

Effect of Pinto, Black and Dark Red Kidney Bean
Consumption as Part of a Meal on Postprandial Glucose

in Adults with Type 2 Diabetes

by

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ABSTRACT

This study examined the effect of consuming pinto, black, and dark red kidney beans with white rice in comparison to a white rice only control meal on the glycemic response of adults with type 2 diabetes (T2D). These bean and rice combinations are part of many traditional diets. Seventeen subjects with T2D treated by diet and/or metformin were randomly assigned to 4 treatments: white rice (control), pinto beans/rice, black beans/rice, and dark red kidney beans/rice. All treatments were portioned by weight and matched for available carbohydrate content of ~50 grams. Capillary whole blood samples were collected at baseline and at 30, 60, 90, 120, 150 and 180 minutes posttreatment and assessed for glucose concentration using the YSI Stat Plus Analyzer. Net change glucose responses were significantly lower for the pinto, black, and dark red kidney bean and rice meals than control at 90, 120 and 150 minutes posttreatment ($P < 0.05$). Incremental area under the curve (iAUC) values were also significantly reduced for the bean/rice meals containing pinto ($P < 0.01$) and black beans ($P < 0.05$) in contrast to the rice control. Results suggest that the combination of whole beans and rice may be beneficial to those with T2D to assist with blood glucose management.

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CHAPTER 1

INTRODUCTION

The Centers for Disease Control (CDC) estimate that 25.8 million people, or approximately 8% of the population in the United States, have been diagnosed or have undiagnosed type 2 diabetes mellitus (T2D). This disease affects a disproportionate number of Hispanics (11.8%) and African Americans (12.6%) (CDC, 2011). Diet and lifestyle changes are the first intervention steps recommended by leading health agencies to control T2D. Dietary modifications have the added benefit of improving overall health and reducing the risk of other nutrition-related chronic diseases such as cardiovascular disease, hypertension, and cancer (O’Keefe & Bell, 2007; Eckel, Kahn, Robertson & Rizza, 2006).

Many persons with T2D fail to reach glycemic control goals. Despite the known benefits of lifestyle change, there is often poor adherence to dietary recommendations (Knowler et al., 2002; Herman et al., 2005; Knight, Dormant & Bundy, 2006; Vijan et al., 2004). Difficulty meeting dietary guidelines is a frequently reported concern, particularly among Hispanic (Caban, Walker, Sanchez & Mera, 2008; Rustveld et al., 2009; Wen, Parchman & Shepherd, 2004, McCloskey & Flenniken, 2010) and African American populations with T2D (Two Feathers et al., 2005; de Groot et al., 2003). Two dietary adherence barriers often mentioned are exclusion of cultural foods and the inability to eat the same foods as the rest of the family (Caban et al., 2008; Rusveld, Pavlik, Jibaja-Weiss, Kline & Gossey, 2009; de Groot et al., 2003).

Epidemiological studies have shown associations with decreased legume consumption and increased rates/prevalence of chronic diseases, including T2D (Leterme, 2002; Darmadi-Blackberry et al., 2004; Bazzano et al., 2001). Beans have a low glycemic index (GI) which by definition means they reduce the rise in glucose after a meal (Brand-Miller, Hayne, Petocz & Colagiuri, 2003; Bornet et al., 1987; Sievenpiper et al., 2009). In contrast, high GI items like white rice can cause postprandial glycemic elevations that are damaging to vascular tissues and other organs (Sugiyama, Tang, Wakaki & Koyama, 2003; Ceriello et al., 2008). In mixed-meal settings, beans combined with a high GI or refined carbohydrate food produced a glycemic response that is intermediate between the high and low GI foods (Bornet et al., 1987; Sugiyama et al., 2003; Winham, Hutchins & Melde, 2007). These findings have important implications for chronic disease risk reduction since elevated blood glucose is a contributor to cardiovascular risk (O’Keefe & Bell, 2007; Ceriello et al., 2008). Inclusion of culturally familiar beans in the therapeutic diets of immigrants and minorities with T2D may decrease postprandial glycemic variability, maintain vascular health, and improve dietary compliance and quality of life (Knight et al., 2006; Vijan et al., 2004; Caban, Walker, Sanchez & Mera, 2008; Jimenez-Cruz, Loustaunau-López, Bacardi-Gascón, 2006).

Phaseolus vulgaris species such as pinto, dark red kidney and black beans with rice are classic food combinations in many areas of the world, especially in the Caribbean, Latin America, Middle East, and Mediterranean (Leterme, 2002).

Beans have been customarily eaten with cereal grains or maize in societies dating back to the Aztecs, Mayas, Incas and local native populations within Central America (Leterme & Munoz, 2002). Beans are low in fat and high in fiber, vegetable protein, folate, iron, magnesium, zinc, omega-3 fatty acids, and antioxidants (Leterme, 2002; Darmadi-Blackberry et al., 2004; Mitchell, 2009). They also contain phytate and phenolic compounds that may function in similar ways to alpha glucosidase or alpha amylase inhibitor T2D medications like the oral hypoglycemic agent acarbose (Tormo, Gil-Exojo, de Tejada & Campillo, 2004; Sievenpiper et al., 2009). The retention of beans in the diet may have positive implications for those with T2D, as beans are known low GI foods, in that they produce an attenuated blood glucose increase after consumption in comparison to a reference food such as white bread (Rizkalla, Bellisle & Slama, 2002).

Purpose of study

The primary objective of this study was to determine the effects of consuming three bean types (pinto beans, black beans and dark red kidney beans) on the postprandial glycemia of adult individuals with non-insulin-dependent T2D using a placebo-controlled 4 x 4 randomized block study design. This study appears to be one of the first to look at the effect of these culturally appropriate beans for the Americas combined with rice among people with T2D.

Research aims

This research aimed to determine if pinto beans, black beans and dark red kidney beans will affect the glycemic responses of individuals with T2D when consumed as part of a high GI meal containing white rice. If the beans studied do, in fact, improve postprandial metabolic control in the participants studied, they could be used as an effective, inexpensive, nonpharmacologic method to assist diabetics in the maintenance of appropriate blood glucose and insulin levels, which can help to prevent or slow the advancement of the disease.

Those with T2D are often given conflicting information about beans or told not to eat them at all due to their carbohydrate content. If the dietary treatments prove effective at controlling blood glucose levels, the study results can also be useful for clarifying and directing the dietary recommendations to individuals with T2D to promote consumption of this low-cost, culturally acceptable food type.

Hypotheses

- Bean consumption as part of a high GI meal will reduce postprandial blood glucose levels in individuals with non-insulin dependent T2D, as compared to a white rice control with a matched available carbohydrate content of 50 grams.
- The glycemic responses will not differ between bean treatments.

Definition of Terms

Glycemic Index- The Glycemic Index is a classification system for foods of known available carbohydrate content. It measures the blood glucose response produced after the consumption of these foods in comparison to a known reference food such as glucose or white bread.

Glycosylated hemoglobin A1c - Hemoglobin A1c (HbA1c) is a form of hemoglobin that interacts with glucose. This parameter estimates the average blood glucose levels over an approximately three month period.

Delimitations

Research participants were recruited from the metro Phoenix area. Participants were between 35 and 70 years of age, had a body mass index (BMI) value between 22-40kg/m², were physician diagnosed with non-insulin dependent T2D for at least 6 months, and managing their diabetes using the oral hypoglycemic agent Glucophage (metformin) and/or through diet and exercise.

Limitations

The results of this study only apply to individuals with non-insulin dependent T2D. Results are not applicable to those with insulin-dependent T2D, healthy individuals or those with other chronic diseases. A convenience sample was used, making the study results less generalizable to the larger American population with T2D.

Recruitment efforts included grocery stores, doctor's offices, 55+ communities and neighborhoods near the ASU Polytechnic campus. While

participant food intake was monitored through the use of 24 hour dietary records and food frequency questionnaires, it was impossible to get a completely accurate assessment. It is also possible that participant compliance with fasting and dietary changes wavered during the course of the study, leading to potential errors in the data collected.

CHAPTER 2

REVIEW OF LITERATURE

The Centers for Disease Control (CDC) estimate that 25.8 million people have diabetes, or around 8% of the population in the United States. Almost all of these individuals (90-95%) are affected by T2D (CDC, 2011). T2D is progressive condition characterized by inappropriate insulin action and/or inadequate insulin production. Pancreatic beta cells are gradually destroyed as the disease progresses, reducing the amount of insulin released and resulting in chronically high blood glucose levels (ADA, 2009). Recurring hyperglycemia produces a deterioration of body tissues, leading to an increased risk for chronic conditions including cardiovascular disease, kidney disease, neuropathy, retinopathy and blindness (American Diabetes Association, 2009). In fact, diabetes complications are currently the seventh most common cause of death in the United States (CDC, 2011). Maintenance of proper blood glucose levels over time is of the utmost importance to avoid these serious, life-threatening problems.

Beans are the large seeds of flowering plants included in the *Fabaceae* family. They are commonly consumed traditional foods within many cultures around the world, especially in Latin America, the Mediterranean and Middle East (Leterme, 2002). Beans have been customarily eaten with cereal grains or maize in societies dating back to the Aztecs, Mayas, Incas and local native populations within Central America (Leterme & Munoz, 2002). Pinto, black and dark red kidney beans are popular bean types within the United States and are

frequently consumed with rice in traditional diets (Sugiyama et al., 2003). The retention of beans in the diet may have positive implications for those with T2D, as beans are known to have low GI values, in that they produce an attenuated blood glucose increase after consumption in comparison to a reference food such as white bread (Rizkalla et al., 2002).

The 2010 Dietary Guidelines for Americans recommends that all adults in the United States consume 1 ½ cups of beans per week, or around a ¼ cup per day (USDHHS & USDA, 2010). This recommendation was reduced from the 2005 DGA guidelines of ½ cup daily (USDHHS & USDA, 2005). The 2010 DGA committee cited reasons such as low intakes of beans by American consumers and lack of sufficient scientific evidence to support inclusion of more beans daily (USDHHS & USDA, 2010). Regular bean consumption has been shown to increase one's overall intake of fiber and micronutrients including folate, zinc, iron, and magnesium, while decreasing one's total and saturated fat consumption (Mitchell, Lawrence, Hartman & Curran, 2009). A number of studies in those with T2D have reported reductions in metabolic parameters such as hemoglobin A1c (Brand, Colagiuri, Crossman, Allen & Roberts, 1991) (Jarvi, Karlstrom, Grandfeldt, Bjorck, Asp & Vessby, 1999), fructosamine (Jarvi et al., 1999; Fontvieille, Rizkalla, Penfornis, Acosta, Bornet & Slama, 1992) as well as short and long term glucose and insulin levels (Jarvi et al., 1999; Fontvieille et al., 1992; Rivellese et al., 1980; Jenkins et al., 1988) when diets containing low GI foods, including beans, were consumed.

However, a majority of these studies have looked at the metabolic responses to mixed meals or low GI diets containing variable types and amounts of beans combined with other foods. Little information exists as to the glycemic effects of consuming individual bean types as part of a white rice meal by individuals with non-insulin dependent T2D. Previous research, conducted in healthy subjects, sought to determine the glycemic and insulinemic response to pinto beans, navy beans and black eyed peas in the form of a spread (Winham, Hutchins & Melde, 2007). A significant reduction in blood glucose and insulin levels were not seen, but this may be due to the form in which the treatments were given. Conversely, a similar study found a significant reduction in the blood glucose and insulin levels of healthy adults after consumption of whole chickpeas and black beans with white rice in comparison to a control meal containing solely white rice (Thompson, Winham & Hutchins, 2009). The aforementioned research design was extended in this study to include individuals with non-insulin dependent T2D, and to provided dietary treatments including three of the most popular bean types within the United States: pinto beans, black beans and dark red kidney beans (Lucier, Lin, Allshouse & Scott Kantor, 2000). The proposed research also included some new parameters, including an analysis of capillary blood samples, the use of the Block Fat and Fruit and Vegetables screeners and the Block 2005 Food Frequency Questionnaire (FFQ) (NutritionQuest, Berkeley, CA) to assess dietary changes and overall quality.

Diabetes

Diabetes mellitus is a condition of insulin inaction and/or improper insulin usage (ADA, 2009). Since insulin brings glucose into the cells and converts it to energy, alterations in its ability to work cause problems with carbohydrate metabolism. Diabetes causes hyperglycemia and a variety of serious side effects including heart disease, diabetic retinopathy, nephropathy, peripheral neuropathy and dementia (ADA, 2009).

There are three types of diabetes: type 1 diabetes, gestational diabetes and T2D. T2D is the most commonly seen version of diabetes, affecting 90-95% of all individuals with diabetes (ADA, 2009). Type 1 diabetes accounts for 5-10% of diabetes diagnoses in the United States (CDC, 2007). This condition is primarily diagnosed before the age of 30 and is typified by pancreatic beta cell destruction leading to a lack of insulin production. Autoantibodies to one or more of the following are found in 85-90% of individuals diagnosed with type 1 diabetes: insulin, pancreatic beta cells, tyrosine phosphatases and glytamic acid decarboxylase (ADA, 2009). A genetic predisposition to type 1 diabetes may also be causative in the development of the disease (ADA, 2009). Individuals with type 1 diabetes require exogenous insulin to prevent diabetic ketoacidosis, coma and death. Gestational diabetes is a condition of altered carbohydrate metabolism that occurs during pregnancy. This type of diabetes is most often diagnosed through the use of a 75g oral glucose tolerance test between the 24th and 28th week of pregnancy for women considered to have a low to medium risk of developing

the condition (ADA, 2009). It is recommended that women thought to be at high risk of developing gestational diabetes should be tested earlier in pregnancy in order to prevent complications to the mother and fetus (ADA, 2009). Women who have had gestational diabetes during a previous pregnancy have approximately a 35-60% likelihood of developing type 2 diabetes compared to women who have not had this condition (CDC, 2011). Gestational diabetes occurs in 4% of all U.S. pregnancies and may affect anywhere from 1-14% of the population, depending on the area sampled.

T2D occurs when insulin sensitivity and/or production is gradually diminished, ultimately requiring specific dietary management, medications and other treatments to control chronic hyperglycemia. Insulin insensitivity can occur due to many factors but primarily happens due to obesity/overweight (BMI >30) or advanced age. While only around 4% of individuals aged 20 to 44 years have diagnosed or undiagnosed diabetes, almost 30% of individuals 65 years of age or older have this condition (CDC, 2011). Impaired fasting glucose is defined as a fasting pre-prandial glucose level between 100-125mg/dL. Impaired glucose tolerance is determined during an oral glucose tolerance test (OGTT) and is diagnosed based on a two hour postprandial glucose level between 140-199mg/dL (ADA, 2009).

The Nutrition Transition

Diabetes and other Nutrition-related Non-communicable Diseases are becoming increasingly common worldwide as countries shift from a traditional to

a more “Western” dietary profile through a process called the Nutrition Transition (Popkin, 2004). Often this transition occurs due to globalization and increase in access to new “Western” foods. Traditional diets are typically considered to be healthful and comparatively low energy, containing little fat and saturated fat but abundant in fiber, complex carbohydrates, fruits and vegetables (Winham, 2009). Conversely, the Western diet contains ample high fat and high carbohydrate foods with comparatively low nutrient density to many traditional food patterns (Popkin, 2001). With the Nutrition Transition often comes a reduction in the consumption of traditional foods like beans, vegetables and whole grains and an increase in consumption of animal products such as meat and dairy (Popkin, 2001). Epidemiological studies have associated low legume consumption with increased rates and prevalence of chronic diseases including T2D (Leterme, 2002; Darmadi-Blackberry, Wahlqvist & Kouris-Blazos, 2004; Bazzanno et al., 2001). Inclusion of culturally familiar beans in the therapeutic diets of immigrants and minorities with T2D may decrease postprandial glycemic variability, and improve dietary compliance and quality of life (Knight et al., 2006; Vijan et al., 2004; Caban, Walker, Sanchez & Mera, 2008; Jimenez-Cruz, Loustaunau-López & Bacardi-Gascón, 2006).

Dietary Acculturation

After immigration to a new country, individuals typically acculturate to the predominant culture in that country during a multidimensional process called acculturation. Acculturation is defined as the adopting of the cultural pattern of

the host country such as language, religion and cultural practices (Satia-Abouta, Patterson, Neuhouser & Elder, 2002). Dietary acculturation refers to the adopting of the predominant food patterns of the dominant country by immigrant minority individuals. This is a complicated, dynamic, non-linear process.

Immigrants may lose the peripheral and perhaps even secondary foods common to their traditional diets but often retain the primary staple foods such as rice and bread (Satia-Abouta et al., 2002). The evening meal may continue to contain traditional foods but breakfast and lunch may be comprised of “Western” foods. Frequently plant protein foods like beans and grain foods are replaced by animal products. Those with a higher level of education, income and similar physical characteristics as those in the host country are less likely to experience cultural isolation than those who move to monocultural enclaves with similar individuals from their home country (Satia-Abouta et al., 2002). Intakes of fruit, vegetables, rice and beans have been found to decrease with acculturation in Latino immigrants (Ayala, Baquero & Klinger, 2008). Conversely, fast food and fatty foods were found to increase with an increase in acculturation measures. Therefore, retention of traditional dietary patterns can be more beneficial for recent immigrants as acculturation to a more “Western” style diet has been associated with the development of many chronic diseases, including diabetes (Satia-Abouta et al., 2002).

Prevalence

As of 2011, 25.8 million people had diabetes, although only 18.8 million were ever formally diagnosed with the disease (CDC, 2007). Individuals with T2D make up the majority of those with diabetes (ADA, 2009). The number of diabetes diagnoses is expected to further increase in the future due to a heightened prevalence of overweight, obesity, poor dietary habits and sedentary lifestyles. One may be diagnosed with T2D if they meet the following criteria: fasting glucose ≥ 126 mg/dL, casual glucose level ≥ 200 mg/dL and/or 2 hour postprandial glucose level ≥ 200 mg/dL (ADA, 2002).

It is estimated that close to 79 million American adults ages 20 and older have pre-diabetes, a condition that greatly increases the risk that they will develop full-blown diabetes in the future if glycemic control is not maintained via positive changes such as weight loss, dietary alterations and an increase in physical activity (CDC, 2011; Mahan & Escott-Stump, 2008). Pre-diabetes may be diagnosed due to the presence of impaired fasting glucose and/or impaired glucose tolerance. Impaired fasting glucose is defined as fasting glucose levels between 100-125 mg/dL and impaired glucose tolerance is defined as a 2 hour postprandial glucose level between 140-199 mg/dL (Mahan & Escott-Stump, 2008).

Risk factors

A diverse group of risk factors have been associated with the development of T2D. Some of these include: advanced age, overweight or obesity (BMI

$\geq 25\text{kg/m}^2$), a lack of physical activity, and being part of a high-risk racial or ethnic group such as African Americans, Native Americans, Latinos, Alaskan Natives or Pacific Islanders. The presence of certain conditions such as dyslipidemia (HDL < 35 mg/dL or triglycerides > 250 mg/dL), hypertension, gestational diabetes (delivering a macrosomic infant ≥ 9 lbs at birth), polycystic ovary syndrome, impaired fasting glucose and impaired glucose tolerance have also been connected to an increased risk of T2D (Mahan & Escott-Stump, 2008).

Symptoms/Complications

Individuals with T2D may initially have no disease symptoms. As the disease gradually progresses they may, however, experience acute warning signs such as polyphagia, polyuria, weight loss, fatigue, irritability, and blurred vision (ADA, 2002). Diabetic ketoacidosis is not a frequently seen symptom among those with T2D because their level of insulin production exceeds that of those with type 1 diabetes (ADA, 2009). Long term complications of diabetes include: heart disease, diabetic retinopathy, nephropathy, peripheral neuropathy and dementia. Acute and chronic diabetic complications have been associated with consistently high blood glucose levels, especially in the postprandial absorptive state (Rizkalla, Bellisle & Slama, 2002). Consistent glucose management is needed to prevent both acute and chronic diabetic complications.

Carbohydrate Metabolism

T2D results from deficits in carbohydrate metabolism. Carbohydrates are an important macronutrient group responsible for many functions in the body.

They are the body's main energy source, exist as energy reserves in the form of glycogen or fat and provide needed dietary fiber and vitamins and minerals to the human diet (Gropper, Smith & Groff, 2009).

Carbohydrate Types

Simple carbohydrates include the monosaccharides and disaccharides.

Monosaccharides are single carbohydrate units. Three types of monosaccharides exist: glucose, fructose and galactose. Glucose is the body's main energy source and the primary monosaccharide in the blood (Gropper et al., 2009). Glycogen, a storage form of carbohydrate found in the liver and skeletal muscle, is made of highly branched glucose units (Gropper et al., 2009). Fructose is a monosaccharide located in fruit and galactose is found in milk products.

Disaccharides consist of two monosaccharide units. These include sucrose, lactose and maltose. Sucrose, also known as table sugar, is a combination of glucose and fructose. Lactose is made up of glucose and galactose and is located in milk products. Maltose is a disaccharide consisting of two glucose units. It is produced by the breakdown of larger starch units and can be found in beer and other fermented beverages (Gropper et al., 2009).

Complex carbohydrates consist of the oligosaccharides and polysaccharides. Oligosaccharides are short chains of 3-10 monosaccharide units found in foods such as beans and whole grains (Gropper et al., 2009).

Oligosaccharides cannot be digested by human enzymes but can be broken down by bacteria found in the gastrointestinal system.

Polysaccharides include starch, glycogen and cellulose. Starch is the main form of carbohydrate storage in plants. There are two types of starch: amylose and amylopectin. Amylose is the unbranched form of starch consisting of many glucose units linked by alpha 1-4 glycosidic bond. Amylopectin contains both alpha 1-4 linkages and alpha 1-6 branch points (Gropper et al., 2009). Amylopectin is responsible for 80-85% of starch, while amylose makes up the other 15-20% (Gropper et al., 2009). Glycogen is the storage form of glucose in animals, consisting of extensively branched glucose units. Cellulose is also present in plants, but is used to promote cell structural integrity. This polysaccharide is made up of glucose units with beta 1-4 glycosidic bonds.

Carbohydrate Digestion

Carbohydrate digestion begins in the mouth using the enzyme salivary alpha amylase. This enzyme is released from the salivary glands and serves to hydrolyze the alpha 1-4 linkages found in amylose starch. Digestion continues in the small intestine with the primary used in carbohydrate digestion, pancreatic alpha amylase. This enzyme is released from the pancreas and serves to break down alpha 1-4 glycosidic bonds. This action produces the smaller carbohydrate molecules maltose and limit dextrans (Gropper et al., 2009). These molecules are further hydrolyzed to disaccharides and monosaccharides at the intestinal brush border. The enzyme lactase is responsible for cleaving the disaccharide lactose, sucrase hydrolyzes sucrose, maltase breaks down maltose and isomaltase

hydrolyzes the alpha 1-6 bonds of isomaltose (where the branches of amylopectin originated) (Gropper et al., 2009).

Carbohydrate Absorption

Di and monosaccharides are absorbed at the intestinal brush border throughout the small intestine. Glucose and galactose enter the intestinal mucosa through the SGLT1 transporter. This transporter uses the sodium/potassium ATPase pump and requires two sodium ions per glucose/galactose molecule (Gropper et al., 2009). Fructose is absorbed by facilitated diffusion using the glucose transporter GLUT5. Following absorption, all of the monosaccharides enter the portal blood through the glucose transporter GLUT2. They then enter the liver where they are either metabolized or released into the blood. Fructose and galactose are converted to glucose in the liver or used to make energy or other substances such as amino acids. In the liver glucose may be used for energy, converted to glycogen through a process called glycogen synthesis, used to create fatty acids, or amino acids or released into the blood (Gropper et al., 2009).

At the peripheral tissues, glucose enters using through a number of specific transport proteins, either through active transport using SGLT proteins or through facilitated transport using GLUT proteins (Gropper et al., 2009). Twelve GLUT transport proteins exist, although only GLUT 4 is insulin regulated. The primary GLUT transporters include varieties 1, 2, 3, 4, 5 and 7. GLUT 1 is found in the red blood cells and fetal tissues, GLUT 2 is found in the liver, kidney, pancreatic beta cells, and small intestine, GLUT 3 is found in the brain, GLUT 4

is found in the muscle, heart and adipose tissues, GLUT 5 is found in the intestines and kidneys. However, it is not currently known where GLUT 7 is located within the body. GLUT 4 transport proteins allow for glucose-responsive tissues to receive this nutrient. Metabolic alterations produced by insulin resistance may make these transporters less active (Gropper et al., 2009).

T2D results from progressive insulin resistance at the glucose-responsive tissues, primarily skeletal muscle. It is thought that this resistance occurs after insulin has bound to the cells but before the insulin-binding signal can be processed by the cell (Gropper et al., 2009). This may be due to inadequate production and/or use of the GLUT glucose transporters. The mRNA for GLUT4 has been found to be reduced in the adipose of individuals with insulin resistance. This also reduces the number of cellular transporters and subsequently reduces the amount of glucose that can get in (Gropper et al., 2009).

Treatment methods for Diabetes

Overview of pharmacologic methods

By CDC estimates, 58% of those with T2D treat their condition through the use of oral hypoglycemic agents (CDC, 2011). These medications are often prescribed when lifestyle modifications fail to bring about long term glycemic control. A variety of non-insulin treatment options currently exist for individuals with T2D, including: biguanides, the insulin secretagogues sulfonylureas and meglitinides, thiazolidinediones, DPP-4 inhibitors, alpha glucosidase inhibitors and two recently approved injectable hormonal medications. These medications

may be combined as they have multiple modes of action and can be more effective used together.

Biguanides

This research study will be limited to individuals who are managing their blood glucose using the biguanide metformin (Glucophage). This medication works at the liver to reduce glucose production, decreases glucose absorption at the intestine and increases glucose uptake and use at the peripheral tissues to lower insulin resistance (ADA, 2002; ADA, 2011). Metformin does not produce hypoglycemia or hyperinsulinemia but may result in abdominal pain and diarrhea if taken on an empty stomach (ADA, 2011).

Insulin Secretagogues

Insulin secretagogues include sulfonylureas and meglitinides (ADA, 2009). These medications act directly upon the beta cells of the pancreas to heighten insulin production. They also work at the tissues to increase insulin sensitivity. Sulfonylureas include first generation medications such as Tolbutamide (Orinase) and second generation medications including glimepiride (Amaryl), glipizide and glyburide (DiaBeta) (ADA, 2009).

Thiazolidinediones

Thiazolidinedione medications such as pioglitazone (ACTOS) and rosiglitazone (Avandia) work to reduce insulin resistance at both the hepatic and peripheral tissues through activation of peroxisome proliferator activated (PPAR) receptors throughout the body (ADA, 2011). PPAR receptors regulate the

transcription of insulin responsive genes to improve glucose sensitivity (ADA, 2009). Regular liver enzyme tests are required when taking these medications.

DPP-4 Inhibitors

Sitagliptin (Januvia) and saxagliptin (Onglyza) are part of a category of medications known as DPP-4 inhibitors. These medications act on GLP-1, a compound that reduced blood glucose concentrations. DPP-4 inhibitors extend the half-life of GLP-1, thereby lowering blood glucose without causing hypoglycemia (ADA, 2011).

Alpha Glucosidase Inhibitors

Alpha glucosidase inhibitors postpone glucose absorption by delaying carbohydrate digestion (ADA, 2002; ADA, 2009). Medications that fall under this category include acarbose (Precose), and meglitol (Glyset). These medications do not affect insulin sensitivity or secretion and have been found to delay diabetes progression when used in individuals with impaired glucose tolerance (Chiasson et al., 2002). Beans lower the GI of the diet and have been shown to replicate the action of alpha glucosidase medications. This may be potentially due to their fiber, amylose starch and phytonutrient content (Sievenpiper et. al, 2009).

Non-Insulin Injectable Medications

Byetta, or exenatide, is a unique type of injectable hormonal medication called an incretin mimetic. It is often used with individuals who have not achieved glycemic control with oral medications such as metformin and/or sulfonylureas. This medication replicates exendin-4 and works to increase insulin secretion when

blood glucose levels are high (ADA, 2011). Byetta is injected with meals and has been found to produce weight loss and glycemic control when used appropriately. Side effects can include nausea, and hypoglycemia if taken in conjunction with a sulfonylurea medication (ADA, 2011).

Symlin, or pramlintide, imitates amylin, a hormone that is also synthesized by the pancreatic beta cells. Amylin works in concert with insulin and glucagon to promote glycemic control. Symlin is approved for individuals with type 1 diabetes and T2D who are not reaching their goal HbA1c values through use of insulin injections. This medication is also injected with meals and has been shown to produce weight loss and nausea (ADA, 2011).

Dietary treatment methods

Dietary methods are often used previous to or during treatment with other diabetes medications to promote long term glycemic control. These methods have fewer side effects than oral medications and can be adapted to one's individual dietary preferences. It has been shown that T2D can be prevented through lifestyle changes such as proper diet and regular exercise (Knowler et al., 2002). The Diabetes Prevention Program study found that lifestyle changes including a low-energy low calorie diet and regular exercise were more effective (58% reduction versus 31% for the metformin arm) in lowering diabetes incidence over a 2.8 year follow-up than regular intake of metformin or placebo (Knowler et al., 2002). Many individuals with T2D experience difficulty adhering to lifestyle changes and knowledge alone does not equate to positive behavior modifications

(Knight et al., 2006). Dietary isolation from friends and family through an inability to eat culturally important foods is a major adherence obstacle (Caban et al., 2008; Rusveld, Pavlik, Jibaja-Weiss, Kline & Gossey, 2009; de Groot et al., 2003). Inclusion of traditional foods, such as beans, within T2D dietary recommendations can help to increase dietary adherence and improve glycemic control.

Beans and are often included in various food categories (e.g. starchy vegetables, vegetables protein sources) as part of T2D diet prescriptions. However, little evidence exists regarding their actual promotion, or lack thereof, by Registered Dietitians and other healthcare practitioners (Desrochers & Brauer, 2001). The American Diabetes Association encourages bean consumption for individuals with T2D, considering them to be a starchy vegetable and a “Diabetes Superfood” due to their low GI values and ample micronutrients (ADA, 2008; ADA, 2011; Leterme, 2002). The ADA states that the type of carbohydrate consumed affects postprandial glucose secondary only to the amount of carbohydrate consumed and that those with T2D should choose carbohydrate foods with a low GI, such as beans, whenever possible (ADA, 2008).

Carbohydrate Counting

Carbohydrate counting is a widely used dietary treatment method for those with T2D. The American Diabetes Association recommends some form of Carbohydrate Counting as the first step to achieving glycemic control through dietary measures. This method promotes mindfulness of carbohydrate

consumption and division of carbohydrate foods into 15 gram intervals in order to improve blood glucose control (ADA, 2011). Initially, a range of 45-60 grams of carbohydrate are recommended per meal. Beans are included as carbohydrate containing foods and their consumption is recommended in ½ cup serving sizes. As one discovers the level of carbohydrate and specific foods that affect their glucose levels, they can adjust their intake accordingly. One's carbohydrate intake may also need to be changed with alterations to one's medications or exercise frequency/duration.

ADA Exchange List

The American Diabetes Association Exchange List is a system of food exchanges that assists diabetic individuals with meal planning. Dietary information is provided for over 700 food items in a booklet compiled by the American Diabetes Association (Geil, 2008). Food items are divided by category and serving sizes. Four categories (carbohydrates, meat and meat substitutes, fats and alcohol) and eight subcategories are included, along with their estimated carbohydrate, protein, fat and caloric content (Geil, 2008). Beans are included in ½ cup serving sizes both within the starch and plant-based protein food groups. Carbohydrate foods are divided into starches such as breads, cereals, starchy vegetables, fruits, milk as well as sweets, desserts, other carbohydrates and nonstarchy vegetables (Geil, 2008). The meat and meat substitutes grouping includes four sub-categories that differ in their fat and caloric content: lean, medium-fat, high-fat and plant-based proteins. An index is available within the

Exchange List booklet for easy access to specific food items. This method for dietary control may be somewhat daunting at first due to the complexity of meal planning, but would provide one with excellent oversight into what they consume daily.

The Plate Method

The Plate Method or “Create Your Plate” is a process recommended by the American Diabetes Association to promote portion control and healthier food choices. “Create Your Plate” encourages those with T2D to divide their plate into three sections: half of the plate designated for non-starchy vegetables such as lettuce or green beans and a quarter of the plate for starchy foods and meat or meat substitutes, respectively (ADA, 2011). However, unlike the ADA Exchange List, beans are included only within the starchy foods category and are recommended to be consumed in moderation.

Glycemic Index

The glycemic index model was developed in the 1980’s as a means of classification for the glycemic response of carbohydrate-containing foods (Jenkins et. al, 1981; Wolever, Jenkins, Jenkins & Josse, 1991). The GI refers to the increase in blood glucose after consumption of carbohydrate foods compared to the blood glucose increase from consumption of a reference food, often glucose or white bread. GI values are determined through calculation of the iAUC for blood glucose of both the test and reference foods, preferably in the same participant to avoid potential glucose deviations. Low GI foods typically have a GI below 55

(Foster-Powell & Miller, 1995). Moderate GI foods have values between 55 and 70 and high GI foods have values in excess of 70 (ADA, 2002). Beans, as a whole, are considered to be low GI foods and have been found to produce some of the lowest glucose responses of any carbohydrate containing foods (Foster-Powell & Miller, 1995). The glycemic load is the GI of each individual food multiplied by the amount of each food consumed (Riccardi, Rivellese & Giacco, 2008). Controversy remains regarding the GI concept. Some researchers have stated that the GI may hold little clinical significance due to variability in glycemic responses and GI measures across research trials (Hollenbeck & Coulston, 1991; Jenkins & Jenkins, 1995). Conversely, other studies have shown that chronic consumption of low glycemic load diets containing low GI foods improve the metabolic parameters of healthy individuals and those with T2D and reduce one's risk of developing the disease (Riccardi et al., 2008; Granfeldt, Wu & Bjorck, 2006).

Meal planning using the Glycemic Index

The American Diabetes Association suggests that those with T2D increase their consumption of foods with a low or moderate GI values as a simple way to improve glycemic control (ADA, 2011). This method can be easily combined with Carbohydrate Counting. Using this method, one would utilize GI information for specific foods from the ADA's website or from other educational materials and intentionally choose foods with a low GI value (i.e. below 55) or a moderate GI value (between 55 and 70) instead of high GI foods.

Beans

Definition

Legumes are part of the *Leguminosae* family which includes beans, lentils, dried peas and peanuts. These foodstuffs have been defined as “annual leguminous crops yielding from one to twelve grains or seeds of variable size, shape and colour within a pod” by the Food and Agriculture Organization of the United Nations (FAO, 1994). Beans are the large seeds of flowering plants included in the *Fabaceae* family. There are an extensive number of bean types around the world, including around 619 genera and 18,815 species (Albala, 2007). Bean types such as black-eyed peas and mung beans are encompassed within the *Vigna* species and soybeans are included within the *Glycine* species. Within the *Fabaceae* family, the common bean (*Phaseolus vulgaris*) refers to a large group of beans originating in the New World. *P. vulgaris* beans are most often used for food consumption and include hundreds of different subtypes such as the navy bean, green beans and string beans (Albala, 2007). Pinto beans, black beans and dark red kidney beans, also members of the *P. vulgaris* species, are some of the most commonly consumed beans in the United States and around the world.

History

Legumes are also often referred to as beans or pulses, depending on one’s geographic location. The words used to describe legumes have been taken from many parts of the world. The word legume is derived from the Latin “to gather”, *legere*. The origin of the word bean is not known, although it is thought to be

derived from the German word *bauno* or Old Saxon *bona* (Albala, 2007). Pulse is a synonym for bean that was derived from the Roman bean dish called *puls*. Carbon dating has provided records of bean consumption dating back to around 11,000 BCE (Albala, 2007). Lentils are the bean type first thought to be domesticated in approximately 7,000 BCE. The species *Phaseolus vulgaris* originated in Mexico and South America, seen first around 6,000 BCE in the mountains of Peru (Albala, 2007). Two sub-species were domesticated in different areas: the *aborigineus* in Peru and the *mexicanus* in Mexico. Beans were vital foodstuffs among the historical societies of the New World, where maize was a central staple food. Bean consumption provided the necessary amino acids (lysine, isoleucine and tryptophan) not present in maize and supplemented a diet containing little meat from sources such as guinea pigs, turkeys and wild animals (Albala, 2007).

The Mayans of South America consumed black beans in dishes containing local ingredients such as chili, epazote, ground squash seeds and green onions. The Aztecs also grew beans using traditional terraced agricultural techniques. Many of their dishes continue to be consumed today within Mexican cuisine. In North America, beans of the *P. vulgaris* species were also a staple food for the Native Americans. The Iroquois were said to rely on the “three sisters,” or corn, beans and squash as their primary food sources (Albala, 2007). A frequently prepared food within the Cherokee tribe was a bean and corn meal loaf that was boiled in hickory leaves. This foodstuff and many other traditional foods

containing foods are still consumed today (Albala, 2007; Dilis & Trichopoulou, 2009).

Nutrient content and health benefits of beans

Beans contain a number of nutrients that are beneficial for human health. These include, but are not limited to, insoluble, fermentable and soluble fiber, amylose starch, vegetable protein, calcium, iron and folate (Leterme, 2002; Sievenpiper et al., 2009). Beans are good source of the amino acid lysine, but are low in methionine, making them an ideal supplement to grain products when combined using a grain to bean ratio of 1:2 or 1:4 (Leterme, 2002). Consuming beans with lysine deficient but methionine rich cereal grains, such as rice, can help to overcome the amino acid inadequacies of both foods (Albala, 2007). Beans also contain non-nutritive dietary fiber and resistant starch that may slow digestion and absorption of carbohydrate, as shown by Bednar et al. in an animal model (Bednar, Patil, Murray, Grieshop, Merchen & Fahey, 2001). Beans are also rich in a variety of phytochemicals and antinutrients such as phenols, enzyme inhibitors and phytates. These compounds have also been shown to slow carbohydrate digestion in a manner similar to alpha glucosidase and alpha amylase inhibitors (Sievenpiper et al., 2009; Tormo et al., 2004). Beans also help to reduce the GI of the diet which has been shown to improve glucose control.

Current consumption patterns

Bean consumption in traditional diets

Beans are commonly consumed traditional foods within many cultures around the world. They have been customarily eaten with cereal grains or maize in societies dating back to the Aztecs, Mayas, Incas and local native populations within Central America (Leterme & Munoz, 2002). Of the countries in Central and South America, Brazil consumes, on average, the highest amount of beans per person. Black beans are the primary bean type consumed in this country (Leterme & Munoz, 2002). Individuals in Nicaragua consume the highest amount of beans worldwide with an estimated consumption of approximately 25kg per capita (Leterme & Munoz, 2002). Rice is often consumed with beans as part of traditional meals in many cultures around the world (Sugiyama et al., 2003).

Traditional consumption of beans and legumes has been established due to factors such as geographical isolation and a reluctance to give up long-standing dietary practices. Beans and legumes are consumed more frequently by those of lower socioeconomic status and by those who live in rural areas (Leterme & Munoz, 2002; Kabagambe, Baylin, Ruiz-Narvarez, Siles & Campos, 2005). Conversion from a rural to urban lifestyle often leads to a reduction in available time and resources to prepare traditional foods. Urban living in general is associated with both an increase in consumption of processed foods and animal-derived foods with and a decrease in consumption of traditional foods such as beans (Leterme & Munoz, 2002). Furthermore, many immigrants experience a

Nutrition Transition to a more Western style diet in their host country, resulting in the gradual replacement of high nutrient-density traditional food with less healthful processed high energy food items (Popkin, 2004).

Bean consumption trends in the United States

Bean consumption in the United States is much lower than what is recommended by health organizations and also lower than consumption levels in other countries around the world (Guenther, Dodd, Reedy & Krebs-Smith, 2006). Between the years of 1997 and 1999, the USDA's Economic Research Service estimated that individuals in the US consumed 7.7 pounds of beans per year (Lucier, Lin, Allshouse & Scott Kantor, 2000). According to NHANES 1999-2000 data, only a minority of US adults (7.9%) consumed beans daily and the average daily consumption ranged from 0.1 to 0.3 ½ cup servings (Mitchell, Lawrence, Hartman & Curran, 2009). Lucier et al. (2000) reported that, within the 1994-1996 Continuing Survey of Food Intakes by Individuals, 14% of individuals included ate a minimum of one food including beans over the two day recording period. In contrast, 33% of Hispanic individuals consumed beans over those two days. However, lentils, split green peas, yellow peas and lima beans were not included in the survey, potentially reducing the reported intake (Lucier et al., 2000). In the United States, the South and West regions have been found to be the largest consumers of dried beans. Navy beans, pinto beans and lima beans were found to be consumed by those of lower socioeconomic status (Lucier et al., 2000).

Recommended intake

The 2010 Dietary Guidelines for Americans recommends consumption of 1 ½ cups of beans per week or around ¼ of a cup daily (USDHHS & USDA, 2010). The Dietary Guidelines for Americans considers beans to be unique in that they can be counted either a vegetable or a protein food. Beans are considered to be a vegetable for omnivores and a protein food for vegetarians (alterations to overall recommendations for this group includes 1.4 oz. per day for lacto ovo vegetarian and 1.9 oz. daily for vegans). However, most people do meet the Dietary Guideline recommendations (Guenther et al., 2006; Mitchell et al., 2009). The USDA MyPyramid includes dry beans and peas both as part of the vegetable and meat and beans groups (USDA, 2011). Included in this category are dry beans such as pinto, black and dark red kidney beans and peas such as chickpeas, black eyed peas and lentils. The USDA recommends including dry beans and peas in the vegetable group if one consumes meat (USDHHS & USDA, 2010). Dry beans and peas are included in the meat and beans group for those who consume limited meat or those who are vegetarian.

Glycemic response studies using beans

Beans consumed alone as part of a mixed meal

Akhtar and colleagues (1987) tested the glycemic response to seven traditional Pakistani food combinations of beans and white flour chapatti bread or rice in comparison to a control meal in 14 healthy men and an equivalent number of male subjects with T2D. The control meal included bread, egg fried in ghee

and milk. Four bean, bread and milk treatments were also tested. These included chickpeas, lentils, mung beans (*P. radiatus*), and urad dahl (*P. mungo*). The lentil and urad dahl treatments were then repeated with white rice substituted for white bread. Participants with T2D took their diabetes medications (oral agents and/or insulin injections) 5-10 minutes prior to test meal consumption and all treatments were eaten within 10 minutes. Blood glucose concentrations were assessed using fingerstick blood samples collected at fasting and at 30 minute intervals over a three hour testing period. Analysis included peak increase in blood glucose concentrations and area under the glucose response curve calculations. The rice, milk and urad dahl meal produced the highest glycemic response, followed by the control meal in both participant groups ($P \leq 0.05$) (Akhtar, Asim & Wolever, 1987). The chickpea meal produced the lowest glycemic response in the healthy participants but an intermediate response in those with T2D. The bread and lentil meal produced the lowest average iAUC for the T2D participant group and the second lowest response for the healthy participant group. The rice and bean meals had, on the whole, a higher glycemic response than the bread and bean meals. The researchers thought this may have been due to the use of polished rice, which has been shown to produce a higher glycemic response than parboiled rice and the chapatti bread (Akhtar et al., 1987).

Bornet et al. (1987) looked at the glycemic responses to six different foods consumed by 18 persons with non-insulin-dependent T2D. Those taking oral hypoglycemic agents were allowed to participate. Test meals included kidney

beans, lentils, white rice, wheat flour spaghetti, potato and white bread in servings providing 50g of available carbohydrate. Each of these carbohydrate rich foods was consumed alone with coffee (meal A) and in a mixed meal containing coffee, cheese and butter (meal M). A 50g oral glucose tolerance test was used as control. Each of the six foods was tested by three participants. Venous blood samples were collected at baseline and at 30, 60, 90, 120 and 180 minutes following treatment consumption. The researchers found that the GI values for the foods when consumed alone were highest for bread (95%), followed by potato (74), spaghetti (64), white rice (56), lentils (30) and kidney beans (23). Mixed meals had a similar order of GI ranges but were typically around 20% higher than the carbohydrate foods consumed alone (Bornet et al., 1987). The mixed meals also produced an increased insulinemic index but the treatments continued to be in the same order despite this increase. Incremental changes with regard to blood glucose and insulin as well as iAUC values were not discussed in detail within the manuscript. Dietary treatments were not matched for dietary fiber content, causing the researchers to surmise that the fiber content of the beans and lentils could have promoted the significantly lower glycemic effect (Bornet et. al, 1987).

Indar-Brown and colleagues (1992) tested the glucose and insulin response to consumption of five ethnically unique mixed meals in 25 healthy participants and 17 individuals with non-insulin dependent T2D. A 50g oral glucose tolerance test was compared to mixed meals of American, Yemenite, Syrian, Polish and Moroccan origin. Each of the meals was standardized to

contain 50g of carbohydrate, 15g of protein and 15g of fat and was consumed within 15 minutes. Two of these meals also included legumes: Syrian (lentils), and Moroccan (chickpeas). Blood samples were collected at baseline and at 30, 60, 120 and 180 minutes after the meals were consumed. Outcome measures included glucose, insulin, total cholesterol and triglyceride concentrations. GI values for the meals and iAUC for glucose and insulin were also calculated. Each of the mixed meals produced a lower iAUC for blood glucose than control in the T2D group ($P \leq 0.01$). However, the Syrian dish containing lentils was found to have the lowest predicted GI (49), observed glycemic and insulinemic index values as well as a significantly lower glucose iAUC than both the glucose control and the other test meals within the T2D group ($P \leq 0.01$) (Indar-Brown, Noreberg & Madar, 1992). IAUC for insulin was also lower for this treatment than the Polish treatment, but not for the control treatment. The researchers suggested that it was the fiber content of the Syrian meal (although the type of fiber was not specified) along with the fiber and starch content of the lentils that exerted the glucose lowering effects in these subjects (Indar-Brown et al., 1992).

Jang and colleagues (2001) studied the glycemic and insulinemic effects of consuming a whole grain diet containing black beans over a 16 week period compared to a typical South Korean diet containing refined rice. Participants included a group of 76 men with coronary artery disease. Twenty one of these individuals were found to have T2D. Individuals consuming the bean treatment were instructed to substitute refined rice with the a whole grain and black bean

powder, brown rice, barley, whole black beans, vegetables and seasonings.

Participants came to the test site after each 16 week treatment period to take part in a 75g oral glucose tolerance test. Venous blood samples were taken before and 30, 60, 90 and 120 minutes after the glucose test. Fasting glucose and areas under the curve for glucose and insulin were found to be significantly reduced following the whole grain diet in those without T2D ($P \leq 0.000$, 0.000 and 0.022 , respectively). However, in the T2D group, only fasting glucose and glucose iAUC were found to be significant following the whole grain treatment period ($P \leq 0.023$ and 0.021) (Jang, Lee, Kim, Park & Lee, 2001).

Nestel, Cehun and Chronopoulos (2004) conducted both acute and long-term six week trials comparing chickpea and wheat based meals in healthy adults. Treatments were matched for an available carbohydrate content of 50 grams. Nineteen individuals participated in the acute study and a similar number ($n = 20$) took part in the long-term trial. Both trials had an unblinded crossover study design. In the acute study, meals were consumed within 10 minutes and blood samples were collected at baseline and at 30, 60, 120 and 180 minutes posttreatment. Glucose concentrations were found to be significantly lower at 30 and 60 minutes following the chickpea based meal than after the control meal ($P \leq 0.05$). Significance was also found for plasma insulin at 120 minutes postmeal ingestion ($P \leq 0.05$). The long term study included three treatments: the participant's normal, or baseline, diet, a higher fiber chickpea based diet and a wheat based diet. Blood samples were collected in a similar manner to the acute

study during 2 consecutive days at the end of each six week treatment period. Significant differences between test meals were not seen for glucose or insulin during the long term study, however. This lead the researchers to hypothesize that the insulin sensitivity improvements seen in an acute setting may not continue over longer term periods in healthy individuals without apparent insulin resistance (Nestel et al., 2004).

Panlasigui et al. (1995) assessed the glycemic response and GI of five test meals containing 50 grams of available carbohydrate from chickpeas, black beans, mung beans, white beans or pigeon pea, as compared to a control meal containing white bread. Eleven healthy individuals participated in this study. All treatments were consumed within 15 minutes and capillary blood samples were collected at fasting and 15, 30, 45 and 60 minutes post meal ingestion. All legume treatments were found to have a significantly reduced glycemic response in comparison to the white bread control meal ($P \leq 0.01$). The glycemic response to the chickpea meal was the lowest of any legume and was significantly lower than the mung beans, black beans and pigeon peas. The chickpea treatment was also found to have the lowest GI of any legume (13.87%), followed by white beans (19.48), black beans (29.91), pigeon peas (30.99) and mung beans (44.38) (Panlasigui, Panlilio & Madrid, 1995). It was assumed that the fat content of the chickpeas produced the lowered glycemic effect and that the fiber, amylose and antinutrient content of the beans resulted into the lower glycemic response than the control meal (Panlasigui et al., 1995).

Tappy et al. utilized test meals containing 50 grams of carbohydrate from either white kidney bean flakes or a potato flake control meal in six healthy subjects and four individuals with T2D (Tappy, Wursch, Randin, Felber & Jequier, 1986). Venous blood samples were collected and analyzed for glucose and insulin concentrations at fasting and then every 30 minutes for three hours posttreatment for the T2D group and over four hours in the healthy participant group. Individuals with T2D were instructed not to take their medications prior to test days and all meals were consumed within a 20 minute time period. The healthy subject group experienced a significantly attenuated increase in both glucose ($P \leq 0.01$) and insulin ($P \leq 0.001$) 30 minutes after bean consumption in comparison to control. However, the bean flakes produced an increase in postprandial glucose and insulin after 150 minutes posttreatment compared to control in this group. In the healthy participants, the average glucose and insulin iAUC calculations were also lower for the bean flakes than for the control ($P \leq 0.02$). In the T2D group, the glucose and insulin levels after bean consumption were also lower than that for the control, but these values were not statistically significant (Tappy et al., 1986). A more gradual increase in glucose and insulin was also seen in this group compared to the healthy participants.

Winham, Hutchins and Melde studied the glycemic and insulinemic response to pinto beans, navy beans and black-eyed peas in low dose (~1/2 cup) and high dose (~1 cup) amounts compared to a high GI meal containing a bagel and orange juice in healthy participants aged 20 to 65 years. The cooked beans

were mechanically altered to form a paste which was provided on a bagel with mayonnaise and seasonings along with orange juice. Treatments were matched for a carbohydrate content of approximately 120 grams. Venous blood samples were collected at fasting and at 30, 60, 90 and 120 minutes post meal ingestion and subsequently analyzed for glucose and insulin content. Significant differences between the control and bean treatment meals were not seen with regard to glucose or insulin measures. The authors hypothesized that this lack of significance was seen due the destruction of the bean cell walls that occurred during treatment preparation (Winham, Hutchins, & Melde, 2007).

Individual bean types used in the study

Three beans of the *P. vulgaris* species were used in this research study including pinto beans, black beans and dark red kidney beans.

Pinto beans

A number of large scale studies have reported that the most frequently consumed bean containing foods include plain pinto beans, refried pinto beans and chili containing pinto beans (Mitchell et al., 2009; Lucier et al., 2000). Winham, Hutchins and Melde also used pinto beans in a study looking at the glycemic and insulinemic responses of three bean types prepared as a spread in normoglycemic adults. A significant difference in the glucose response of study participants was not seen, potentially due to the treatment preparation (Winham et al., 2007).

Black beans

Black beans are one of the most commonly consumed bean types in the United States, especially in the southern areas of the country (Lucier et al., 2000). They are also popular within Latin American countries including Brazil, Cuba and other areas of South and Central America (Leterme & Munoz, 2002). Black beans are often paired with rice in these areas (Kabagambe, Baylin, Ruiz-Narvarez, Siles & Campos, 2005). Jang and colleagues (2001) tested a whole grain meal containing black bean flour against the participants' usual diet containing refined rice in a group of individuals with coronary artery disease and T2D. They found a 24% and 14% decrease in fasting glucose and insulin, respectively after the 16 week whole grain treatment period (Jang et al., 2001).

Dark red kidney beans

Dark red kidney beans are also popular bean types within the United States (Lucier, 2000). Bornet and colleagues (1987) included kidney beans as one of six carbohydrate rich treatments in individuals with T2D. However, it was not stated whether these kidney beans were of the red or white variety. The beans were provided alone and in mixed meals and venous blood samples were collected at fasting and every half hour for a three hour period and analyzed for GI, insulinemic index and iAUC for glucose and insulin. The GI of this treatment provided alone was found to be the lowest of all six treatments (23) and significantly reduced compared to bread ($P \leq 0.001$), potatoes ($P \leq 0.01$) and white rice ($P \leq 0.05$).

Beans consumed as part of a low glycemic index diet

A number of studies have included beans as part of a low GI diet. These treatments have found such diets to be beneficial with regard to the glucose and insulin response to such foods (Brand-Miller, Hayne, Petocz & Colagiuri, 2003; Miller, 1994).

Brand and colleagues assessed the short and long term metabolic effects of consuming a low GI diet containing beans, as compared to a similar diet containing foods with a high GI using outcome measures including HbA1c, 8 hour postprandial glucose, fasting glucose levels and lipid profiles (Brand, Colagiuri, Crossman, Allen, Roberts & Truswell, 1991). Sixteen subjects with non-insulin-dependent T2D were recruited for this randomized crossover study. Six subjects managed their glucose levels through diet and the remaining ten used oral hypoglycemic agents. The two diets were matched for fiber, carbohydrate, protein and fat but differed in their expected GI values by approximately 15% (Brand et al., 1991). The researchers found that the low GI diet lowered the participants' HbA1c values by around 11% and that the glucose iAUC was significantly lower for the low GI diet in comparison to the high GI diet. However, significance was not found for lipid or fasting glucose levels (Brand et al., 1991).

Fontvieille and colleagues looked at the metabolic effects of consuming a low GI diet in comparison to a high GI diet over a five week period in 18 diabetic individuals (Fontvieille, Rizkalla, Penfornis, Acosta, Bornet & Slama, 1992). This

crossover study used 12 individuals with Type 1 diabetes and 6 individuals with non-insulin dependent T2D. Participants were fed a low GI and a high GI diet for 5 weeks each. The low GI diet contained legumes, pasta and rice and the high GI diet contained ample amounts of bread and potatoes. HbA1c, body weight and medication requirements were not significantly different between diets (Fontvieille et al., 1992). However, metabolic parameters including fructosamine, fasting glucose levels and postprandial glucose levels two hours after meal consumption were significantly lower after consumption of the low GI diet in comparison to the high GI diet ($P \leq 0.05$, 0.02 and 0.02, respectively).

Jarvi et al. (1999) conducted a study looking at the glucose and insulin concentrations and incremental areas under the curve for glucose and insulin in two groups of 10 adults ($n = 20$) with non-insulin dependent T2D. A low GI diet (average of 56.8%) was compared to a high GI diet (average 82.7%) over consecutive 24 day periods in an unblended crossover study design. Both diets contained a variety of beans (e.g. white beans, red kidney beans and brown beans) and utilized 1 week repeated menus over the study period (Jarvi, Karlstrom, Granfeldt, Bjorck, Asp & Vessby, 1999). Study participants came to a metabolic ward for 2 days at the start and end of each 24 day dietary period. Blood samples were obtained at fasting and at 60, 120, 180, 240, 300, 360, 480 and 540 minutes afterward. Regular meals adhering to the low or high GI requirements were provided. The researchers found that the glucose iAUC following consumption of the low GI diet was 31% lower ($P \leq 0.05$) than after the high GI diet and that the

iAUC for insulin was 27% lower ($P \leq 0.01$). Fasting blood glucose levels were significantly reduced by approximately 14% following both diet periods ($P \leq 0.001$). Jarvi et al. (1999) concluded that reducing the GI of the diet would be useful in management of T2D.

Rivellese and colleagues (1980) conducted a crossover study looking at the glycemic effects of consuming various amounts of fiber in three different meals. Study participants include eight individuals with T2D, four of whom were using insulin and four who were using diabetes medications. Participants were confined to a metabolic ward during the study and consumed each diet for ten days. Blood samples were obtained at 0800, 1200, 1400, 1800 and 2000 hours at the end of each ten day period. The first diet, A, included 53% carbohydrate and 16 grams of fiber and was intended to act as a control treatment that replicated the standard Italian diet. The second diet, B, contained the same amount of carbohydrate but included 54 grams of fiber. This treatment contained approximately 45% of dietary fiber from an assortment of beans, peas and lentils. A third diet, C, included less carbohydrate than the first two (42%) and a fiber content of 20 grams. It was determined that glucose levels two hours after meal consumption were significantly lower after the high fiber meal B was consumed compared to diets A ($P \leq 0.01$) and C ($P \leq 0.05$). The glucose average for the 5 timepoints was also significantly lower ($P \leq 0.05$) for the high fiber diet than for the control or low carbohydrate diets (Rivellese, Riccardi, Giacoo, Pacioni, Genovese, Mattioli & Mancini, 1980).

Schafer et al. conducted an acute study to determine the effects of dried pea consumption on the glycemia of nine individuals with T2D (Schafer, Schenk, Ritzel, Ramadori & Leonhardt, 2003). Participants who were taking medications known to affect blood glucose levels such as oral diabetes medications and insulin were excluded from the study. A mixed meal containing dried peas was compared to two similar meals, one containing potatoes and another with a combination of the two foods. All meals were matched for a total carbohydrate content of 36 grams. The researchers found that postprandial glucose and insulin concentrations were significantly lower for the test meal containing peas in comparison to the potato meal. Glucose incremental areas under the curve calculations were found to be significantly lower for the pea meal than for the potato control ($P \leq 0.01$), but the insulin iAUC did not hold significance. Schafer and colleagues concluded that the consumption of high-fiber, low GI foods such as dried peas should be recommended for individuals with T2D to assist in postprandial glucose control (Schafer et al., 2003).

Suitability of Rice as a Reference Food

A study conducted by researchers in Japan (Sugiyama et al., 2003) looked at the GI values of commonly consumed Japanese food items and a comparison of a white rice control meal to a glucose challenge to determine if white rice was a suitable reference food for GI research studies. Japanese adults were fed dietary treatments (either white rice or white rice and a treatment food) containing 50g of carbohydrate. Capillary blood glucose concentrations were determined and the

iAUC for glucose calculated for each treatment in all participants. The correlation between the iAUC values of the two control meals (glucose and white rice) was statistically significant at $r = 0.853$. Therefore, the researchers concluded that a white rice control meal is a useful alternative for use in glycemic response studies (Sugiyama et al., 2003).

The Second Meal Effect

Many glycemic response studies do not control for the previous evening's meal consumed by their participants. Studies have shown that one's evening meal can help to moderate morning glucose levels (Granfeldt, et al., 2006; Wolever, Jenkins, Ocana, Rao & Collier, 1988). Granfeldt and colleagues (2006) assessed morning glucose and insulin after consumption of three evening meals, each containing 50g of available carbohydrate: barley kernels, spaghetti or a control meal containing white bread. Fourteen healthy, normal weight participants were included in the study. Capillary blood samples were taken at fasting and 15, 30, 45, 70, 95, 120 and 180 minutes after consumption of a standardized bread based meal. This meal contained 50g of available starch and was consumed within 10 minutes. The GI and insulinemic index for the spaghetti and barley kernel treatments were determined and blood samples were assessed for glucose and insulin. IAUC for glucose and insulin was also calculated between 0 and 95 minutes and 0 and 120 minutes postprandial. The GI and insulinemic index of the treatments were found to be 54 and 53 for spaghetti and 53 and 50 for barley kernels. Average fasting glucose concentrations were not found to significantly

differ between treatments. However, 30 minute postprandial glucose levels and 45 minute postmeal insulin concentrations following consumption of the evening meal containing barley kernels were significantly lower than the other two treatments ($P \leq 0.05$) (Granfeldt et al., 2006). Postprandial iAUC for glucose between 0-95 minutes was also found to be significantly reduced by 23% for the barley kernel treatment compared to the spaghetti and white bread. The researchers concluded that the composition of the evening meal affected the morning glycemic and insulinemic response (Granfeldt et al., 2006).

Three similar studies were conducted by Wolever and colleagues (1988) to test the glycemic results of six separate evening meals in healthy adults. The first study compared a high GI meal containing glucose and soybeans against a low GI meal including red lentils. Glucose levels were assessed in the morning after a breakfast containing glucose was consumed. The second study included meals containing whole wheat bread (low GI) or white bread (high GI) in ten healthy volunteers. Glucose values were determined after a breakfast containing cornflakes and 2% milk was consumed. The third study used mixed meals as evening test treatments in a group of six healthy men. The low GI meal consisted of glucose, red lentils, barley, peas, cheese and margarine and the high GI meal consisted of potato, bread, peas, cheese and margarine. A cornflake and milk breakfast was provided. In studies one and two, glucose was assessed using capillary blood obtained by fingerstick and analyzed using an YSI glucose analyzer. Venous samples were assessed for glucose concentrations in the third

study. It was determined that the participants' morning glucose levels were significantly lower after consumption of the low GI meals in comparison to the meals with higher GI values. While the aforementioned studies were conducted in individuals without T2D, this study will provide standard evening meals to all participants. These meals will fit within the participants' individual diets to avoid any variation in morning glucose levels due to potential changes in evening meal consumption.

CHAPTER 3

MATERIALS AND METHODS

Participant Selection

Adults aged 35-70 years old from the college campus and neighboring communities with T2D controlled by metformin or diet/exercise were recruited to participate through the use of fliers (Appendix A), newsletters and e-mail announcements. Participant eligibility was determined through telephone oral interviews or through online screening (www.surveymonkey.com). Persons using insulin or other diabetic drugs besides metformin were excluded to minimize potential confounding from multiple hypoglycemic medications with various modes of action. All participants were physician-diagnosed with T2D at least 6 months prior to starting the study. The method of diabetes control had to be the same for at least 3 months prior to study entry. Eligible participants had an HbA1c value of <10% at screening and had no evidence of condition(s) that would influence their ability to complete the study as determined from medical record analysis. Those with weight changes +/- 5kg within 6 months, women who were either pregnant or breastfeeding, and individuals with allergy to beans or latex were excluded during the screening process.

It was determined that a minimum of nineteen (19) diabetic adults was needed to test our study hypotheses at a power level of 80% and an error value of 0.05, as indicated through power analysis (Appendix B). Twenty-eight individuals with T2D enrolled in the study. Twenty-one successfully completed the study in

its entirety, but four participants were excluded from final analysis. Three of the latter participants did not fully disclose medical conditions until after they started the study and were ineligible. An additional participant was determined noncompliant with the pre-test date dietary protocol during data entry. Data from 17 individuals (9 men and 8 women) aged 38-70 years were analyzed (**Table 1**).

Study Design

Participants provided written, informed consent prior to their participation in the study (Appendix C). A HIPAA Waiver of Authorization (Appendix D) was also signed for researcher access to participant medical records, in order to obtain information related to diabetes diagnosis, diabetes medication prescription (if applicable), weight changes, concurrent disease diagnoses and blood chemistry parameters including: blood glucose, insulin, HbA1C and lipid levels. Participant medical records were accessed twice: once shortly after the initial screening appointment and again 3-6 months after study completion. Medical records access was obtained through the use of a participant-signed form faxed directly to their primary care physician (Appendix E). This study protocol was approved by the ASU Institutional Biosafety Committee of the Office of Research Integrity and Assurance, IRB Protocol # 0907004180 (Appendix F).

Subject screening and recruitment occurred on a rolling basis. Screening protocol consisted of completion of a medical history screening form (Appendix G), general and HIPAA informed consent forms and a brief food screener including questions created by the researchers that inquire about bean

consumption as well as the Block Fat and Fruit and Vegetable Screeners (Appendix H). The 2005 Block FFQ was completed once during the study (Appendix I). During the screening appointment, subjects were also trained on how to complete the FFQ and the 24-hour dietary records prior to each test day (Appendix J).

Participants who met the screening criteria were given a subject number, randomized to a treatment group and scheduled for their first test day. Participants were also provided with a packet of information to assist them with study compliance. This packet included printed calendars with their scheduled test days, detailed participant instructions and researcher contact information; copies of their consent forms; and 24-hour dietary record forms.

Participants were administered four different test meals separated by one week as part of this randomized crossover study (clinical trial number: NTS0020). At the time of study consent, participants selected a commercial frozen entrée meal, e.g. Lean Cuisine or Marie Callender's, which they consumed for each of the four pre-test evening meals. These meals were obtained from local markets and meal composition (namely, carbohydrate content) coincided with the subjects' normal dietary intake pattern as determined from pre-study discussion with them. Nutrient composition of these meals is provided in **Table 2**. Consuming the same evening meal the night before testing helped to reduce any variation in glycemic response due to the second meal effect (Venn & Mann, 2004; Brand-Miller et al., 2003). The researchers provided the participants with

the frozen meal and instructions for completing a 24-hour dietary recall for the day before testing. Since alcohol and caffeine can affect blood glucose levels, these substances were restricted for 24 hours prior to each test day. Light, moderate and heavy physical activity was also limited 24 hours prior to testing to prevent exercise-related glycogen depletion (Gropper et al., 2009).

After consuming the provided meal on the eve of testing, participants drank only water until they arrived at the test site 12 hours later. Upon arrival at the test site, participants were weighed using a digital scale (Seca Model 880, Hamburg, Germany) and confirmed fasting. Standing height was assessed at the first test day meeting using a wall-mounted stadiometer (SECA, Ontario, CA). Next, a fasting capillary blood sample (~100µl) was collected from a fingerstick using Safe-T-Fill[®] Lithium Heparin Mini Capillary Collection centrifuge tubes (RAM Scientific, Yonkers, NY). After the fasting blood sample collection, participants consumed one of the four bean/rice test meal options within 5-10 minutes under researcher supervision. Whole blood glucose concentrations at baseline and at 30, 60, 90, 120, 150, and 180 minutes post-treatment were analyzed using a Yellow Springs Instrument 2500 Stat Plus Analyzer (YSI Life Sciences, Yellow Springs, OH) immediately after blood collection. After all blood samples have been collected (approximately 4 hours total), subjects were provided a \$30 gift card to either Target or Wal-Mart and were given their next pre-test meal. Participants who completed the study in its entirety received an additional \$40 gift card to the above retailers.

Test meals

Participants received the four test meals in random order. Three meals included one of the commercially canned *P. vulgaris* market classes: pinto beans, black beans or dark red kidney beans along with ~1/2 cup of white rice. A control meal containing 180 grams or approximately 7/8 cup of cooked white rice was included as the fourth meal. Enriched long grain white rice was used as part of the test meals due to its comparatively high GI value to the beans used and for its suitability as a reference food (Sugiyama et al., 2003). Nutrient composition of these meals is provided in **Table 3**. The amount of the beans was standardized to provide 50 grams of available carbohydrate. Available carbohydrate was calculated by subtracting the dietary fiber from the total carbohydrate value listed on the manufacturer's nutrition facts label (Schakel et. al, 2008; Foster-Powell, 2002; Asp, 1995). This number coincides with the 45-60g carbohydrate per meal recommended by the American Diabetes Association (ADA, 2009). Fifty grams of carbohydrate is a standard amount used to test glucose response among persons with and without T2D (Bornet et al., 1987; Josse, Kendall, Augustin, Ellis & Jenkins, 2007; Panlasigui et al., 1995). White rice was prepared in an electric automatic rice cooker (Black & Decker RC400, Miami Lakes, FL). Based on the manufacturer's instructions and using the measuring container provided with the rice cooker, the rice and water amounts were standardized for preparation consistency. Proportions of 945g of bottled drinking water was added to 420g of dry white rice and steamed for around 30 minutes. The canned beans (Bush

Brothers & Company) were drained and heated in a microwave for 1 minute at medium power. The test meal was prepared by weighing out the cooked rice, then adding the appropriate weight of warmed beans, and 15 grams of the drained can liquid for moisture. The digital scale was tared to zero after addition of each food item (Salter, Fairmont, MN).

Randomization of dietary treatments

Participants received a total of four dietary treatments (pinto beans, black beans and dark red kidney beans with white rice and a white rice control) spaced a minimum of five days apart, as part of a 4x4 randomized block design. Dietary treatments (Appendix K) were randomized using the RAND random number function in Microsoft Excel (2007). This function produces a random number between 0 and 1 and a column including treatments 1 through 4 was sorted by these numbers.

Laboratory analyses

Screening blood tests including HbA_{1c}, total cholesterol, HDL-cholesterol, triglyceride as well as LDL-cholesterol calculations were obtained for participants lacking these values in their medical records within three months previous of their screening date. Blood samples for these tests were analyzed by Sonora Quest (Tempe, AZ). HbA_{1c} was determined from a venous whole blood sample contained in a lavender top EDTA tube. The blood sample was then analyzed through photometric assay. Lipid values were assessed using whole blood samples collected in a red top Vacutainer[®] serum barrier tube. Total

cholesterol and triglyceride values were determined through photometric assay. HDL cholesterol levels were determined through homogenous enzyme immunoassay (Sonora Quest, Tempe, AZ).

Capillary blood samples were collected by a trained graduate student using Safe-T-Fill[®] Lithium Heparin Mini Capillary Collection 125µl centrifuge tubes (RAM Scientific, Yonkers, NY). Whole blood samples were analyzed for glucose content using the Yellow Springs Instrument Stat Plus Analyzer (YSI Life Sciences, Yellow Springs, OH) immediately after blood collection. This instrument can evaluate glucose concentrations up to 900mg/dL using an Immobilized Enzyme Biosensor (Appendix L). Glucose levels are determined through the following process: the sample is treated with the enzyme glucose oxidase, the enzyme becomes immobilized between two membranes and is oxidized to form D glucono- δ -lactone and hydrogen peroxide. The hydrogen peroxide is then filtered through the second membrane and oxidized by a platinum electrode. The electrical current produced by the oxidization reaction is proportional to the glucose concentration of the sample.

Statistical analyses

The SPSS Statistics software version 19.0 (IBM Corporation, Somers, NY) was used for statistical analyses. The Food Processor SQL (ESHA Research, Salem, OR) was used for analysis of the 24-hour dietary recall data and the Block dietary screeners for fat and fruit and vegetable intake were analyzed online via the NutritionQuest website (www.nutritionquest.com). The level of significance

was $P \leq 0.05$. Time point differences between fasting and post-treatment glucose concentrations were determined and iAUC calculations were completed using the trapezoidal rule (**Table 4**) (Sheng, Lefebvre, Fastenau, Tak Piech & Waltzman, 2005). Incremental areas under the curve for blood glucose were assessed between 0-60, 0-120, and 0-180 minutes postprandial for all participants. Effect size, or the “substantive significance” of the treatments were calculated and assessed using Cohen’s (1988) interpretation (Hill, Bloom, Black & Lipsey, 2008). As part of this interpretation, a small effect size ranges from 0.20 to 0.50, a medium effect is between 0.50 and 0.80 and a large effect size is a value ≥ 0.80 . Multiple analysis of variance (MANOVA) for repeated measures with time and diet as factors was used to establish differences between the four meal treatments. Following a significant MANOVA, paired t tests were used to identify differences between specific bean treatments and the rice control. Independent t tests were also used to analyze differences by gender and treatment type. Continuous variable data are reported as mean \pm standard error.

TABLE 1. Baseline characteristics of study participants ($n = 17$)

Variable	Mean \pm SEM	Range
Age (y)	58.6 \pm 2.3	(38-70)
Race/Ethnicity: n, (%)		
Non-Hispanic	16 (94%)	
White	14 (82%)	
Other	3 (18%)	
Weight (kg) ¹	93.4 \pm 4.0	(67.8-120.9)
Height (cm) ¹	170.7 \pm 2.1	(154.4-184.5)
BMI (kg/m ²) ¹	31.9 \pm 1.0	(26.9-38.8)
TC (mg/dL)	172.9 \pm 7.5	(119.0-220.0)
TG (mg/dL)	156.4 \pm 18.8	(68.0-328.0)
HDL-C (mg/dL)	44.4 \pm 1.9	(36.0-65.0)
LDL-C (mg/dL)	98.9 \pm 5.6	(59.0-133.0)
HbA1c (%)	6.5 \pm 0.1	(5.8-7.8)

¹ Values obtained at study entry. BMI = body mass index, TC = total cholesterol, TG = triglycerides, HDL-C = high density lipoprotein cholesterol, LDL-C = low density lipoprotein cholesterol, HbA1c = hemoglobin A1c

TABLE 2. Macronutrient composition of evening meals consumed prior to test days¹

Characteristics	Value	Range
Energy (kcal)	517.4 \pm 29.0	(300.0-710.0)
Total fat (g)	24.8 \pm 3.1	(9.0-43.0)
Saturated fat (g)	10.6 \pm 1.6	(2.0-17.0)
Cholesterol (mg)	118.4 \pm 16.3	(25.0-205.1)
Carbohydrate (g)	39.6 \pm 2.5	(26.0-53.0)
Total fiber (g)	5.7 \pm 0.5	(3.0-11.0)
Protein (g)	33.6 \pm 2.0	(13.0-44.0)

¹ All values are means \pm standard error of the mean (SEM) (range)
kcal =kilocalorie, mg=milligram, g=gram

TABLE 3. Descriptive characteristics of test meals¹

Characteristics	White Rice Control	Pinto Beans/ Rice	Black Beans/ Rice	Kidney Beans/ Rice
Total weight (g)	180.0	305.0	243.0	267.0
Rice (g)	180.0	128.0	128.0	128.0
Beans (g)	---	177.0	115.0	139.0
Energy (kcal)	232.0	273.9	257.9	277.2
Total carbohydrate (g)	49.5	59.7	55.5	58.7
Available CHO (g)	48.8	49.7	49.7	49.7
Rice (g)	48.8	34.7	34.7	34.7
Beans (g)	---	15.0	15.0	15.0
Fiber (g)	0.7	10.0	5.8	9.1
Protein (g)	4.8	11.6	9.6	10.9
Fat (g)	0.5	0.4	0.8	0.4

¹All values are means \pm standard error of the mean (SEM) (range).
kcal = kilocalorie, mg = milligram, g = gram

CHAPTER 4

RESULTS

Descriptive statistics at study entry for the 17 participants are shown in **Table 1**. A majority of the participants were White (82%) and non-Hispanic (94%). Participants were also, on average, considered to be obese according to their BMI values ($31.8 \pm 1.0 \text{ kg/m}^2$). Fourteen participants used the medication metformin to manage their T2D and the remaining three used dietary methods and/or physical activity. Data were analyzed by gender and treatment type prior to analysis of the pooled data. Body weight and BMI were not found to significantly differ between test days. No significant differences were seen between those in the diet/physical activity group ($n = 3$) and those taking metformin ($n = 14$) with regard to descriptive statistics, time point glucose differences or iAUC values. However, there may not have been adequate power to detect such differences due to small sample size.

Some differences were seen between gender groups with regard to descriptive characteristics, timepoint glucose differences and iAUC values. As expected, body mass and height were significantly higher for the men ($P = 0.012$ and $P = 0.000$, respectively) than for the women. Conversely, total cholesterol was found to be lower in the men than women (155.8 ± 9.7 versus 192.3 ± 7.3 , $P = 0.010$). Significance was also seen between gender groups for a few timepoint glucose differences (**Table 4**). These significant differences occurred at 30 minutes for the black bean and rice treatment ($P = 0.012$) and at 60 minutes for

the control meal and black bean and rice meal ($P = 0.036$ and $P = 0.023$, respectively). In all cases, the men were found to have lower values than the women. With regard to glucose iAUC, the male participants were also found to have lower values than the female participants for the black bean and rice treatments between 0-60 minutes as well as 0-120 minutes ($P = 0.006$ and $P = 0.038$, respectively) (**Table 5**).

When participant data were pooled, time point glucose differences (**Table 6, Figure 1**) were found to be significantly lower at 90 minutes postprandial for the pinto beans and rice ($P = 0.011$), black beans and rice ($P = 0.004$), and dark red kidney beans and rice ($P = 0.040$) compared with the white rice control meal. Similar results were seen at 120 minutes ($P = 0.000$, 0.001 and 0.026 for the pinto beans, black beans, and dark red kidney beans respectively) and 150 minutes postprandial ($P = 0.000$, 0.002 , and 0.0049). The black beans and rice meal was also found to be significantly lower than control at the 180 minute time point ($P = 0.015$). The 90 minute difference had an effect size of 0.469 (small, power = 0.729), meaning that approximately 47% of glucose measures at this time point were affected by bean consumption. The effect sizes were larger at the 120 and 150 minute glucose time points with η^2 values of 0.634 (medium, power = 0.960) and 0.554 (medium, power = 0.873), respectively.

Incremental areas under the curve for blood glucose were assessed between 0-60, 0-120 and 0-180 minutes postprandial for all participants (**Table 7, Figure 2**). Significant differences were found between the control meal and the

pinto beans and rice and black beans and rice at 0-120 ($P = 0.009$ and 0.002) and 0-180 minutes ($P = 0.017$ and 0.007). Effect sizes via repeated measures ANOVA were found to be 0.431 (small, power = 0.656) and 0.501 (small, power = 0.787) for the iAUC at 120 and 180 minutes, respectively.

The participants' evening meal choices and 24-hour dietary recalls were analyzed for macronutrient content using the Food Processor SQL (EHSA Research, Salem, OR) (**Table 8**). Carbohydrate intake was found to be significantly higher during the pre-pinto beans and rice days as compared to the other treatments ($P = 0.032$). However, no other macronutrients during these pre-test days were found to differ significantly from one another.

TABLE 4. Mean \pm SEM incremental changes in blood glucose for all treatments by gender¹

	White Rice Control	Pinto beans and white rice	Black beans and white rice	Kidney beans and white rice
<i>Men (n = 9)</i>				
Fasting glucose (mg/dL)	96.2 \pm 5.2	100.1 \pm 4.7	101.8 \pm 4.5	96.8 \pm 4.3
30 min glucose (mg/dL)	49.4 \pm 2.9	42.5 \pm 5.7	42.4 \pm 4.1*	51.3 \pm 6.0
60 min glucose (mg/dL)	64.7 \pm 5.4*	62.3 \pm 7.0	59.9 \pm 5.9*	67.6 \pm 7.6
90 min glucose (mg/dL)	53.3 \pm 6.7	41.9 \pm 9.9	41.4 \pm 7.3	45.1 \pm 7.4
120 min glucose (mg/dL)	32.0 \pm 5.3	14.8 \pm 8.5	18.3 \pm 7.4	25.8 \pm 7.7
150 min glucose (mg/dL)	14.7 \pm 6.1	2.6 \pm 5.4	4.0 \pm 6.3	9.7 \pm 6.5
180 min glucose (mg/dL)	-0.0 \pm 6.9	-5.7 \pm 3.1	-8.9 \pm 5.5	-2.2 \pm 4.9
<i>Women (n = 8)</i>				
Fasting glucose (mg/dL)	102.4 \pm 7.4	106.5 \pm 5.1	102.1 \pm 7.1	103.7 \pm 7.5
30 min glucose (mg/dL)	60.8 \pm 7.4	55.4 \pm 7.3	63.5 \pm 6.4	56.0 \pm 8.0
60 min glucose (mg/dL)	85.2 \pm 7.3	77.9 \pm 8.3	79.1 \pm 4.4	78.5 \pm 6.1
90 min glucose (mg/dL)	69.3 \pm 9.0	50.7 \pm 5.4	53.0 \pm 6.0	57.3 \pm 6.9
120 min glucose (mg/dL)	42.3 \pm 8.0	23.6 \pm 5.9	25.5 \pm 6.3	31.9 \pm 5.6
150 min glucose (mg/dL)	20.1 \pm 6.8	6.1 \pm 3.8	4.9 \pm 4.2	10.3 \pm 5.0
180 min glucose (mg/dL)	1.6 \pm 5.4	-5.0 \pm 3.6	-7.9 \pm 5.0	-3.3 \pm 4.0

¹ All values are means \pm standard error of the mean.

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

Min=minutes, mg/dL=milligrams per deciliter

TABLE 5. Postprandial areas under the curve for blood glucose by gender^{1, 2, 3}

	White Rice Control	Pinto beans and white rice	Black beans and white rice	Kidney beans and white rice
<i>Men (n = 9)</i>				
0-60 min	2461.1 ± 119.6	2225.3 ± 216.0	2160.8 ± 159.8**	2552.4 ± 270.8
0-120 min	5505.9 ± 422.5	4690.7 ± 589.7	4587.4 ± 495.8*	5319.4 ± 635.5
0-180 min	6575.2 ± 653.1	5191.5 ± 755.9	5198.9 ± 684.8	6208.8 ± 860.3
<i>Women (n = 8)</i>				
0-60 min	3103.0 ± 301.5	2829.2 ± 323.7	3089.8 ± 249.9	2855.5 ± 300.5
0-120 min	7095.6 ± 744.6	5871.1 ± 513.5	6248.6 ± 538.8	6231.5 ± 524.5
0-180 min	8406.2 ± 1038.9	6462.1 ± 550.7	6883.4 ± 670.2	7094.1 ± 614.3

¹ All values are means ± standard error of the mean. ² Mg * min/dL (calculated by the trapezoidal rule). ³ For variables in which the treatment x AUC interaction was significant, paired *t* tests were conducted to assess within-group change.

* *P* < 0.05, ** *P* < 0.01, *** *P* < 0.001

TABLE 6. Incremental changes in blood glucose for all treatments ($n = 17$)^{1,2}

Glucose Concentrations (mg/dL) ²	White rice Control	Pinto beans and white rice	Black beans and white rice	Kidney beans and white rice
Baseline	99.1 ± 4.4	103.1 ± 3.4	101.9 ± 3.9	100.1 ± 4.1
30 min	54.8 ± 4.0	48.6 ± 4.7	52.3 ± 4.4	53.5 ± 4.8
60 min	74.3 ± 5.0	69.6 ± 5.5	68.9 ± 4.4	72.7 ± 5.0
90 min	60.8 ± 5.7	46.0 ± 5.8*	46.9 ± 4.9**	50.9 ± 5.2*
120 min	36.8 ± 4.7	18.9 ± 5.2***	21.7 ± 4.8**	28.7 ± 4.8*
150 min	17.3 ± 4.5	4.2 ± 3.3***	4.4 ± 3.8**	10.0 ± 4.0*
180 min	0.8 ± 4.3	-5.4 ± 2.3	-8.4 ± 3.6*	-2.7 ± 3.1

¹ All values are means ± standard error of the mean (SEM).

² Incremental change refers to glucose at timepoint x – glucose at baseline

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

Min=minutes, mg/dL=milligrams per deciliter

TABLE 7. Postprandial areas under the curve for blood glucose ($n=17$)^{1, 2,3}

	White rice control	Pinto beans and white rice	Black beans and white rice	Kidney beans and white rice
0-60 min	2763.2 ± 170.0	2509.5 ± 199.0	2598.0 ± 181.8	2695.1 ± 199.0
0-120 min	6254.0 ± 448.0	5246.2 ± 409.9**	5369.2 ± 409.6*	5748.6 ± 420.1
0-180 min	7436.8 ± 622.4	5789.4 ± 488.7**	5991.6 ± 510.7**	6625.4 ± 534.6

¹ All values are means ± standard error of the mean (SEM).

² Mg * min/dL (calculated by the trapezoidal rule)

³ For variables in which the treatment x AUC interaction was significant, paired t tests were conducted to assess within-group change.

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

TABLE 8. Macronutrient composition of dietary intake 24 hours prior to test days
(n=17)¹

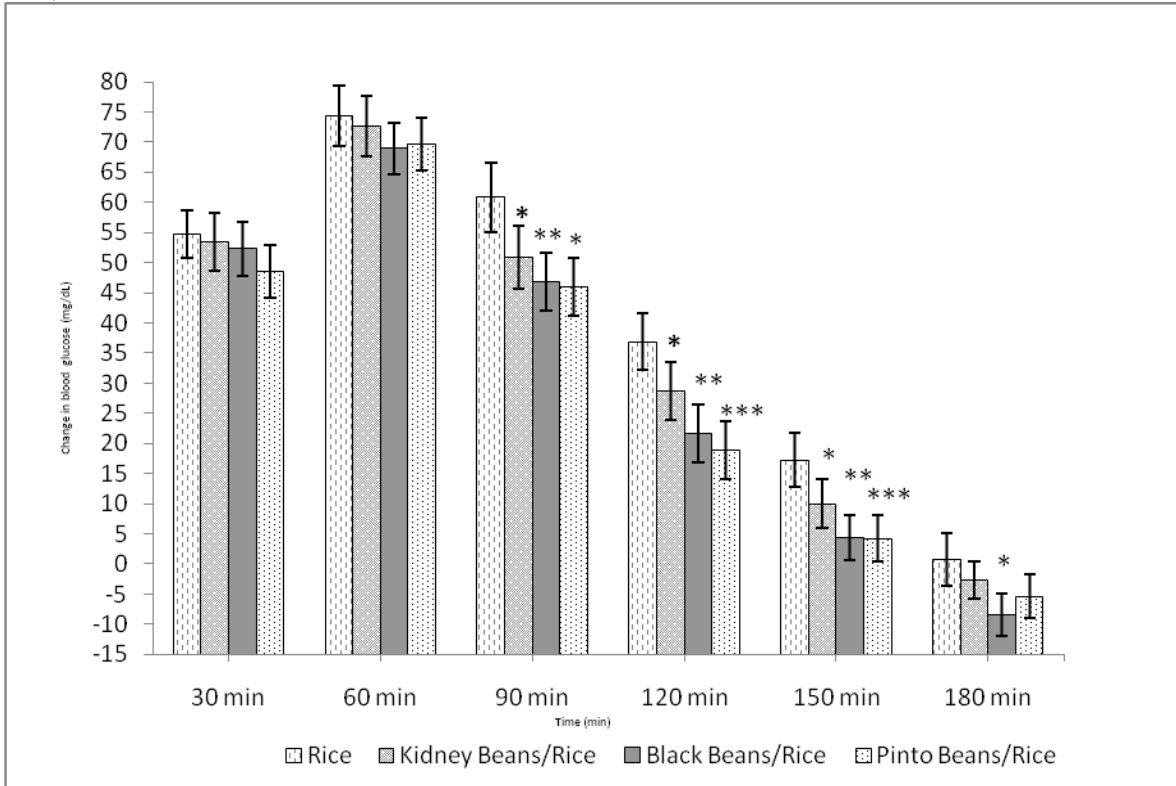
Nutrient	White rice control	Pinto beans and white rice	Black beans and white rice	Kidney beans and white rice
Energy (kcal)	1736.8 ± 135.6 (992.4-3114.7)	1840.5 ± 149.5 (1042.8-3243.4)	1560.1 ± 76.1 (1067.3-2292.7)	1611.3 ± 114.0 (1000.9-2529.0)
Total fat (g)	78.5 ± 7.9 (30.9-158.9)	73.2 ± 8.2 (33.5-148.0)	65.2 ± 4.7 (40.6-101.4)	68.9 ± 6.7 (21.1-128.5)
Saturated fat (g)	24.6 ± 2.3 (6.4-47.4)	25.2 ± 3.5 (6.9-62.4)	22.6 ± 2.0 (9.4-40.6)	24.8 ± 3.4 (5.9-60.1)
Cholesterol (mg)	271.6 ± 38.5 (102.7-693.5)	239.0 ± 32.9 (90.0-553.4)	293.6 ± 50.7 (97.7-749.8)	254.6 ± 33.6 (109.2-527.0)
Sodium (mg)	3619.1 ± 215.9 (2135.4-5465.3)	3958.1 ± 288.3 (2543.7-6762.9)	3542.7 ± 223.3 (2307.2-5482.5)	3612.2 ± 298.5 (1786.5-5835.3)
Potassium (mg)	1071.2 ± 131.8 (309.7-2375.4)	964.8 ± 133.5 (238.6-2084.4)	1039.7 ± 104.7 (341.3-1973.3)	1062.6 ± 142.9 (338.0-2737.9)
Carbohydrate (g)*	174.8 ± 16.6* (77.5-328.8)	212.0 ± 22.9 (112.9-415.3)	162.4 ± 14.4** (67.6-273.2)	166.0 ± 18.9** (48.2-354.6)
Total fiber (g)	20.6 ± 1.2 (14.7-28.0)	20.1 ± 1.8 (6.2-34.0)	20.1 ± 1.7 (9.6-34.9)	19.2 ± 1.7 (10.9-36.4)
Protein (g)	88.7 ± 6.4 (55.8-168.8)	91.3 ± 4.8 (58.0-124.4)	88.1 ± 4.6 (59.8-121.4)	86.4 ± 4.8 (55.5-122.7)

¹ All values are means ± standard error of the mean (SEM) (range)

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

kcal =kilocalorie, mg=milligram, g=gram

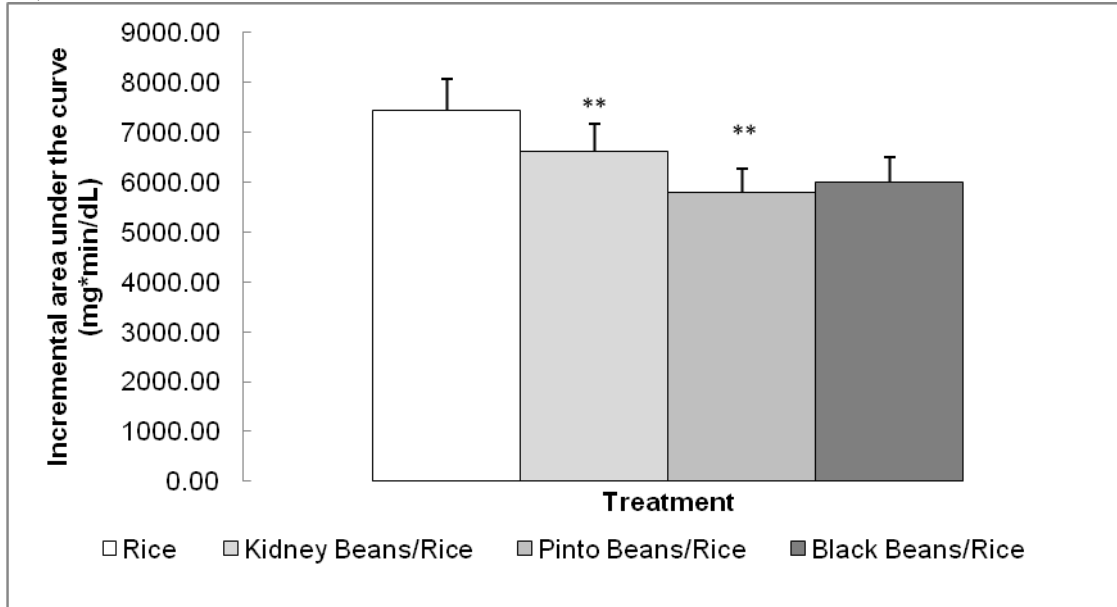
FIGURE 1. Influence of treatments on postprandial net glucose ($n = 17$)¹.



¹ All values are means \pm standard error of the mean (SEM).

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

FIGURE 2. Incremental area under the curve differences in net glucose ($n = 17$).^{1,2}



¹ All values are means \pm standard error of the mean (SEM). ² Mg * min/dL (calculated by the trapezoidal rule)

* $P < 0.05$, ** $P < 0.01$

CHAPTER 5

DISCUSSION AND CONCLUSION

This study found that bean and rice meals produce an attenuated glucose response in comparison to rice alone in equal available carbohydrate treatments. These results reinforce previous studies that show intermediate responses with mixed meals of high and low GI foods. These lower responses are favorable to the higher response produced by white rice alone, and can help prevent the detrimental effects of extended glycemic elevations. Prolonged elevated glucose levels contribute to the well-known macrovascular (cardiovascular disease and peripheral vascular disease) and microvascular (nephropathy, retinopathy and neuropathy) complications associated with T2D. Attenuating postprandial glucose changes by encouraging people with T2D to combine beans with a high GI food like rice can contribute to a lower risk for the complications associated with T2D. Also worthy of note is that all study treatments reduced the 2 hour postprandial glucose below 140 mg/dL, which is a goal value recommended by the International Diabetes Federation (Ceriello, Colagiuri, Gerich, Tuomilehto, 2008).

P. vulgaris beans such as those included in this study (pinto, black and dark red kidney beans) along with white rice is a traditional food combination consumed by many in the U.S. and around the world, particularly those in Latin America and countries within the Mediterranean and Middle East. Jimenez-Cruz and colleagues found that traditional Mexican foods like corn tortillas and pinto beans had a low GI, were satiating, and improved glycemic control in T2D adults

(Jimenez-Cruz et al., 2006). As this study demonstrates, the exclusion of cultural foods like the rice/bean combination may be unwarranted for persons with T2D. On the contrary, retention of traditional dietary patterns including beans may be beneficial to health, reduce T2D complications, and improve dietary adherence (Caban, Walker, Sanchez & Mera, 2008; Leterme, 2002; Jimenez-Cruz et al., 2006).

An e-mail survey of Canadian dietitians found that 68% of those surveyed stated that they recommend legume consumption to individuals with diabetes, in comparison to the 87% who recommended legumes to individuals with known cardiovascular disease (Desrochers & Brauer, 2001). The American Diabetes Association recommends taking “into account personal and cultural preferences” as a goal for T2D Medical Nutrition Therapy (ADA, 2008). However, it is not clear in the published scientific literature that culturally appropriate foods such as legumes are being recommended to individuals with diabetes in accordance with this goal.

The three *P. vulgaris* market classes exhibited different levels of glucose response. The pinto and black bean/rice combinations produced a lower glycemic response overall than the dark red kidney bean/rice meal despite the black beans lower total fiber content and the treatments being matched on available carbohydrate content. Differences in the specific fiber fractions of the three bean types may offer an explanation for the variation in glycemic response produced. There is some evidence that beans from the Andean center of domestication may

have lower levels of indigestible starch in comparison to beans with Mesoamerican origins like pinto and black. Lower levels of indigestible starch in kidney beans, therefore, would increase the rate of digestion relative to the other bean types (Ospina, 2000).

Phytochemicals and phytonutrients are associated with improvements in glycemic control (Sievenpiper et al., 2009). These characteristics in the beans are likely to vary, as well. In general, beans have high levels of phytate which may bind to calcium thus reducing it as a cofactor for amylase enzyme activity (Josse et al., 2007). Inhibition of alpha amylase by cooked *P. vulgaris* beans has approximated that of acarbose, a popular diabetes medication (Helmstadter, 2010). Sievenpiper et al. (2009) reported in a meta-analysis that long term use of some beans normalized HbA1c almost as well as acarbose in two other meta-analysis reports. Uncooked pinto beans were found to have higher levels of flavonoids than some other beans, and the sum of phenolic acids in the pinto beans was greater than chickpeas, split peas, lentils and a variety of broad beans (Kalogeropoulos, Chiou, Ioannou, Karathanos & Hassapidou, 2010). Data on black or red kidney beans were not reported. Pinto beans also reportedly contain high concentrations of antioxidants in comparison to chickpeas and other non *P. vulgaris* species (Halvorsen et al., 2002). The observed differences in effect of the three beans highlights the importance of investigating multiple bean varieties rather than assuming all are the same. Further mechanistic work is needed on these specific varieties as well.

This study demonstrates that culturally relevant *P. vulgaris* species such as pinto, dark red kidney and black beans attenuate the glycemic response to rice, a commonly consumed high GI food. As healthcare practitioners, it is vital that we are culturally competent and sensitive to the needs of others who are different from us. Cultural competency is the “ability to discover the culture of each client/patient and effectively adapt interventions to her or him” (Curry, 2000). Dietary recommendations, materials and counseling should be culturally sensitive and take into account valued traditional foods such as beans, especially when the scientific evidence supports their beneficial role in the diet.

Further research should be completed regarding the physical and chemical structure of various *P. vulgaris* bean types to attempt to address the observed differences in glycemic responses. While promoting traditional foods is a non-medical way to manage T2D, knowing which beans are most effective can help improve dietary adherence with an appropriate cultural twist.

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APPENDIX A
STUDY FLIER



Do you have Type 2 diabetes?

Research participants needed who are:

- ❑ Between 25 and 75 years of age
- ❑ Diagnosed by a physician as type 2 diabetic for at least 6 months
- ❑ Currently controlling their blood sugar through diet and or exercise or the use of oral medications
- ❑ Without any unresolved health conditions, diagnosis of gastrointestinal disease or pregnant or breastfeeding
- ❑ Willing to eat black beans, pinto beans and red kidney beans with rice
- ❑ Willing to come to ASU at the Polytechnic campus once a week for 4 weeks during the study (~4 hours per visit)

Participants will receive:

- ❑ A free evening meal prior to test days
- ❑ Personalized dietary analysis and nutrition counseling
- ❑ Nutrition education sessions including information about the use of beans in the diabetic diet, fun recipes, a food demonstration, activities, prizes and more!
- ❑ \$30 in gift cards for each test day you complete (Target or Wal-Mart) with a bonus \$40 if you complete all 4 test dates properly (\$160).

**Call or email for a screening appointment!
(480) 727-1352 or Sharon.V.Thompson@asu.edu**

Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352	Bean Study ASU Polytechnic Campus 480-727-1352
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APPENDIX B
POWER ANALYSIS

Sample Size Calculations

For 80 % ($\beta = 0.20$) power, $\alpha = 0.05$

$$n = \left[\frac{(Z_{1-\alpha} + Z_{1-\beta})\sigma}{\Delta} \right]^2$$

$$SD = SEM \times \sqrt{n}$$

Change in glucose (mg/dL) at 30 minutes from fasting values

$$N = [2.8 * 11.9 / 9.0]^2 = 11.71 = 12$$

$$N = [2.8 * 11.4 / 9.0]^2 = 12.58 = 13$$

Change in glucose (mg/dL) at 60 minutes from fasting values

$$N = [2.8 * 17.9 / 15.0]^2 = 11.16 = 11$$

$$N = [2.8 * 28.5 / 15.0]^2 = 28.30 = 28$$

Average = $16 \times 1.2 = 19.2 =$ at least 19 participants needed to account for 20% attrition

Sample size calculation data obtained from Johnson et al (2005) ($n = 11$ healthy adults) and Johnston et al (2004) ($n = 10$ individuals with type 2 diabetes)

APPENDIX C
INFORMED CONSENT

CONSENT FORM
EFFECT OF PINTO, BLACK AND DARK RED KIDNEY BEAN
CONSUMPTION
AS PART OF A MEAL ON POSTPRANDIAL GLUCOSE
IN ADULTS WITH TYPE 2 DIABETES

Introduction

Dr. Donna Winham, Assistant Professor, Department of Nutrition has invited your participation in a research study. The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research, and to record the consent of those who agree to be involved in the study.

Study Purpose

The purpose of the research is to determine the effect of different types of beans (pinto beans, black beans, dark red kidney beans) and rice on how much blood sugar rises after a meal. This is also known as the glycemic response. The study will also look at other blood biomarkers of chronic disease (i.e. lipids, insulin, antioxidants, vitamins, minerals).

Description of the Research Study

If you decide to participate, you will join a study that looks at the effects of eating beans on blood glucose levels in the blood. Your participation will initially involve going to the test site (the Nutrition Program at Arizona State University at the Polytechnic Campus) to complete a questionnaire about your recent food intake and a medical history screener in order to assess your health and diet status. Your signature on a separate HIPAA form will allow access to your medical records in order to obtain measures of your body weight and blood chemistry values including: blood glucose, insulin, HbA1c and cholesterol levels for a maximum period of 1 year before and up to 1 year after the study period. To access these records, a separate release of medical records form, signed by you, will be sent to your primary care physician. With your permission, we will access your medical records 2 times – once shortly after you enroll in the study, and a 2nd time 6-8 months after you complete the study. If you have not had a lipid panel or HbA1c test as part of your regular medical treatment within 30 days of your study enrollment, we will measure these as part of the study. An additional amount of blood will be taken while you are fasting on the 2nd or 3rd test date. Alternatively, you may be given a requisition order for these tests to be performed at Sonora Quest laboratories. All laboratory testing costs will be at the expense of the study.

Then, you agree to fast overnight for 12 hours (no food or drink with the exception of water) and report to the test site the following morning or scheduled day to provide a fasting blood sample to assess your blood glucose and

cholesterol concentrations. Your blood pressure along with measurements of height, weight and hip circumference will also be assessed on this day.

If you meet the health assessment criteria, and you agree to follow the experimental protocol, you will be eligible to participate in the study. The experimental protocol includes consuming a test meal ($\frac{1}{2}$ cup white rice + either $\frac{1}{2}$ c of pinto beans, black beans or dark red kidney beans or approximately $\frac{7}{8}$ cup of white rice) on each of the 4 test mornings. You will also record all foods and beverages consumed for the 24 hours prior to each test day, using a form provided by the researchers.

At the beginning of the study and on each testing day, your body weight and blood pressure will be recorded. An interviewer will also discuss your food intake records for the previous day at this time. These procedures will take around 30 minutes to complete. Finger stick blood samples will be collected while you are fasting, 30 minutes after you have finished the test meal, and then every half hour thereafter for a 3 hour period (0, 30, 60, 90, 120, 150, 180 minutes or 7 finger stick blood samples total). The time required to complete the experimental protocol on each of the testing days will be ~ 4 hours from start to finish. This includes 30 minutes for the above measurements and ~3.5 hours for the meal and blood draws. You must remain in the vicinity of the study site during this time.

You will consume a meal paid for by the investigators approximately 12 hours prior to each testing day. This meal will consist of a frozen prepared meal. The same meal selections will be consumed for the 4 pre-test evenings. You will then fast for 12 hours prior to each testing day in that you will not consume any food or beverage with the exception of water after 7 pm on the night prior to a testing day. During the final testing day you will complete a final diet questionnaire. Blood (identified only by your participant number) will be analyzed at the conclusion of each test day within the ASU Nutrition Department; what remains of the blood samples will be destroyed within 2 years of the completion of the study. Approximately 25 participants will be participating in this study and your testing times may overlap.

You will complete a Food Frequency Questionnaire, a questionnaire related to legume intake and a separate screener inquiring about your thoughts related to diabetes during screening. This will allow the researchers to determine the quality of your diet, your knowledge of beans and your feelings about diabetes. The questionnaires will also be mailed to you at the 3 months after you have completed the study to assess any changes.

One-on-one nutrition counseling will be provided to you after you have completed all 4 test days. You will receive a packet containing your blood values, dietary intake information and blood glucose responses to each test meals. Nutrition education sessions will be offered at the test site on various days following completion of the study. The sessions will include information about beans, how to include beans in a diabetic diet, a cooking demonstration and a variety of informative items to take home with you. These sessions are optional, although you and your adult family members are welcome to attend.

Risks

A trained graduate student will perform the capillary finger sticks for glucose analysis under standard and sterile conditions. Temporary bruising of the skin, a feeling of faintness, and/or a small degree of discomfort or pain are possible. As with any research, there is some possibility that you may be subject to risks that have not yet been identified, in addition to the potential risks associated with the blood draws as listed above.

Benefits

You understand that the possible benefits of your participation in the research include providing information helpful in the understanding of how bean consumption as part of a meal impacts the glycemic response to the meal. In addition, you will receive information about your dietary intake, cholesterol status and glucose responses to the test foods.

Confidentiality

All information obtained in this study is strictly confidential unless disclosure is required by law. The results of the research study may be published and used in presentations or reports, but the researchers will not identify you. In order to maintain confidentiality of your records, the investigators will use participant codes on all data collected, including the blood obtained during the blood draws, maintain an emergency contact list and a master list separate and secure from all data collected, and limit access to the confidential information to the principal investigators in the study. The signed informed consents will be kept in a locked cabinet in Dr. Winham's office.

Withdrawal Privilege

It is ok for you to say no. Even if you agree to participate now, you are free to say no later, and withdraw from the study at any time. Nonparticipation or withdrawal from the study will not affect your relationships with ASU in any way.

Costs and Payments

The researchers want your decision about participating in the study to be absolutely voluntary. Yet they recognize that your participation may pose some

costs and inconvenience. In order to help defray your costs and compensate you for your incontinence, you will receive a \$30 gift certificate to a major retailer (Target, Walmart, Home Depot) for each testing day of the study that you complete. If you are compliant with the research protocol and complete all four study days, you will receive an extra \$40 for a total of \$160.

Compensation for Illness and Injury

If you agree to participate in the study, then your consent does not waive any of your legal rights. However, in the event of (harm, injury, illness) arising from this study neither Arizona State University nor the researchers are able to give you any money, insurance coverage, free medical care, or any compensation for such injury.

Voluntary Consent

Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by Dr. Donna Winham (480-727-1722). If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at (480) 965-6788.

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

SUBJECT'S SIGNATURE PRINTED NAME DATE

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

SIGNATURE OF INVESTIGATOR DATE

APPENDIX D
HIPAA AUTHORIZATION FORM



HIPAA AUTHORIZATION FORM

Protocol Title: Effect of pinto, black and dark red kidney bean consumption on postprandial glucose and insulin in adults with T2DM

ASU HS # 07-12002492

Principal Investigator: Donna M. Winham, DrPH

AUTHORIZATION TO COLLECT, USE, AND SHARE HEALTH INFORMATION FOR RESEARCH

By law, researchers must protect the privacy of health information about you. This form and the attached research consent form need to be kept together.

We are asking you to take part in the research described in the attached consent form. The researchers are not authorized to collect any health information about you unless that information is described in the consent form that you sign.

What is “health information”?

As used in this form, the phrase “health information” includes:

- Health information that identifies you.
- Information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, x-rays, diagnostic and medical procedures and your medical history. We will access records two times over the course of the study. This refers to the future and previous 6 months from the time you start the study.

The specific information that will be collected in this research is described in the attached consent form. For you to be in this research, we need your permission to collect and share this information.

Who will see the health information collected in this research?

If you agree to participate, you are giving permission for the researchers to share your health information with the following people and groups:

- Anyone listed in the informed consent document as a person or group that you agree may receive information about you (Dr. Donna Winham and Sharon Thompson, BS)
- Anyone listed in a separate authorization for release of medical records or information that is signed by you.

- Government agencies, review boards, and others who watch over the safety, effectiveness, and conduct of the research.
- Other researchers when a review board approves the sharing of the health information.
- Others, if the law requires.

The researchers cannot control what any of these persons or groups may do with the information they receive about you and the privacy of your information may no longer be protected by federal privacy rules after it is disclosed to them.

What if you do not want to participate in the research?

You do not have to sign this permission (“authorization”) form if you do not want your medical records released for this research. If you do not sign, then you will not be allowed to participate in the study. If you decide not to sign, it will not result in any penalty or loss of benefits to which you are entitled.

If you sign this form and then change your mind later, and do not want us to use and share your health information, you will need to send a letter to the researcher at the address listed on the attached consent form. The letter will need to say that you have changed your mind and do not want the ASU researcher to collect and share your health information. The researcher may still use the information they have already collected.

Will you get to see the health information collected about you?

Depending on the nature of the research, it is possible that you will not have access to health information about you that is created during the study until after the study is complete.

If you have any questions, please contact the researcher listed on the attached consent form. You may also call the ASU Research Compliance Office at 480-965-6788 with questions about the research use of your health information. Your researcher will give you a signed copy of this form.

I agree to the collection, use, and sharing of my health information for purposes of this research study.

- [This permission will expire on September 1, 2010.](#)

Signature of research subject or subject’s legal representative	Date
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Printed name of research subject or subject’s legal representative
 Representative’s relationship to subject

APPENDIX E
MEDICAL RECORDS AUTHORIZATION FORM

Donna M. Winham, DrPH
Arizona State University Polytechnic Campus
Department of Nutrition
6950 E. Williams Field Road, HSC 1401
Mesa, AZ 85212
Office: 480-727-1722 Fax: 480-727-1064

Date: _____

Physician's name: _____

Physician's phone number: _____

RE: RELEASE OF MEDICAL RECORDS

Patient's name: _____

Date of birth: _____

Medical items to be released:

_____ All records for the past 12 months previous to the date of this release

_____ Height/Weight

_____ Date of type 2 diabetes diagnosis

_____ Date of oral hypoglycemic medication(s) prescription (if applicable), type

of medication(s) prescribed and most recent dosage

_____ All lab values for the past 12 months previous to the date of this release

_____ HbA1c

_____ Lipid profile

_____ Fasting blood glucose or results of OGTT

_____ Fasting insulin

Signature: _____

Witness: _____

Please fax the requested information to Donna M. Winham at 480-727-1064


APPENDIX F

HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD APPROVAL



Office of Research Integrity and Assurance

To: Donna Winham
HSC 1401

From:  Carol Johnston, Chair
Biosci IRB

Date: 08/06/2010

Committee Action: Renewal

Renewal Date: 08/06/2010

Review Type: Expedited F2 F5 F7

IRB Protocol #: 0907004180

Study Title: Effect of pinto, black and dark red kidney bean consumption as part of a meal on postprandial glucose and insulin in adults with type 2 diabetes

Expiration Date: 08/30/2011

The above-referenced protocol was given renewed approval following Expedited Review by the Institutional Review Board.

It is the Principal Investigator's responsibility to obtain review and continued approval of ongoing research before the expiration noted above. Please allow sufficient time for reapproval. Research activity of any sort may not continue beyond the expiration date without committee approval. Failure to receive approval for continuation before the expiration date will result in the automatic suspension of the approval of this protocol on the expiration date. Information collected following suspension is unapproved research and cannot be reported or published as research data. If you do not wish continued approval, please notify the Committee of the study termination.

This approval by the Biosci IRB does not replace or supersede any departmental or oversight committee review that may be required by institutional policy.

Adverse Reactions: If any untoward incidents or severe reactions should develop as a result of this study, you are required to notify the Biosci IRB immediately. If necessary a member of the IRB will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Biosci IRB. The new procedure is not to be initiated until the IRB approval has been given.

APPENDIX G
MEDICAL HISTORY QUESTIONNAIRE

BEAN GLYCEMIC INDEX STUDY Phase III

MEDICAL HISTORY QUESTIONNAIRE Participant

ID# _____

Age: _____ Gender: Male Female Smoker: Yes No

Height _____ ft. _____ in. Weight: _____ lbs. (must weigh at least

115 lbs).

1. Are you taking any medications regularly? (including insulin, aspirin, etc.)
Y N

If yes, what medications and how often? _____

2. Do you currently take supplements (vitamins, minerals, herbs, etc.)?
Y N

If yes, what supplements and how often? _____

3. Have you been diagnosed with diabetes within the last 6 months?
Y N

4. Has a doctor ever told you that you have any of the following conditions:

Mental illness? Y N Kidney disease? Y N

Liver disease? Y N Thyroid problems? Y N

Eating disorders? Y N Cancer? Y N

Gastrointestinal disease or disorders? Y N

5. Do you have a pacemaker? Y N

6. Are you allergic to any foods? Y N

If yes, please specify _____

7. (Women Only) Are you pregnant or breastfeeding? Y N
8. Are you willing to consume black beans, pinto beans, dark red kidney beans and white rice?
 Y N
9. Will you have a problem coming to ASU Polytechnic for four trial related appointments, each lasting ~4 hours?
 Y N
10. Will you have a problem providing 4 venous and 7 finger-stick blood samples during each appointment (total amount ~ 2 tsp per appointment)?
 Y N
11. Do you have a tendency to faint when a blood sample is taken?
 Y N
12. Do you have an allergy to tape or latex (e.g., latex gloves)?
 Y N
13. Please describe any other medical conditions that may affect your participation on the backside of this form.

APPENDIX H
SCREENING FOOD SURVEY

Type 2 Diabetes Health Survey

Dietary Assessment Screener

Think about your eating habits over the past month or so. About how often do you eat each of the following foods either at home or in restaurants? Mark an "X" in ONE box for each food.

<i>How often do you eat ...</i>	[A-0] Once per MONTH or less	[B-1] 2-3 times per MONTH	[C-2] 1-2 times per WEEK	[D-3] 3-4 times per WEEK	[E-4] 5 or more times per WEEK
Hamburgers, cheeseburgers, ground beef					
Beef or pork, such as steaks, roasts, ribs, or in sandwiches					
Fried Chicken					
Hot dogs, or Polish or Italian sausage					
Cold cuts, lunch meats, ham (not low-fat)					
Bacon or breakfast sausage					
Salad Dressings (not low-fat)					
Margarine, butter or mayonnaise on bread or potatoes					
Margarine, butter or oil in cooking					
Eggs (not Egg Beaters or just egg whites)					
Pizza					
Cheese or cheese spreads (not low-fat)					
Whole milk (not low-fat or skim)					
French fries, fried potatoes					
Corn chips, potato chips, popcorn, crackers					
Doughnuts, pastries, cake, cookies (not					

low-fat)					
Ice Cream (not sherbet or low-fat)					

Other Foods <i>If you do not know what these foods are or do not eat them, please mark the column for "once per month or less"</i>					
How often do you eat ...	[A-0] Once per MONTH or less	[B-1] 2-3 times per MONTH	[C-2] 1-2 times per WEEK	[D-3] 3-4 times per WEEK	[E-4] 5 or more times per WEEK
<i>For these types of beans, include the number of times eaten as part of another dish or alone</i>					
Black eyed peas					
Garbanzo beans, chickpeas					
Red kidney beans					
Pinto beans including refried beans					
Navy or white beans					
Baked beans; pork & beans					
Black beans					
Lentils					
Dry split peas					
Other "dried" beans: specify name: _____					

NOTE: These questions ask about what you eat each WEEK or by DAY, not by the month as in the previous questions.

Think about your eating habits over the past month or so. About how often do you eat each of the following foods either at home or in restaurants? Mark an "X" in ONE box for each food.

How often do you eat ...	[A-0] Less than once per WEEK	[B-1] About 1 time per WEEK	[C-2.5] 2-3 times per WEEK	[D-5] 4-6 times per WEEK	[E-7] Once per DAY	[F-14] 2 or more times per DAY
Fruit juice, like orange, apple, grape, fresh, frozen or canned (Not soda or other drinks)						
Not counting juice , how often do you eat any fruit fresh, canned, or in smoothies?						
Vegetable juice, like tomato juice, V-8, carrot						
Green salad (like lettuce or spinach salad)						
Potatoes, any kind, including baked, mashed or French fried						
Vegetable soup or stew with vegetables						
Any other vegetables, including green beans, peas, tomatoes, corn, broccoli, or any other kind						
Fiber cereals like Raisin Bran, Shredded Wheat or Fruit-n-Fiber						
Dark bread such as whole wheat or rye						

Bean Purchasing Habits

Think about when you buy beans (dry beans, not string or green beans):

- What percentage of the time do you buy beans that need to be cooked?
_____ %
- What percentage of the time do you buy canned beans?
+ _____ %

100 %

Should add up to 100%



- I do not buy canned beans or beans that need to be cooked. (check here)

Think about when you buy canned beans of any type:

Which brands do you usually buy? (Check all that apply)

- Bush's..... 1
- Campbell's..... 2
- Rosarita..... 3
- Hormel..... 4
- S&W..... 5
- Heinz..... 6
- Van Camp's..... 7
- Ranch Style Beans..... 8
- Other (Please specify):..... 9

-

Why do you buy these brands of canned beans? (Check all that apply)

- Tradition..... 1
- Lower cost..... 2

- Quality..... 3
- Recognized brand..... 4
- Taste..... 5
- Nutritional value..... 6
- Other (Please specify):..... 7

-

APPENDIX I

BLOCK 2005 FOOD FREQUENCY QUESTIONNAIRE

APPENDIX J

24-HOUR DIET RECORD FORM

**Food Intervention Study
Participant Food Log
Study Entry Form**

Thank you for participating in the ASU Nutrition Department Food Intervention Research Study. Before you begin eating the food product as part of the study, we want to know what you eat on ordinary days.

Please complete the following food record as best as you can for two continuous days starting when you wake up. Bring the forms with you when you come in for your first meeting. The nutritionist will go over the forms with you and answer questions you may have. Handwritten forms are ok. You do not need to complete this on the computer.

On the forms provided, please record ALL food and beverages that you consume. Water should be included. Please use SEPARATE FORMS for each of the two days. ***If you are receiving this as an email attachment, print two (2) copies of pages 3-5 so you have another form for the second day of your food record.*** Try to provide as much detail as possible about the foods or beverage that you consumed.

For example, instead of listing “ham and cheese” sandwich, write out the specific ingredients that went into the sandwich on the lines below the item. See the examples below:

How not to do it:

Time of Meal	Food Item	Brand or Source	Ingredients and/or Type of Preparation	Amount
Noon	Ham and cheese sandwich		ham, cheese, bread, mustard, lettuce, lettuce, tomato	one

How we would like you to record the foods:

Time of Meal	Food Item	Brand or Source	Ingredients and/or Type of Preparation	Amount
Noon	Ham and cheese sandwich	Safeway deli	ham, deli	two slices (1 ounce each)
		Safeway deli	cheese, Swiss	two slices (1 ounce each)
		Safeway	wheat bread	two

		Bakery		slices
		Kraft	mustard, Dijon	1 teaspoon
		Kraft	mayonnaise	1 teaspoon
			lettuce, red leaf	1 leaf
			tomato	2 slices

Where possible, please bring in the labels from convenience and/or packaged foods. You can attach these to your forms.

Remember to include beverages (including water) and snacks that are consumed between meals or afterwards.

Be sure to write down any supplements or medications you might be taking. Please attach a label for the supplement or write the information from the label on the record form.

Time: Note the time you ate or drank an item and indicate if am or pm for clarity.

Food Item: Write what the food or drink item was, e.g. crackers, casserole, shrimp, Coca-Cola

Brand or Source: In this space, please write down what the brand name is for the food item or where it came from. Examples: Nabisco Wheat Thins, Burger King, church potluck supper, or homemade.

Type of Preparation: Write down how a food was prepared if not obvious. Some common ways of preparing foods include baking, boiling, frying, micro waving, steaming or roasting. If you use oil or other sauces in preparing the food item, list them on a separate line.

Amount: Record how much of an item you ate or drank. Example- orange juice, 6 ounces. You do not need to weigh or measure your foods at this time. However, please record as much detail as you can.

Here is another example:

Time (am/pm)	Food Item	Brand or Source	Ingredients or Type of Preparation	Amount
<i>Example: 6:45 am</i>	<i>Raisin Bran</i>	<i>Post</i>		<i>1/2 cup</i>
<i>6:45 am</i>	<i>skim milk</i>	<i>Good Day</i>		<i>1/2 cup</i>
<i>6:45 am</i>	<i>egg</i>	<i>don't know</i>	<i>scrambled, used Pam nonstick spray</i>	<i>1 large</i>

If you have questions or difficulties before we meet next week, please feel free to email me or call donna.winham@asu.edu, (480) 727-1722. I do check my email and voice mail frequently even on weekends. We are very excited about starting this project and look forward to your participation!

DAILY FOOD LOG

Date: _____

Was this a typical day for you in terms of what you ate or drank?

Yes No (if No, What was atypical about the day?).

Code # _____

Day of the Week: M T W Th

F S Sun

(Nutritionist will fill in)
one)

(Circle one)

Please write down ALL food and beverages (including water) you eat throughout the day. Remember to give as many details as possible. Please list any vitamins or mineral supplements (include herbal supplements, protein supplements, etc.). Attach labels of food products and supplements if possible.

Food Record Page 1 of _____

Time (am/pm)	Food Item	Brand or Source	Ingredients or Type of Preparation	Amount

Food Record Page 2 of _____

Time (am/pm)	Food Item	Brand or Source	Ingredients or Type of Preparation	Amount

Please record any dietary supplements or vitamins taken on this day:

Brand dosage (potency) number of
tablets/amount:

APPENDIX K
DIETARY TREATMENT RANDOMIZATION

BGR III Participant Randomization				
Subject #	TX 1	TX 2	TX 3	TX 4
401	2	1	4	3
402	3	2	1	4
403	2	1	3	4
404	2	3	4	1
405	4	2	1	3
406	1	2	3	4
407	1	4	2	3
408	2	1	3	4
409	1	2	4	3
410	1	4	3	2
411	3	4	1	2
412	3	1	4	2
413	4	2	3	1
414	4	3	2	1
415	1	4	3	2
416	3	4	2	1
417	4	2	3	1
418	1	3	4	2
419	2	1	4	3
420	1	4	3	2
421	2	3	4	1
422	3	4	1	2
423	2	4	1	3
424	3	2	4	1
425	1	4	2	3
426	3	1	2	4
427	2	3	4	1
428	3	1	2	4
429	3	4	2	1
430	4	2	1	3

1 = rice/rice, 2 = pinto beans/rice,

3 = black beans/rice, 4 = dark red kidney beans/rice

APPENDIX L
GLUCOSE ASSAY AND BLOOD COLLECTION PROTOCOL

YSI 2300 STAT

Methods

1. Calibrate the YSI 2300 by entering Run Mode or, if in Run Mode, by pressing the Calibrate key.
1. Each day, prior to runs, test the linearity of the system with 0.90% w/v glucose using YSI 1531 (9.00 g/L glucose) linearity standard.
2. When idle for more than 15 minutes during sampling without calibration (should automatically calibrate every 5 samples), initiate a calibration.
3. Provide participant with a hand warmer approximately 5 minutes before their scheduled blood draw time as displayed on the digital timer. Have them hold the hand to be used for blood collection within this hand warmer until their scheduled blood draw time.
4. Clean participant's finger using a sterile alcohol wipe. Allow to dry and use a BD Microtainer lancet (Franklin Lakes, NJ) to firmly pierce the skin of the top of the finger.
5. Collect about 100 μ l of capillary blood from the participant in a capillary microtube. Blood collection should be completed within 5 minutes or results will not be valid.
6. Immediately after the time of the blood draw has been written in the subject's file and the timer reset, walk the blood sample to the YSI STAT plus for analysis.
7. Press Sample. The sipper should then move to the Manual Station. Enter the subject's number and draw (e.g. #4021 for 30 minute draw).

8. Present the sample to the Sipper and press Sample again to begin aspiration.
9. After 4 seconds the Sipper will ascend.
10. Remove the sample container and look for results to appear within one minute.
11. Write the time of the blood draw on the results printout and leave printout on the machine until the participant has finished all blood draws.