetes and Endocrinology, 630 fit the inclusion criteria. In order to ensure a high probability of detecting a meaningful difference while accounting for dropout and non-response, the goal was to achieve a sample size of $n = 30$ (89). In the end, an SRS of 29 willing subjects was achieved, of which 23 came to the arranged appointment and provided written consent. As the sample size goal was large enough to account for dropout and non-response, this sample size was considered large enough to yield statistically significant results for a pilot study.

Return rate of the food records was 78% (6 males and 12 females). The PI used box plots to analyze the characteristics of the subjects as defined by the independent variables age, BMI, and A1C (Figure 3–Figure 5). Because the means and the standard deviations for both males and females were very similar for all independent variables, the PI analyzed the subjects together instead of separated by sex. After calculating the mean whole grain intake of the subjects, the PI examined the environmental factors that may contribute to whole grain intake (Figure 2). The strength of their influence was confirmed by correlating the relevant factors to actual mean intake.

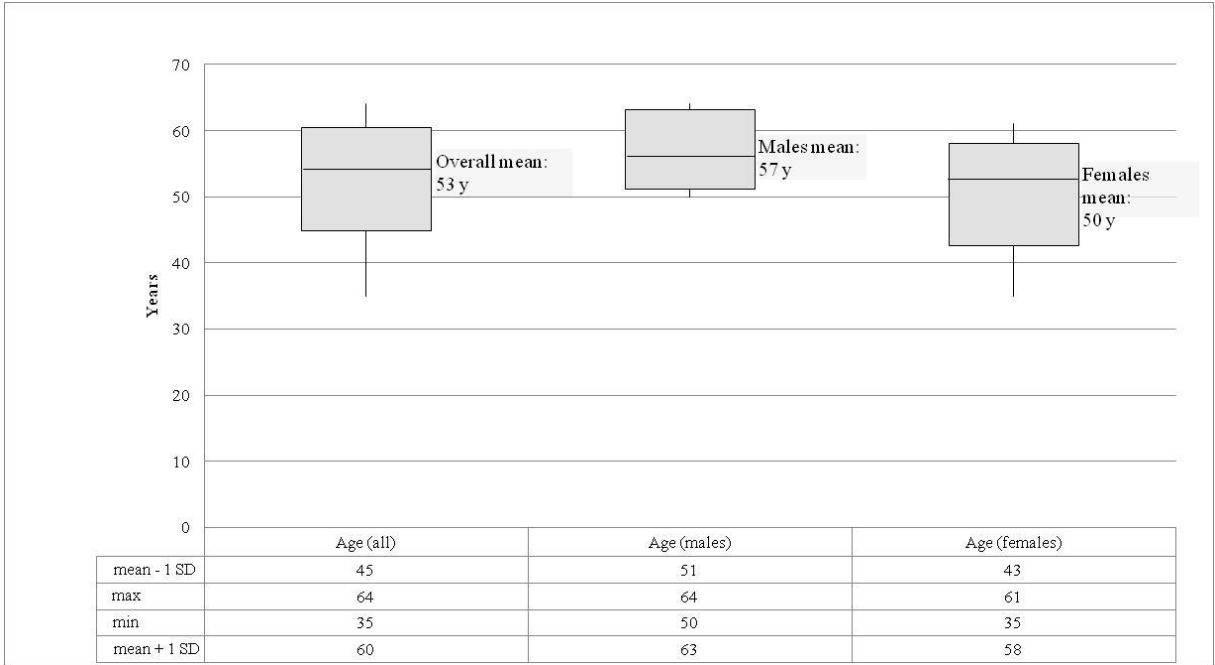


Figure 3: Questionnaire Results: Age of Subjects

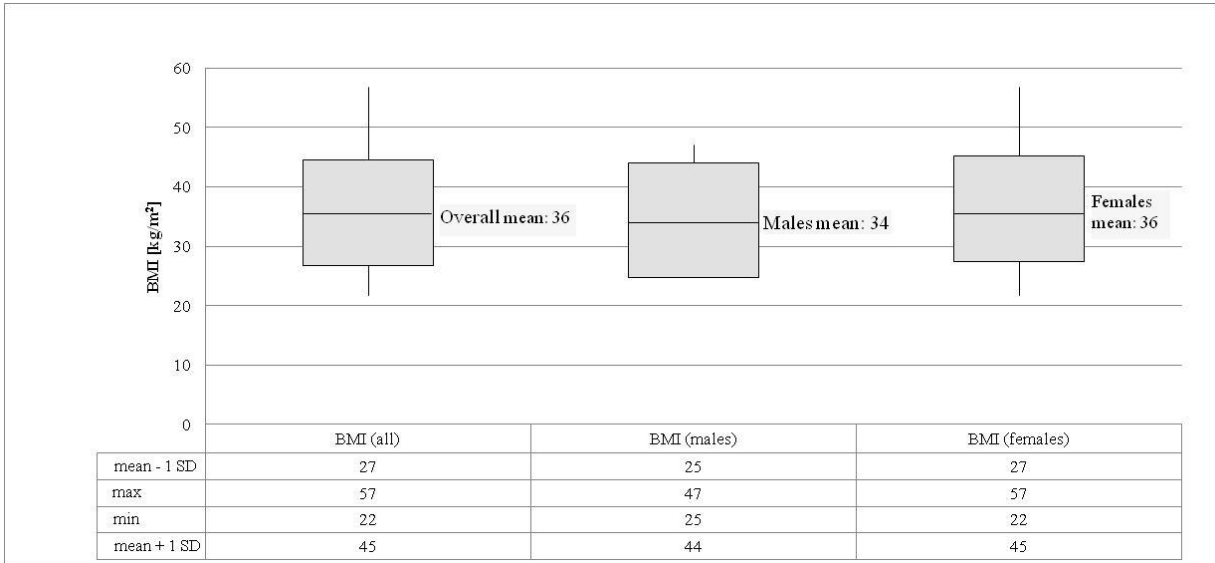


Figure 4: Questionnaire Results: BMI of Subjects

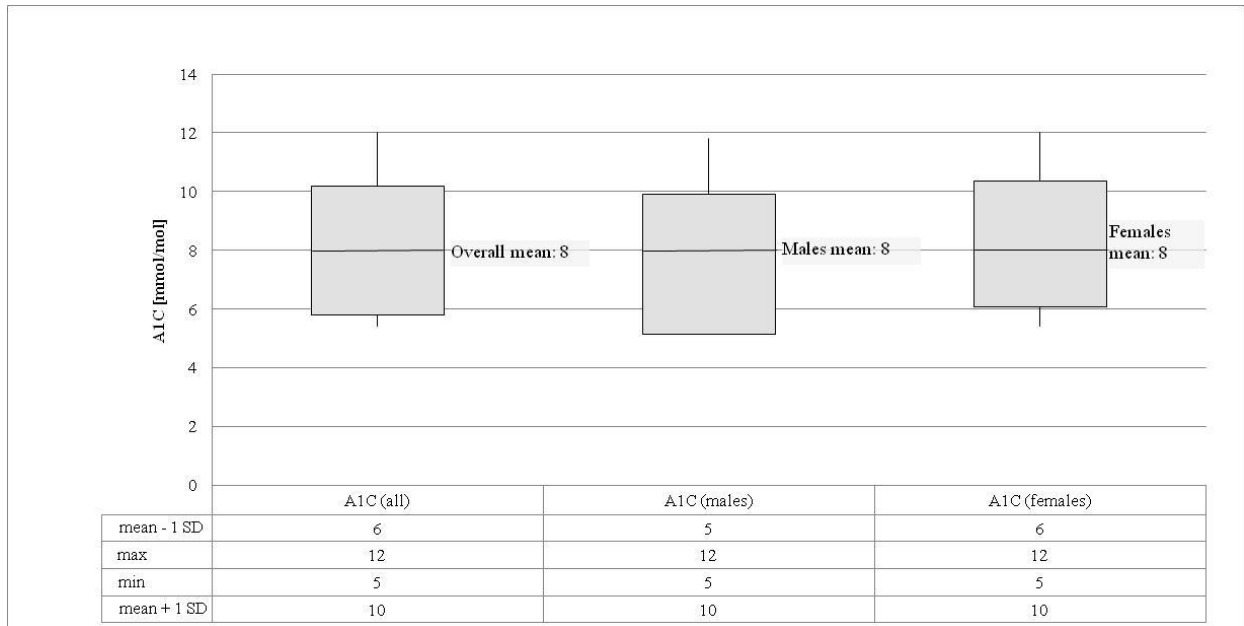


Figure 5: Questionnaire Results: A1C of Subjects

Results: Daily Whole Grain Intake

The PI defined whole grains according to the HEALTHGRAIN definition, which mirrors the new definition of whole grains recently applied to the MPED in the United States (35, 90). These definitions all exclude added bran and germ. Unlike the HEALTHGRAIN definition, the MPED definition also excludes pearled barely. As subjects in this study did not consume pearled barley, this discrepancy was not an issue. The Harvard Food Database did not contain separate tables based on the old and new definitions, so the PI chose the MPED to determine whole grain and non-whole grain content in grams for each food or ingredient consumed. The PI converted the ounce equivalent measurements in this database to grams as outlined by the database guidelines: 16 g per ounce equivalent for bread-type foods (including crackers and baked products such as cakes, tortilla chips, etc.) and a factor of 28.35 g per ounce equivalent for all other types of food (including cereals, rice, and noodles) (86). In all cases, an exact match was found. To ensure accuracy, the PI cross-checked the whole grain content in grams derived from the MPED with the Harvard Food

database. Since the food lists in the two databases do not match exactly, the PI used this exercise to indicate major inconsistencies and not to make exact comparisons. This exercise did, however, detect that the MPED considers corn-based tortilla chips to be non-whole grain. Since corn products made from whole corn kernels are considered whole grain in this study and participants consumed corn-based tortilla chips in two instances, the PI changed the grain type from non-whole grain to whole grain.

Thereafter, daily average consumption of whole grains, non-whole grains, and calories were calculated from the 3-day food diaries returned by the subjects (Table 1).

Table 1: Summary of Results for Whole Grain Consumption

ID	Sex	Age [y]	Height [in]	Weight [lbs]	BMI [kg/m ²]	A1C [mmol/mol]	Calories [kCal]	Calories per day [kCal]	Calories from grain products [%]	Whole grains per day [g]	Non-Whole grains per day [g]	Total grain consumption [g]	% whole grain of total	Whole Grain excl. bread	Claimed Whole grain excl. bread per
001	f	35	63	204	36	6	6545	2182	43%	5	229	234	2%	0	16
003	f	50	63	320	57	9	5377	1792	31%	60	78	138	44%	43	8
008	f	47	65	224	37	7	5056	1685	21%	37	50	88	43%	0	4
009	f	44	65	238	40	12	6973	2324	20%	112	7	119	94%	71	138
011	f	61	65	180	30	5	4401	1467	34%	44	81	125	35%	25	36
013	f	50	63	176	31	10	7730	2577	22%	95	49	144	66%	60	34
015	f	54	68	265	40	9	4967	1656	20%	56	27	83	68%	33	28
020	f	58	62	170	31	7	5950	1983	34%	57	111	168	34%	36	24
021	f	54	62	196	36	8	4393	1464	30%	20	90	110	18%	4	12
022	f	41	64	175	30	7	4534	1511	24%	37	54	90	41%	0	49
025	f	60	69	146	22	6	5867	1956	28%	65	71	136	48%	47	32
030	f	50	62	243	45	12	7083	2361	21%	66	56	123	54%	0	24
004	m	58	68	165	25	5	7041	2347	16%	70	25	95	74%	35	24
005	m	59	67	177	28	5	6746	2249	31%	33	140	173	19%	0	8
014	m	50	54	190	46	8	6914	2305	17%	6	94	99	6%	0	41
017	m	50	60	240	47	7	7178	2393	18%	6	102	107	5%	6	4
026	m	62	74	225	29	12	5357	1786	31%	60	81	141	43%	40	28
027	m	64	73	237	31	8	4267	1422	19%	34	33	67	51%	10	36
Mean		53	65	210	36	8	5910	1970	26%	48	77	125	41%	23	30
SD		8	5	43	9	2	1143	381	7%	29	51	40	25%	23	30

A histogram of the results revealed that a few subjects consumed almost no whole grain and two subjects consumed a large amount (Figure 6). The remaining subjects had daily whole grain consumption around the overall mean of 48 g. For the purpose of this study, the PI considered this distribution normal.

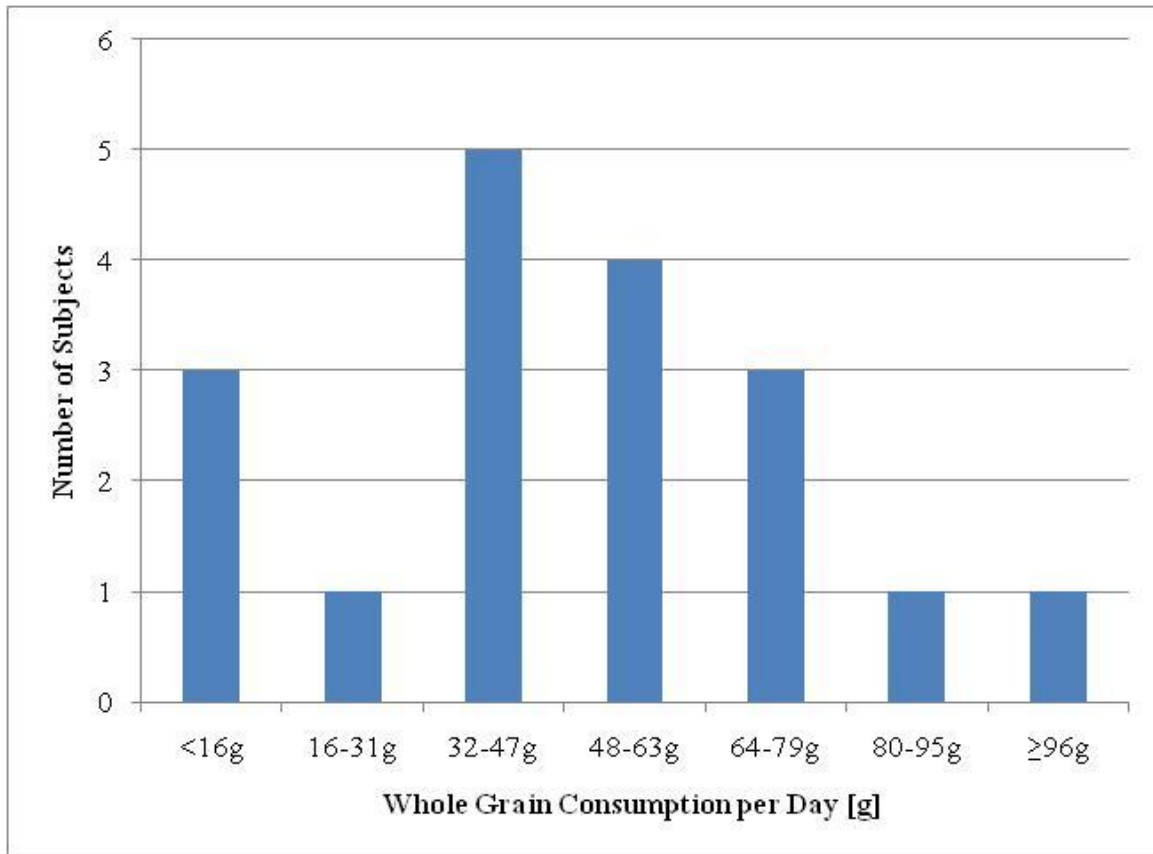


Figure 6: Amount of Whole Grain Consumed per Day

The PI calculated whole grain consumption as a percentage of total grain consumption (see last column of Table 1). The inter-quartile range helped detect potential outliers. For example, subject number 001 had a total grain consumption of 234 g/d. This would be considered an outlier based on the inter-quartile range, which gives an upper outlier limit of 206 g/d for this group of subjects. Similarly, 98% of the total grain consumed by subject number 001 is non-whole grain. Therefore, the 229 g/d of non-whole grain consumption also exceeds the upper outlier limit of 157 g/d in this category. A closer look at this subject's food diary reveals that 43% of the total caloric intake was from grains. In contrast, the average subject consumed only 26% (SD \pm 7%) of their calories from grain. This explains the results of the outlier test reasonably well. Nevertheless, since the purpose

of this study is to investigate barriers to whole grain intake, the data are still relevant and valid and, in this case, were not excluded.

The PI then plotted correlation charts to examine relationships between the A1C and the following independent variables: whole grain intake, BMI, grain as a percent of total caloric intake, and total caloric intake. There was a positive linear relationship between A1C and whole grain consumption (g/d). While this result contradicts past research in this area, the correlation was very weak ($r^2 = 0.29$) (91). This finding may be explained by the fact that whole grains also contribute to blood sugar values and thus could raise a subject's A1C when not consumed in controlled amounts. Similarly, the PI found a very weak positive linear correlation between A1C and BMI ($r^2 = 0.13$). However, the PI did not find a correlation between A1C and grain intake as a percent of total calories ($r^2 = 0.05$) or between A1C and total caloric intake ($r^2 = 0.02$). Considering that the box plots including all subjects for age, BMI, and A1C demonstrated a homogenous group with a mean weight of 210 ± 43 lb, these results cannot be generalized to the broader population.

Factors Influencing Whole Grain Consumption

Barriers: The PI examined the grain questionnaire (Appendix B) in detail and correlated the results with actual whole grain intake. Barriers to whole grain intake included a misunderstanding of food labels, non-availability in supermarkets and/or restaurants, dislike of taste and/or texture, cost, preparation time, and other. Table 2 describes how the PI calculated each factor. Next, the PI performed a Pareto analysis (Figure 7). Note that the factors listed in the figures are not mutually exclusive, and thus the sum of relevancies is greater than 100%.

Table 2: Barriers to Whole Grain Consumption	
Barrier	Criteria for calculating barriers from questionnaire
Misunderstanding of food labels	100% correct answers to questions 13 and 14-22 meant that subject understands food labels
Non-availability in supermarkets and/or restaurants	“No” to questions 9 or 12 (not necessarily both)
Dislike of taste and/or texture ^a	“No” to question 5 or negative text in question 6 referring to either taste or texture
Cost	“Yes” to question 10
Preparation time	“Yes” to question 11
Other	Text in question 6. In this study, 7 subjects identified a low carbohydrate content as the primary reason for their choice of bread.
^a “Taste and/or texture dislike” and “taste like” do not add up to 100% because no negative text regarding taste or texture was given in question 6 and not all subjects had an opinion on this factor.	

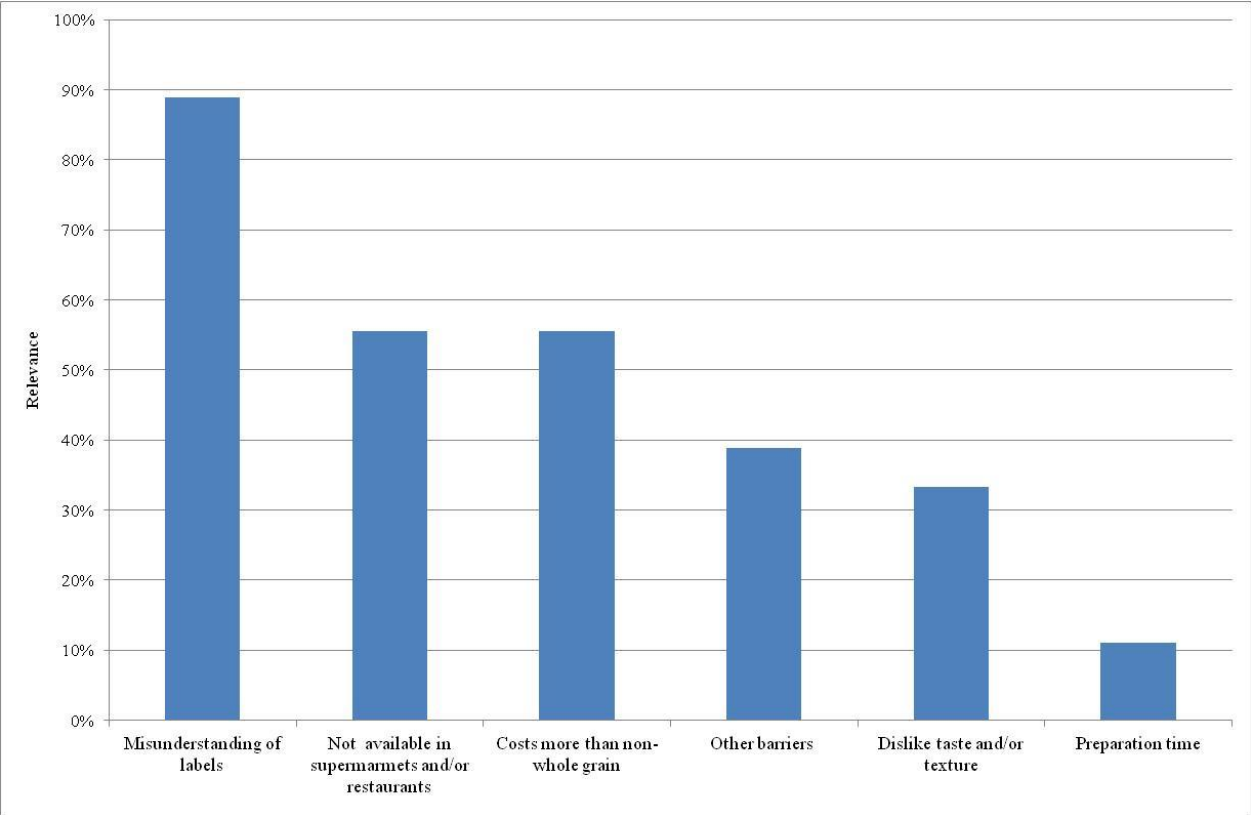


Figure 7: Barriers to Whole Grain Consumption

The Pareto analysis (Figure 7) clearly illustrates that a misunderstanding of food labels appears to be the most prominent barrier to whole grain consumption among this group of subjects. In fact, only two subjects understood food labels 100% correctly. Many subjects in this study misinterpreted words like “wheat,” “brown,” and “multigrain” to mean whole grain.¹ Upon closer examination of the returned questionnaires, it also becomes apparent that the root of the misconceptions stems from the subjects being unaware of the whole grain logo. The intent of the whole grain stamp is to avoid consumer misinterpretation of product labels (39). In fact, >65% of subjects demonstrated, with answers to the same question worded slightly differently, that they were not aware of the whole grain logo (Table 3).

Table 3: Percent of Subjects Who Misinterpreted Labels^a

	Multi-grain	Brown color	Wheat in the name	Stone-ground	Whole grain health claim	Whole grain logo	First ingredient is whole grain	100% Whole wheat or whole grain
Question 13 wrong answers	33%	22%	17%	6%	50%	72%	28%	17%
Questions 14-22 wrong or don't know	44%	22%	33%	44%	89%	67%	44%	22%

^a See Appendix B for questions 13-22.

To better analyze the strength of the influence of each barrier, the PI divided the subjects into two groups, those with and those without each barrier. For example, regarding the barrier “misunderstanding of labels,” Group 0 included those who were able to read the labels correctly and Group 1 included those who misunderstood labels. Thereafter, the PI calculated the mean whole grain intake in grams per day. Table 4 contains a summary of the relevance of each barrier to actual whole grain intake based on the Pareto analysis.

¹ None of these words alone guarantees whether a product is whole grain or refined grain.

Table 4: Relevance of Barriers in Relationship to Actual Whole Grain Intake

	Misunderstanding of labels	Not available in supermarkets and/or restaurants	Costs more than non-whole grain	Other barriers	Dislike taste and/or texture	Preparation time
Relevance	89%	56%	56%	39%	33%	11%
Whole grain mean [g/d] Group 0 ^a	80 ± 21	40 ± 31	46 ± 35	46 ± 34	49 ± 28	44 ± 28
Whole grain mean [g/d] Group 1 ^a	44 ± 28	54 ± 28	49 ± 26	51 ± 22	46 ± 35	82 ± 18

^aGroup0 = subjects who did not demonstrate the barrier; Group 1 = subjects who demonstrated the barrier.

The barriers were considered significantly influential if the difference between the mean whole grain intakes was above 16 g/d (which equals 1 serving/d). This condition was present only for the barriers “misunderstanding of labels” and “preparation time.” To further investigate these barriers, the PI performed an MWW test on the two groups. A statistically significant difference between the underlying distributions indicated that misunderstanding labels contributed to a significant reduction in whole grain consumption ($z = 1.69, P = 0.09$). The MWW test for the barrier “preparation time” detected a statistically significant difference between the two groups ($z = 1.96, P = 0.05$). However, note that 11% of subjects who claimed that preparation time was a barrier ate almost double the amount of whole grain as the other group (82 ±18 g/d versus 44 ±28 g/d). It was thus concluded that preparation time is not a significant barrier to whole grain consumption in this study.

Positive Factors: Positive factors included taste preference, familial influence, education received from the medical staff, and an awareness of health benefits of whole grain. Table 5 describes how the PI calculated each factor.

Table 5: Positive Factors Contributing to Whole Grain Consumption	
Positive factors	Criteria for calculating positive factors from questionnaire
Taste preference ^a	“Yes” to question 5 only
Familial influence	“Yes” to question 3. Since question 3 is general (“Do your parents share your preference?”), positive answers were limited to those who liked whole grain
Education received from the medical staff	“Yes” to either question 4 or 23
Awareness of health benefits of whole grains	“Yes” to either question 24 or 25

^a“Taste and/or texture dislike” and “taste like” do not add up to 100% because no negative text regarding taste or texture was given in question 6 and not all subjects had an opinion on this factor.

A subsequent Pareto analysis (Figure 8) revealed that the greatest positive influence on whole grain consumption appears to be education by medical staff. The relevance in percent from the Pareto analysis for positive factors as it relates to whole grain intake is summarized in Table 6. The subjects who recalled being educated on the benefits of whole grain intake had significantly higher mean whole grain intake (26 g/d) than the subjects who had no education/no recollection thereof. The MWW test subsequently confirmed the strength of this association ($z = 1.4$, $P = 0.14$). Hence, education by medical staff should be considered a significant positive factor influencing whole grain intake.

Contrary to previous studies, the Pareto analysis reflects that taste appears to play a positive role in whole grain consumption. First, dislike of taste and/or texture had only 33% relevance as a barrier (see Table 4) with no impact on whole grain consumption, whereas explicit liking of taste had 83% relevance as a positive factor (see Table 6) with an increase in mean whole grain intake of 16 g/d (35 ± 52 versus 51 ± 25). However, the MWW test indicated only a weak statistical difference between the two groups ($z = 1.01$, $P = 0.31$). Thus

the evidence derived from this study is not strong enough to draw any conclusions about the role of taste preference in whole grain consumption.

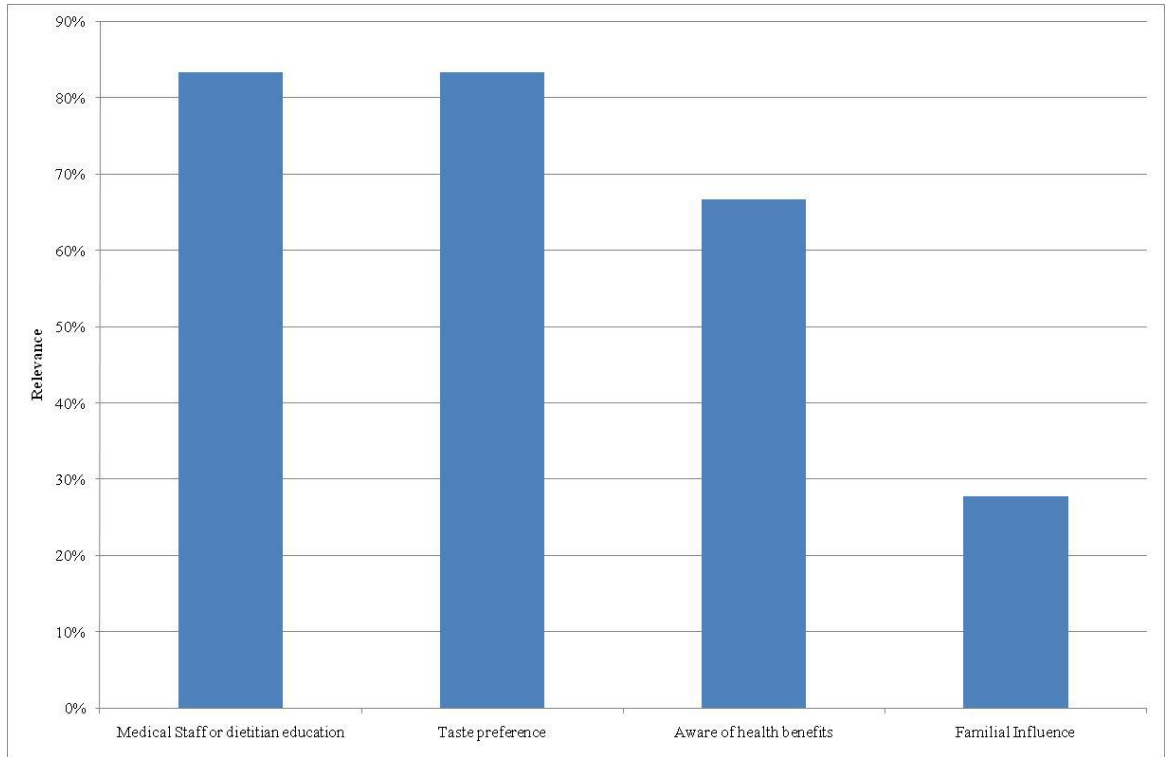


Figure 8: Positive Factors Influencing Whole Grain Consumption

Table 6: Relevance of Positive Factors in Relationship to Actual Whole Grain

	Medical staff or dietitian education	Taste preference	Aware of health benefits	Familial influence
Relevance	83%	83%	67%	28%
Whole grain mean [g/d] Group 0 ^a	26 ± 17	35 ± 52	47 ± 40	40 ± 27
Whole grain mean [g/d] Group 1 ^a	52 ± 30	51 ± 25	48 ± 24	68 ± 28

^aGroup 0 = subjects who did not demonstrate the factor; Group 1 = subjects who demonstrated the factor

Familial Influence: Does German Heritage Play a Role?

The main purpose of this study was to explore if familial/cultural heritage plays a significant role in whole grain consumption or if other environmental factors dominate. In this study ($n = 18$), the mean whole grain consumption ($\bar{x} = 48 \pm 30$ g/d = 3 ± 2 servings/d) is much higher than the US average ($\mu \leq 1$ serving/d) (9, 11-13).² A one-sided hypothesis test confirmed the validity of this difference ($z = 4.6$, $P < 0.001$). In addition, of the six subjects who said that their parents shared their preference, only one subject also said they preferred white bread. Therefore, if familial/cultural heritage played an influential role, it was toward whole grain consumption by a factor of 5:1. Additional evidence of this association is confirmed by performing a MWW test. The results reflected a 24 g/d increase in the mean whole grain consumption for subjects with a shared familial preference as compared to those subjects who claimed that their family did not share their preference ($z = 1.73$, $P = 0.08$).

Because subjects in this study are a simple random sample of a special subset of the general population, the results cannot be applied to the general population. However, the PI used an inference test to estimate the average whole grain intake for any population with the conditions of this subset. The results provided evidence that the average whole grain intake of Americans with diabetes and German heritage (this subset) is between 34 and 62 g/d ($z^* = 1.96$, Confidence Interval = 95%), which is approximately 1-3 more servings per day than the nation's average.

²A serving of whole grain is calculated as 16 g, based on the MyPyramid database guidelines, which also concur with the more internationally oriented guidelines developed by the Whole Grains Council (39,85).

Chapter Five: Summary and Conclusions

Summary and Interpretation of Findings

This study attempted to provide insight into the leading environmental factors which positively and negatively affect whole grain consumption. Previous research has found that the level of exposure to whole grain foods and family preferences play a large role in actual consumption (21). The objective of this study was to show that non-familial environmental factors are dominating whole grain consumption by focusing on environmental factors only and by correlating the strength of their influence with actual consumption. For this population, the mean whole grain intake was higher than the national average ($\bar{x} = 48$ g/d versus $\mu \leq 16$ g/d; $z = 4.6$, $P < 0.001$).

Considering the fact that the subjects in this study were a special subset of the general population, the PI must attribute their higher mean whole grain intake to their unique characteristics. The sum of the evidence allows the higher mean consumption to be attributed to both the German heritage ($z = 1.73$, $P = 0.08$) and the nutrition education by medical staff necessitated by the diabetes ($z = 1.4$, $P = 0.14$). Comparing the results of the MWW analysis, the PI inferred that German heritage has a slightly stronger positive influence on whole grain consumption than education ($P = 0.08$ versus $P = 0.14$). However, misunderstanding of labels was the most obstructive barrier to whole grain intake, affecting more subjects (89% versus 28%), giving evidence that other environmental factors may be more influential.

This finding is particularly significant when one considers that all the subjects received comprehensive nutrition education related to their diabetes ($n = 18$). While 83% recall that the practitioner recommended whole grains, only 11% were capable of correctly interpreting and/or correctly identifying a whole grain product. The importance of this

finding is twofold when one considers the fact that the greatest positive influence contributing to whole grain consumption appears to be education by medical staff ($z = 1.4$, $P = 0.14$). The implications are that while nutrition education encourages increased whole grain consumption, the inability to correctly interpret product labels still serves as a powerful barrier. Therefore, practitioners should be made aware of the importance of incorporating a focus on whole grains into their comprehensive nutrition education. The education component should be designed to help patients both identify whole grain foods using labels and understand their health benefits.

There is also evidence that the misunderstanding of labels may lead to consumer confusion and thwart well-intended attempts to consume whole grains. In this study, 44% of the subjects recorded eating a whole grain product in their diet records, but the label provided by them revealed that the product contained little or no whole grains. Schwartz proposed that whole grain messages need to include all four of the following tactics to be successful: be positive, be short and simple, be practical and flexible, and be promoted with a united voice (92). Successful campaigns such as the message to “make half your grains whole” run by the United States Department of Agriculture and those of the Whole Grains Council have already helped raise consumer awareness of the need to consume whole grains (27, 58). However, information regarding portion sizes, quantities of whole grains in products per serving, and ease of identification are not always presented in a unified manner or in a consumer-friendly way (21, 57).

The Whole Grain Council’s Whole Grain Stamp Program has attempted to respond to this problem. Phased into the market starting in 2005, the stamp is designed to help consumers identify whole grains quickly and easily. The Stamps depict three levels of clearly

defined terms. The term “Good Source” is defined as a product containing a minimum of 8 g of whole grains; an “Excellent Source” refers to a product containing a minimum of 16 g of whole grains; and the term “100% Whole Grain” is used only when the product contains a minimum of 16 g of any type of grain, all of which are whole (39). Despite the fact that, as of October 2010, the Whole Grain Stamp is now displayed on over 4500 different products, only 66% of subjects in this study were aware of the Whole Grain Stamp. Practitioners should therefore more readily point clients toward resources, such as those provided by the Whole Grains Council, that may increase understanding of product labels.

The food industry must also take responsibility for mixed messages and misleading product labels. This study found that misunderstanding labels contributed to a significant reduction in whole grain consumption and thus provided evidence that product labels may not always relay their information in an understandable way ($z = 1.69$, $P = 0.09$). This evidence indicates a need for legislative action to require standardized terminology and consistent product labels. Action is also needed to limit the industry’s ability to make misleading product claims such as a “made with whole grain” by clearly defining when and how this terminology may be utilized. A set of regulated, uniform definitions of terms and claims such as those already applied to organic products could be an effective approach. The definitions produced by the Whole Grain Council are a step in the right direction, yet clearly more action and consistency is needed to create an environment in which consumers can more easily implement dietary change.

Limitations

The purpose of this pilot study was to uncover new insights and improve the proposed design and methodology of a major study, therefore enhancing its utility in future research

(93). The PI chose to use pre-existing databases and modify a pre-existing questionnaire in order to increase the reliability of the results. In retrospect, to better serve the objectives of the study, the questionnaire should have included more questions probing the familial influence. This inclusion would provide future researchers with more data on which to base their conclusions and produce even stronger supporting evidence.

A known limitation to this study is the fact that researchers still employ varying definitions of whole grains. In fact, the lack of a uniform definition of whole grains combined with a lack of uniform quantification methods serves as a limitation to any study investigating whole grain consumption. The newest definition that was applied to the MPED database most closely mirrors the latest definition developed by the HEALTHGRAIN Institute. However, until this new definition is completely accepted by researchers, and until studies have utilized the same definition more consistently, the comparative value of studies about whole grain consumption is diminished. The problem is further complicated by the use of different databases, as the content of each database is defined by differing whole grain definitions. Thus, the quantification of amounts of whole grains consumed can also vary substantially, simply by entering the data into two different databases. This study utilized the MPED database because it provided quantified measures of whole grain foods under the new definition and also separated data for similar products of differing brands. However, this database provided quantified data in ounce equivalents, which then had to be converted back into internationally accepted gram amounts. While this conversion was carried out using the specific instructions described in the database, the gram amounts may be less precise than if they were calculated directly. The possibility of this discrepancy may in turn limit the reliability of the data.

A further complication in quantification of whole grains is caused by self-reported data when participants' understanding of what constitutes a whole grain food is limited. While this study attempted to limit such complications by requesting brand names for every product consumed, only 77% of subjects complied with this request. Among those who did comply, it was evident that they consumed products they considered to be whole grain, such as dark bread, when in fact the product actually contained little or no whole grain. Because 89% of the subjects demonstrated an inadequate ability to identify a whole grain product, 23% of the data could be considered questionable. This limitation may have been avoided by eliminating these subjects; however, the PI instead chose to contact these subjects and interview them about the questionable items, requesting information about the brands they used. Therefore, the data was considered admissible but may be influenced by recollection errors.

The last known limitations in this study were the small sample size and the limiting selection criteria. Whole grain consumption is governed by a multitude of complex factors spanning economic, environmental, behavioral, cultural, and psychological realms, making it very difficult to correctly identify barriers and contributing factors (21, 30). Therefore, a focused approach combined with the elimination of as many confounding factors is necessary for any investigation into whole grain consumption. However, limiting selection criteria effectively results in such a homogeneous population that it becomes impossible to apply results to the general population. Limiting selection criteria also further reduces the number of potential subjects at any one site.

Recommendations for Further Research

Future research should consider the complexities of investigating whole grain consumption and attempt to focus the methodological approach appropriately. Research into whole grain consumption will become more relevant when a uniform definition is utilized and systematically applied to all databases. Furthermore, if future researchers ever attempt to compare whole grain consumption on a national and international level, a unified quantification method should be utilized. Gram amounts, being the most internationally recognized unit, are the most logical choice for this purpose.

Research clearly shows the health benefits of whole grains. Practitioners, countries, and organizations around the globe are increasingly including whole grains in their dietary recommendations (13, 31, 39, 70, 85). However, as noted in the 2010 Report of the Dietary Guidelines Advisory Committee, for this message to be effective, the lack of standards for defining whole grain foods and measuring whole grain content of foods must be addressed (57). Furthermore, we must understand all the underlying reasons why current consumption patterns remain low. While much research into whole grains is focused on consumption levels, research into what factors contribute to consumption levels is sparse. More research aimed at identifying which factors influence whole grain consumption is needed for both specific and generalized populations. Such research will likely provide greater insights that, in turn, can be used as evidence for instigating necessary changes to improve consumption.

Research into the knowledge and abilities of dietitians and health care providers to provide consistent and useful information about the health benefits of whole grains and correct product identification is also sparse. Surveys probing professionals' general

knowledge about whole grains could provide insights that may be useful in creating future education programs for professionals and clients alike. Similarly, research probing the abilities of consumers to correctly interpret a whole grain product label may lead to changes in nutrition education programs. Results could also serve as evidence for initiating new policies and regulations about product labels.

Conclusion

This study provides preliminary evidence that a misunderstanding of labels is the strongest environmental barrier to whole grain consumption, while nutrition education plays an important role in increasing consumption. These results imply that while nutrition education produces positive effects, the message about the benefits of whole grains will increase in effectiveness when a component on correct product identification is included in the education. Practitioners such as Registered Dietitians and Certified Diabetes Educators should be made aware of the possible effects of including a component about whole grains and the correct identification of whole grain products into their nutrition education.

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APPENDICES

Appendix A: 3-Day Diet Record Form

Food Record

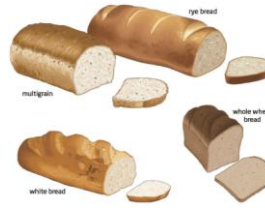
Day: _____

Date _____

ID: SUSA 0001

<u>Meal</u>	<u>Place</u>	<u>Food and Beverages</u>	<u>Please specify grains:</u>	<u>Brand</u>	<u>Amount</u>
B=Breakfast	P =Prepared		White; Wheat;		
L =Lunch	H = Home		Multigrain; Rye,		
D =Dinner	R=Restaurant		honey wheat; 12		
S =Snacks	Other (please specify)		Grain; 100% whole wheat/grain etc.		

Appendix B: Grain Questionnaire



Please be as honest as possible.

Grain Questionnaire

Rank

For questions 1-5, please circle 1 or more reasons that apply to you. If you circle more than one please rank them in order of importance to you 1 being the most important 5 being the least.

1. What type of Bread products (including English muffins and bagels) do you prefer? (Note: Participants will be asked to bring a bread wrapper from home to verify bread preference. If bread is fresh from a bakery, the name of bread and bakery will be requested)

- a. White
- b. Wheat
- c. Multigrain
- d. Rye
- e. 100% whole wheat/grain
- f. Other (please specify) _____

2. Why do you choose the type of bread you most frequently eat?

- a. Because it tastes good
- b. I like the texture
- c. I was brought up eating this type of bread (i.e. my parents ate it)
- d. It is cheap
- e. I can find it easily in the store
- f. Other (please specify) _____

3. Do/does your parents share your preference?

- a. Yes
- b. No
- c. Other (please specify) _____

4. Do you recall your medical care team (doctors, nurses, dietitian, etc) recommending whole grains?

- a. Yes
- b. No
- c. Other (please specify) _____

5. Do you like the taste of whole grain foods (breads, cereal, pasta, oatmeal, etc.)?

- d. Yes
- e. No
- f. Other (please specify) _____

6. Please freely describe the taste of whole grain foods. Include why you like/do not like them.

7. Excluding bread products, do you consume any of the following?

- a. Oatmeal
Total 1 cup servings per week: _____
- b. Popcorn
Total 1 cup servings per week: _____
- c. Brown Rice
Total 1 cup servings per week: _____
- d. Whole grain pasta
Total 1 cup servings per week: _____
- e. Quinoa
Total 1 cup servings per week: _____
- f. Bulgur
Total 1 cup servings per week: _____
- g. Barley
Total 1 cup servings per week: _____
- h. Whole wheat couscous
Total 1 cup servings per week: _____
- i. Millet
Total 1 cup servings per week: _____
- g. Granola
Total 1 cup servings per week: _____
- h. Muesli
Total 1 cup servings per week: _____
- i. Amaranth
Total 1 cup servings per week: _____
- j. Buckwheat
Total 1 cup servings per week: _____
- k. Other (please specify)
Total 1 cup servings per week: _____
- l. Whole wheat crackers
Total 1 cup servings per week: _____

8. How many whole grain servings should people eat each day?

- a. 1
- b. 2
- c. 3
- d. 4
- e. Other (please specify) _____

9. Do you think that your grocery store has a wide selection of whole grain foods (breads, cereal, oatmeal, pasta, etc.)?

- a. No
- b. Yes
- c. Don't Know

10. **Do you think that whole grain foods (breads, cereal, oatmeal, pasta, etc.) cost more than no whole grain foods?**
 - a. No
 - b. Yes
 - c. Don't Know
11. **Do you think that whole grain foods like cereal, oatmeal, pasta, etc. take longer to prepare?**
 - a. No
 - b. Yes
 - c. Don't Know
12. **Are whole grain foods (breads, cereal, oatmeal, pasta, etc.) available at the restaurants you frequent?**
 - a. No
 - b. Yes
 - c. Don't Know
13. **How many different ways can you tell if foods are whole grain, for example, if bread is whole grain? Please circle one or more.**
 - a. By the brown color – such as brown bread
 - b. “Wheat” is in the name
 - c. “Multigrain is in the name
 - d. “Stone-ground” is in the name
 - e. 100% Whole wheat or 100% whole grain is in the name
 - f. Whole grain health claim is on package
 - g. Whole grain logo is on package
 - h. First ingredient is a whole grain (e.g., whole wheat flour, whole rye flour, oatmeal, etc.)
 - i. Other _____
 - j. Don't know

Please Indicate “true” (T) or “False” (F) or “Don't know” (DK) for the following questions

14. A food is whole grain if the whole grain logo is on the package.
15. A food is whole grain if a whole grain health claim is on the package
16. Bread is always whole grain if it is brown in color
17. All “wheat” bread is whole grain.
18. All “multigrain” bread is whole grain
19. All 100% whole-wheat bread is whole grain
20. All “stone-ground” bread is whole grain
21. White bread is whole grain.
22. A food is whole grain if the first ingredient is a whole grain, like whole wheat, whole rye or whole oats.

- 23. Do you think that eating more whole grain foods will help control your blood sugar?**
- a. No
 - b. Yes
 - c. Don't Know
- 24. Do you think that eating more whole grain foods will help any of the risks associated with type 2 diabetes?**
- a. No
 - b. Yes
 - c. Don't Know
- 25. Can you think of some diseases or conditions that might be decreased by a diet high in whole grain foods? List:**
-
-
-
- 26. Do you try to follow a healthy diet?**
- a. No
 - b. Yes
 - c. Don't Know
- 27. Do you plan the meals you eat?**
- a. No (please fill out below)
 - b. Yes
- If No, who does? _____
- 28. Do you cook the meals you eat?**
- a. No (please fill out below)
 - b. Yes
- If No, who does? _____
- 29. Do you use a microwave at home?**
- a. No
 - b. Yes
- 30. Do you use a stove at home?**
- a. No
 - b. Yes

Adapted from Whole grain survey developed by College of Family and Consumer Sciences (93)

Appendix C: Informed Consent Agreement

Informed Consent Agreement
CAROLINA CENTER FOR DIABETES AND ENDOCRINOLOGY
RESEARCH SUBJECT
INFORMED CONSENT FORM

Protocol Title: Investigation of Whole Grain Intake Among Diabetics in Munich, Germany and South Carolina, USA -A Pilot Study

Principal Investigator: Nicole Erickson
4 Tallin Court
Greenville, SC 29607
Email: nericks1@emich.edu

Supervising Faculty: Judith T Brooks PhD, RD - Associate Professor

Emergency Contact: Cindy Norris, RN, CDE at: (864) 849 9336

Why am I being asked to volunteer?

You are being asked to participate in a research study about whole grains and diabetics. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. You are being asked to volunteer since you meet the requirements for enrollment into this study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Please take time to review this information carefully. After you have finished, you should talk to the research team about the study and ask them any questions you have. You may also wish to talk with family, friends or family doctor about your participation in this study. If you decide to participate, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

What is the purpose of this research study?

This study is a research project aiming to find ways to help improve your diet. These improvements may have many health benefits. Specifically, this study will find out how much whole grain is eaten by diabetics in Germany and diabetics with German heritage (a family member was German) in the USA. It is a pilot study -this means the results will help design follow-up studies by identifying factors that could improve the amount of whole grain diabetics eat. These results may also lead to other studies that could help the general population or improve the care you receive from your medical team.

How long will I be in the study? How many other people will be in the study?

You will be asked to attend a 1 hour meeting with the Principal Investigator. In this meeting the study and procedures will be thoroughly explained and you will be asked to fill out a questionnaire about what you eat and why. After the meeting, you will be asked to keep a 3 day diet record of all foods eaten. The approximate total time to complete the food record should be about 20 minutes total per day for a 3 day period. When you complete this record you will be asked to return it to the Office at the Carolina Center for Diabetes and Endocrinology. The total time you invest in this study will be approximately 3 hours. Thirty people will participate in this study with you at this time. Another 30 people in Germany will be asked to do the same thing. Since the second group of people will be in Germany, the study will take until May 2011 to complete. It is important to know that your part will be complete within a week of returning your food record.

You must be at least 18 years of age and below 65 years of age to take part in this study.

What am I being asked to do?

You are being asked to fill out a questionnaire and to keep a food diary that concentrates on grain. This means it will be most important to include information about the grains in this record. You will be told what is considered a grain. Help will also be given on guessing serving size and amounts eaten. Where possible, you will be asked to weigh your grains and provide labels. For the grains, brand and manufacturer (who made it) information from the label will be requested wherever possible. A copy of the recipe for homemade dishes will also be requested. The Principal Investigator, (PI) Nicole Erickson, will explain the study to you, answer any questions you may have, and watch you sign this consent form. You will be asked to complete a 3 day food record about your food intake which will also include your Age, BMI, Gender, Race, A1C, and type of Diabetes. Before you complete this record, you will be given a duplicate copy of this informed consent, which includes follow-up contact information, if needed.

What are the possible risks or discomforts?

As this pilot study includes only a diet record, there is very little risk to you.

- Results will not be able to be connected with your name in any way within one week's time after completion of the diet record.
- Results will not be shared or discussed with their medical providers without your express written permission.

Most likely risk is discomfort:

- You may find it inconvenient to keep a food record, or to drop it off at the office. If this is a problem for you, please discuss your options with the Principal Investigator, Nicole Erickson.
- The diet record needs to be accurate and could be embarrassing if you feel you are not following known guidelines. If you become uncomfortable or distressed, you only should continue if you want to.

PLEASE NOTE: *You may stop at any time without any effect on the normal course of your treatment and with no negative consequences.*

What are the possible benefits of the study?

Education about the benefit of eating whole grains will be included with participation in this study. Also, in describing how to keep a good diet record, subjects will receive education on estimating portion sizes better. This is valuable information for any diabetic. An information sheet about whole grains and some recipes will be given to all subjects. Subjects will also be invited to attend a free class on a topic relevant to diabetes care, designed and delivered by the PI with input from Cindy Norris, RN, CDE. Gifts from sponsors will be also given after full participation.

The results of this study may also help to find ways to improve whole grain intake in the general population.

What other choices do I have if I do not participate?

You are not required to participate in this study.

You may stop at any time without any effect on the normal course of your treatment and with no negative consequences, penalty or problems. If you just want to learn more about your diet you can make an appointment with the Diabetes Educators on site.

Will I be paid for being in this study?

You will not be paid for taking part in this study. You will not be paid in the future if this research leads to a profitable product or service.

Will my study leader be paid for my being in this study?

The Principal Investigator is a student writing a Master's Thesis. No grants or scholarships will be funding this study.

Will I have to pay for anything?

There are no treatments and procedures that would be done or associated with this study. The only possible cost incurred would be transportation to study site.

What happens if I am injured or hurt during the study?

The likelihood that you are injured or hurt as a result of this study is slim to none.

If you have a *medical emergency* during the study, you should go to the nearest emergency room.

In the case of injury or sickness resulting from this study, medical treatment is available but will be provided at the usual charge. You or your insurance company will be charged for this medical care and/or hospitalization. No funds have been set aside to compensate you in the

event of injury. There is no payment for such things as lost wages, disability, or discomfort due to any injury or side effect from this study.

Legal rights:

You do not lose any of your legal rights by signing this form. This research protocol and informed consent Agreement has been reviewed and approved for use by the Eastern Michigan University Human Subjects Review Committee and by the Spartanburg Regional Healthcare System. It has also been reviewed by Corporate Integrity for HIPAA purposes as well as by Internal Review Board staff. The Principal investigator has completed training in Human Subjects. If you have any questions about the approval process or your rights please contact:

Talley Kayser, CIP
IRB Program Manager
Corporate Integrity
Spartanburg Regional Healthcare System
(864) 560-1957/864-415-3769

Dr. Deb Laski-Smith
Interim Dean of the Graduate School
Administrative Co/chair of the UHSRC
Eastern Michigan University
(734) 487 0042

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed the food records and questionnaire and all information has been collected. This study may also be stopped at any time by your physician, or the Food and Drug Administration (FDA), or the Spartanburg Regional Health Care System without your consent because:

- The Principal investigator or Spartanburg Regional Health Care System feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Principal Investigator, Spartanburg Regional Health Care System, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Confidentiality of Study Records and Medical Records

Information collected for this study is confidential. However, the thesis board at Eastern Michigan University will receive copies of the de-identified study records. The Spartanburg Regional Healthcare System Institutional Review Board and the Eastern Michigan University Institutional Review Board may see parts of your medical records related to this study if they feel it is necessary. Data collected and entered into the Case Report Forms are the property of Nicole Erickson. In the event of any publication regarding this study, your identity will not be disclosed.

Other organizations that may inspect and/or copy your research records for quality assurance and data analysis include:

Professors employed at Eastern Michigan University: Specifically the Thesis Chair, Dr. Judi Brooks, PhD.

Who can see or use my information? How will my personal information be protected?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care.

Information about you may include information about your health and your medical care before, during, and after the study, even if that information wasn't collected as part of this research study. For example:

- Hospital/doctor's office records, including test results (blood tests, urine tests, etc.)
- Records confirming that you have type 2 Diabetes.
- Your telephone number

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- Safety monitors or committees may need the information to make sure that the study is safe.
- The researchers may need to use the information to create a databank of information about your diet or its possible affect on your diabetes.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

Only a code number will identify you with your responses on the food record. The results will be stored separately from the consent form, which includes your name and any other identifying information. A key linking your name to the food record will be kept separately for a period of seven days in order to allow, the PI to clarify any unclear responses with you. After this time the key will be destroyed and no further information linking you to the food record will exist. All information will be kept in locked file cabinets of the study investigator.

What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To confirm or clarify information you provided.
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help Eastern Michigan University and Spartanburg Regional hospital to make sure that the study was conducted properly

When does my permission expire?

Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to the study staff listed on the first page of this document.

Who can I call if I have more questions about this research study?

If you have questions regarding your participation in this research study, do not hesitate to speak with the Principal Investigator or Emergency Contact listed on page one of this form.

Who can I call about my rights as a research subject?

If you have questions regarding your rights as a research subject, do not hesitate to contact the Spartanburg Regional Healthcare System Institutional Review Board (IRB) at (864) 560-6892 or the Eastern Michigan University Institutional Review Board (IRB) (734) 487 0042

Volunteer’s Statement

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. If you have additional questions about taking part in this study or research-related injury, you may contact Nicole Erickson via e-mail at nericks1@emich.edu. You can also contact Cindy Norris at: (864) 849 9336.

You understand taking part in this research study is voluntary. You may quit the study at any time without harming future medical care or losing any benefits to which you might otherwise be entitled.

I have read and understand the above information. I agree to take part in this study. I will be given a copy of this document for my own record.

Name of Subject (Please Print) Signature of Subject Date and Time

Name of Person Obtaining Signature Date
Consent (Please Print)

For Use with Authorized Representative Signature

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject Authorized subject Date
Representative [**print**] Representative Signature

Provide a brief description of above person authority to serve as the subject’s authorized representative.

Name of Principal Investigator Signature Date
(Please Print)

HIPPA AUTHORIZATION FOR RESEARCH USES AND DISCLOSURES OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION BY A COVERED HEALTH CARE PROVIDER

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to the Carolina's Center for Diabetes and Endocrinology to use your health information that identifies you for the research study described here:

Project Title: Pilot Study: Investigation of Whole Grain Intake Among Diabetics in Munich, Germany and South Carolina, USA

Investigator: Nicole Tonya Erickson, Eastern Michigan University

Supervising Faculty: Judith T Brooks PhD, RD - Associate Professor

Staff Sponsor at Spartanburg Regional Hospital: Cindy Norris, RN, CDE

A pilot study which seeks to establish if the assumption that Germans eat more whole grain is true and to identify significant factors that may account for the difference. This is achieved by studying random samples of type 2 diabetic Germans living in Munich, Germany, and type 2 diabetic Americans of German decent living in South Carolina, USA. In addition to recording the whole grain intake, the study will probe subjects' knowledge of the benefits of whole grains and reasons for their grains preferences. The findings can then be used to design separate follow-up studies of a larger scale investigating the most significant factors contributing to this difference.

The health information that we may use or disclose (release) for this research includes:

Telephone number, Age, BMI, Gender, Race, A1C, and type of Diabetes, and heritage.

The health information listed above may be used by and/or disclosed (released) to:

Nicole Erickson, M.S. student at Eastern Michigan University and Research Assistant Cindy Norris RN, CDE

The Carolina's Center for Diabetes and Endocrinology and Spartanburg Regional Hospital are required by law to protect your health information. By signing this document, you authorize The Carolina's Center for Diabetes and Endocrinology and Spartanburg Regional Hospital to use and/or disclose (i.e. release the information to Nicole Erickson) your health information for this research. Your information will not be released to any third parties without your signed consent and will be used solely for purposes of this research project.

Please note that:

- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.
- You do not have to sign this Authorization, but if you do not, you may not participate in this research study.
- The Carolina’s Center for Diabetes and Endocrinology and Spartanburg Regional Hospital may not condition (withhold or refuse) treating you on whether you sign this Authorization.
- You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, Nicole Erickson and Cindy Norris may still use the health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to The Carolina’s Center for Diabetes and Endocrinology. 2755 S highway 14, Suite 1200 K, Greer South Carolina, 29650
- If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

This Authorization expires at the end of the research study. I will be given a copy of this document for my records.

Signature of participant or participant’s personal representative

Printed name of participant or participant’s personal representative

_____ Date _____

If applicable, a description of the personal representative’s authority to sign for the participant

Appendix D: Internal Review Board Approval Letters



EASTERN MICHIGAN UNIVERSITY

October 8, 2009

Nicole Erickson
c/o Judith Brooks
Eastern Michigan University
School of Health Sciences
Ypsilanti, Michigan 48197

Dear Nicole Erickson,

The CHHS Human Subjects Review Committee has reviewed the revisions to your proposal entitled: "Barrier to Whole Grain Consumption Among Diabetics of German Heritage Living in South Carolina, USA" (CHHS 09-052).

The committee reviewed your proposal and its revisions and concluded that the risk to participants is minimal. Your study is approved by the committee.

Good luck in your research endeavors.

Sincerely,

A handwritten signature in black ink, appearing to read "George Licpa".

George Licpa, Ph.D.
Chair, CHHS Human Subjects Review Committee



12/14/09

Principal Investigator: Nicole Erickson BA
Study Title: Erickson (Carolina's Ctr for Diabetes/Endocrinology) Whole Grain Intake in diabetics: A Pilot Study; Barriers to whole grain consumption among diabetics of German heritage living in South Carolina, USA
eIRB ID: Pro00004304

Dear Nicole Erickson BA

The above referenced study was approved via expedited approval on 11/28/2009. The Spartanburg Regional Healthcare System Institutional Review Board will be notified of this approval at their next meeting.

This approval is for 12 months (11/28/2009 to 11/27/2010). Before the expiration of this approval interval, should the protocol remain active, please submit in a timely manner a request for extension of the approval accompanied by a progress report indicating the number of subjects on study and unanticipated problems in the design or implementation of the project.

As the investigator, you are reminded to promptly notify the SRHS IRB of any adverse events or changes in the study. Changes in an approved study may not be instituted prior to SRHS IRB approval, except where necessary to eliminate apparent hazards to human subjects.

Respectfully,

Bogdan Gheorghiu, MD

Bogdan Gheorghiu, MD
IRB-A Chairperson

FWA00000622.IRB000001369
101 E. Wood St., 3rd floor, Gibbs Cancer Center, Spartanburg, SC 29303
(864) 550-4392

(Erickson (Carolina's Ctr for Diabetes/Endocrinology) Whole Grain Intake in diabetics: A Pilot Study
Page 1 of 2

PLEASE NOTE THE FOLLOWING IRB GUIDELINES for HUMAN RESEARCH:

- The research must be conducted according to the proposal/protocol that was approved by the IRB.
Changes to the procedures, recruitment materials, or consent document must be approved by the IRB prior to implementation.
If applicable, each subject should receive a copy of the an approved dated consent document
It is the responsibility of the principal investigator to report promptly to the IRB:
o Unanticipated problems and/or unexpected risks to subjects
o Adverse events effecting the rights or welfare of any human subject participating in the project
Research records, including signed consent documents, must be retained for at least three years after the termination of the last IRB approval.
No subjects may be involved in any study procedure prior to the IRB approval date, or after the expiration date. For continuing research, an update of the study is required prior to the expiration date. The PI is responsible for initiating the Continuing Review process. At the time a study is terminated (closed), a final report should be submitted to the IRB.

FWA00000622.IRB000001369
101 E. Wood St., 3rd floor, Gibbs Cancer Center, Spartanburg, SC 29303
(864) 550-4392

(Erickson (Carolina's Ctr for Diabetes/Endocrinology) Whole Grain Intake in diabetics: A Pilot Study
Page 2 of 2

Appendix E: Telephone Script of Recruitment Calls

Hello. This is Cindy Norris calling from the Carolina Center of Diabetes and Endocrinology. May I please speak with _____.

Hello Mr. /Mrs. _____. We are conducting a research study on whole grain intake among diabetics of German descent and was wondering if you would be interested in participating?

Thank you for your interest. May I ask a couple questions to confirm that you qualify?

Do you have any German heritage? This means do you have one or more Grandparent who has German blood?

May I confirm that you are a type two diabetic?

You should be aware that you will not be paid for participation. Participation is voluntary and will not cost you anything but about two to three hours total of your time. You will, however, gain knowledge by participating that will help you deal with your diabetes on a day to day basis.

You will also be doing a great service to the scientific community and to contributing to diabetes and nutrition research.

Study participation requires that you sign a consent form in person and participate in a session explaining the study and exactly what is expected of you. This session will last about an hour. Which of the following days and times would be convenient for you to come and do this?

Please understand that if you come to this meeting and change your mind you are not required to participate any further.

May Nicole Erickson, the principal investigator for the study call you a couple days before the meeting and remind you about the appointment? Thank you for your time.

FFQs : Time: You will need to invest 2-3 hours at the most into this study

Requirements: you will be requested to fill out a survey and keep a 3 day food record (exact instructions will be given at the meeting

Subject: barriers to whole grain intake

How often will I have to come?: You will only need to come to the CCDE once

Appendix F: Dietary Record Instructions

General Instructions:

- Do not change your eating habits. Continue to choose the same foods and amounts that you normally eat
- Please begin tomorrow and keep the record for 3 consecutive days
- Begin each day on a new sheet
- It is important that you keep this record with you and the provided pen at **all times**. It is designed in a foldable style that you can take with you in your purse, pocket, briefcase, or pocket
- Record what you have eaten **immediately** after to eating **not** at the end of the day. This makes it easier to remember and to record accurately.
- Include all meals snacks, granola bars, sandwiches, chocolate, sweets, ice-cream, fruits etc – in short, **everything** that you eat
- Whenever possible use measuring cups and scales to measure your food

Describing Foods Accurately:

- Describe each food in detail as best you can

Include	Example	Brand
Record Brand Name and descriptions	1. Pasta, Long Cuts, Thin Spaghetti	Davinci
	2. Stone Ground Whole Wheat With Honey Bread	Nature's Pride
Anything you might add separately	1. Instant Oatmeal	Kirkland's
	2. 1/2 cup fresh Strawberries	Dole
	3. 1 Tbs raw wheat germ	Bob's Red Mill

- Describe Each Ingredient in a mixed recipe

Dish	Example
Spaghetti and Meatballs	1 1/2 cups cooked Davinci Pasta, Long Cuts, Thin Spaghetti noodles, 5 meatballs, 1/2 cup Ragu Basil Spaghetti sauce, 1 Tbs parmesan cheese

- For Serving size/Portion size Descriptions see the following pages

Describing Amounts accurately

- Avoid terms such as "one bowl" or a "handful"
- Use weights marked on packages

Product	Example
Westbrae Natural Vegetarian Organic Golden Corn, Whole Kernel, 15.25 Ounce Cans	Half of 15.25 ounce can
Quaker Instant Oatmeal Original 1 Packet (28 g)	Entire package

- Use standard terms of measurement to record amounts and measure food if possible

Useful abbreviations		
cup = cup	ounce = oz	Gram = g
Teaspoon = tsp	Tablespoon = Tbsp	Pound = lb

- For Serving size/Portion size descriptions see the following pages

Estimating Serving Size: Grains

Source: Kathleen Zelman, MPH, RD, LD, Director of Nutrition for WISN-TV. Reviewed on November 26, 2008. Available at: www.healthyeating.ucsfed.com. Accessed on July 12, 2009.

Estimating Serving Size: Pocket guide

When you're trying to eat healthfully, it's essential to keep track of just how much you're eating. It's all too easy to misjudge common portion sizes. Here are some easy comparisons to help you figure out how many servings are on your plate.

PORTION SIZE YOUR PLATE

- PLATE VEGETABLES:** Fill half your plate with a variety of different vegetables for good nutrition and fiber to please your palate.
- PLATE PROTEIN:** Leave 1/4 of your plate open for your heart and better for your waistline. Bake, broil, or grill your meat for a delicious and healthy treat.
- PLATE STARCHES:** Whole grain starches are good for your heart and keep you feeling fuller longer. Whole foods like grains, potatoes and corn are considered vegetables, they are high in starch and should be placed on this part of your plate.

BASIC GUIDELINES

- 1 cup = baseball
- 1/2 cup = lightbulb
- 1 oz or 2 Tbsp = golf ball
- 1 Tbsp = poker chip
- 1 slice of bread = cassette tape
- 3 oz chicken or meat = deck of cards
- 2 oz fish = checkbook
- 1 oz lunch meat = compact disc
- 1 oz muffin or biscuit = hockey puck
- 1/2 oz cheese = 3 dice

GRAINS

- 1 cup of cereal flakes = baseball
- 1 package = compact disc
- 1 cup of cooked rice = lightbulb
- 1/2 cup cooked pasta = lightbulb
- 1 slice of bread = cassette tape
- 1 bagel = 8 oz can of fruit
- 2 cups popcorn = 3 baseballs

FRUITS & VEGETABLES

- 1 medium fruit = baseball
- 1/2 cup grapes = about 10 grapes
- 1 cup strawberries = about 12 berries
- 1 cup of salad greens = baseball
- 1 cup carrots = about 12 baby carrots
- 1 cup cooked vegetables = baseball
- 1 salad potato = compact disc

MEATS, FISH & NUTS

- 2 oz lean meat or poultry = deck of cards
- 3 oz fish = deck of cards
- 2 Tbsp peanut butter = golf ball
- 2 Tbsp hummus = golf ball
- 1/2 cup almonds = 12 almonds
- 1/4 cup pistachios = 24 pistachios

DAIRY & CHEESE

- 1/2 cup cheese = 3 stacked dice
- 1 cup yogurt = baseball
- 1/2 cup frozen yogurt = lightbulb
- 1/2 cup frozen yogurt = lightbulb

FATS & OILS

- 1 Tbsp butter or spread = poker chip
- 1 Tbsp salad dressing = poker chip
- 1 slice of cake = deck of cards
- 1 Tbsp oil = poker chip

SWEETS & TREATS

- 1 piece chocolate = dental floss package
- 1 package = dental floss package
- 1 slice of cake = deck of cards
- 1 cookie = about 2 poker chips

©2008 Kathleen Zelman, MPH, RD, LD, Director of Nutrition for WISN-TV. Reviewed on November 26, 2008. Available at: www.healthyeating.ucsfed.com. Accessed on July 12, 2009.

Sample: Food Record

Day: MONDAY Date: 07/09/09 ID: SUSA 0001

Meal	Place	Food and Beverages	Please specify grains:	Brand	Amount
B=Breakfast	H=Home	Instant Oatmeal	White, Wheat, Multigrain, Eye, honey wheat, 12 Grain, 100% whole wheat/grain etc.	Kirkland	1 package (50 grams)
L=Lunch	H=Home	Fresh strawberries		Dole	1 cup
S=Snacks	H=Home	Orange juice		Sunny D	16 oz
	H=Home	Cheedar slices		Sargento	2
	H=Home	English Muffin		Arnolds	1
	H=Home	Mayonnaise, Canela		Spectrum	1 Tbs
	H=Home	Egg		Eggland's Best	1
	H=Home	Non fat skim Latte		Starbucks	16 oz

Sample: Food Record
 Day: Monday Date 01/07/09 ID: SUSA 0001

Meal	Place	Food and Beverages	Please specify grains: Wheat, White, Whole, Multigrain, Rye, Honey wheat, 12 Grain, 100% whole wheat/grain etc.	Brand	Amount
S	P	Chevy Dips Peanut butter granola bar		Quaker	1 bar (31 g)
S	P	Diet Mountain Dew		Coke	12 oz
D	H	Children Broccoli Casserole		Recipe attached	2 servings
D	H	Banana		Dole	1 medium
D	P	Diet Coke		Coke	16 oz
D	P	Fig Newton	100% Whole Grain	Nabisco	2 bars
S	P	Gourmet Microwaveable Popcorn, Natural Simply Salted 50% Less Fat		On the Border	3/4 3.5 oz bag
S	H	Herbal Tea		Celestial Seasonings	1 8 oz mug

Food Record
 Day: _____ Date: _____ ID: SUSA 000__

Meal	Place	Food and Beverages	Please specify grains: Wheat, White, Whole, Multigrain, Rye, Honey wheat, 12 Grain, 100% whole wheat/grain etc.	Brand	Amount

Instructions: Recipes

Describing Recipes Accurately:

If unsure of servings made, think container size and then decide how much you ate:

Container size	Example
Quart pots	A 3 quart pot = 12 cups. You ate ¼. So how many cups did you eat? Answer: 3 cups
13 x 9x2 dish	This size dish is normally divided into 12 servings, perhaps you shared the dish equally with 5 other people. This means you each had 2 servings

Include the recipe in the page designed for recipes

Example: Recipe Form

Recipe Name: Chicken Broccoli Casserole No. of servings made 12 No. of servings you ate 2

Ingredients	Brand	Amount
Broccoli	Green Giant	1 16 oz bag frozen
Boneless Skinless Chicken Breast	Perdue	4 6 oz pieces
Cream of Chicken Soup	Campbell's	12 oz can
Cheddar cheese	Sargento	2 cups
Bread Crumbs, Seasoned (see label)	Old London	¼ of ten ounce container

Recipe Form ID: SUSA 000__

Recipe Name _____ No. of servings made _____ No. of servings you ate _____

Ingredients	Brand	Amount

Appendix G: List of Whole Grains

Whole Grains:

Amaranth, barley (pearled or flour), buckwheat (whole, groats, or flour), quinoa, bulgur, corn flour or corn meal (whole grain, masa), kasha, brown rice, dark breads containing whole grain flour (i.e. German Schwarzbrot) wild rice, rice flour, Rice, brown—medium and long grain

Rice flour, brown, whole rye meal and whole rye flour, triticale flour (whole grain), wheat (all hard/soft, spring/winter), whole wheat, popcorn, corn chips or corn tortillas (made with whole corn), Oats, Oat flour, oatmeal (instant or prepared), granola, muesli, oatmeal cookies, oatmeal bread, popcorn, whole wheat pastas/noodle products, whole grain breads (whole wheat, rye bread, other multi-grain and whole grain breads (including light), whole wheat crackers, whole wheat pancakes, waffles, or bagels, mixed dishes made with whole grains, all cold breakfast cereals (fortified and non-fortified), made with whole grains (42, 82)

Note:

Foods containing high amounts of bran, but being deficient any of the other components of whole grains (endosperm, bran and germ) will not be included as a whole grain. Sweet corn will be coded as a vegetable rather than a grain as done in previous studies in the USA. (54, 93)

