ABSTRACT

OBRIANT, JASON MARK. Engaging Students in Healthcare to Impact Effects of Food Insecurity on Patients with Type 2 Diabetes and Measure the Effects of High Intensity Exercise on Blood Glucose. (Under the direction of Dr. Jonathan C. Allen).

Diabetes is a collection of chronic diseases characterized by elevated blood glucose and is rapidly becoming a leading, world-wide disease burden of mortality. For people dealing with any form of the disease, it significantly increases overall healthcare costs, time spent engaging in glycemic management practices, and the risk for comorbid conditions. Diabetes also has a reciprocal relationship with food insecurity, and prevalence rates tend to be greater in populations where either condition is present. Because type 2 diabetes can almost exclusively be controlled and prevented by optimal nutrition, the impact of food insecurity, which describes a set of economic and environmental barriers limiting access to optimal or sufficient food, is especially deleterious on individuals experiencing both conditions simultaneously. The hallmark, measurable symptom of diabetes is hyperglycemia. After optimal diet, exercise or physical activity is the next most effective way to reduce elevated blood glucose without the use of pharmacological agents or exogenous insulin. Most Americans do not meet the minimum physical activity guidelines set forth by the U.S. Department of Health and Human Services of 150 minutes of moderate-intensity or 75 minutes of high-intensity activity per week.

The aim of this dissertation was to explore barriers to optimal nutrition, test an exercise protocol to reduce postprandial hyperglycemia, and investigate the impact on learning when healthcare students assist with research. There are two primary studies (Project FEED and The CGM-Exercise Trial) which recruited participants from the community. Each primary investigation also has a companion, pedagogical study exploring healthcare students' learning after participating with human health research as part of their required curriculum. The first

study, Project FEED, investigated the unique nutrition barriers faced by patients living in an urban environment when dealing with uncontrolled diabetes and food insecurity. Using a qualitative approach, researchers interviewed patients (n = 14) recruited from a medical clinic. The major dietary barriers described by the patients were transportation and money. Another theme we observed was the reliance on spirituality or faith in God. Spiritual practice served multiple roles in their lives, but overall could be seen as a protective belief which gave access to contentment despite challenging circumstances. These findings may be useful for program planners when designing culturally appropriate interventions to effect behavior change by utilizing and addressing these social determinants of health. Study 2, the pedagogical companion to Project FEED, explored student learning for disease specific topics and their willingness to engage in interprofessional collaborations. Students recruited from a medical school and dietetic internship program (n=28) were partnered together to engage in an interprofessional education experience. Each pairing was assigned a Project FEED patient, and they provided monthly nutrition education in the patient's home for 6 consecutive months. Student teams worked together to teach the content and help establish and monitor goals with their patient. Researchers found that when healthcare students from different disciplines work together, there is an improvement in appreciation for the other profession's role and increases in self-assessed perceived knowledge of disease specific nutritional recommendations.

In study 3, researchers explored a novel approach to meet the physical activity recommendations for Americans by using multiple bouts of high intensity interval training (HIIT) and investigated its effects on postprandial blood glucose (PPBG). Healthy participants (n=18) were recruited from the Triangle region in North Carolina and instructed to consume the same daily diet for four days. On two consecutive days they performed 5 mins of HIIT exercise

immediately before each meal. Blood glucose was measured using a continuous glucose monitor. The data was inconclusive if this regimen was effective at lowering PPBG. The fourth study, the pedagogical companion to the CGM-Exercise Trial, demonstrated that a minimum of 5 hours of participation with clinical skills practice on a research trial, significantly improves student learning and confidence performing entry-level clinical skills. In summary, diabetes and food insecurity are complex public health issues and cause more adverse health outcomes for individuals when they are experienced together. To mitigate the ill effects of these conditions, proper training of future healthcare workers is essential to develop the skills necessary to treat patients in a collaborative, compassionate manner while taking into account their social determinants of health.

Engaging Students in Healthcare to Impact Effects of Food Insecurity on Patients with Type 2 Diabetes and Measure the Effects of High Intensity Exercise on Blood Glucose

by
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DEDICATION

To my beautiful wife, Crystal, and wonderful children, Liam and Vera, this work is dedicated to you. I'm looking forward to our future adventures and time together. To my parents, Mark and Carolyn, thank you for your many sacrifices and teaching us the importance of working hard and delaying gratification. To Samantha, Patty, and Steve, I appreciate all you have done for our family, and the numerous ways you continue to support us.

BIOGRAPHY

Son of Mark and Carolyn O'Briant and brother to Samantha Jonas. Born in Grandy, NC and raised on the brackish waters of the Currituck Sound. There he discovered his love for salt water and passion for nutrition. After becoming a Registered Dietitian, he worked in diabetes education and became interested in human performance and the regulation of macronutrient metabolism. He was later invited to teach Nutritional Biochemistry as an adjunct instructor, which led to his current position as the undergraduate director for a nutrition and dietetics program.

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needed your assistance. In many ways I feel you were the backbone and glue of our lab (yes, an intentional, redundant fail-safe) and always helped us move our projects in the correct direction. Thanks for all your support, words of encouragement, and pleasant conversation.

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Statement of the Problem and Dissertation Overview

Food insecurity, a social determinant of health, and diabetes, a leading cause of death, both have prevalence rates > 10% in the U.S. population. These increasingly common yet complex conditions negatively impact health and increase one's risk of chronic diseases. Food insecurity increases the risk for diabetes and diabetes increase the risk for food insecurity. Both conditions can be significantly improved and even remitted by having access to and consuming a high-quality diet. To better treat patients with either or both conditions, clinicians and future healthcare workers should understand the beneficial role of nutrition while holistically considering the physiological, environmental, economic, and cultural experiences of patients. In this review of the literature, food insecurity and diabetes are framed as significant public health issues. A description of population and individual risk factors, nutrition shortfalls and intervention, condition burden, and other associated risks are discussed. Solutions for each condition are also reviewed here, which were used to inform the methodologies and intervention design of the research projects in Chapters 2-5 that follows. The primary objectives of this dissertation are to (1) understand the unique experiences of patients dealing with the burden of both food insecurity and uncontrolled diabetes, (2) investigate the effect of multiple bouts of premeal high-intensity exercise before meals on postprandial blood glucose, (3) measure perceived learning of healthcare students engaging in interprofessional education, and (4) measure perceived knowledge and confidence after healthcare students participate on a human health intervention trial.

Food Insecurity: Prevalence

The Economic Research Service of the USDA provides an annual report on household food security and food insecurity. Data from civilian households was collected from the Food Security Supplement section of the Current Population Survey (CPS) to estimate food security prevalence in 2020. The CPS data include 34,330 households that completed the survey from 50,000 households selected. In the household report, 89.5% of U.S. households were food secure and 10.5% (13.8 million households) were food insecure. Of the food insecure, 6.6% had low food security and 3.9% had very low food security.[1] Food security definitions are provided in Table 1.1.

Some population subgroups have higher rates of food insecurity. Households with children, Black householders, households in the South, and when the reference person was unemployed all had increased prevalence. In contrast, women and men living alone, White households, households in the Midwest, and when the reference person is employed had decreases in prevalence. Food secure households tend to spend 18% more for food, as a percent of total income, than the typical food insecure household of equivalent size.[1]

Health and Dietary Consequences of Food Insecurity

Food insecurity affects both dietary quality and dietary quantity. Food insecure households frequently worry about food running out, not being able to afford a balanced meal, altering portion sizes, skipping meals, eating less than they feel they should, and experiencing hunger but not eating. Lower food security is associated with a greater risk for many chronic diseases including the following: hypertension, coronary heart disease (CHD), hepatitis, stroke, cancer, asthma, diabetes, arthritis, chronic obstructive pulmonary disease (COPD), and kidney

disease. It is also associated with a higher probability of multiple comorbidities and a 40% increase in overall prevalence of chronic illness which suggests that people with food insecurity will deal with the burden of chronic disease management, greater healthcare costs, and potential for economic hardship.[2]

Table 1.1 Food Security Status Definition and Severity – adapted from *Food Insecurity, Chronic Disease, and Health Among Working-Age Adults, ERR-235* USDA, Economic Research Service (2017)

Food Security Status (2-category)	Food Security Status (4-category)	Definitions	Severity of Food Insecurity
Food Secure	High food security	Households had no problems or anxiety about consistently accessing adequate food	Less severe
	Marginal food security	Households had problems, at times, or anxiety about acquiring adequate food, but the quality, variety, and quantity of their food intake were not substantially reduced	
Food Insecure	Low food security	At times during the year, households reduced the quality, variety, and desirability of their diets due to a lack of resources for food, but the quantity of food intake and normal eating patterns were not substantially disrupted	
	Very low food security	At times during the year, eating patterns of one or more household members were disrupted and food intake reduced because the household lacked money and other resources for food	More severe

Even though some individuals concomitantly experience poverty and food insecurity, food insecurity can exist independently regardless of poverty status. Food insecurity is often associated with higher intakes of highly palatable foods and lower intakes of fruits, vegetables, low-fat dairy, fiber, vitamin A, vitamin B_6, calcium, magnesium, zinc.[3,4] One of the most damaging effects of poor diet is the increased likelihood of malnutrition. Malnutrition previously

has been mostly associated with underweight, encompassing cachexia, sarcopenia, and insufficient nutrient intake, but it is increasingly being observed in overnutrition and obesity which affects more than 40% of U.S. adults.[5] Malnutrition may contribute to the incidence of obesity, and conversely, obesity may similarly contribute to malnutrition. Malnutrition is associated with the development and worsening of chronic diseases, higher incidence of contraction and severe illness from infectious diseases like SARS-CoV-2, poor immune response, and premature mortality.[5-7]

Diabetes is a chronic disease showing a strong relationship to malnutrition. Although the prevalence of malnutrition in people with diabetes has been estimated for specific groups and appears to be greater when compared to matched cohorts, the total population prevalence is not known. A large, domestic data set using Centers for Medicare and Medicaid Services (CMS) beneficiaries showed diabetes with malnutrition was associated with a 69% increase in risk for death compared to the diabetes without malnutrition group. This same group also found similar disease effects of increase risk of death when coupled with malnutrition for other common comorbid conditions including ischemic heart disease (63%), chronic obstructive pulmonary disorder (60%), and heart failure (54%).[5] International studies from China, Spain, and Israel investigating diabetes' risk for malnutrition found consistent results of about a 2-fold increase in malnutrition using odds ratios (OR = 2.12, 1.97, and 2.15 respectively).[8-10] In Turkey, 14.4% of patients in a diabetes outpatient clinic received a positive screening for increased risk of malnutrition using a nutritional assessment tool.[11]

Home Health

Roughly half of older adults being admitted for hospital services are malnourished. Of these, adults living alone or experiencing a reduction in social engagements have higher rates of

malnutrition and worse health status.[12] Malnourished patients in acute care receiving treatment experience a greater risk of complications and adverse health events both during hospitalized care and after discharge. Although malnutrition can be addressed while hospitalized, it's unlikely that all parameters of the condition can be resolved. This affects postacute care outcomes and may lead to greater readmissions.[13,14] Home health agencies (HHA) are uniquely positioned to provide timely, impactful, and preventative care to this vulnerable patient population. Preventing hospital readmissions is a goal for HHAs and other postacute providers. Postacute care has observed one of the largest increases in spending from Medicare.[13] Two possible interventions to reduce the strain of malnutrition on readmissions, poor patient outcomes, and the overall economic burden of the healthcare system are nutrition provisions via supplemental food assistance and nutrition education. Since access is often a barrier, home delivery of nutrition resources and education is a plausible workaround.

A large, nonprofit health care system screened over 5000 patients for malnutrition and identified that 2135 patients were at moderate nutrition risk, and of these 1546 met eligibility requirements to receive oral nutrition support for one month. The nutrition support products were delivered directly to the patients' homes. The absolute reduction in 30-day hospitalization was 3.6% with a relative risk reduction of 24.3%. Net savings per treated patient was $1,500.[13] Although nutrition support services, such as oral nutrition support and home meal deliveries, appear to be cost effective and can reduce the risk of all-cause mortality, they typically do not address the deleterious impact of social isolation and psychological well-being.[15] Programs utilizing a combination approach of supplemental nutrition support, nutrition education, and direct human interaction to reduce time in solitude may address immediate health risks related to malnutrition and psychological disposition. Nurses and physicians report feeling undereducated

and lack the necessary skills to provide nutrition education and nutrition counseling services and would prefer to refer these services to registered dietitians nutritionists (RDN). Individualized nutrition education has the potential to improve and reduce malnutrition for isolated individuals and older adults experiencing environmental barriers and trying to manage chronic diseases.[12]

Slowing the Diabetes and Obesity Epidemics

The World Health Organization and others have described the staggering increases in rates of obesity and type 2 diabetes over the last 40 years as global epidemics. Obesity and T2DM are largely preventable, so it is imperative to treat early and often by addressing dietary and lifestyle behaviors to mitigate the pathological nature and progression of either disease.[16-18] Although primary care physicians (PCP) are frequently the sole providers responsible for the management of these conditions, RDNs should be utilized for their unique training and educational background. Additionally, RDNs have proven to be cost-efficient providers.[19] Registered dietitians receive training in the treatment and prevention of diseases by administering nutrition therapy independently or as part of a medical team.[20,21]

Obesity and T2DM place a tremendous cost burden on health care systems and individual health.[22-24] Optimal management of these chronic diseases and others should include a RDN or other nutrition practitioner because they are usually the only member of a health care team with substantial training in nutrition. In 1985, the Food and Nutrition Board of the National Academy of Sciences-National Research Council issued a report that recommended the addition of nutrition education in medical schools.[25] There has been some increase in medical schools incorporating nutrition education into their curriculums since then, but overall, the amount of nutrition-specific training medical students receive is limited.[26]

Nutrition Education in Medical Training Programs

Increasing rates of hospital malnutrition, diabetes, obesity, heart disease, and cancer all have a strong link to poor diet and physical inactivity.[19] Medical education, perhaps less holistically, often focuses on disease pathogenesis, rather than learning about prevention and salutogenesis. Salutogenesis is the process through which health and well-being are produced or the generation of health and wellness.[27-29] Graduate medical education (GME) is limited in educational competencies targeting disease prevention and optimizing health span. Since most chronic diseases and many acute illnesses are affected by poor nutrition, it is important for physicians to have basic working knowledge of how an optimal diet can improve the health of their patients. Nutrition education, as defined by Contento, is "Any combination of educational strategies, accompanied by environmental supports, designed to facilitate voluntary adoption of food choices and other food- and nutrition-related behaviors conducive to health and well-being. Nutrition education is delivered through multiple venues and involves activities at the individual, community, and policy levels."[30] A 2013 survey assessed the degree to which U.S. medical schools were providing the minimum recommendation of 25 hours of nutrition education. Only 29% of schools out of 121 institutions were meeting the minimum requirement. Thirty-six percent of the schools were not even meeting half of the requirement.

The Academy of Nutrition and Dietetics has advocated for interprofessional education in nutrition as an essential component of GME.[19] From surveys between 2010-2017, medical students report feeling that their nutrition knowledge is inadequate and practicing physicians felt their nutrition training was insufficient. Common barriers to nutrition counseling for physicians were perceive lack of nutrition knowledge, insufficient skills and confidence, poor attitudes, and low outcome expectancy. Even a brief, low-intensity nutrition curriculum significantly improved

medical students' knowledge, behaviors, confidence, and willingness to engage in nutrition counseling.[19,31,32]

Diabetes Mellitus: Types, diagnostic criteria and health impacts

Diabetes mellitus is a group of chronic diseases characterized by the reduced ability to take up glucose for normal metabolism. It affects over 500 million people world-wide, is a leading cause of death in industrialized countries, and a significant cost burden for individuals and healthcare systems. Despite its immense reach and negative implications to individuals and large populations, it remains largely preventable and is very responsive to behavioral changes and pharmacological treatments if needed. The primary feature of the disease is elevated blood glucose (hyperglycemia) which is often a secondary response to low insulin production or insulin resistance. Diabetes mellitus, or *diabetes*, is sub classified into three primary types: Type 1 diabetes (T1DM), Type 2 diabetes (T2DM) and Gestational diabetes (GDM). Other types of diabetes have various etiologies ranging from genetic defects of B-cell function, insulin action, endocrinopathies, surgery induced, and diseases of the pancreas. Prediabetes, a subthreshold diagnosis for diabetes, is also a major health concern because of the high risk it poses for developing diabetes.[33] The following review of the literature will focus primarily on T2DM which is the most prevalent and preventable form. Many of the management approaches that are helpful for T2DM may have similar benefits and utility for those with T1DM and GDM; however, these patients are considered more vulnerable and require intensive medical management and oversight.

Type 2 diabetes account for 90-95% of all diagnosed cases. Type 2 diabetes is characterized by insulin resistance and to some degree beta-cell failure. Insulin resistance results in hyperglycemia due to the decreased tissue sensitivity and responsiveness to insulin. Most

individuals with T2DM are obese which itself causes some degree of insulin resistance. Risk factors for developing T2DM are increasing age, obesity, low physical activity, low education levels, hypertension, dyslipidemia, belonging to certain racial/ethnic groups (African American, American Indian, and Hispanic), or having a prior diagnosis of gestational diabetes.[34,35]

Prediabetes is not a clinical entity; however, it is used to describe blood glucose levels that are elevated above the normal lab reference range but below the levels required for the diagnosis of diabetes. Elevated blood glucose values for the diagnosis of prediabetes can be determined by measuring glycated hemoglobin (HbA_{1c}), impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Consequently, individuals with prediabetes have a greater risk for diabetes and cardiovascular disease. Prediabetes has an association with other comorbidities like obesity, hypertension, and dyslipidemia with a presentation of high triglycerides and low HDL cholesterol.[34]

Diagnostic criteria for testing for diabetes in nonpregnant individuals can be performed by evaluating blood glucose levels exceeding thresholds established for fasting plasma glucose (FPG), two-hour plasma glucose after a 75-g oral glucose tolerance test (OGTT), or using HbA_{1c} measures. Values exceeding thresholds for FPG or the OGTT are diagnosed with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) respectively.[36,37] Either diagnosis is indicative of prediabetes. Table 1.2 shows blood glucose and HbA_{1c} cut points recommended by the American Diabetes Association (ADA).[34] Unlike FPG and the OGTT, HbA_{1c} does not have to be obtained while in a fasted state, which offers some convenience, and it is less susceptible to daily fluctuations from exercise, stress, illness, or short-term medication use. The HbA_{1c} measurement is contraindicated in pregnancy, for patients experiencing blood loss,

erythropoietin therapy or hemolysis. Only FPG or OGTT are appropriate to diagnose diabetes given these conditions.[38]

Table 1.2. Diagnostic Criteria for Diabetes Mellitus and Prediabetes – adapted from the American Diabetes Association Position Statement (2013)

	Test		
Diagnosis	**FPG** (mg/dL)	**OGTT** (mg/dL)	**HbA_{1c} %**
Normal (Nondiabetic)	< 100	< 140	≤ 5.6
Prediabetes 1. Impaired Fasting Glucose 2. Impaired Glucose Tolerance	100-125 (1.)	140-199 (2.)	5.7-6.4*
Diabetes	≥ 126	≥ 200	≥ 6.5

*The American Association of Clinical Endocrinologists (AACE) recommends using an HbA_{1c} range of 5.5-6.4% for High Risk for Diabetes, and they recommend following up with either FPG or OGTT to confirm a diagnosis of prediabetes.[39]

Asymptomatic adults with risk factors for diabetes or prediabetes have a greater propensity of developing T2DM and should be considered for testing. Screening before the age of 45 should occur if one or more of the following are present: first-degree relative with diabetes, high-risk race/ethnicity, previous diagnosis of GDM, history of CVD, hypertensive, dyslipidemia, polycystic ovary syndrome, physical inactivity, severe obesity or acanthosis nigricans. After the age of 45, all patients should be tested. Testing should be repeated at least every 3 years even with an initial negative screening.[34]

Diabetes Mellitus: Disease prevalence and burden (cost, time and health)

Prevalence. World-wide, diabetes affected 537 million adults in 2021, an increase from 463 million in 2019.[17,40] The *National Diabetes Statistics Report* of the Centers for Disease Control and Prevention (CDC) estimated that 34.2 million (10.5%) of the U.S. population had

diabetes in 2018. Over the age of 18 years, the prevalence increases to 13.0%. For the 34.1 million U.S. adults with diabetes, 26.7 million are diagnosed (10.2%) and 7.3 million are undiagnosed (2.8%). Of these, only 5-10% are type 1 diabetes; the rest are type 2 diabetes.[41] Rates are highest among American Indians, Black, and Hispanic ethnic groups; counties in the southern and Appalachian regions of the U.S.; individuals over the age of 44; and with obesity. Those with less than a high school education have nearly twice the incidence rate compared to those completing high school. The racial differences in diabetes incidence are likely explained by modifiable biological differences and a combination of environmental, psychosocial, socioeconomic, and behavioral factors (Table 1.3). Biological factors exert the strongest association and produce the greatest hazard ratio compared to the other factors from the groups.[42]

There were significant, annual increases in both disease incidence and prevalence from 1990-2008. Since then, there has been a leveling-off of prevalence from 2009-2017 and a slight decrease in incidence during the same period that is attributed to the decline in incidence in non-Hispanic Whites and Asians. Incidence in Hispanic and Non-Hispanic Black populations are mostly level over the last 20 years although higher overall compared to Whites and Asians.[35] Another group, using NHANES data from 2011-2012, a representative sample of the U.S. adult population (age $\geq$ 20 years), estimated total prevalence of 12-14% for total diabetes (9.1% diagnosed cases and 5.2% undiagnosed diabetes).[43]

The estimated prevalence of prediabetes reported by the CDC for 2018 was 88 million (34.5%) of U.S. adults aged 18 years or older. Almost half of adults 65 years or older had prediabetes.[41]

Disease burden. Presently, no curative agents for diabetes exist; therefore, when an individual is diagnosed with diabetes, they usually deal with all aspects of the burden of the

Table 1.3 Modifiable Diabetes Risk Factors

Group	Risk Factor
I. Biological	i. Waist circumference ii. Body weight iii. Medications iv. Blood lipids (HDL, LDL, triglycerides) v. Blood pressure
II. Environmental	i. Racial composition of neighborhood ii. Neighborhood poverty
III. Psychosocial	i. Depressive symptoms ii. General disposition
IV. Socioeconomic	i. Educational level ii. Education level of parents iii. Employment status iv. Marital status v. Difficulty paying for necessities
V. Behavioral	i. Smoking ii. Alcohol consumption iii. Dietary intake (fruits, vegetables, whole grains, sodium, and SSBs) iv. Physical activity

disease for the duration of their life. Individuals with diabetes have, on average, a greater *financial burden* because it is costly to treat and manage the disease compared to individuals without diabetes. Globally, diabetes was estimated to cost $0.96–1.32 trillion USD in health care expenditures annually.[17,44] The United States ranks number one worldwide in diabetes-related health expenditures. The economic burden of diagnosed diabetes in the U.S. in 2017 was estimated to be $327 billion ($237 billion in direct medical costs and $90 billion in reduced productivity) an increase of $66 billion (25% increase) since 2007 (Figure 1.1) Direct costs are the costs attributed to the health expenditures paid by the patient or the government of which the patient receives medical benefits. Individuals with diabetes on average incur medical

expenditures of $16,750 per year ($9,600 is attributed to diabetes), and these expenses are estimated to account for 20% of the nation's health care dollars going to treating people with diabetes. Annual per capita medical spending for people with diabetes is 2-3 times more than for people without the disease.[45,46]

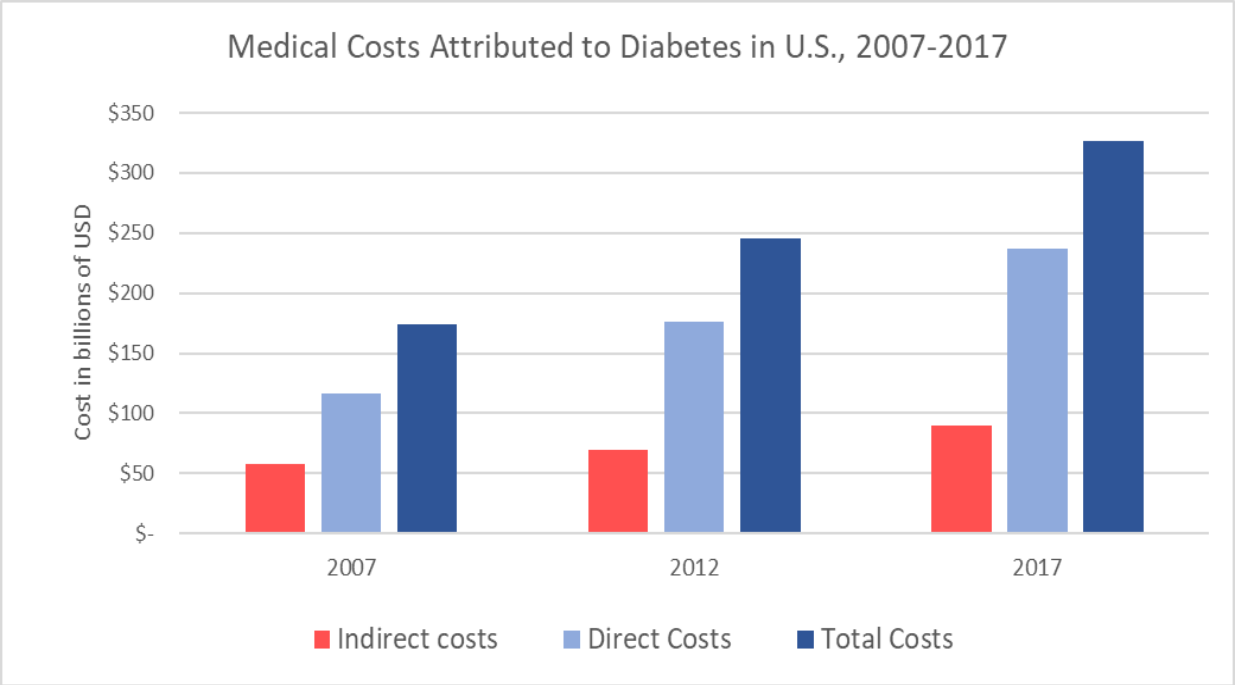

Figure 1.1. Economic Burden of Diabetes Mellitus in the United States from 2007-2017 – adapted from *Economic Costs of Diabetes in the U.S. in 2017* (2018)

The most commonly diagnosed form of diabetes is type 2 diabetes, so a lot of work has gone into the investigation of prevention through lifestyle changes. Diabetes related self-care behaviors can impart a significant *time burden* on individuals with diabetes. For optimal disease management, patients may need to perform a combination of the following self-care activities: monitor blood glucose, take oral antihyperglycemic medications, inject insulin, monitor feet and skin care, shop for medicines and other health items, monitor blood pressure, buy food, cook, and/or engage in physical activity. A German questionnaire estimated that patients with diabetes had on average 4 hours per week of self-care behaviors exclusive to the time-consuming

self-care activities were monitoring blood glucose (58 minutes per week) and injecting insulin (41.7 minutes per week).[47]

One of the primary disease markers in the *health burden* of diabetes is hyperglycemia management. If hyperglycemia is minimized and overall glycemia is controlled safely within the healthy glycemic range (minimizing episodes of hypo- and hyperglycemia), the adverse health outcomes associated with diabetes can be substantially reduced—even over a 30-year period.[23,48] A primary concern for individuals with poorly controlled diabetes mellitus are the health endpoints of micro- and macrovascular events. Hyperglycemia has a causal role in the development and progression of microvascular conditions like retinopathy, nephropathy and neuropathy.[49-51] Macrovascular complications appear to have a stronger associative relationship with elevated C-peptide than hyperglycemia.[24] C-peptide or connecting peptide is a short, 31 amino acid polypeptide that connects the alpha and beta chains of insulin together when it is in its immature pro form. Even still, compared to age-matched, nondiabetic individuals, diabetes confers a 10-fold increase in risk of myocardial infarction and stroke.[23,24,52]

Type 2 Diabetes Mellitus: Prevention efforts and disease management approaches

Type 2 diabetes is characterized by improper utilization of insulin which results in an increase in blood glucose. The primary treatment regimen for people with type 2 diabetes is dietary and lifestyle changes; however, pharmacological therapies may be needed to improve disease management. To avoid using pharmacological interventions, people with T2DM can reduce circulating blood glucose by limiting carbohydrate intake, adjusting the timing of consumption, changing meal composition, and increasing physical activity.

For the prevention and management of T2DM, it is well understood that two of the most important lifestyle factors are diet and regular physical activity. Exercise is a useful tool for

improving glucose tolerance and insulin sensitivity[53], may increase GLP-1 concentrations in the fed state[54], reduces postprandial blood lipids[55], and reduces the amount of exogenous insulin needed and other glycemic-lowering pharmacological aids.[56]

Screening and risk assessment may be valuable tools to enroll participants in intervention programs and serve as external motivators. In a systematic review of prospective studies, HbA_{1c} values in the ranges of 5.0-5.5%, 5.5-6.0%, and 6.0-6.5% were respectively associated with 2, 5 and 20 times the relative risk of developing diabetes compared to HbA_{1c} values < 5.0%. For the same HbA_{1c} ranges (5.0-5.5%, 5.5-6.0%, and 6.0-6.5%), 5-year disease incidence rates were estimated at <5-9%, 9-25% and 25-50% respectively.[36] A summary of these figures are found in Table 1.4. Therefore, monitoring and screening for diabetes risk using HbA_{1c} may be an effective tool for prevention and initiating behavior changes in at-risk individuals.

Table 1.4. Using HbA_{1c} as a Predictive Tool for Diabetes Risk and Disease Development

HbA_{1c}	Relative Risk of Developing DM	5-Year Incidence Rates of DM
< 5.0%	Baseline	Baseline
5.0 – 5.5%	2	5 – 9%
5.5 – 6.0%	5	9 – 25%
6.0 – 6.5%	20	25 – 50%

Exercise or physical inactivity is now identified as a leading risk factor for global mortality. Physical activity, as defined by the World Health Organization, is bodily movement requiring energy expenditure to support the contractions of skeletal muscles. This includes working, playing, performing chores, travelling and engaging in recreational pursuits. Physical activity does not require or imply any specific aspects or quality of movement. Exercise is a subset of physical activity, and described as planned, physical movement performed with the intent to improve or maintain one or more components of physical fitness. Exercise may be used

for sports training, chronic disease management and prevention, and overall well-being.[57] The *Physical Activity Guidelines for Americans*, released by the U.S. Department of Health and Human Services recommends that adults should perform a minimum of 150-300 minutes of moderate-intensity physical activity while also performing resistance exercises on two or more days each week. The recommendation minimums for physical activity for adolescents and children are even greater. In 2015, almost a third of Americans were considered "inactive" or had less than 10 minutes of activity per week, 19% had "insufficient activity", 16% had "sufficient activity", and the remaining 33% were considered "very active" or obtaining greater than 300 minutes of activity per week (Figure 1.2).[58]

Physically active individuals have less chronic disease risk, reduced depressive symptoms and anxiety, sleep better, report improvements in mood, and better overall function. Half of the U.S. population currently does not meet the minimum recommended dose of exercise. Sedentary behavior is characterized by an energy expenditure of ≤ 1.5 METs

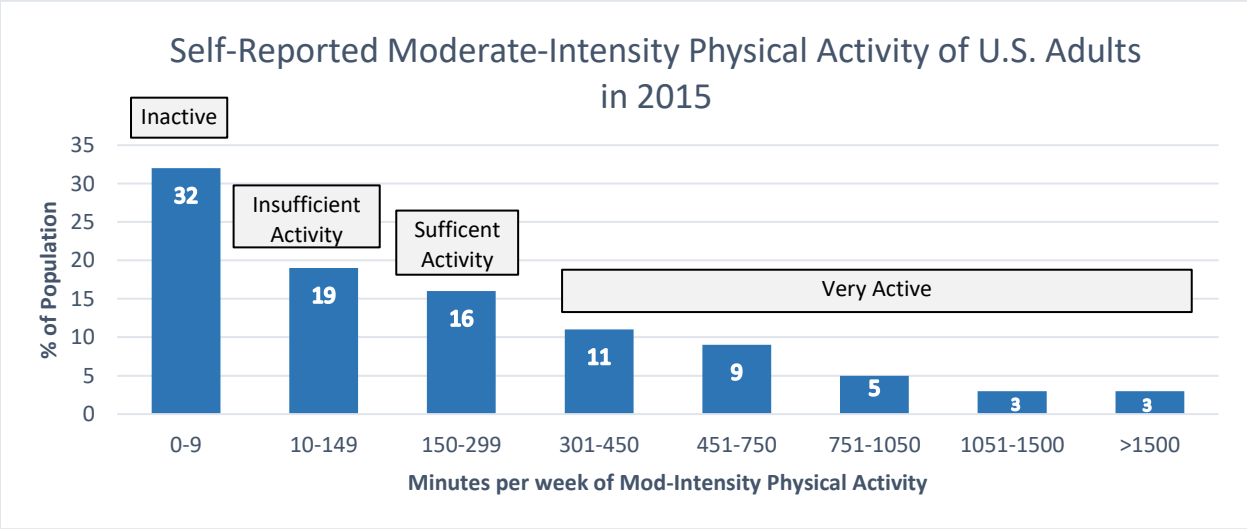

Figure 1.2. Weekly Physical Activity Dose in Minutes by Percentage of U.S. Adult Population from 2015 – adapted from *2018 Physical Activity Guidelines Advisory Committee Scientific Report*

(metabolic equivalents). Moderate-intensity is defined as roughly 3-6 METs and vigorous-intensity as > 6 METs.[59] One metabolic equivalent (MET) is the amount of oxygen consumed while sitting at rest and is equal to 3.5 ml O_2 per kg body weight x min.[60] A noteworthy amendment in the 2018 Scientific Report is the omission of the minimum bout requirements.[58] In the 2008 report, the duration of an exercise bout was set at a minimum of 10 minutes.[59] The 2018 committee concluded that bouts of any length can accumulate and contribute to the overall health benefits of physical activity. Table 1.5 contains a summary of the physical activity related terms and threshold levels for different exercise intensities. Among individuals who are or become more physically active, they will experience less severity and incidence of the following noncommunicable diseases: heart disease, stroke, hypertension, type 2 diabetes, dementia, depression, postpartum depression, excessive weight gain, falls with injuries among the elderly, and breast, colon, endometrial, esophageal, kidney, stomach, and lung cancer.[58]

Table 1.5 Physical Activity Terms for Evaluation of Level or Dose[a]

Terms	Categories [Steps][b]		
Intensity [Dose][a]	Light [Low]	Moderate [Moderate]	Vigorous [Optimal]
Absolute	< 3.0 METs	3.0 – 5.9 METs	≥ 6.0 METs
Relative			
Maximal HR	0 – 39%	40 – 59%	60 – 84%
Perceived Exertion[c]	0 – 4	5 – 6	7 – 10
Steps[d]	< 5,000	5,000 – 10,000	> 10,000

[a]Amount of physical activity performed during a specific time. Dose is cumulative over a 24-hour period
[b] Bracketed terms are associated with number of Steps
[c]Scale from 0-10, where 0 is level of effort while sitting and 10 is maximal effort
[d]Not a guideline, but can contribute to total physical activity

Even though any dose of physical activity appears to confer some benefit, it is still unclear what the optimal duration, intensity, frequency, and timing of exercise should be for various age groups, races, and illness to optimally manage health, chronic disease, and overall

well-being.[58] An exercise prescription should at a minimum have the appropriate intensity titrated to an individual's specific level of fitness. For clinicians, they must consider the metabolic effects of exercise and its potential to improve serum postprandial carbohydrate and lipid metabolites.[53,61-68] The 'postprandial phenomenon' suggests that the accumulation of blood glucose and triglycerides contributes to the development and progression of diabetes and atherogenesis respectfully.[66] Many, mostly small trials have investigated the effect of various doses and exercise protocols on postprandial blood glucose and lipids (primarily nonesterified fatty acids and triglycerides). Hypertriglyceridemia combined with high levels of blood glucose impairs metabolic flexibility and likely induces insulin resistance.[69,70]

Inclusion of any movement produced by the contraction of skeletal muscles has been shown to improve glycemic control in carbohydrate intolerant subjects and those with type 2 diabetes. Many studies have utilized aerobic activity in doses $\geq$ 30 minutes; however, there are beginning to be more trials that incorporate shorter durations, varying intensities, and protocols that include resistance training.

The relative intensity of exercise can be measured clinically by using either the percent of aerobic capacity (VO_2max) or percent of maximal heart rate. Subjective measures also exist, like the rating of perceived exertion scale, a simple tool the exerciser can use to self-assess effort level on a numerical scale which corresponds to intensity. These tools are beneficial for finding an optimal exercise prescription and titrating appropriately. For example, a more well-trained individual may be able to generate a higher wattage of work in a shorter duration compared to a sedentary individual. To equalize effort or intensity the more well-trained individual may need to perform an activity at a greater speed or with more relative resistance.

Medical Nutrition Therapy (MNT) is individualized nutrition care provided by a registered dietitian nutritionist or another nutrition professional meeting alternative criteria set forth by the representative state. In 2001, MNT was included in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) authorizing provider coverage for the provision of nutrition services for patients with diabetes and renal disease. Medical nutrition therapy services are defined by CMS as "nutritional diagnostic, therapy, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing disease".[71] Although carbohydrate counting and the diabetic exchange method may be two of the most common methods of nutrition education for patients requiring glycemic management, other dietary techniques and protocols are emerging as alternative, workable approaches. The following is a brief review of novel dietary approaches that have been investigated for the control of T2DM.

Food Order. The order in which nutrients in a meal are consumed has been shown to significantly lower postprandial hyperglycemia in patients with type 2 diabetes. A small pilot of 11 subjects were given the same isocaloric meal on two separate, fasted occasions. The meal contained high glycemic index carbohydrates, low-fat protein, and nonstarchy carbohydrates. When the protein and nonstarchy carbohydrates were consumed first, they observed a decrease in postprandial glucose levels at 30 (-28.6%), 60 (-37%), and 120 (-16.8%) minutes, and serum insulin at 60 (49.6%) and 120 (-40.2%) minutes.[72]

Similar results were observed in a slightly larger Japanese study that employed the strategy, '*vegetables before carbohydrate*'. They included a second arm that was evaluated over a 30-month period using monthly nutrition education sessions on free-living patients with diabetes. The intervention group had a significant decrease in HbA_{1c} from (8.2% to 7.1%) over

the 30-month intervention.[73] The same group later demonstrated in an educational intervention the advice to consume vegetables before carbohydrates was more effective than focusing on an exchange-based meal plan.[74]

Fasting protocols. There are a variety of fasting protocols that have become more popular. The three most common regimens are: (1) continuous energy restriction, i.e. caloric restriction (total daily kcals do not typically exceed 1200); (2) intermittent energy restriction (2 days, usually nonconsecutive, of energy intake $\leq$ 0-600 kcal/d), i.e. alternate day fasting or the 5:2 diet; and (3) time restricted eating or time restricted feeding (the feeding window of an individual is reduced to a 4-8 h time period).[75,76] A study comparing continuous vs intermittent fasting observed improvements in HbA_{1c}, weight loss, and fat mass loss although there were no significant differences between the groups.[77] Another group found intermittent fasting more advantageous for weight loss compared to continuous energy restriction in obese men.[78] The authors postulated that intermittent fasting is easier to execute since it only requires attention two days per week, requiring less consistency, and that it may produce 'rest periods' that minimize the compensatory metabolic responses or reductions in resting energy expenditure.[77,78] Simplicity, circadian rhythm regulation, reduced daily fed-state, and relying less on glucose are possible reasons why time restricted feeding regimens are able to produce lower blood pressure, decrease inflammation, and reductions in body weight in a small human trial and in rodents.[75,79]

Meal Frequency. The fed-state, i.e. the postprandial phase, lasts roughly 3 hours after the ingestion of a meal. After consuming a mixed meal containing carbohydrates, there is an increase in insulin, blood glucose, glycogenesis, and in caloric excess the potential for fatty acid synthesis.

Eating less frequently, i.e. 2 meals per day may be more advantageous than eating six smaller meals. This is similar to the principles of time restricted feeding by extending time between meals. Both practices, in theory, are simple to execute and both can reduce the length of time an individual is in the fed-state. One randomized crossover study showed improvements in body weight, hepatic fat content, fasting plasma glucose, C-peptide, glucagon, and oral glucose insulin sensitivity when the subjects with T2DM consumed only breakfast and lunch compared to when they were assigned a six meal per day regimen.[80]

Diabetes Prevention and Management Programs. Lifestyle interventions can prevent or delay development of T2DM in individuals with prediabetes and may be more effective than first-line pharmacological therapies as demonstrated in the National Diabetes Prevention Program (DPP) trial.[81] The National DPP is a year-long, group-based model, created in 2010 to address the increasing burden of prediabetes and T2DM in the U.S. It is a cost-effective intervention centered on behavior change, focusing on healthy eating and physical activity, and was initially established by the CDC to improve evidence-based prevention programming in clinical and community-based settings. Organizations that enroll individuals in a DPP will use a CDC-approved curriculum, host a minimum of 22 sessions over at least a 1-year time frame and submit participant attendance, weight loss, and physical activity every 6 months.[82] Despite positive outcomes from DPPs, referral (4.2%) and participation (2.4%) rates among qualified adults remain low. Although Blacks and Asians reported receiving more referrals, white females were most likely to participate. More concerning, it also appears potential participants lack an interest in enrolling in the offered programming. Seventy-four percent of adults who were not referred, reported a lack of interest in engaging in a year-long diabetes prevention program.[83]

Diabetes Mellitus: Technological management devices

Continuous Glucose Monitoring. Continuous glucose monitoring (CGM) also known as continuous glucose monitoring system (CGMS) has been approved by the FDA as recently as the late 1990's. These medical devices measure blood glucose concentration in subcutaneous tissue at set time intervals (usually every 5 mins) for the duration of the wear period. The CGM has a sensing monofilament that is inserted in the abdomen or backside of the upper arm. Newer models have a battery life to sustain a wear period that is approved for 7-10 days although the earlier models were only accurate up to 72 hours. Fingerstick glucose readings are often necessary for device calibration.[84]

An article by Clark & Lyons from 1962 proposed the first-generation of glucose biosensors in their review of the uses of electrode systems for continuous monitoring of pH, pCO_2 and pO_2 in cardiovascular surgery. They described placing a thin layer of the enzyme, glucose oxidase (GOx or GOD), containing dialysis membranes and a detector electrode to determine glucose by measuring the decrease in O_2 concentration and the liberation of hydrogen peroxide.[85] In the second generation of glucose sensors, the electron-acceptor, O_2, was replaced with a synthetic electron redox mediator. This resolved the deficit caused by oxygen concentrations being one order of magnitude lower than measured glucose concentration.[86] This eventually led to the development of the modern-day glucometer, which is a personal, portable blood-glucose meter, for the use of self-monitoring of blood glucose (SMBG).[87,88]

The ultimate use and benefit of CGM devices is to reduce hypo- and hyperglycemic excursions, obtain overnight blood glucose data and trends, and increase convenience to the patient by decreasing some of the time burden of conventional SMBG using invasive finger sticks. Conventional SMBG involving finger sticks has notable weaknesses for its diagnostic

capabilities. Finger sticks only measure blood glucose at a single point in time, nor do they provide information on the direction or velocity of changing glucose.[89] For T1DM, insulin requiring T2DM and insulin-naïve T2DM patients, most evidence indicates that consistent, frequent SMBG improves overall glycemic control, which imparts a subsequent reduction in HbA_{1C}, and an overall reduction in risk of adverse events.[90] Although testing frequency appears to improve control, testing is burdensome.[47] The profile of individuals most likely to test more regularly are older, female, living with a partner, longer duration of diabetes, multiple daily injection therapy (MDI), lower HbA_{1c}, poor hypoglycemic awareness, and recent hypoglycemic events.[91]

Newer CGM models are beginning to receive FDA approval for "non-adjunctive use", which means treatment decisions can be made without the use of additional finger sticks. At the time of this writing, two types of CGM systems are currently available: real-time CGM (rtCGM) and intermittently scanned continuous glucose monitoring (isCGM) also known as 'flash' monitoring.[89]

Behavioral Change Theories and Models

Among the leading causes of death in the U.S., diet and exercise, both lifestyle behaviors, are two modifiable factors that can help reduce the risk of disease onset or improve disease management. Most Americans do not consume enough fruits, vegetables, fiber and micronutrients while simultaneously consuming too many processed foods, sugars, salt, saturated fat, and calories. As mentioned previously, less than half of all Americans obtain enough levels of physical activity. Even though much is known about the positive benefits of optimizing diet and physical activity, very few people prioritize their time and take the necessary actions to execute these powerful health modifying behaviors. The execution of these changes, behavior

change or lifestyle change, describes changes in activities or practices by individual or groups that may improve health outcomes, decrease risk factors for chronic disease or improve disease management. The following sections will explore behavior change theories and examples of successfully employed techniques. Although in this writing, the primary focus of behavior change and behavior change theories reviewed will be related to diet and physical activity

Table 1.6 Summary Table of Behavior Change Models with Key Constructs and Determinants

Models and Theory	Key Constructs and Determinants	Miscellaneous Features
Health Belief Model	1) Perceived susceptibility 2) Perceived severity 3) Perceived threat or risk* 4) Perceived benefits* 5) Perceived barriers* 6) Self-efficacy* 7) Cues to action	Modifying factors can impact some constructs* 1) Age 2) Gender 3) Ethnicity 4) Personality 5) Socioeconomics
Social Cognitive Theory	1) Knowledge 2) Perceived self-efficacy 3) Outcome expectations 4) Goals 5) Perceived facilitators 6) Impediments	There is continuous interaction between: 1) Personal factors 2) Behavior 3) Environmental factors
Transtheoretical Model/ Stages of Change (SOC)	1) Precontemplation 2) Contemplation 3) Preparation 4) Action 5) Maintenance 6) Termination	The Processes of Change explain advancement through SOC 1) Consciousness-raising 2) Dramatic relief 3) Self-reevaluation 4) Environmental reevaluation 5) Self-liberation 6) Helping relationships 7) Counterconditioning 8) Reinforcement management 9) Stimulus control 10) Social liberation

modifications, much is written on addictive behaviors such as alcohol and smoking cessation, mental health disorders, and more currently, addictive gaming, and screen-time use.

Information and knowledge are useful tools to aid in behavior change; however, independently, they appear to have many inadequacies for sustained, motivated lifestyle changes required to observe significant, measurable improvements in health outcomes. The provision of knowledge about a given topic is referred to as education, or in this context, nutrition education.

Nutrition education can be delivered to individuals or groups and is typically seen to be more useful as a preventative tool rather than a therapeutic one.[69] Modern definitions of nutrition education include knowledge, skills, supports, and food and nutrition-related behaviors that can be used to inform the design process for intervention programs and educational curricula.[70]

Behavioral change theories attempt to explain the decision-making process of why and/or how individuals or groups change modify specific activities and behaviors.[71] *Theories* are useful tools for planning, implementing and evaluating interventions by answering 'what' information is needed and 'why' and 'how' individuals may respond or feel. Although there are multiple definitions of theory, the one used for this paper is from Kerlinger which states that a theory is "*a set of interrelated constructs (concepts), definitions, and propositions that present a systematic view of phenomena by specifying relations among variables, with the purpose of explaining and predicating phenomena"*. A *concept* is a major component of a theory and when a concept is adopted in a theory it is termed a construct. *Variables* specify how a construct can be measured in a specific situation and should be matched to constructs.[72] Many factors affect an individual's decision-making process and their perceived ability to execute a change. The behavior change theories reviewed here use a combination of the following factors: determinants, motivation, ability, support (interpersonal and environmental). The three most reviewed behavior change

theories and models in the published literature are the health belief model, social cognitive theory, and transtheoretical model.[72,73] Table 1.6 provides a summary of the key features of each of the models described here.

The **Health Belief Model (HBM)** was one of the earliest conceptual models used to explain health behaviors for the prevention or avoidance of diseases. It is a combination of Kurt Lewin's theory that an individual's perception of reality, rather than objective reality, influence behavior.[74,75] Lewin is considered by many to be the "father of social change theories".[76] His theory was later extended by Leventhal and others to explain the variations in adherence to treatment and integrating stimulus-response theory with cognitive theory to predict and explain behavior. Put simply, the HBM describes that an individuals' willingness to change is influenced by their health beliefs or convictions. The HBM offers explanations to some of the specific determinants or constructs that influence behavior.[72,73,77]

The determinants of action or key constructs of the model proposes that action is primarily motivated by the beliefs or convictions held by an individual about specific health-related information. The key constructs are (1) perceived susceptibility, (2) perceived severity, (3) perceived threat or risk, (4) perceived benefits, (5) perceived barriers, (6) self-efficacy and (7) cues to action. The model also acknowledges that age, sex and ethnicity exert indirect behavioral influences by impacting perceived threat, barriers and benefits.

The HBM was originally used to guide public health workers to design preventative interventions and predict behaviors related to health conditions. It is found in the literature as a tool to evaluate the effectiveness of health intervention use and educational programming. A study evaluating the effects of an educational intervention on 120 (60 intervention, 60 control) T2DM patients used the HBM to assess for effectiveness. Changes were measured at baseline, 3

and 6 months for the key constructs, and self-efficacy through a questionnaire data collection tool. The researchers found an increase in perceived susceptibility, perceived severity, perceived benefits, self-efficacy and a decrease in perceived barriers after attending only two 30-45 m education sections. Although they observed changes in beliefs, it is unclear if this will result in significant improvements in short or long-term health outcomes.[78]

Social Cognitive Theory (SCT) was born from social learning theory and developed and described in books authored by Albert Bandura.[82,83] The primary assumption of SCT is that human behavior is explained by the dynamic interactions between personal, behavioral, and environmental determinants. It has a core set of determinants which include knowledge, perceived self-efficacy, outcome expectations, goals, perceived facilitators and impediments.[84] Although the HBM and the TTM are models of individual health behavior, the SCT is a model of interpersonal health behavior where individuals interact with the environment and influence each other in a form of reciprocal determinism.[72]

Transtheoretical Model (TTM) and Stages of Change (SOC) was originally developed in the late 1970s and 1980s by James Prochaska and others from a comparative analysis of the leading theories of psychotherapy and behavior change. The stages of change were discovered from subjects' disclosing that they used different processes at different times in their attempts to stop smoking. This led to the concept that behavior change happens through a series of stages. The TTM is built on the stages of change which contain six core constructs: (1) precontemplation, (2) contemplation, (3) preparation, (4) action, (5) maintenance and (6) termination. Some newer interpretations of the model omit termination leaving five core constructs. The TTM model describes change as a gradual, continual process that develops overtime, but it may also be dynamic and nonlinear.[72,79] The TTM does not help predict

behavior; however, it proposes self-change is a model of behavior change that can help guide planned change efforts.[72] Although not reviewed here, other theories, like the theory of planned behavior (TPB), identify intentions as the best predictors of behavior change.

Behavior change can be described by the phenomena of all the pre-action(s) and motivation(s) that takes place before an actionable step is performed. Pochaska provides an explanation of progress through the SOC by the Processes of Change (POC) which contain ten constructs: (1) consciousness-raising, (2) dramatic relief or emotional arousal, (3) self-reevaluation, (4) environmental reevaluation, (5) self-liberation or commitment, (6) helping relationships, (7) counterconditioning, (8) reinforcement management (managing rewards), (9) stimulus or environmental control, and (10) social liberation. The POC have practical implications when designing an intervention. Figure 1.3 illustrates the processes that typically support progression between the SOC. If an intervention was designed to improve stimulus control or provide helping relationship to a population that is mostly in the precontemplation and contemplation stages of change, the intervention would likely be less effective than a targeted one based on the subject's stages of change. Prochaska's reports most at-risk populations align with the following stage of change distributions: 40% of the population are precontemplators, 40% are contemplators and 20% are preparing although other studies show some discrepancy to this generalizable rule observing the precontemplation distribution closer to 20%[79-81].

Foregoing a formal assessment of a target populations SOC, or the lack of informed studies, could result in a fundamental design flaw of a well-intended intervention if the distribution in the stages of change, a variable, does not match the process of change.[79]

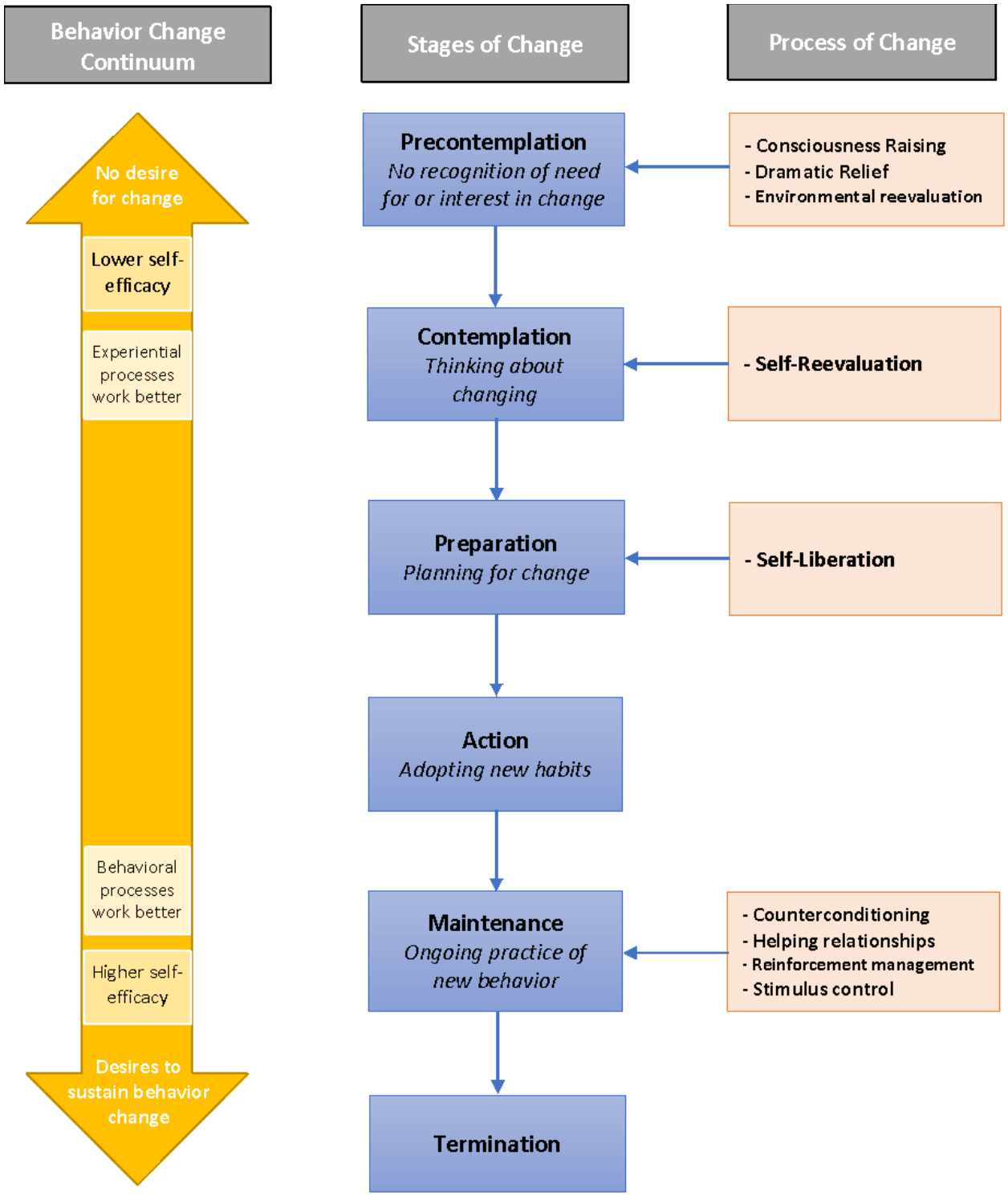

Figure 1.3. Conceptual Overlay of the Constructs of the TTM/SOC for Intervention Design

TTM/SOC Informed Behavioral Change. Some studies have solely examined the scales and measures for assessing stages of change, decisional balance, situational self-efficacy and processes of change for specific populations.[81] These preliminary findings may be particularly helpful for informing future clinical or public health interventions to tailor the behavior change strategies to the individual stage of change subgroups in a study.

Since behavior change cannot take place until an individual has taken an actionable step and had a change in beliefs or cognition, the TTM can help researchers and program designers create individualized interventions designed to help people progress along the stages of change. To aid in the movement along the stages of change, interventions may use the process of change constructs to influence desirable behaviors. The ten processes of change can be divided into the following two process categories: experiential/cognitive and behavioral. Experiential processes are (1) consciousness-raising, (2) dramatic relief or emotional arousal, (3) self-reevaluation, (4) environmental reevaluation, (5) self-liberation or commitment whereas the behavioral processes are (6) helping relationships, (7) counterconditioning, (8) reinforcement management (managing rewards), (9) stimulus or environmental control, and (10) social liberation.[73].

CHAPTER 2: HEALTH AND DIETARY BARRIERS OF FOOD INSECURE PATIENTS WITH DIABETES: A MIXED-METHODS ANALYSIS OF PROJECT FEED

ABSTRACT

Objectives: The aims of this study were to (1) evaluate dietary quality and psychological disposition and (2) explore psychosocial and environmental barriers and facilitators to healthy eating in food insecure patients with uncontrolled type 2 diabetes mellitus.

Methodology: A total of 14 participants were recruited from an outpatient clinic in the Triangle region of North Carolina. Dietary quality was assessed using the 24-hour recall method and psychological screenings were done using the HRQOL and PHQ-2. Semistructured interviews contained questions from three primary categories: perception of healthy eating, barriers to healthy food, and experience with discrimination. Interviews were recorded, transcribed, coded, and analyzed using thematic analysis. All data and interviews were obtained from the participants' homes.

Results: The mean energy intake was 1358 kcal. Shortfall nutrients were vitamin A, folate, vitamin C, vitamin D, calcium, potassium, magnesium, and fiber while saturated fat, sodium, phosphorus, and niacin were greater than reference amounts. Deficiencies were observed in all food groups except refined grains and oils. Thirty-three percent of participants had a positive screening for the likelihood of a major depressive disorder. Two major themes emerged: barriers to healthy behaviors (subthemes: transportation, money, and comorbidities) and reliance on God.

Conclusion and Implications: Based on these findings, programs working with patients dealing with food insecurity and chronic conditions should consider reducing the barriers for obtaining healthy, suitable foods by addressing their financial constraints, obstacles with transportation, and the physical and psychological burden of comorbidities. A component of

spirituality may be beneficial because it appears this population relies on their faith in God for comfort and to experience contentment.

INTRODUCTION

Food insecurity (FI) and diabetes mellitus are both independently associated with poor health, inadequate or improper nutrient intake, and exert an additional financial burden on individuals dealing with either of these issues.[2-5,7,22,24,45,46,52] When both issues are present in an individual, they synergistically confound health and create additional obstacles for disease treatment. Food insecurity is a social determinate of health and can be identified and categorized by the 6, 10, or 18 item survey screeners developed by the USDA's Economic Research Service.[92] Diabetes is a chronic medical condition with tiered criteria to describe severity and a leading cause of death in the United States.[39] The prevalence rates of FI and diabetes are greater in minority and economically disadvantaged groups. Diabetes is an independent risk factor for food insecurity, and food insecurity is associated with an increase in mortality. Food insecurity and diabetes are multidimensional issues requiring comprehensive interventions and an interdisciplinary care approach for these patients. Because access to nutritious foods and healthcare utilization are typically low in these patients, they have a greater risk of developing comorbidities and experience substantial barriers to appropriate disease management behaviors.[5,10,11,42,43]

In 2020, the prevalence of food insecurity was estimated to effect 10.5% of U.S. households. Of these households, 6.6% had low food security and 3.9% had very low food security.[1] *Low food security* reduces access to desirable foods, but quantity of food intake is not severely disrupted. Whereas households with *very low food security* experience reduced food intake due to a lack of money or other resources for food. Households in the South, containing children, Black householders, and when the reference person is unemployed all have greater food insecurity prevalence. Food secure households tend to spend 18% more, as a percent of total

income, for food than the typical food insecure household of equivalent size, and the latter may make tradeoffs that reduce their access to healthcare and disease management equipment or treatment.[1]

In 2018, the Centers for Disease Control and Prevention (CDC) estimated that 10.5% of the U.S. population had diabetes, and for adults over the age of 18 years, the prevalence increases to 13.0%.[41] Rates are highest in American Indians, Black, and Hispanic ethnic groups; counties in the southern and Appalachian regions; individuals over the age of 44; and those with obesity (BMI $\geq$ 30).[42,93] Adults who did not complete high school have nearly twice the incidence rate compared to those who completed high school. Racial differences in diabetes incidence are likely explained by modifiable biological differences and a combination of environmental, psychosocial, socioeconomic, and behavioral factors. Biological factors like elevated waist circumference, body weight, blood pressure, and dyslipidemia exert the strongest association with disease incidence. Other risk factors include racial and poverty composition of neighborhoods, depressive symptoms, educational level, employment and marital status, difficulty paying for basic needs, smoking and alcohol use, dietary intake (low intakes of fruits, vegetables, and whole grains and high intakes of sodium and sugar sweetened beverages), and physical inactivity.[42]

Food insecurity negatively affects both dietary quality and quantity. People experiencing FI tend to have lower intakes of fruits, vegetables, low-fat dairy, fiber, vitamin A, vitamin B_6, calcium, magnesium, zinc, and higher intakes of ultra-processed foods.[3,4,94] Multiple international and domestic groups have identified that a Western dietary pattern containing nutrient poor foods consisting of refined grains, sugar sweetened beverages, and low nutrient density foods is associated with a significantly greater risk of developing diabetes than a more

traditional, cultural, and plant-based diet.[42,43,95-99] These findings explain, in part, why chronic disease rates, like diabetes, are 40% greater in people with FI. Because poor dietary quality is a risk for disease development, it is not surprising that these issues are interconnected and confounding.[1,2,100] If diabetes precedes FI, the individual experiences significant increases in health care expenses and the additional time burden for disease management. The costs associated with diabetes may stress already limited financial and time resources leading to the disruptions in one's ability to procure suitable foods in sufficient quantities.[45-47]

Food pantries, soup kitchens, and shelters are the most common nonfederal form of emergency nutrition support for people dealing with food insecurity. These hunger-relief charities help reduce or eliminate the barriers associated with cost and access to food. These agencies were initially designed to provide temporary assistance; however, many households utilize these services regularly.[101] Through the Feeding American network, there are approximately 60,000 charity agencies that serve customers directly and 200 food banks which act as larger distribution hubs for the smaller point-of-access agencies.[102] Although food pantries do not appear to be effective at reducing food insecurity, they do seem to decrease the impact and overall burden somewhat.[101] Another notable shortcoming of food pantries is the poor nutritional quality of the available foods. Since most food pantries do not have refrigeration or freezer storage, they often lack the capacity to distribute perishable food. Without refrigeration, food must be shelf-stable, so the largest percentage of distributed items and calories are nonperishable.[103-105]

The conundrum food assistance agencies face is offering sufficient calories to reduce the impact of hunger and low food resources while being mindful of the impact poor dietary quality has on the health of their customers. For agencies to offer more nutritious foods they must

navigate issues with supply and acquisition and then satisfy their clients' preferences and the demands for specific food items.[103,105,106] Various interventions have been piloted in food pantries, and modest improvements in supply and customer food selection behaviors were observed. Intervention programs designed to improve the dietary quality of food pantry users mostly utilized some form of nutrition education to affect the desired behaviors. Strategies included more traditional education sessions and brochures to target a specific nutrient or food group, like sodium[107] or whole grains,[108] or more novel approaches using a peer mentor model,[109] color-coded food quality ranking system,[110-112] or food sampling/exposures.[103,108,113]

Other qualitative studies have explored the general experiences of food pantry customers and their barriers and facilitators to healthy eating. To expand on previous work, our study investigates the health profile and experiences of a medically vulnerable cohort of patients dealing with food insecurity and uncontrolled diabetes in an urban environment who were participating in a fresh produce home delivery program. The aims of this study were to investigate (1) dietary profile and psychological disposition and (2) through semi-structured interviews, explore the perceptions and decisions made when choosing foods, challenges obtaining foods, and experiences with discrimination in healthcare.

METHODS

Study Design

This cross-sectional, mixed-methods study obtained data from a medically vulnerable cohort of patients participating in a home delivered fresh produce program. Data was collected from multiple short surveys and an in-depth interview. Diet and psychological disposition were assessed using an ASA24 hour food recall[114] and through surveys assessing self-efficacy, disposition, and mood.[115,116] Recorded, semistructured interviews were used to explore the specific barriers and facilitators of food insecure patients with uncontrolled diabetes. Participants who enrolled in the study program, Project FEED (Feeding Empowerment and Educational Delivery), were provided monthly in-home nutrition education by a FEED team and a monthly bag of fresh produce. Participants received these services at no cost for 6 months. Project FEED is an interinstitutional collaboration between a medical school and a dietetic internship (DI) program in the Triangle region of North Carolina. FEED teams contained a first-year medical student partnered with a graduate level dietetic internship student. Each FEED team was responsible for following their assigned patient for the duration of the 6-month in home, nutrition education and produce delivery program.

Student Teams Training

Each FEED team had one medical school student and one dietetic student. All teams were required to attend an initial orientation, two training sessions, provide informed consent (Appendix A1), and complete a survey, which was used for the analysis of a separate study. The orientation provided an overview of the program, expectations, and an opportunity for student participants to ask the researchers questions. The first training session, taught by a medical school faculty member, covered basic motivational interviewing techniques. Students met their

teammate and performed a team building activity. On a separate evening, the second training session reviewed the nutrition education curriculum and how to establish appropriate goals with the patient participant. FEED teams were assigned their patient during the second session and medical staff provided an overview of the patient's health history, contact information, and any confounding health, social, or living issues that could make the sessions more challenging.

Nutrition Education Curriculum

The nutrition education curriculum was written and organized by an RDN and designed by one of the medical research team members. The curriculum was written at an 8th grade reading level and contains six units which introduced and reviewed the following topics: vegetables, fruits, grains, protein, quick meals, and snacks. Educational content was primarily sourced and adopted from the United States Department of Agriculture's MyPlate and Dietary Guidelines for Americans, 2015-2020.[117] Additional information was obtained from the Centers for Disease Control and Prevention, the National Institute of Diabetes and Digestive and Kidney Diseases, and the American Diabetes Association. Each unit was specifically designed to address optimizing dietary strategies to improve blood glucose control and improve other diabetes related outcomes through nutrition. The complete manual is located in Appendix A2.

Participants

Purposive, convenience sampling was used to recruit participants from a large, outpatient university medical center during the Spring of 2018. Potential participants were screened using a multiple pass method to ensure all eligibility requirements were met. The first screening pass was conducted internally by clinic staff. Food insecurity screening was performed using the Economic Resources and Food Security USDA 6-item questionnaire.[92] If patients were positive for food insecurity, they were invited to participate in the clinic's on-site fresh produce program.

The clinic's fresh produce program provides a free bag of fresh fruits and vegetables each week that could be picked up for personal use. From the fresh produce program patient pool, a second pass was done to sort for the appropriate medical characteristics. The eligibility requirements were: two or more comorbidities and at least one was diabetes with an $HbA_{1c} \geq 8.0$. If all eligibility requirements were met at this point, contact from the outpatient medical staff was made and an invitation to participate in Project FEED was offered. For interested patients willing to participate, the third pass was done to ensure home suitability and safety. A visit to the patient's residence was performed by a licensed clinical social worker (LCSW) or a registered dietitian nutritionist (RDN) to ensure a safe environment for researchers and students. Other exclusionary criteria were: lack of stable housing, unable to communicate, unable to consent, Spanish speaking only.

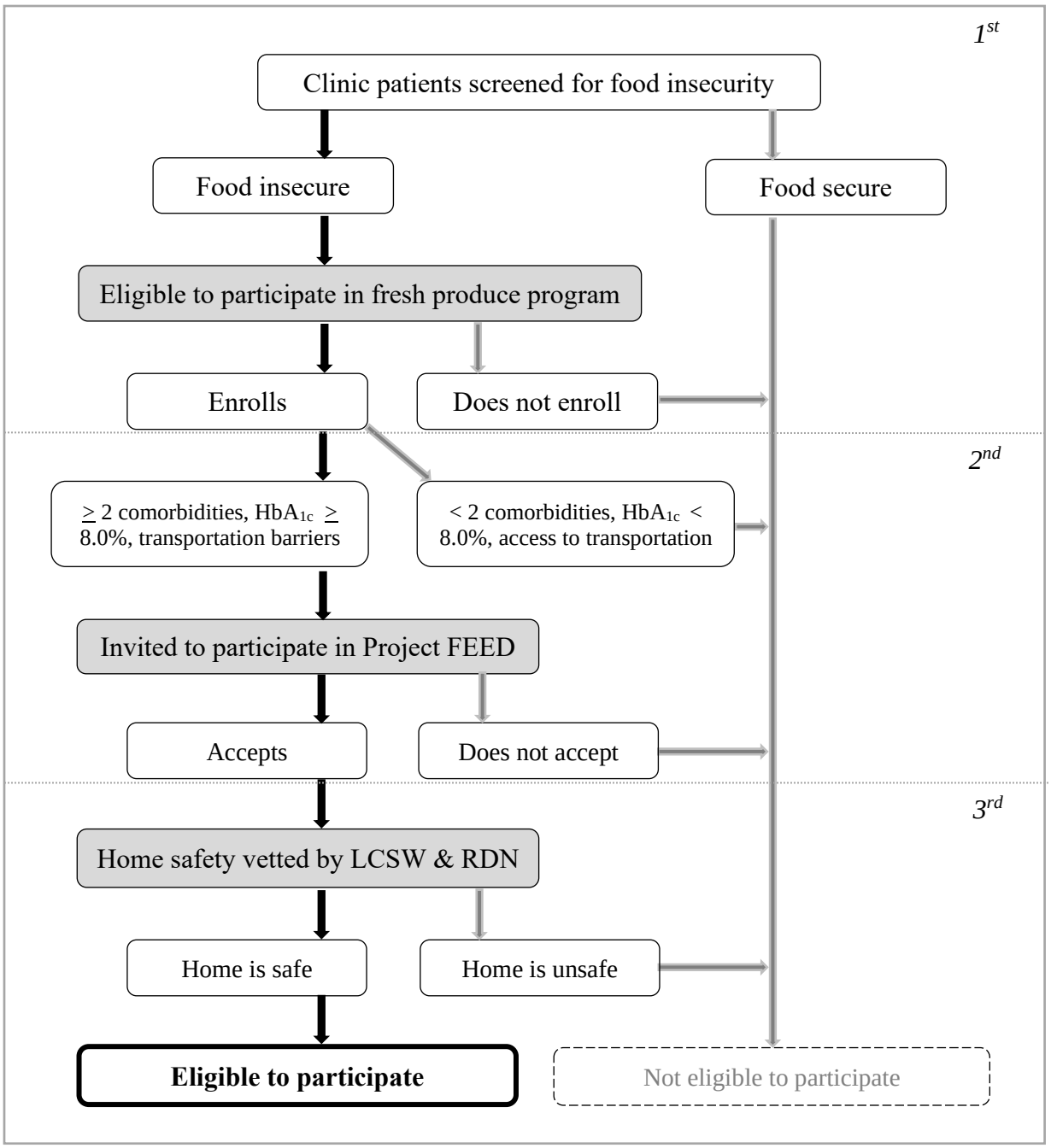

Figure 2.1. Project FEED Participant Eligibility Flow Diagram *Spring 2018*

Materials and Instruments

Semi-structured Interview Guide

Researchers developed a semi-structured interview guide with a series of open-ended questions organized into three different categories exploring facilitators of healthy eating, barriers to healthy food, and experiences with discrimination in healthcare. There were eight required questions with the option of up to six additional probing questions to explore a positive response and obtain more context from a required question. Interviews were recorded using Olympus digital voice recorders. *Interviewers* completed ethics training and received basic qualitative research methodology education from content area experts from their respective universities. All interviewers had experience in health care, treating patients with food insecurity, and diabetes. Interview questions were reviewed by content area experts and then the researchers conducted internal, mock interviews. Some minor edits were made to several questions for clarification and the order of the questions was changed to improve cohesiveness and flow of interview.

Other Instruments

During enrollment visits with participants, researchers obtained a 24-hour dietary recall and read aloud and recorded their responses for three short surveys. Dietary recalls were obtained using the National Cancer Institute, Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24).[114] The Healthy Days tool or Health-Related Quality of Life (HRQOL) is a surveillance tool to assess "an individual's or group's perceived physical and mental health over time". We used the 4 question HRQOL which uses scaled responses. The tool is maintained in the Centers for Disease Control and Prevention's Division of Population Health and can be used as a proxy to measure the health component of overall quality of life.[115] The

Table 2.1 Semi-structured Interview Guide for Project FEED Participants

Category	Prompts and Questions
Perception of Healthy Eating	Prompt: *I'm going to ask you some question about the types and kinds of foods you typically eat.* 1. Tell me about the foods you eat on a regular basis. 2. What do you eat at home that you consider to be a healthy meal? 3. What makes it easy for you to eat healthy?
Barriers to Healthy Food	Prompt: *I'm going to ask you some questions about issues that could make eating more challenging.* 4. What makes it difficult for you to eat healthy? 5. Can you tell me about the things that make it hard to get food. Probe: For example, some people don't have transportation to a grocery store. Prompt: *Being able to eat and have access to food are really important to health and wellbeing. Other things that are also important include having a safe place to live and exercise, having supportive relationships, and being able to get around.* 6. Can you describe how these issues are going for you? Probe: a) What makes these things difficult? b) What helps you with meeting these needs?
Experience with Discrimination	Prompt: *I am going to ask you some question about discrimination. If you are uncomfortable answering any of these questions, feel free to decline a response.* 7. Have you ever experienced discrimination or been treated unfairly because of your weight, what you eat, or how you look when obtaining medical services? Probe: a) If so, can you tell me about the last time this happened? b) Why do you think it happened? c) How does that make you feel? 8. Have you ever experienced discrimination because of your race or gender? Probe: How do you think that affects the healthcare you receive?

Patient Health Questionnarie-2 (PHQ-2), 2 question screener, was used to screen for depression in a first-step approach.[116] Researchers developed three questions to assess perception of self-efficacy related to shopping and cooking. The self-efficacy tool was not validated.

Data Collection

Researchers contacted research participants by phone to schedule a time for home interviews and data collection. Researcher first reexplained the purpose of the study, provided an overview of Project FEED, expectations for participants, benefits, potential risks, and then encouraged questions before obtaining consent. One researcher from the team conducted the interview and obtained responses to the three surveys in the participants' main living space or kitchen. Interviews were recorded then downloaded from an audio recording device to a HIPAA compliant repository. Participants were asked not to have other household members present during the data collection session to reduce any bias. Total time spent in each participants' home ranged from 60-90 minutes and most recorded, semi-structured interviews took approximately 15 minutes. Surveys were read to participants and responses were recorded by the research staff member on behalf of the participant. The multiple pass ASA24 dietary recall was also read and recorded by the researchers based on the participant's responses. Dietary recalls were cleaned and reviewed in detail for missing data. All recalls were inspected for breakoffs, outliers, and entry duplications. All interviews and survey data were collected during May and June of 2018.

Data Analysis

Interview recordings were transcribed verbatim and time stamped by undergraduate research assistants who were trained to transcribe audio files. Transcriptions and audio files were then reviewed by a researcher to ensure text and audio matching. To develop the codebook, each participants' transcript was reviewed in triplicate by the research team. During weekly meetings,

the team discussed first impressions, emerging themes, notes, and memos. The initial transcription review process yielded four coding categories with a total of 21 individual codes. Final edits were made to the codebook including code exclusionary criteria (e.g. when a code is not appropriate to use for a particular circumstance) and any code definition which shared overlapping meaning were redefined. Two codes were removed, which left four code categories and 19 individual codes. Table 2.2 provides a summary of the final code book, and the full manual can be found in Appendix A4.

Before research assistants could begin assigning codes to the transcriptions, they had to complete coder training. Coders completed ethics training using a self-paced module, reviewed basic qualitative research methodology and theory, and practiced with an actual passage. Coders were required to assign codes to a passage from a deceased participant's interview transcript. The code associations were discussed in a group setting and examples were provided on why a code may be a good or poor fit for different scenarios. After coders were trained, all transcripts were reread and coded using codes from the revised coding manual. To increase trustworthiness, all interviews were coded independently by a lead researcher, registered dietitian, and research assistant. The researchers continued to meet weekly during the coding process and used consensus coding to determine appropriate assignment of codes. When consensus was unable to be reached after group discussions, the lead researcher would make the final decision.

Raw counts, means, and percentages were used to quantify demographic characteristics, health metrics, food security, self-efficacy, health related quality of life, and depression from the three surveys and screeners. Using a single pass 24-hour recall, we calculated averages for total energy, macro and micronutrients, saturated fat, added sugars, food groups, sources of foods, and

beverage consumption patterns. We also looked at number of eating occasions, feeding window, and eating environment.

Table 2.2 Summary of Code Categories and Individual Codes from Project FEED Code Book *Spring 2018*

Code Category	Individual Codes
Dietary Habits	Food Decisions (healthy)
	Food Decisions (unhealthy)
	Food Choice Compromises
	Skipping Meals
	Ability to Prepare Meals
	Nutrition Facts Panel Understanding
Barriers to Healthy Eating	Financial
	Miscellaneous
	Perceived
	Environmental
Motivations	God
	Coping Strategies
	Physical Activity
	Assistance/Support Structures
Social Determinants of Health	Comorbidities
	Experience with Crime or Violence
	Physical Safety
	Health Literacy
	Discrimination

RESULTS

Demographic Profile

A total of 14 participants were enrolled and consented to Project FEED. Baseline data was obtained for 12 of 14 (86%) and interviews were obtained for 14 of 14 (100%) of individuals. Participants complied with the request to conduct the interviews in private although during two interviews we were briefly interrupted by other household occupants. These slight interruptions did not appear to disrupt the candor of the interview process. Two participants became deceased during the 6-month nutrition education intervention portion and two more were lost to follow up, so they were unable to complete the nutrition education component. The average age of the participants was 55 years old (range 23-74 years), 11 (79%) were female, 12 were Black (86%), 1 was White (7%), and 1 identified as Other (7%). All participants were unemployed or retired and had an annual income of less than $35,000. Only 3 (21%) lived with a partner or were married, and the rest, 9 (79%), were single or resided alone.

The mean BMI (body mass index) for the group was 40. All participants had more than two comorbidities, and the average number of chronic disease diagnoses per person was 4.8

Table 2.3 Project FEED Patient Demographics

Participant Characteristics	Number of Participants (%)*
Total No.	14 (100%)
Age, y	
Range	23-74
Mean	55
Sex	
Male	3 (21%)
Female	11 (79%)

Table 2.3 Continued	
Ethnicity	
Black	12 (86%)
White	1 (7%)
Other	1 (7%)
Income	
< 25K	11 (92%)
25-35K	1 (8%)
Education	
HS_{some}	4 (33%)
HS_{grad}	6 (50%)
BS	2 (17%)
Relationship Status	
Single	5 (42%)
Partner	1 (8%)
Married	2 (17%)
Widowed	2 (17%)
Separated	2 (17%)
Food Security Status	
Food secure	0 (0%)
Marginal food security	1 (8%)
Low food security	5 (42%)
Very low food security	6 (50%)
Health Metrics	
BMI	9 (40)*
Chronic Diseases	14 (4.8)*
HbA_{1c} %	11 (9.7)*

*****Health metric values in parenthesis are calculated means

(range 2-8 separate diagnosis). All participants had "uncontrolled" diabetes and the mean HbA_{1c} was 9.7%. Nearly all participants had a food security status of Low Food Security or Very Low Food Security, 42% and 50% respectively. One person had Marginal Food Security (8%).

Psychosocial Screeners

Self-efficacy and confidence in ability to eat a healthy diet were assessed from three questions related to food quality, preparing, and obtaining healthy foods. Three (27%) respondents felt they ate healthy "most of the time", six (50%) felt that they ate healthy "sometimes", and the remaining 3 (27%) chose "not very often" or "none of the time". Eight of 12 (66%) reported "some" or "completely confident" preparing healthy meals. Most, 10 out of 12 (83%), participants felt at least "somewhat confident" in their ability to choose healthy foods from the grocery store.

Table 2.4 Healthy Eating Self-Efficacy Screener

	Level of Confidence				
Question/Item	**Not at all**	**Not very often**	**Sometimes**	**Somewhat confident**	**Completely confident**
Ability to eat healthy	1 (08%)	2 (17%)	6 (50%)	3 (25%)	0 (00%)
Preparing healthy meals	1 (08%)	2 (17%)	1 (08%)	5 (42%)	3 (25%)
Choosing health foods	2 (17%)	0 (00%)	0 (00%)	7 (58%)	3 (25%)

From the four question Health Related Quality of Life Scale (HRQOL), most respondents, 9 (75%), said their health was "fair" or "poor", 1 (8%) person chose "good", and 2 (17%) chose "excellent". Over the last 30 days, 6 (50%) participants reported that their physical health was not good "more than half days" or "nearly every day", 5 (42%) chose "several days", and only 1 stated "not at all". Mental health was slightly better than physical health for the last

30 days. Four (33%) participants reported their mental health was not good “more than half days” or “nearly every day”, 5 (42%) chose “several days”, and 3 (25%) stated “not at all”.

Four out of 12 (33%) participants scored ≥ 3 on the PHQ-2 which suggests a major depressive disorder is likely. When asked about having low interest or pleasure when doing things only 3 (25%) chose “more than half of the days” or “nearly every day”, 6 (50%) chose “several days”, and 3 (25%) reported not experiencing low interest or pleasure. For disposition, 5 (42%) reported not ever feeling down, depressed, or hopeless; however, 4 (33%) reported a negative disposition on “several days”, and 3 (25%) on “more than half of the days”.

Table 2.5 Health Related Quality of Life Scale (HRQLS) and Patient Health Questionnaire-2 (PHQ-2)

	Perceived Physical and Mental Health Over Time			
Question/Item	**Not at all**	**Several days**	**> Half days**	**Most days**
How many days during the past 30 days was your physical health not good?	1 (08%)	5 (42%)	4 (33%)	2 (17%)
How many days during the past 30 days was your mental health not good?	3 (25%)	5 (42%)	3 (25%)	1 (08%)
How many days did poor physical or mental health prevent usual activities?	3 (27%)	4 (36%)	1 (09%)	3 (27%)
	Depressed Mood			
How often have you had little interest or pleasure in doing things?	3 (25%)	6 (50%)	2 (17%)	1 (08%)
How often have you felt down, depressed, or hopeless?	5 (42%)	4 (36%)	3 (25%)	0 (00%)

ASA24

The mean energy intake was 1358 kcal, which is lower than the reference value for individuals over the age of 50 years old. Fiber was also notably lower than the recommended

amount at 11 grams. Fat and protein were consisted with reference amounts and saturated fat was 19 grams. On average participants consumed approximately 10 teaspoon-equivalents of added sugars.

Table 2.6 Energy and Macronutrient Profile

Dietary Component (Value)	**Project FEED [mean]**	**Reference Value[a] [F > 50 years old]**	**± difference (%)[e]**
Energy (kcal)[a]	1358	1600	-242 (85%)
Protein (g)[b]$_{RDA}$	60	46	+14 (130%)
Fat (20-35% of total E in g)[c]	54	36 – 62	0 (100%)
Saturated Fat (g)[d]	19	20	-1 (95%)
Carbohydrates (g)$_{RDA}$	160	130	+30 (123%)
Sugar (g)	61		
Added Sugar[d] (t equivalents)	10	12	-2 (83%)
Fiber (g)$_{AI}$	11	21	-10 (52%)

[a]based on EER (Estimated Energy Requirement) using a reference female that is sedentary, 55 years old, 126 lbs and 64”
[b]Value based on reference weight using 0.8 g/kg/d
[c]AMDR (Acceptable Macronutrient Distribution Range)
[d]% DV (Daily Value)
[e]percentages are provided as a reflection of adequacy to the Reference Value

Participants consumed lower than the reference value for total fruit, total vegetable, legumes, total grains, whole grains, and dairy. They consumed greater than the reference value for refined grains, protein, and oils. On average less than a half serving of whole grains were consumed. Most dietary protein came from poultry (42%) and other meats like pork and beef (31%). Cured meats (i.e. processed meats, “lunch meats”) and eggs accounted for 11% each. Less than 1% of calories from protein each came from seafood, legumes, and soy, while nuts accounted for approximately 2% of protein intake mostly from peanut butter. For vegetables,

more than half of the participants only consumed potatoes or other starchy vegetables like peas or corn. This subset also lacked any intake of red, orange, or dark green vegetables nor did they consume a source of legumes. Only one participant consumed a partial serving of legumes.

Table 2.7 Food Group Equivalents and Intake

Food Group[a] (serving size)	Project FEED [mean]	Reference Value [F > 50 years old]	± difference (%)[b]
Fruit, Total (c-eq)	0.5	1.5	-1.00 (33%)
Vegetables, Total (c-eq)	1.35	2	-0.65 (68%)
Vegetables, Starchy (c-eq)	0.6	0.6	0.00 (100%)
Legumes (c-eq)	0.04	0.14	-0.10 (29%)
Grains, Total (oz-eq)	3.7	5 (3 whole)	-1.30 (74%)
Grains, Refined (oz-eq)	3.4	2	+1.40 (170%)
Protein (oz-eq)	5.25	5	+0.25 (105%)
Dairy (c-eq)	0.6	3	-2.40 (20%)
Fats, Oils (g)	13.5	5 (t)	+8.50 (270%)
Fats, Solid (g)	26	NA	NA

[a]US Department of Agriculture, Healthy U.S.-Style Eating Pattern for 1,600 calorie level pattern
[b]percentages are provided as a reflection of adequacy to the Reference Value

Of the micronutrients, vitamin A, folate, vitamin C, vitamin D, calcium, potassium, and magnesium were below recommended dietary intake levels. Iron, sodium, phosphorus, and niacin were consumed in amounts greater than reference values. When comparing mean intakes to the median values, significant decreases were observed in iron (13 grams to 9 grams), vitamin A (329 mcg to 223 mcg), vitamin C (55 mg to 33 mg), and vitamin K (88 mcg to 58 mcg). Nearly two-thirds of the participants (64%) reported drinking sugar sweetened beverages or fruit-flavored beverages. Only 3 (21%) participants consumed any tap water, and 79% consumed only

Table 2.8 Mineral and Vitamin Intake

Dietary Component (Value)	Project FEED [mean]	Reference Value[a] [F > 50 years old]	± difference (%)
Calcium (mg)$_{RDA}$	537	1200	-663 (45%)
Copper (mg)$_{RDA}$	88	90	-2 (98%)
Iron (mg)$_{RDA}$	13	8	+5 (163%)
Potassium (mg)$_{AI}$	1663	4700	-3037 (35%)
Sodium (mg)$_{AI}$	2610	1300	+1310 (200%)
Magnesium (mg)$_{RDA}$	180	320	-140 (56%)
Phosphorus (mg)$_{RDA}$	858	700	+158 (123%)
Selenium (mcg)$_{RDA}$	88	55	+33 (160%)
Zinc (mg)$_{RDA}$	8	8	0 (100%)
Vit A$_{RDA}$	329	700	- 371 (47%)
Thiamin (mg)$_{RDA}$	1.2	1.1	+0.1 (109%)
Riboflavin (mg)$_{RDA}$	1.2	1.1	+0.1 (109%)
Niacin (mg)$_{RDA}$	20	14	+6 (142%)
Vit B6$_{RDA}$	1.7	1.5	+0.2 (113%)
Folate, total (mcg)$_{RDA}$	257	400	-143 (64%)
Vit B12 (mcg)$_{RDA}$	2.7	2.4	+0.3 (112%)
Vit C (mg)$_{RDA}$	55	75	-20 (73%)
Vit D (mcg)$_{RDA}$	2	15	-13 (13%)
Vit K (mcg)$_{AI}$	88	90	-2 (98%)

[a]based on EER (Estimated Energy Requirement) using a reference female that is sedentary, 55 years old, 126 lbs and 64”

bottled water. The average total moisture intake from both foods and beverages was 1712 grams. No one reported any consumption of alcohol.

Semi-structured Interviews

Fourteen of 14 (100%) semi-structured interviews were completed. The average length of the interviews was 13.51 minutes, and the range was 3:31-48:52 minutes. All participants were asked 8 questions from three categories: Perception of Healthy Eating, Barriers to Healthy Food, and Experience with Discrimination. The Experience with Discrimination section contained two close-ended questions with follow up probes if the interviewer received a positive response. Two dominant themes emerged from this cohort of patients as they described the burden of living with uncontrolled diabetes and food insecurity and their attempts to reconcile poor health and environmental circumstances. The patient experiences are described in the following sections 1) barriers to healthy behaviors and 2) and thankfulness for God.

Barriers to Healthy Behaviors

Participants consistently described transportation and money as barriers that limited access to self-defined healthy foods. Additionally, confounding psychological stressors existed simultaneously. Participants expressed concerns related to the management burden of comorbidities and experiences with violence. This confluence of stressors and barriers appeared to challenge the adoption of otherwise healthy behaviors, caused worsening health outcomes, and effectively reduced their ability to properly engage in consistent disease management practices.

Transportation

Participants frequently cited limited financial resources as a significant impediment to being able to afford a convenient mode of transportation to access preferred foods. Transportation posed a significant barrier to preferred grocers or food retailers which they

described as having a better selection and a higher quality of food. These food retailers were usually further away, so public or private transportation was required. Since most participants did not have access to a private vehicle, they relied on rides from friends, family, public transportation if they lived in close proximity to a bus line, or had enough money to purchase a nonshared, commercial ride service. When the cost of transportation became prohibitive, there was a greater reliance on local stores such as Dollar Tree, Family Dollar, or private corner stores. Participants reported that when they have to rely on stores that are closer to home, they have to accept the trade-off on quality for convenience. Food costs were not always cheaper in the stores with a closer proximity to their residence; however, their selection and overall food quality were described as worse. Participants often had to contend with the dilemma of spending more money on transportation to procure desired foods versus obtaining food from local retailers. The cost of transportation would therefore reduce the total available funds for food potentially resulting in an unacceptable quantity.

> "*Well, my aid takes me to the store. So, if she don't come it's hard for me to get there because, uh, if I don't have the money to pay the cab then I can't [get] there. So, that's hard for me to get there to the store, mainly because if I don't have the finances to get there or the money to buy the food*."

Some participants utilized a supplemental approach using both public transportation and support from friends and family. This individual expresses her frustration of having to wait for her daughter to drive her to the store on the weekend. If she chooses to take the bus mid-week, she has to make a 1-hour bus trip to Walmart each way. She stated her daughter was only available to transport her on the weekends because she is working. She describes her two options of waiting and going without preferred foods versus enduring a long trip that ultimately costs more.

"*Yeah, it can get aggravating, if it comes to that point. I'm like, you know what, let me wait until the weekend. That's what I normally try to do, unless it's something I really, really want to eat and I don't have it in the house*."

There was also a general perception that healthier foods are more difficult and costly to access.

"*It is harder to get healthy food because of the money. Getting healthy food is more expensive*."

Money

Although money was frequently cited as a common barrier to transportation, they were not always blended areas of concern. Money still appeared to be an independent underlying stressor and functioned as another barrier to healthy food access and healthcare utilization. This participant, immediately preceding this passage, stated that transportation was not an issue for her. She cognitively separates the two and sees money as an insufficient resource to bridge the gap between other supplemental resources and aid programs.

"*Sometimes money makes it hard for me to get food. um...I don't get uh a lot of food stamps and I uh have two grandkids that um I take care of and I uh be working part-time because I'm disabled. I get a disability check, but that whole check goes to my bills, so the only money I have...the money I get from my little part time job so [it] makes [it] kinda hard sometimes*".

This participant found an innovative strategy to maximize her money. She frequents a variety of different food retailers and developed relationships with many of the store employees and managers. Employees of the store will give her a call, or she will call them to learn if there are any deals on food items.

> "*I let them know I am on a budget, and I need a little help. He [the manager] said, "we always [give] help if you askin", so I say "let me ask", and I've been asking. And that's what, that's what they do*."

The store manager and workers are more than willing to assist her by providing this information if she calls the store. Another participant employs a similar strategy. She described a challenging scenario where she didn't have enough money to afford formula and diapers. She concluded that the baby was at risk of becoming malnourished, so she pursued assistance from the store managers rather than utilizing federal or state sponsored nutrition support programs.

> "*If you got to go in the store, and you don't have the money, just walk up to the lady, tell the lady, "say look I don't have the money to get my baby no milk or get my baby no Pampers, so can you please help me out?", and if she can help you, she going to help you, or either she going to send you somewhere else where you can get help*."

Comorbidities

Comorbidities were common in this cohort of participants. Twelve of the 14 (86%) participants had 4 or more diagnosed conditions. All participants had a diagnosis of diabetes, and other common conditions that were described were health issues (nonspecific), lethargy, pain, and depression. They acknowledged the complexities of trying to manage these chronic conditions and the mental and physical exhaustion they experience as a result. Some participants admitted to enduring bouts of lethargy that made it more difficult to actively manage their conditions and engage in health promoting behaviors. Here a participant describes how physical exhaustion interferes with her motivation to cook and eat healthier foods so she resorts to consuming convenience, highly processed food items.

"I just don't feel like preparing nothing and maybe even eat the wrong stuff like the Weenies and stuff, and stuff like that. Just sometimes too tired and just don't feel like it."

Another participant acknowledges that constant effort is required to control and maintain blood glucose. She also mentions how critical the timing of management is and, at times, must be acted on immediately to avoid a dire outcome.

"*Cuz blood sugar may want to decide to go high and you gotta. you gotta fight for that. You gotta be like aight, I know I'm gonna be tired, maybe if I take this insulin, then I can relax, or then you gotta wake up to low blood sugar, you'll be like, ugh.*"

There is also a sense of concern that current conditions could worsen and negatively impact other conditions or health attributes. Some references were made to specific biometrics and labeled as "under" or "out of" control. Here, a participant refers to the length of time dealing with a foot ulcer and its impact on quality of life. There is also the awareness that when blood glucose and HbA_{1c} are elevated, this correlates to a poor healing environment for the ulcer, and the persistence of the ulcer is causing frustration.

"*Next week it's going to be four months, that's ridiculous, yeah, it's like the more your blood elevates, is the more the wound stop trying to heal. Because he's like when you bring down the your A_{1C} level you will notice how the wound start healin' good. It has to do when your, ya know, your blood level and it was elevated, up to a nine. I think it'd be, it would bring back up my mood, cause right now I feel so depressed with ya know the foot."*

Similarly, this participant understands the importance of exercise to help improve diabetes and other illnesses; however, she suffers from chronic pain which is a cited barrier to her engaging in exercise.

> "*…it's kinda hard for me to do exercises and things cuz, um, I be in a lot of pain most of the time so that kinda makes it hard*."

This participant commented that the lack of money, onset of neurological symptoms, and depressed mood were all reasons why she described her health as "bad". Like others she has multiple physicians and there appears to be a management burden as they work with her to attempt to find a solution for the bouts of vertigo. She describes the scope of impact as a *part of [her] life*.

> "*...money is a main factor and then umm. You know, like I was saying before, I have to base my days, based on my dizzy spills. So, when I would like to go to the pantry or the shelter, but sometimes I am not able to because I'm too dizzy to get out or too dizzy to go for a walk. It's just that part of my life; it's a main obstacle in my life. But I'm trying really hard with my primary doctor, specialist, and all the different medical [people] and then there is my mental health you know. When I get in one of my real bad depression episodes, I just don't want to do anything. and that's not healthy*."

Spirituality

Faith in God was a consistent theme throughout our interviews. Participants described God as a source of contentment, hope, and safety. There was an awareness of the severity of one's conditions, health status, and financial limitations; however, their belief in God allowed an optimistic reframing to one of "this could be worse". Participants displaying an attitude of

contentment appeared to find solace that any predicament they were currently facing would be temporary or a predetermined challenge in which they were provided the strength by which to overcome. In this example, a participant was responding to a question related to being able to afford preferred foods. Initially her responses were,

> "*…you got to make with what you got*." and "*I can afford what I need to afford*."

She describes not being able to afford some foods that she desired, but at the same time suggesting she has her minimum needs met. She finds security and trust in God, and that He will provide food for her, so she must be patient.

> "*…if I want something and I know I can't afford it…I got God on my side and he's going to make it happen. He may not make it happen when you want it to happen, but he will make it happen right on time*."

This participant described suffering with poor health for the last 20 years, and she stated she is a difficult patient to diagnose and treat because of the complexity of her symptoms and health conditions. She spoke appreciatively of her relationship and the work a cardiologist performed to successfully diagnose and treat her when she underwent triple bypass surgery and received multiple stints. She believes the cardiologist's work and God's intervention were responsible for keeping her alive. She believes God has preserved her life and that she must now help others.

> "*But I'm not complaining because a lot of people wouldn't still be here. It's God. It's just nobody but the Lord. I know who it is. So, I try not to complain*."

A different participant similarly gave context to her financial concerns related to food access. She admitted to not having enough money for food or having the "right food in the house" because of her lack of available transportation. She described having limited mobility and having

to rely on forearm crutches which she explained made mobility and obtaining food difficult. When asked about other aspects of her health, she explained that she relies on a relationship with God for guidance, comfort, and daily support.

> "*It could be better. You know, I, um, I take it day by day. You know [trying to] improve on things, but ya know if I don't keep God in [the midst] of it, it would never work for me. Which I gotta keep God in a relationship for spiritual guidance and get through my daily process, yeah*."

DISCUSSION

Other qualitative studies have previously investigated the impact of food insecurity on type 2 diabetes in similar populations;[118-121] however, this is one of the first to take a mixed-methods approach to investigate other stressors and barriers to a healthy diet. Money and transportation were the two most commonly reported barriers to obtaining healthy foods while physical pain, experiences with violence, and relying on others to access goods and medical services were also mentioned as frequent stressors. The nutritional patterns we observed were consistent with many dietary risk factors for the development and progression of chronic illnesses. Managing and worrying about comorbidities, especially diabetes, was both a time burden and stressor. Many of the participants relied on their faith in God and had a spiritual practice to cope with these stresses. Our findings appear to be consistent with the work of other groups and further builds on the literature to understand the characteristics and behaviors of this medically vulnerable population dealing with food insecurity and type 2 diabetes.

Barriers to Healthy Food

Money is clearly linked to food insecurity and food insecurity is associated with higher rates of diabetes, other comorbidities, and worse health outcomes overall.[2,6,7] Even though money was expressed as a barrier for acquiring food, it was not apparent that the participants saw their economic position as a potential cause for their current health status. Since this line of questioning was not explicitly asked, it's unclear if this association was present or not. Money was not described as a barrier for larger purchases or expenses like rent or mortgage payments, utilities, medical bills, or debt, but there was a heightened sense of monetary awareness around the costs of smaller purchases. Exact costs for certain products and services were often cited and

mentioned. Participants performed many micro decisions for smaller expenses and calculated costs to stay within the confines of their budget.

A commonly described barrier that money presented was access to food. “Access” for the participants could be defined as suitable *grocer location* and desired *mode of transportation*. For the participant to have full access to preferred foods, they had to have sufficient money to afford both the cost of the food and the transportation necessary to travel to the food retailer. Oftentimes, the preferred grocer was further away, thereby increasing the cost for transportation and causing a redistribution of food-funds for travel expenses. Conversely, grocers with a more ideal proximity were reported to have less food variety and lower quality products. Other qualitative analysis of persons dually experiencing food insecurity while managing diabetes also found transportation as a major barrier to food access, the ability to meal-plan, and obtaining preferred foods.[119-121] Our study cohort used a variety of public and private transportation methods to gain access to food. No one blamed their health on or suggested that owning a private vehicle would result in an improvement in their health. Relying on public transportation and others, such as friends and family members, seemed commonplace. Food access related to limitations in transportation were exacerbated because the participants resided in known food desert tracts.[122]

People experiencing food insecurity tend to have a lower overall dietary quality,[3,4] which is an outcome we also observed. Overall, their consumption patterns could be described as pro-hypertensive or a pro-oxidative stress diet. The average diet was characterized by high intakes of saturated fat, sodium, sugar, and sugar sweetened beverages, while calcium, potassium, magnesium, whole grains, fiber, and plant-based sources of protein were low. Commonly consumed foods were refined grains from white bread, hush puppies, and pasta; from protein

ground beef, chicken, and lunch meats; the most common vegetables were white potatoes, green beans, corn, and cabbage; very little fruit was consumed; and snack foods like potato chips, ice cream, crackers, and pork rinds were abundant. No one consumed sufficient water. Most meals that were consumed came from prepared or convenience foods. Participants reported feeling confident in their ability to cook. However, in this sampling, cooking was almost never performed other than warming up canned or frozen food in the microwave or on the stovetop.

Spirituality

Resilience was an emergent theme in other studies containing similar participant demographics who were also experiencing a combination of food insecurity, diabetes, or mental health issues.[118-121] Although resilience was not an independent and dominant theme in our study, it was present and intertwined throughout the participants' faith and trust in God, which was a major theme. This phenomenon has been described as "God-reliant". Relying on God in this context allows emotional stresses to be shared or fully transferred to an external entity alleviating some or all the worry.[123] Spirituality may provide the capacity to transcend what may be otherwise perceived as bleak circumstances such as poor or worsening health conditions and limited financial resources. Walker et al. explored potential intervention programs for food insecure, African Americans living in the inner city with diabetes. They found that faith in God and religion were important facilitators, and participants relied on these beliefs as plausible coping mechanisms. Paradoxically, negative health outcomes were not attributed to God or "His plan",[121] which we similarly observed. Some participants appeared to be more than accepting of their health and economic situation and may even hold a theological deterministic position. This position of accepting what is and what is to come threatens personal responsibility and the will to make executive changes. They also reported that participants desired interventions that had a

peer-relational component, access to community resources, and stress management.[121] Two participants from our cohort suffered massive heart failure and described being thankful for their health and the blessing of life which they attributed to God's mercy and grace. The ability to be resilient, appears to be the result of consciously remaining in a state of contentment. Suffering and enduring hardships are common themes found throughout many religious doctrines including the Bible. This phenomenon is likely tied to the spiritual practice of actively trying to emulate or endure similar experiences held by the primary deity of a particular religion. Resilience may emanate from spirituality, and spirituality is a common coping mechanism in African Americans dealing with financial stress and illness. Spirituality is used to cope with the stress of family pressures, parenting, and daily psychological distress.[121,123,124]

Another similar study conducted by Myers, et al., investigated the coping strategies of African Americans diagnosed with a mental illness and experiencing food insecurity. When asked about their relationship with food, the researchers learned that participants were lonely and isolated. During moments of stress or sadness, participants reported either eating more due to boredom, or less because they felt preparing food for one was too burdensome.[119] We observed the potential for these effects also. Most of our participants lived alone and ate meals in isolation. All interviews were conducted in the participants' homes during daytime hours. Our researchers reported that windows were covered by blinds or curtains to restrict natural light, and televisions were often left on without anyone watching. Nearly all participants reported eating with the television on. Myers, et al., concluded that a strong social theme related to food and mental health exists in this population. The desire to eat communally was tied into aspects of familial, social bonding, and even nostalgia. Even though this group was economically disadvantaged, there was a strong desire to share resources with others.[119] Our findings confirmed the outcomes

described in the literature that external social supports, coping strategies, and concern of one's health may have a greater place of importance than money alone. These factors should be considered and incorporated into any thoughtful programmatic design and when proposing policy to help this population. Faith-based features may increase relatability, improve relational development, and increase acceptance. A biopsychoscocial-spiritual approach may be needed to improve desired behavioral and health outcomes.[125]

Limitations

Although we did not intentionally seek out African American participants, our multiple pass screening criteria yielded a patient cohort that was predominately African American (86% and 93% nonWhite). This did not impact any procedures of the study design but does reflect the local population for the specific geographical area where we recruited. One of our main objectives was to explore barriers to healthy eating. We did not explicitly survey how well utilized or knowledgeable they were of federal or state sponsored nutrition support services. SNAP was mentioned by two participants, but we did not explore the benefit amount or if the benefits were consistently used.

Instead of obtaining 3 separate 24-hour recalls from each participant, which is more in line with a higher level of rigor, we only obtained one 24-hour recall from each participant. It usually took multiple attempts to schedule an appointment and cancellations, rescheduling close to the appointment time, and no shows were common. Feasibly, it would have been very difficult to obtain two additional passes for each participant and potentially subject them to an unnecessary burden.

CONCLUSIONS

In this cohort of individuals experiencing food insecurity and uncontrolled diabetes, money and transportation were consistently expressed as significant barriers to a healthy diet and preferred foods. Future programs attempting to improve food access should address these two barriers while also considering incorporating components of faith-based practices to enhance acceptance and connect with these individuals at a spiritual level. If faith-based practices are not feasible or acceptable, using community or family may improve social bonding and reduce isolation. Although pain was not a dominant theme, it was noted during several interviews. Future studies may consider exploring meditation in the form of prayer or other biofeedback techniques to help reduce pain associated with chronic illness and other etiologies not explored here. If addressed, the determinants described in this study may yield an improvement in quality of life by improving overall health from a biopsychosocial-spiritual perspective.

CHAPTER 3: INTERPROFESSIONAL EDUCATION BETWEEN DIETETIC INTERNS AND MEDICAL STUDENTS IMPROVES CONFIDENCE IN NUTRITION EDUCATION DELIVERY SKILLS

ABSTRACT

Research Question/Aims

Does participation with an interprofessional education program between students enrolled in two different medical specializations increase confidence in delivering nutrition education and improve willingness to collaborate with other healthcare providers?

Methodology

Graduate students from a dietetic internship (DI) program and first year medical students were partnered together in teams of two. Each student team was assigned a patient who had received a positive screening for food insecurity and uncontrolled diabetes from a local clinic. For 6 months, student teams delivered fresh produce to their patient and provided monthly nutrition education in the patient's home. The nutrition education curriculum covered basic nutrition information such as serving sizes, food groups, label reading, and how to improve blood glucose control. The students completed pre- and post-participation surveys to self-assess their knowledge and skills gained from participating in the program.

Results

Students' *Change in Perceived Confidence* after the 6-month program compared to baseline demonstrated significant (p-value < 0.05) increases in confidence for 7 of the 9 items. Confidence increased in students' ability to obtain a diet history, counsel patients, make a referral, and the nutritional management of common chronic diseases.

Conclusion/Importance

Healthcare training programs should consider utilizing interprofessional educational opportunities to increase confidence, learning, and the ability to collaborate within the healthcare interdisciplinary team, which may improve overall patient care and health outcomes.

INTRODUCTION

Interprofessional education (IPE) is thought to be a precursor to productive and effective interprofessional collaborations (IPC), especially in health care delivery.[126] The World Health Organization (WHO) defines IPE as occurring *when students from two or more professions learn about, from and with each other to enable effective collaboration and improve health outcomes*.[127] In a comprehensive update of a large meta-analysis, the Institute of Medicine, found that IPE was associated with stronger competency specific knowledge, improvements in perception and attitudes, and changes in skills. To a lesser degree, some studies observed changes to the delivery of patient care and improvements in clinical outcomes.[126] A logical progression is that IPE will lead to more IPC which will lead to better patient outcomes and satisfaction for both healthcare workers and patients. Providers engaged in interprofessional collaborative practices should know how to work in an interprofessional team with health workers from different professional backgrounds and competently communicate within the team to patients, families, and communities.[127]

Models that have been used for IPE often feature designated courses with specific learning outcomes targeting IPE. They often involve bringing together student representatives from a variety of medical and allied health specializations. In diverse teams, they will engage in collaborative patient-centered care, evidence-based practice, communication, and/or quality improvement assignments and projects.[28,128] Possible barriers for academic programs adopting an IPE framework are curricula coordination and planning and interpersonal relationship development. Students from different disciplines often arrive at specific professional training degrees with different levels of knowledge, and this can lead to lower levels of appreciation towards a profession that may have less rigorous admittance standards.[129]

METHODS

During Fall 2018 in the Triangle region of North Carolina as part of an interinstitutional collaboration, graduate students from a dietetic internship (DI) program and first year medical school students participated in a fresh produce home delivery and nutrition education program. Students from each institution were partnered with a student from the other program and these student teams were assigned a patient for whom they were responsible for delivering fresh produce and monthly nutrition education in the patient's home.

Student Recruitment

Both cohorts of students were recruited through their program's experiential learning competencies that were aligned within an academic training course. Student participation in the program through the course was mandatory; however, students had to opt-in to the study and complete informed consent found in Appendix A1. Information sessions were held separately for each group of students and their respective course instructors to explain the program, study design, expectations for participation, and answer any preliminary questions. Training was held over the course of two evenings. Each training session taught motivational interviewing skills, held team-building exercises, and an opportunity to review and practice the delivery of the nutrition education curriculum. Training was provided by a medical doctor and registered dietitian and the topics were: *Engaging Hard-to-Reach Patients; Tips for Effective Nutrition Education;* and *Motivational Interviewing*.

Nutrition Education Curriculum

The nutrition education curriculum was written and organized by an RDN and designed by one of the medical research team members. The curriculum was written at an 8th grade reading level and consisted of six units which introduced and reviewed vegetables, fruits, grains,

protein, quick meals, and snacks. Curriculum workbook content was adopted from publicly available nutrition information from the USDA, CDC, ADA, and NIDDK. Each unit was specifically designed to address optimizing dietary strategies to improved blood glucose control and improve other diabetes related outcomes through nutrition. The workbook is located in Appendix A2.

Patient Recruitment

Patients were recruited from a large outpatient university medical center during the Spring of 2018. Patients already participating in the clinic's on-site fresh produce program were used for the sampling pool because they already met an initial screening criterion for food insecurity. The fresh produce program provided eligible patients with a free bag of fresh fruits and vegetables each week that they could pick up for personal use. Food insecurity was identified by the Economic Resources and Food Security USDA 6-item screener by one of the clinic's medical staff.[92] Additional eligibility requirements included a diagnosis of two or more comorbidities with at least one being diabetes and an $HbA_{1c} \geq 8.0$. For interested patients willing to participate, a social worker or registered dietitian conducted a home visit to ensure a safe environment for researchers and students. Exclusionary criteria were lack of stable housing, unable to communicate, unable to consent, Spanish speaking only.

Procedures and Outcomes Measured

Student teams contacted their assigned patient and scheduled a convenient time to deliver the fresh produce and conduct the hour-long nutrition education. This procedure was repeated for 6 months. Using the curriculum, students would set monthly dietary goals for the patients and follow up with achievement of each at the subsequent visit. One DI and one medical student were paired and assigned to a patient that they would visit together and provide nutrition

education monthly for a total of 6 months. Patient evaluations were conducted separately, as a part of a larger study, and will not be reviewed here.

Students were asked to fill out a survey describing their skills and confidence for various topics related to diabetes management and care (Appendix B1). The first survey was administered at the beginning of the initial training session which all students were required to attend. The follow up survey was administered at a 6-month wrap-up session. Skills and confidence were self-assessed by each student using a 5-point Likert scaled response. Paired t-Tests were used to check for significance ($\alpha = 0.05$) between group means.

RESULTS

Fourteen dietetic internship students were matched with 14 first-year medical students. All 28 students (100%) completed the baseline survey and 20 of 28 (71%) completed the 6-month follow up survey after their participation with the home delivered nutrition education program. The survey investigated items related to clinical skills, overall patient care, and disease specific nutrition management knowledge. The first category included clinical skills and overall patient care. Of the 5 items assessed in this category, all were significant except the perceived importance to refer to a nutrition professional. The mean score of the post group for this item still

Table 3.1 Students' Change in Perceived Skills and Confidence After Participating in an Interprofessional Education Program

Question	Baseline Mean (variance)	6-Mo Mean (variance)	p-value
Clinical Skills			
Obtain Diet Hx	3.20 (1.12)	4.00 (0.74)	0.002
Counsel Patients	3.25 (1.57)	3.80 (0.69)	0.024
MI Skills	3.15 (0.66)	3.85 (0.56)	0.005
Referral (Teammate)	2.80 (1.22)	3.75 (1.88)	0.002
Referral (Other Nut. Prof.)	1.35 (0.45)	2.05 (3.10)	0.100[NS]
Nutritional Management of Disease			
LDL	3.20 (1.75)	3.60 (1.20)	0.057[NS]
Renal	2.60 (1.94)	3.50 (1.11)	0.000
T2DM	3.10 (1.88)	4.00 (1.05)	0.001
Celiac	3.10 (2.52)	3.65 (2.03)	0.030

[NS] = Not Significant

observed an increase (0.70) although it did not meet significance (0.100). This was likely do to confusion in the participant responses since it was the only item with a high variance value (3.10). For knowledge related to nutritional management of diseases, three of the four items were significant. The only item that did not reach significance (p-value = 0.057) was management of

LDL cholesterol although the mean value for that item did improve (0.40).Participants were also asked where they gained most of their relevant knowledge on nutrition during their educational training. Most students chose traditional lectures followed by case studies and not receiving any relevant training at all. The graph below demonstrates the format and distribution of receiving relevant nutrition education to help patients treat diseases using nutrition.

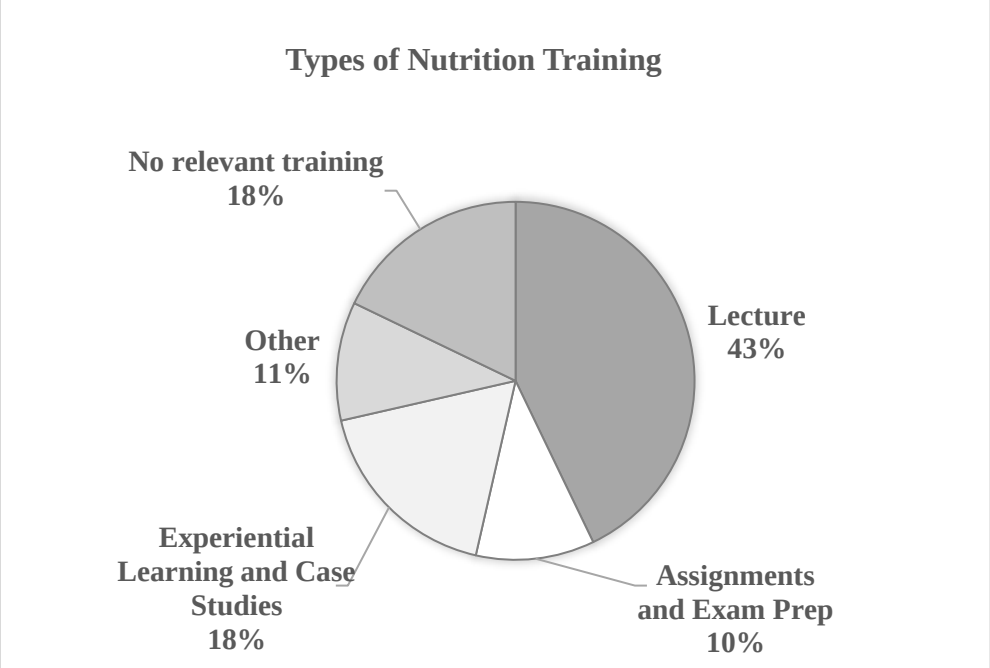

Figure 3.1 Type of training where most nutrition knowledge was obtained by medical students and dietetic interns

DISCUSSION

This study was one of the first to use IPE and IPC with students from a dietetic internship program and a medical school to provide nutrition education for a medically vulnerable patient in the patient's home. Each student was able to learn more about the educational requirements and professional skills of their partner's healthcare professional area. Each pairing also received the experience of working with a patient for 6 months. Using a team-based collaboration method likely decreased the anxiety and responsibility compared to working with a patient alone.

When medical students are exposed to nutrition in their training curriculums, they report an increase in knowledge, confidence, and both a willingness to provide nutrition education and refer to nutrition professionals.[31,32] Since nutrition is such an important factor for the development of noncommunicable diseases such as diabetes, heart disease, obesity, cancer, and hypertension, earlier preventative nutrition education and counseling could reduce and prevent the onset and worsening of these conditions. Poor dietary habits are associated with the greatest reduction of disability-adjusted life years. After tobacco, which is second, elevated BMI, blood pressure, and fasting plasma glucose are the third through the fifth most significant contributors to lifespan reduction, and they are all modifiable lifestyle factors that are strongly tied to diet.[130] If physicians appreciate the role diet and lifestyle have in preventing these chronic conditions, they may be more willing to refer their patients to registered dietitian nutritionist or address these issues themselves.[21,27,131,132]

Our findings did demonstrate an increase in medical students' willingness to refer to other healthcare professionals and a stronger understanding of the nutrition specific factors effecting chronic and autoimmune illnesses. These benefits were also observed in their improvements in confidence levels to deliver nutrition education, provide nutrition counseling,

and understanding of the role of nutrition in disease management. Although this was not an evaluation metric, the student pairings appeared to enjoy each other's company and formed strong bonds during the experience. We did not receive any negative feedback from either student group during the first year of the program. The program is now in its fifth year and both institutions are satisfied with the success of the program and the work performed by their respective students.

The dynamic nature of health systems requires more intentional efforts for educators and curriculum planners to continually coordinate redesign efforts to ensure training is aligned with practices. Student healthcare training programs are rarely reformed in real time after a health system undergoes a redesign.[126] Both cohorts of students were recruited through their program's experiential learning competencies that were aligned with an academic training course. Professional healthcare training courses should consider utilizing these experiences to expose students to industry standards and common practices. An added benefit could also be early practice and interactions with actual patients. Utilizing an interprofessional education approach, collaboration of resources between other medical training programs could enhance knowledge and confidence of entry level clinical skills for their graduates.

Most medical education tends to take a traditional approach, which is less holistic in nature, and more emphasis is given to disease pathogenesis and symptom management. The traditional approach relies on pharmacological therapies to address unfavorable symptoms and out-of-range biometrics. Prevention and salutogenesis are rarely taught and are underutilized in the traditional medical model.[27-29] Salutogenesis is the process through which health and well-being are sustained, and it highlights the behavioral patterns associated with the ability to maintain or generate optimal health. Graduate medical education (GME) is limited in

competencies targeting disease prevention and health span optimization. It has been well documented that most students in GME training programs in the U.S. do not receive more than approximately 25 hours of nutrition education.[25,28,133,134] Since most chronic diseases and many acute illnesses are affected by poor nutrition, it is important for physicians to have at least a basic working knowledge of how an optimal diet can improve the health of their patients. A 2013 survey assessed the degree to which U.S. medical schools were providing the minimum recommendation of 25 hours of nutrition education. Only 29% of schools out of 121 institutions were meeting the minimum requirement. Thirty-six percent of the schools were not even meeting half of the requirement. Efforts have been made to ensure nutrition education is covered in GME curriculums, and although some improvements have been noted, there is still a shortfall in content hours.[135] This is a consistent finding observed in medical schools in Europe and from other continents.[136,137] Traditional medical training does not equip physicians with the skills needed to help patients contented with real-world nutrition challenges and optimizing an individual's diet for health, wellness, and healing.[29] Interprofessional educational programs appear to increase the perceived value of the other partnering profession. This should lead to more intentional collaborations and foster a robust interdisciplinary team for comprehensive patient care.

CONCLUSION

Increasing partnerships with interprofessional educational experiences between healthcare training programs is an excellent way to satisfy experiential learning competencies. Having early exposure to IPE may improve willingness to engage in IPC, particularly when treating complex patients as a part of a healthcare team. Our findings suggest that an IPE experience also increases treatment knowledge, professional referral competence, and may improve offerings of preventative services.

CHAPTER 4: EFFECTS OF SHORT-INTERVAL, HIGH INTENSITY EXERCISE ON POSTPRANDIAL GLUCOSE

ABSTRACT

Aim: To examine the effects of short bouts of high intensity interval training (HIIT) before meals on postprandial blood glucose.

Methods: Fourteen healthy adults participated in this randomized, crossover study. The trial lasted for 1 week (day 0-day 6). On day 0, a daily, repeatable menu was individualized, continuous glucose monitor fitted, and anthropometric measurements were obtained. The menu plan was repeated on days 1, 2, 4, and 5. Meals were consumed at the same time each day. In one arm of the study, a 5-minute HIIT workout video was performed before each meal on days 1 & 2. All activity was restricted for days 3-5. The other arm restricted activity on days 1-3 and performed the exercise on days 4 & 5. Day 3 was a washout for both groups and diet was liberalized. The primary outcome investigated was change in postprandial blood glucose assessed at 120 minutes after each meal by the difference from baseline glucose measurements.

Results: Postprandial blood glucose was lower for 4 (29%) participants on exercise days compared to nonexercised days. Participant level significance was determined by at least 2 of 3 aggregated meal groupings reaching a level of significance which was determined by a p value < 0.05. Total significant meal groupings were 12 of 42 (29%) for T = 0-120 minutes and 16 of 42 (38%) for T = 30-120 minutes.

Conclusion: In healthy, young adults, HIIT before meals did not significantly reduce PPBG for most participants.

INTRODUCTION

In 2018, there were 34.1 million U.S. adults (13.0%) living with diabetes.[41] Another 29.6 million more adults are estimated to be undiagnosed. The prevalence of diagnosed and undiagnosed when combined may account for more than one quarter of the U.S. adult population.[17] Diabetes was the 7th leading cause of death in the U.S in 2019, yet with the addition of Covid-19 in 2020, it dropped to 8th with over 100,000 deaths and a year-over-year increase of almost 17%.[138,139]

Diabetes mellitus is a group of chronic diseases characterized by a reduction in the capability of cells to uptake glucose to use for normal metabolic processes.[33] Type 2 diabetes mellitus (T2DM) account for 90-95% of all diagnosed cases. Type 2 diabetes is primarily characterized by insulin resistance which is a condition that decreases tissue sensitivity and responsiveness to insulin resulting in an increase in the concentration of blood glucose. Most individuals with T2DM are also obese, which itself causes some degree of insulin resistance. Other common risk factors for developing T2DM are low physical activity, poor dietary quality, or having a prior or existing diagnosis of gestational diabetes or prediabetes.[34,35]

Physical inactivity is now identified as a leading risk factor for global mortality. Physically active individuals have less chronic disease risk, reduced depressive symptoms and anxiety, sleep better, report improvements in mood, and better overall health and function. Physical activity is bodily movement requiring energy expenditure to support the contractions of skeletal muscles. This includes working, playing, performing chores, and engaging in recreational pursuits. Exercise is a subset of physical activity and described as planned, physical movement performed with the intent to improve or maintain one or more components of physical fitness.[57] The *Physical Activity Guidelines for Americans* recommends that adults should

perform a minimum of 150-300 minutes of moderate-intensity physical activity while also performing resistance exercises on two or more days each week. In 2015, almost a third of Americans were considered “inactive” or had less than 10 minutes of activity per week and another 19% had “insufficient activity”.[58] In total, over half of all American adults are not meeting the minimum activity level dose of 150 mins per week. With the onset of Covid-19, almost a third of adults in the U.S. and in other countries further reduced physical activity levels. Physical activity levels declined because of social distancing measures; school, work and business closures; and concerns of contracting the virus.[140-142]

Sedentary behavior is characterized by an energy expenditure of $\leq$ 1.5 METs (metabolic equivalents). Moderate-intensity is defined as roughly 3-6 METs and vigorous-intensity as > 6 METs.[59] One metabolic equivalent (MET) is the amount of oxygen consumed while sitting at rest and is equal to 3.5 ml O_2 per kg body weight x min.[60] A noteworthy amendment in the 2018 Scientific Report is the omission of the minimum bout requirements.[58] In the 2008 report, the duration of an exercise bout was set at a minimum of 10 minutes.[59] The 2018 committee concluded that bouts of any length can accumulate and contribute to the overall health benefits of physical activity. This amendment to the definition of exercise could result in different strategies and approaches to fulfilling physical activity requirements. Individuals may have more flexibility in how, where, and when they exercise to reap the positive health benefits of being active. Any dose of physical activity appears to confer some benefit, but it is still unclear what the optimal duration, intensity, frequency, and timing of exercise should be. An exercise prescription should, at a minimum, have the appropriate intensity titrated to an individual’s specific level of fitness. When individualizing physical activity, considerations

should be made to ensure suitability for different age groups, races, and type of illness to optimally prevent or manage chronic disease and improve overall well-being.[58]

For clinicians, they must consider the metabolic effects of exercise and its potential to improve serum postprandial carbohydrate and lipid metabolites.[53,61-68] The 'postprandial phenomenon' suggests that the accumulation of blood glucose and triglycerides contributes to the development and progression of diabetes and atherogenesis.[66] Although blood is an excellent transporter of nutrients to peripheral tissues, it should not be relied on as a reservoir for excesses because of the unfavorable health consequences mentioned above. Some small trials have investigated the effects of various exercise doses and protocols on reducing postprandial blood glucose and lipids. [68,143-152] Hypertriglyceridemia combined with high levels of blood glucose impairs metabolic flexibility and likely induces insulin resistance.[69,70] Metabolic flexibility is an individual's ability to effectively oxidize both carbohydrates and lipids at rest. Inclusion of any movement produced by the contraction of skeletal muscles has been shown to improve glycemic control in carbohydrate intolerant subjects and those with T2DM. Many studies have utilized aerobic activity in doses $\geq$ 30 minutes; however, there are beginning to be more trials that incorporate shorter durations, varying intensities, and protocols that compare the effects of short bouts to longer durations.[143,147,150,151,153-155] The current study attempts to explore a simple, calisthenics-based HIIT workout that could be performed quickly without any equipment to reduce postprandial blood glucose. More work has been done into post-meal activity, so there is some novelty in exploring the effects of pre-meal activity. Exercising before eating may also be an advantageous approach if completing exercise first will mitigate or lessen the perceived time restrictive barrier to exercise.

METHODS

This premeal exercise trial recruited healthy individuals during Spring 2021 from the Triangle region in North Carolina. This study was funded in part by a Dean's Teaching Fellowship Grant. The multi-institutional site research took place in the Department of Human Sciences, North Carolina Central University in Durham, NC and the Department of Food, Bioprocessing, and Nutritional Sciences at North Carolina State University in Raleigh, NC.

Participants and Eligibility Requirements

Participants > 18 years old were recruited through research marketing fliers (Appendix C1), student list servs, social media, and word of mouth. Interested participants were contacted by a researcher and described the trial's expectations. Participants were required to have access to food, be willing to eat the same daily menu for four days, exercise before meals, wear a continuous glucose monitoring device, have access to a compatible smart phone, and check blood glucose via finger stick a minimum of four times per day. Exclusionary criteria: insulin-dependent, dual pharmacotherapy for glucose management, incompatible smart phone, BMI < 23 or $\geq$ 40, known physical activity restrictions or ambulatory disabilities, pregnancy, or < 18 years old. An honorarium was offered to all individuals that completed the 7-day trial.

A total of 22 participants were recruited and met the demographic and health-related inclusionary criteria. During the initial enrollment session, 4 of the participants' smart phones were deemed to be incompatible with the CGM application. Eighteen were randomized and 9 were place in each exercise arm. Four participants dropped out (2 from each arm) for frequent device synching errors (n=2) or withdrew (n=2). Participants unable to adhere to the protocol, disclosed this to the researchers and voluntarily withdrew. For a summary, see Figure 4.1.

Trial Design

Participants came to one of the university sites on Sunday (day 0) to enroll. Enrollment sessions took approximately 90 minutes to complete informed consent (Appendix C2), download and synch smartphone application for the continuous glucose monitor (CGM), obtain anthropometric measurements, provide glucometer training and supplies (OneTouch Verio®, Lifescan, Inc., Milpitas, CA, USA), and fit CGM to abdomen or back of arm (Guardian™ Connect CGM, Medtronic, Minneapolis, MN, USA). Research assistants trained in

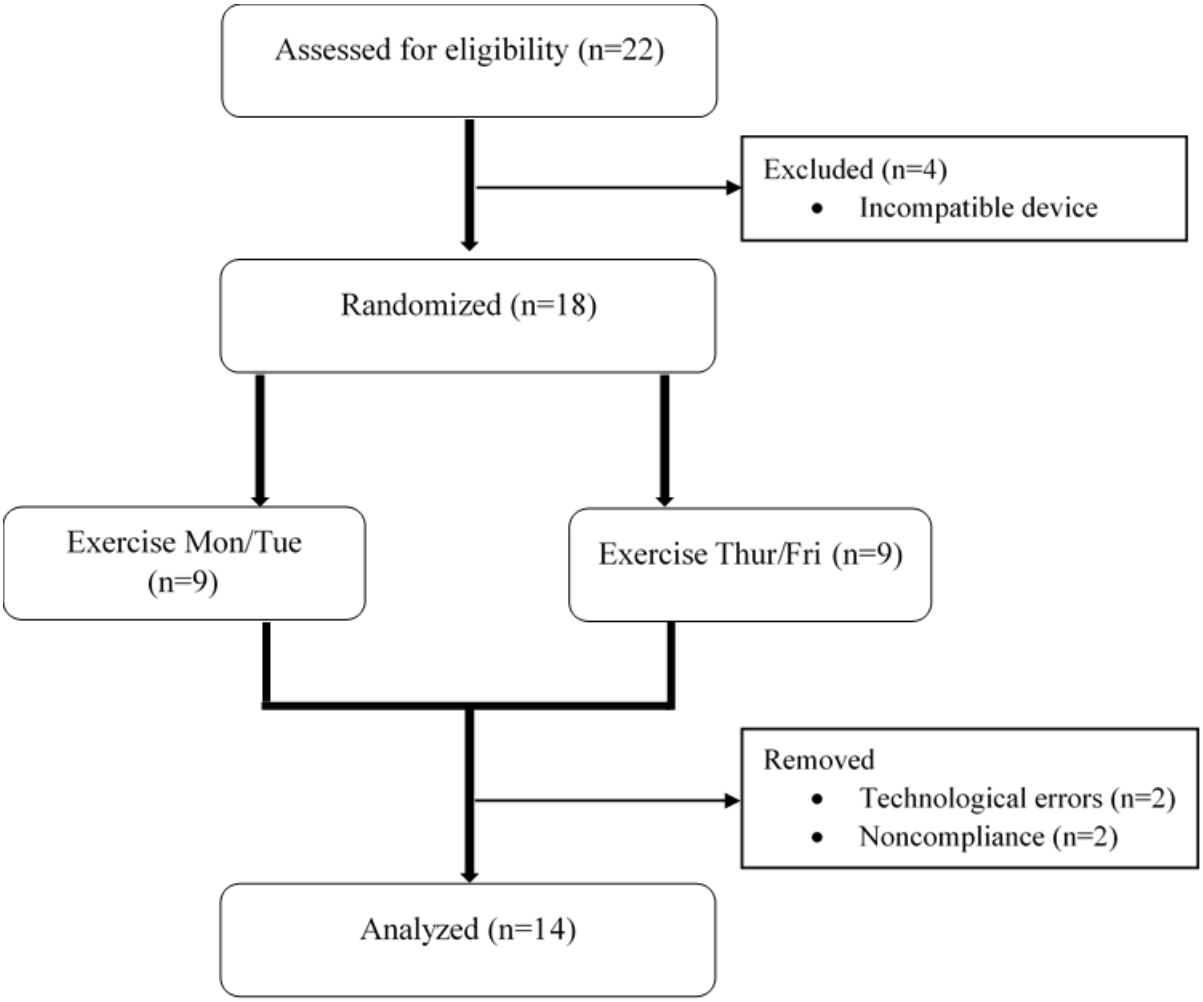

Figure 4.1 CONSORT diagram of subjects in analysis cohort

nutrition helped participants plan a daily menu that would be repeated on days 1, 2, 4, and 5. Day 3 was a washout day where participants were not required to consume the standard meal and had to restrict activity. Repeated meal plans contained 3 meals and 1 snack. Meals and snack were consumed within the same hour during each of the four trial days. All meals and snacks contained a minimum of 30 grams of carbohydrates. A food record was kept during the entire trial. Participants received instructions on how to appropriately record food, drinks, and the time on their meal record. Abstinence from alcohol was required throughout the duration of the trial. On day 6 the CGM was removed, supplies returned, and final surveys completed. Participants were divided into two groups: exercise before meals on days 1 and 2 (n=9) or exercise before meals on days 4 and 5 (n=9). Figure 4.2 shows an overview of the crossover trial design and protocol order. A series of three high intensity interval training (HIIT) routines using only body weight were designed by an exercise physiologist. Exercise routines were recorded and posted online to make viewing accessible and to standardize the dose of activity (Appendix C3). Each video targeted a separate lower and upper body muscle group. There were four exercises for each routine which were repeated twice each. Exercises were performed for 20 seconds followed by a 10 second rest for a total of 4 minutes with a 60 second warm up. Each session lasted 5 minutes for a total of 15 minutes of high-intensity exercise during each exercise day. The 3 video series was repeated on the second exercise day. Participants were instructed to maintain vigorous intensity while performing the exercise repetitions during the 20 second work period. Exercise was not permitted on nonexercised days or during the washout day. Other instructions included avoiding strenuous or demanding physical work and keep walking consistent on all days. Participants were provided with an instructional packet to reference the protocol at home and a contact number was provided if any questions or concerns arose (Appendix C4).

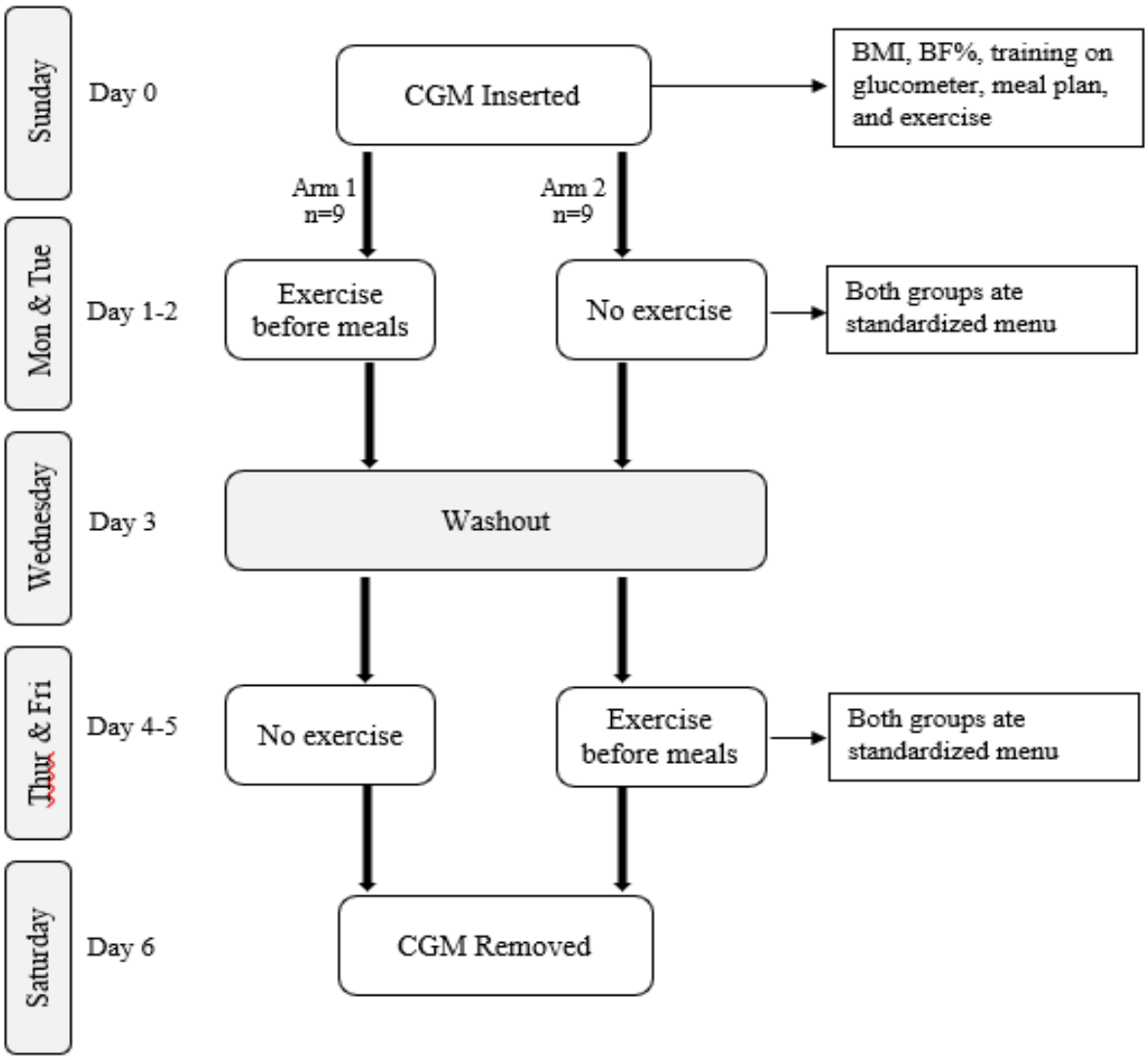

Figure 4.2 Overview of Trial Design

Measurements

Weight, height, BMI (kg/m^2), and body fat percent using an Omron HBF-306 handheld, bioelectrical impedance body fat analyzer (Omron Healthcare, Inc; Lake Forest, IL) were obtained on day 0. Blood glucose was recorded every 5 minutes by the CGM for the entire wear period (day 0-6). The glucometer was used to obtain four daily capillary blood glucose measurements to calibrate the CGM. Capillary blood glucose measurements were entered into

the smart phone application four times per day. Dietary composition was calculated using Cronometer (Cronometer Software Inc., Revelstoke, B.C., Canada).

Statistical Analysis

Primary outcomes were the differences in glucose excursions on intervention days compared to control days. We used spaghetti plots to graph and visually inspect differences in the matched breakfast, lunch, and dinner meals per person. The plotted measurements are 180-minute post-prandial blood glucose measurements where time 0 is considered the baseline blood glucose measurement for that meal. Time 0 began at the first bite of a meal. A double-matched day overlay approach was used to compare the duplicated intervention meals to the duplicated control meals. To control for carbohydrate intake, participants not meeting the acceptable macronutrient distribution range of 45% were arbitrarily labeled as having *moderate* intake. Those consuming $\geq$ 45% of calories from carbohydrate were labeled as *high*.

T-tests were used to statistically evaluate the postprandial effects using time 0-120 mins and time 30-120 mins. The PPBG difference from baseline between intervention days 1 and 2 were compared to the average PPBG difference from baseline between control days 1 and 2, for each meal, for each individual. The inflated Type I error rate stemming from multiple comparisons was adjusted for by using the Bonferroni test. Participant level significance was determined by at least 2 of 3 aggregated meal groupings achieving a level of significance which was determined by a p value < 0.05. Follow up surveys were also administered at the completion of the trial on day 6. Questions evaluated how well the subject was able to execute the protocol and the degree to which this protocol deviated from their typical dietary and physical activity regimens. The pre and post survey questions are found in Appendix C5.

RESULTS

A summary of participant characteristics is shown in Table 4.1. The mean body mass index and body fat % between treatment arm groups was similar however mean body weight differed. Age, sex, ethnicity, academic rank, employment status, weekly working hours, and

Table 4.1 Research Subjects

Participant Characteristics	Treatment Arm 1	Treatment Arm 2
Total No.	7	7
Mean Baseline Anthropometrics		
Height (inches)	71.14 (+/- 4.95)	67.86 (+/- 4.30)
Weight (lbs)	191.86 (+/- 44.31)	178.40 (+/- 36.78)
BMI	26.32 (+/- 3.36)	27.11 (+/- 4.47)
Body Fat (%)	23.50 (+/- 7.33)	22.14 (+/- 11.30)
Age, years		
18-20	1 (14.29%)	0 (00.00%)
21-23	0 (00.00%)	1 (14.29%)
24-29	2 (28.57%)	2 (28.57%)
30-39	2 (28.57%)	1 (14.29%)
40-49	2 (28.57%)	2 (28.57%)
50+	0 (00.00%)	0 (00.00%)
Sex		
Male	5 (71.43%)	3 (42.86%)
Female	2 (28.57%)	3 (42.86%)
Ethnicity		
American Indian	0 (00.00%)	0 (00.00%)
Asian	0 (00.00%)	1 (14.29%)
Black	0 (00.00%)	0 (00.00%)
Hispanic	2 (28.57%)	1 (14.29%)
White	5 (71.43%)	3 (42.86%)
Other	0 (00.00%)	1 (14.29%)
Typical Exercise Frequency		
Never	1 (14.29%)	0 (00.00%)
1-2/month	2 (28.57%)	0 (00.00%)
1-2/week	0 (00.00%)	2 (28.57%)
3-4/week	2 (28.57%)	2 (28.57%)
5-6/week	0 (00.00%)	2 (28.57%)
7/week	1 (14.29%)	0 (00.00%)

Table 4.1 continued		
Collegiate Status		
1st year	0 (00.00%)	0 (00.00%)
2nd year	0 (00.00%)	0 (00.00%)
3rd year	1 (14.29%)	1 (14.29%)
4th year	1 (14.29%)	0 (00.00%)
5th year	0 (00.00%)	0 (00.00%)
2nd BA/BS degree	1 (14.29%)	1 (14.29%)
Graduate school	2 (28.57%)	3 (42.86%)
Not a student	2 (28.57%)	1 (14.29%)
Employment		
Unemployed	2 (28.57%)	3 (42.86%)
On campus	2 (28.57%)	0 (00.00%)
Not on campus	3 (42.86%)	3 (42.86%)
Working Hours		
0-10	0 (00.00%)	0 (00.00%)
11-20	1 (14.29%)	2 (28.57%)
31-40	3 (42.86%)	1 (14.29%)
40+	1 (14.29%)	0 (00.00%)
Living Conditions		
On campus	0 (00.00%)	0 (00.00%)
Apartment	1 (14.29%)	2 (28.57%)
Lives w/ family	3 (42.86%)	1 (14.29%)
Single-family residence	1 (14.29%)	0 (0%)

living environment were all reported but did not contribute to the final analysis.

Analysis of Blood Glucose

Spaghetti plots overlaying 2 intervention meals (red) matched to 2 control meals (black) can be found in Appendix C6. There are three separate mealtime plots per participant with four total meals overlayed on each one. The measurements in the plots are 180-minute postprandial blood glucose measurements beginning at time 0 minutes which is considered the baseline blood

Table 4.2 Summary of Postprandial Blood Glucose Spaghetti Plot Observations

Subject	Breakfast	Lunch	Dinner
Arm 1			
2	Greater difference for one of the intervention days initially and then a large plummet. Both control curves similar	One control had a different pattern, otherwise not a significant difference in shape or return to baseline	Very different patterns compared to breakfast and lunch. Controls didn't return to baseline until after 3 hours. Controls and intervention days have later peak with slow drop.
3	Interventions have higher peaks and controls drop significantly below baseline after 1 hr	Intervention and control have similar pattern*	Intervention and control have similar pattern*
4	Intervention peaks are higher and take longer to return to baseline	Intervention peaks are slightly higher*	Multiple peaks for control and interventions, higher peaks for interventions*
5[a]	Similar curves, intervention peaks slightly greater*	Intervention peaks are delayed compared to control, slightly greater, and return to baseline slower*	Similar curves and pattern*
6[a]	One normal curve and two atypical ones suggesting a steep initial drop^	Overall, curves are fairly similar and all eventually drop below baseline.	Shape of curves are similar; however, one intervention day spikes significantly while the other three drop similarly to the breakfast and lunch patterns
12	All curves dip below baseline. Intervention curves are more negative.	Both control peaks are more greater than intervention peaks	One control curve had a significant spike and remained elevated for almost 3 hours. The other curves are similar at time 100 then intervention curves begin to rebound around 2 hours
17[a]	Similar curves; no differences	Similar curves; no differences	Similar curves; slightly greater intervention peaks

Table 4.2 continued			
Arm 2			
7[a]	One control is significantly greater, and other 3 are similar.	Intervention responses are muted; whereas one control spike and the other plummet s with a greater intensity	All curves have multiple peaks of varying intensities
10[a]	Controls curves drop further below baseline than matched interventions	Three curves follow a normal pattern. One control has a wide initial peak and the other one drops below baseline.	Similar overall. Intervention has greatest peak and both fall further below baseline
11	All curves tightly controlled around baseline. Slightly lower drop from intervention.	For 1 set of matched meal, intervention peak is lower. One control remains at baseline.^	One control and intervention remain slightly under baseline. The other control has 2 distinct peaks.^
13	All curves tend to drop below baseline, no distinguishable differences.	Curves dropping below baseline^	Curves dropping below baseline^
14[a]	Delayed peaks for all curves^	Delayed peaks for 3 of 4 curves; irregular shape	Controls and one intervention curve are similar. One intervention is drastically different from the others.
15	Similar curves	Moderately similar curves	Controls stay relatively flat and interventions peak around 2 hours
16	Interventions are lower than matched controls. Three are similar.	Most values are below baseline although one intervention has a significant peak after 1 hour	No consistent pattern

*missing a control meal
^missing an intervention meal
[a]high carbohydrate meal (≥ 45% total kcal from carbohydrates)

glucose measurement for that meal. Time 0 is the first bite of a meal. All 42 individual mealtime groupings were plotted, and 13 (7 control and 6 intervention meals) were missing one of the four meals. Eight percent of the individual meal data is missing. All but one (12 of 13) of the missing meals occurred during the end of the wear period. Since participants had some freedom in choosing the type and amount of carbohydrates they would consume at each meal, we added a carb-amount descriptor to indicate carbohydrate intake ranges. Carbohydrate intake per meal was categorized as either moderate (26–44%) or high (>45%) based on a percent of calories from carbohydrate compared to the average daily total calories consumed. Table 4.2 shows the mixed mixed results found from the visual inspection of the spaghetti plots. Overall, there was a significant amount of variation in meal blood glucose patterns. The visual inspections yielded observations of potentially 9 comparisons where PPBG was lower for intervention meals and 4 where it was greater. Sixteen had normal shaped curves (i.e. a positive peak around 50-100 minutes followed by a return to baseline by 180 minutes), 11 had negative peaks or plotted primarily below baseline blood glucose, 3 had multiple peaks, and 8 were highly irregular and did not have a discernable pattern.

A statistical representation of the spaghetti plots using t-tests was performed from two separate baseline measurements to 120 minutes. The results test whether the average PPBG difference from baseline is lower for intervention days than control days for each meal grouping per individual. In Table 4.3, we tested the period time 0-120 minutes with a total postprandial time of 120 minutes. As a cohort, 4 of 14 (29%) subjects demonstrated a reduction in PPBG compared to control meals. To satisfy our definition of significant, two of the three mealtime values must show a level of significant reduction from the intervention meals. Per meal grouping, 12 of 42 (29%) were significant (p-value < 0.05). The distribution of significant

findings between treatment arms 1 and 2 was similar. Each arm had 2 significant participants and significant meals were evenly distributed (breakfast, lunch, and dinner all had 4 significant results). Table 4.4 represents the period of T=30 to T=120 with a total postprandial time of 90 minutes. Here we also found 4 of 14 (29%) of the subjects demonstrated significant reductions in the PPBG compared to the controls. Per meal grouping, there was a greater level of significance, 16 of 42 (38%). Across the two arms the significant meals were again very even. There were

Table 4.3 Postprandial Blood Glucose from Time 0 – 120 mins.

SUBJECT	BREAKFAST	LUNCH	DINNER	Total # Meals Significant
2	0.001 (1.37)	$0.0234e^{-4}$ (2.09)	0.059 (0.83)	2
3	0.256 (1.28)	$0.044e^{-7}$ (1.26)	1.000 (0.43)	1
4	1.000 (2.99)	1.000 (1.95)	1.000 (5.41)	0
5	0.097 (3.01)	0.201 (3.24)	1.000 (2.33)	0
6	$0.008e^{-3}$ (4.81)	1.000 (1.43)	0.609 (2.51)	1
12	1.000 (2.50)	1.000 (1.31)	0.001 (2.52)	1
17	0.477 (1.41)	$0.007e^{-2}$ (1.60)	0.039 (1.99)	2
7	1.000 (1.58)	0.395 (1.94)	0.651 (2.51)	0
10	1.000 (1.84)	1.000 (1.44)	1.000 (1.37)	0
11	$0.021e^{-9}$ (0.62)	1.000 (1.95)	1.000 (1.35)	1
13	$0.003e^{-6}$ (1.01)	1.000 (0.91)	$0.007e^{-8}$ (1.26)	2
14	1.000 (0.89)	$0.004e^{-3}$ (3.28)	0.001 (2.08)	2
15	0.011 (2.28)	1.000 (3.06)	1.000 (1.99)	0
16	1.000 (2.74)	1.000 (1.60)	1.000 (2.18)	0

Table 4.4 Postprandial Blood Glucose from Time 30 – 120 mins.

SUBJECT	BREAKFAST	LUNCH	DINNER	Total # Meals Significant
2	0.009 (1.77)	0.004 (2.55)	$0.028e^{-3}$ (1.07)	3
3	1.000 (1.57)	1.000 (1.47)	0.001 (0.41)	1
4	1.000 (3.89)	$0.017e^{-3}$ (2.02)	1.000 (5.35)	1
5	1.000 (3.89)	1.000 (4.15)	0.222 (2.94)	0
6	0.296 (5.22)	1.000 (1.81)	1.000 (2.90)	0
12	$0.007e^{-6}$ (2.72)	0.001 (1.57)	$0.019e^{-4}$ (2.98)	3
17	1.000 (1.77)	0.210 (1.98)	1.000 (2.48)	0
7	$0.036e^{-5}$ (1.75)	1.000 (2.29)	1.000 (3.15)	1
10	1.000 (2.30)	1.000 (1.69)	1.000 (1.74)	0
11	$0.031e^{-4}$ (0.56)	1.000 (2.06)	0.002 (1.48)	2
13	$0.015e^{-3}$ (0.63)	$0.008e^{-2}$ (1.06)	1.000 (1.33)	2
14	1.000 (1.08)	0.727 (4.02)	0.001 (2.46)	1
15	0.121 (2.38)	$0.049e^{-4}$ (1.24)	1.000 (2.20)	1
16	0.001 (3.27)	1.000 (1.74)	1.000 (1.45)	1

6 significant meals for breakfast and 5 for both lunch and dinner.

DISCUSSION

In this study involving healthy, nondiabetic participants, a before meal, 5-minute high-intensity exercise routine did not significantly reduce postprandial blood glucose compared to matched nonexercised days. This exercise prescription was designed to meet the current physical activity guidelines, and it relied on the assumption that participants would be more willing to perform and better tolerate high intensity physical activity before eating rather than after. Both arms of the trial had healthy, active participants who were under the age of 50 years old.

Participant meal plans were not standardized; however, there were specific guidelines they had to follow: eat 3 meals a day (plus a snack if desired), have a contributing source of carbohydrates in each meal, and replicate the daily meals consumed and time of consumption during the four trial days. The consistency in timing and meal composition helped to control variation within an individual. The meal guidelines did not control for variation across individuals in the study because there was not a "set meal plan" that everyone followed. In this regard, our assumption was that individuals would be more compliant eating the same daily meal plan if they were consuming foods they were accustomed to and could choose. This also simulated more of a "free living" or "real world" dietary scenario than providing a standardized meal to all participants. To monitor compliance, a daily food log was recorded that contained type, amount, and time when food was consumed. From a post-evaluation survey, 11 (79%) of participants reported never deviating from the meal plan, and only 3 (21%) reported deviating 1-2 times over the trial week.

At least two systematic reviews have explored the effects of exercise timing on postprandial blood glucose. One review examined post-meal exercise and concluded that the most consistent benefits from exercise were seen in long-duration ($\geq$ 45 minutes) of moderate-

intensity aerobic exercise.[156] The other review included methodologies using either or both pre- and post-meal exercise, and they found that post-meal exercise produced a greater improvement in PPBG.[157] Walking as a form of low-intensity exercise has generally been shown to produce favorable glycemic responses. A 30-minute, 1 time per day walking regimen was less effective at reducing incremental area under the curve (iAUC) when compared to 10 minutes, 3 times per day after each meal.[151] Another similarly designed crossover study included 64 participants with T2DM and using a longer trial length of 60 days and walking duration of 45-minute compared the same 1 time per day bout against three 15-minute bouts after meals. They also found a greater reduction in HbA_{1c} (-0.9%) and in their five-point glucose profile (p value <0.001).[148] Another study using three different regimens found that replacing long sitting periods with some standing (2.5 hours) and short bouts of low-intensity walking (2.2 hours) was significantly more effective at reducing iAUC, time in hyperglycemia, and insulin resistance than a 1-time lengthier bout of moderate-intensity activity (i.e. cycling).[147] With equivalent total daily activity, it appears more advantageous to distribute movement, especially low-intensity exercise, throughout the day in proportional intervals rather than bunching activity into one concentrated time. This effect may be explained by excess post exercise oxygen consumption (EPOC) and the metabolic shifts in macronutrient utilization occurring during the fed phase of metabolism as a result of physical activity. The fed phase lasts approximately 3 hours after the onset of a meal and is primarily characterized by the increase in insulin an anabolic hormone.

Although basic, low-intensity walking has been shown to be a sufficient driver to reduce plasma blood glucose in participants with T2DM, our study was the first to test multiple, short bouts of premeal high intensity interval training on PPBG in healthy individuals. Since “lack of time” is often reported as a barrier to exercise, these small bouts would hopefully reduce the

perception of this barrier. A 2015 meta-analysis compared the effects of HIIT to a control group or other forms of exercise. They found HIIT improved insulin resistance better than other forms of exercise, decreased fasting glucose and HbA_{1c} in those with T2DM, decreased body weight significantly compared to controls but not other forms of exercise, and improved cardiorespiratory fitness.[158] Other studies found similar favorable metabolic outcomes from high-intensity training, and the benefits were greatest if participants were sedentary or untrained, had a diagnosis of T2DM, metabolic syndrome, or were obese.[143-145,155,159] Controlled trials also found HIIT improved intrahepatic triglycerides, visceral lipids,[146] suppressed blood pressure for a longer period of time,[146] and even reduced musculoskeletal pain when untrained participants began an exercise program.[160] One of the most favorable benefits of HIIT, and exercise in general, is its role in preventing the metabolic disorders and symptoms it also tends to improve.[161] During our trial, we were unable to observe significant reductions in PPBG. Since our participants were young, healthy adults and more active than those found in other studies, they likely already had favorable glucose metabolism. As a group, they had optimal blood glucose measurements, and their cumulative, 4-day average blood glucose was 96.53 mg/dL (range 84.93 – 112.90 mg/dL). Only 3 participants had an average BG > 100 mg/dL. We did not measure serum insulin; however, other trials were able to observe a decrease in insulin even though they were unable to detect a significant effect on blood glucose.[144,162] Gay et al, only observed significant blood glucose reducing effects if premeal blood glucose was > 90 mg/dL.[155] High-intensity exercise increases heart rate and requires > 60-65% of VO_{2max} or $\geq$ 6.0 METs.[58,144,158] Vigorous physical activity can increase muscle glycogenolysis, GLUT4 activity, and catecholamine levels. Collectively, these metabolic effect could increase the rate of blood glucose uptake in muscle.

Limitations

Eight percent of the mealtime data was lost due to sensor failures towards the end of the wear period. Sensors coming dislodged was the most common reason, followed by low battery, and the sensor losing communication to the smart phone app. No participants lost more than 1 of the 4 grouped trial meals. Controls and intervention meals were lost evenly because of the crossover design. Carbohydrate intake varied between participants. The average daily carbohydrate intake was 248 g (range 89-452g), and the average percent of calories from carbohydrates was 46% (range 27-66%). Eight (57%) consumed less than the AMDR for carbohydrates of 45%. This more likely resembles a “real world” intake pattern, and to increase compliance, participants were permitted to choose foods of their liking. It is possible meals may have been recorded but not eaten, and food may have been consumed but not recorded; however, in the post-evaluation survey, nearly all participants reported a high degree of compliance.

CONCLUSION

In healthy, young adults performing multiple daily bouts of high intensity interval training before meals, we were unable to detect a reduction in postprandial blood glucose measurements by a continuous glucose monitor. This exercise protocol was not perceived as burdensome, so it may be feasible to reevaluate with participants who have impaired fasting glucose or impaired glucose tolerance.

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CHAPTER 5: CONNECTING DIABETES MANAGEMENT THEORY TO PRACTICE: INTEGRATING RESEARH IN AN UNDERGRADUATE DIETETICS COURSE

ABSTRACT

Background/Aim

Dietetic students often report feeling disconnected from course material and the application of theoretical concepts to actual practices and skills of an entry-level Registered Dietitian Nutritionist (RDN). This study aims to determine if assisting with a human intervention trial integrated in an undergraduate course will increase knowledge, understanding, and confidence of common diabetes mellitus management practices in undergraduate dietetic students.

Methodology

Students from a Spring 2021 nutrition metabolism course were required to assist a minimum of 5 hours on a human blood glucose and exercise intervention trial. The learning outcomes were modified to integrate research assistant work in the course. Students who agreed to participate in this study provided informed consent (n=19) and completed a pre (week 2) and post-participation survey (week 15) administered through Qualtrics. The survey contained a total of 17 items grouped in 4 separate categories.

Results

Fourteen of the 17 (82%) surveyed items demonstrated a statistically significant improvement in the four categories exploring students' self-assessed general knowledge, understanding, and confidence of blood glucose, diabetes, exercise, and clinical research.

Conclusion/Importance

Our findings suggest that when students assist in research related to course learning outcomes, they report greater understanding and confidence of diabetes and blood glucose management practices that would be expected of an entry-level RDN.

INTRODUCTION

The primary goal of a didactic program in dietetics (DPD) is to prepare students with the knowledge needed to begin a supervised practice program. Didactic program in dietetics are typically found at the undergraduate level, require specific coursework, precede supervised practice, and expose learners to mandated competencies. Knowledge and understanding of key nutrition and dietetics concepts should be learned during the DPD portion while skills and practice competence are obtained during supervised practice in a postgraduate setting.[163,164] to train and prepare for a career as a registered dietitian nutritionists (RDN). The core knowledge competencies set forth by ACEND, the international accreditation agency for RDN educational programs, requires all core knowledge to be assessed by the training institution.[165] Although DPDs do not have standardized educational interventions, students should be assessed using a variety of learning activities. Programs may choose to utilize experiential learning techniques to improve the learners experience and help connect the theoretical knowledge to applied skills. Many forms of experiential learning exist and are used in dietetics undergraduate education such as interprofessional education, flipped or team-based leaning, targeted training sessions, cultural immersion, service learning, workshop, simulated practice, and research.[166-172] Dietetics educations, not unlike other healthcare worker training programs, should effectively be graduating students ready for entry-level practice capable of treating a diverse range of patient conditions and backgrounds. Students often report feeling underprepared after completing the DPD training portion and intimidated by the rigor and skills needed to perform at a high level during supervised practice.[169,173]

Similar to dietetics, other healthcare training programs also follow a stepwise path from classroom-based theory and knowledge then progressing to practice-based work skills to develop

readiness for entry-level, professional work for that discipline. Skill-based training is typically preceded by knowledge acquisition from within the classroom setting, but there appears to be a progressive movement and an appreciation for integrating and exposing students to practice-based work earlier in the training process through experiential learning activities. Dietetics educators are under substantial pressure to find balance in their relationships with and between students, stakeholders, preceptors, accreditors, and the associated university.[182]

A commonly utilized experiential activity is simulation.[174] Simulation activities may include hypothetical or real case studies, role play, standardized patients, and lifelike medical manikins (also known as mannequins).[171,172,174,175] Any activity or combination of approaches has demonstrated increases in student learning and confidence in skills.[176] These beneficial teaching methods attempt to simulate the patient-provider experience; however, it is extremely difficult to fully replicate the dynamic, unpredictable, and potentially stressful encounters working with actual patients. It is clear that students benefit from early patient encounters during their training.[177] There is even evidence that patients may benefit from student encounters.[178] Organizational structure, adequate resources, curricular, accreditor requirements, and geographical location are all potential barriers limiting students, especially undergraduates, access to patients. There is a current push in healthcare for service providers to practice patient-centered care.[179] A patient-centered approach positions the patient at the focal point of the treatment plan and provides an individualized service with greater patient agency, education, and involvement in their own care process.[180,181] Training and resources should be available to students to experience this provision of care where the patient is the expert in their own lives and conditions. Dietetic students are interested in relevant experiences, collaborating with other universities and organizations, and opportunities to develop dietetics competencies through

practice. Our study aims to measure the perceived learning and confidence of undergraduate students participating on a research based experiential learning activity. This study may be useful in informing future educational practices.

METHODS

Undergraduate nutrition and dietetics students from a Spring 2021 nutrition metabolism course were required to assist on a blood glucose exercise trial. Prior to the trial, all student research assistants received training for the participant orientation activities. Orientation activities were discussed, practiced, and reviewed during the course lecture time and small assignments were assigned to reinforce concepts. The trial recruited healthy participants to perform high intensity exercise bouts at prescribed times, consume a standardized menu, record daily food intake, and check blood glucose four times per day while wearing a continuous glucose monitoring (CGM) device. The trial period lasted for 7 days, and recruitment and enrollment were continuous from January through May. If a potential participant met all eligibility requirements and consented to complete the trial, they were assigned an enrollment orientation. Trial enrollment took approximately 90 minutes. During the enrollment orientation, participants were fitted with a CGM sensor and received instructions how to use the integrated smart phone Bluetooth application. Student research assistants were responsible for obtaining anthropometric measurements (height, weight, BMI, and body fat percent), helping participants plan an individualized menu meeting carbohydrate requirements, providing glucometer training, and reviewing the trial and exercise protocols. Dietetics students assisted on all aspects of the research for a minimum of 5 hours except inserting the CGM sensor. Although students were required to assist with the trial to satisfy the course requirement, they were not required to consent and participate with the educational evaluation portion of the study. Students were also informed that they were able to withdraw from the study at any time without penalty to course standing or grade.

Twenty-five students were enrolled in the course, and 19 completed both the pre (week 2) and post-participation (week 15) survey. One student dropped the course, 2 did not complete the pre survey, 2 did not complete the post survey, and 1 declined to consent. Surveys were completed through Qualtrics (Appendix D1). Unique identifiers were provided to match surveys while maintaining anonymity. Perceived learning and confidence were measured using a seven-point Likert scale (1-Strongly Agree – 7 Strongly Disagree) over 17 items grouped into 4 separate categories: general glucose control, exercise, assessment skills, and clinical research. Paired t-tests and Wilcoxon signed rank tests were used to evaluate significance using an alpha of < 0.01.

RESULTS

Normality via quartile-quartile plots was first checked, and although there was a slight deviation from the fitted line, the assumption of normality was valid. Each survey contained 17 unique items which tested for significance using a p-value of < 0.01. These results are shown in Table 5.1. Students' perceived knowledge and confidence improved for 16 of 17 measured items and reached significance for 14 of 17 (82%). Items were grouped across four categories and the aggregate mean difference is provided in parenthesis following each category title: I. Diabetes and Glucose Control (0.93); II. Exercise and Diabetes (0.72); III. Treating Individuals with Diabetes (1.20); and IV. Clinical Research (0.83). Twelve items from categories I, II, and IV primarily assessed change in knowledge and five items from category III assessed confidence in performing basic clinical dietetics skills related to diabetes care. The greatest categorical change was in confidence followed by glucose regulation knowledge. Exercise had the lowest level of improvement followed by clinical research. Students responded that they already had a good understanding and awareness of the benefits and uses of each before participating on the research. Pretest measurements of the perceived understanding of the mechanisms by which exercise can improve health outcomes in persons with diabetes and the value of clinical research to improve the human condition were both very high. Although both items improved after participation, neither reached significance. The only item that did not reach a significant level of improvement ($p=0.03$) and did not have a high initial level of understanding or confidence was student's perceived comfortability making lifestyle recommendation for patients with diabetes. The skills included from this item were exercise prescription, meal timing, meal composition, and sleep.

Table 5.1 Students' Perceived Learning and Confidence in Dietetics Related Skills

Category and Item	Mean (SD) n=19 Pre	Post	Mean diff.	P-value[a]
I. Diabetes and Glucose Control				
1. I am knowledgeable about diabetes.	2.74 (0.87)	2.11 (0.57)	0.63	< 0.01
2. I am knowledgeable about glucose diagnostic devices.	3.74 (0.99)	2.32 (1.29)	1.42	< 0.001
3. I am knowledgeable about insulin.	2.84 (0.90)	2.11 (0.66)	0.73	< 0.001
4. I understand how glucose metabolism is regulated in the human diabetic model.	3.58 (1.17)	2.26 (1.05)	1.32	< 0.001
5. Diagnostic medical devices are important tools for managing glucose in persons with diabetes.	2.00 (0.94)	1.47 (0.77)	0.53	< 0.01
II. Exercise and Diabetes				
6. I understand how exercise improves health outcomes in diabetes.	2.00 (1.05)	1.68 (0.82)	0.32	0.04
7. Exercise can significantly lower blood glucose.	2.32 (0.95)	1.79 (1.09)	0.53	0.01
8. I understand the metabolic changes that occur after exercise.	3.63 (1.40)	2.31 (0.95)	1.32	< 0.001
III. Treating Individuals with Diabetes				
9. I am confident obtaining anthropometric measurements.	4.26 (2.00)	2.95 (1.61)	1.31	< 0.01
10. I would feel comfortable planning a diabetic menu	4.10 (1.73)	2.98 (1.00)	1.12	< 0.01
11. I am comfortable assessing diets using food records.	3.21 (1.72)	2.32 (0.82)	0.89	< 0.001
12. I feel comfortable making lifestyle (i.e. exercise, meal timing, meal composition, sleep) recommendations for patients with diabetes	3.79 (1.81)	3.05 (1.47)	0.74	0.03
13. I have experience using diagnostic medical devices, interpreting reports, and making therapeutic recommendations.	5.26 (1.66)	3.31 (1.67)	1.95	< 0.001
IV. Clinical Research				
14. I am aware how to conduct human clinical research.	4.63 (1.83)	2.74 (1.48)	1.89	< 0.001

Table 5.1 continued				
15. I am aware of ethical consideration in human research.	2.79 (1.58)	2.05 (1.03)	0.74	0.01
16. I am aware of privacy issues for research participants.	2.47 (1.31)	1.79 (0.85)	0.68	0.01
17. I think clinical research is important to help understand ways to improve adverse human conditions.	1.31 (0.48)	1.32 (0.75)	-0.01	0.5

The mean difference of the average total survey score comparing pre and post surveys was 16.21 with a standard error of 3.19. The paired t-test resulted in a p-value of < 0.001. These results were confirmed when using the Wilcoxon signed rank test. The Wilcoxon statistic was $W^{+} = 162.5$, which resulted in a p-value of < 0.001. This provides evidence that the pre-survey score population shifted above the post-survey score population, indicating that students' self-assessed understanding of the topics increased after participating on the trial.

DISCUSSION

To our knowledge, this is one of the first studies exploring the benefits of incorporating research assistant work into an undergraduate dietetics course as a form of experiential learning. We found that when students assisted on a human research intervention trial, they improved their perceived knowledge of a disease state and self-assessed confidence performing clinical skills common to the dietetics profession. Experiential learning in the form of research assistant work may also increase entry-level competence, an appreciation for the importance of substantiating evidence-based practice, and executing research projects to advance the profession.[183] Very little research has been done on the perceived readiness of entry-level dietitians. In an Australian review of almost 70 papers associated with types of dietetics workforce preparation and preparedness methods, the researchers found only 1 paper focusing on development using the area of research or research skills.[184] As the profession grows, it's imperative that more dietetics specific research is conducted to explore novel approaches that improve patient outcomes and satisfaction.

In our study, student research assistants were able to interact, educate, and practice communication skills with the research participants. Many of the techniques performed are the same skills that entry-level dietitians will use when conducting a thorough patient assessment. Students are often only trained in the classroom setting or taught treatment theory, but they are rarely given the opportunity to practice on actual people or patients outside the classroom. In the context of this trial, there was an opportunity to practice these skills on low-risk individuals in a less intimidating environment. Since this participant cohort was not being treated for any condition nor did they require any management of disease, they were not exposed to any appreciable risk interacting and working with the undergraduate research assistants. Dietetic

students tend to have positive attitudes towards teaching and experiential methods that they perceive will benefit their ability to effectively communicate with and treat patients.[185] Although these research participants were not actual patients, all the training and clinical procedures performed by student research assistants are directly transferable skills that can be used with a wide range of patients and patient conditions.

Although we did not directly measure communication comfortability, four of the assessed items required direct communication with the service-user. All other knowledge areas assessed require effective communication during nutrition education and nutrition counseling. Communication is a foundational skill necessary to bridge the gap from traditional point-of-care healthcare service utilization to patient-centered care. The patient-centered approach has been endorsed by the Institute of Medicine and the World Health Organization and appears to be an approach that is preferred by patients receiving healthcare services.[178-180] Students and dietetics professionals alike may possess the technical knowledge to treat patients, but there is often a disconnect or lack of follow through from patient education to actual, measurable behavior change. Experiential learning in various forms can help improve the application of knowledge to the practice setting by increasing skills, confidence, and engagement.[170-172,174,177] A theoretical framework is provided in Figure 5.1 demonstrating the learning synergy that can occur when multiple pedagogical methods are utilized to reinforce key concepts. There are many drivers involved with a patient's ability to effectively engage in change. When they feel supported and their problems understood, they are more likely to change. The patient-centered care approach helps reduce the effects of some behavioral change barriers by improving the dietitian-patient relationship, using appropriate communication methods, and allowing the patient to be the primary driver for their own care.

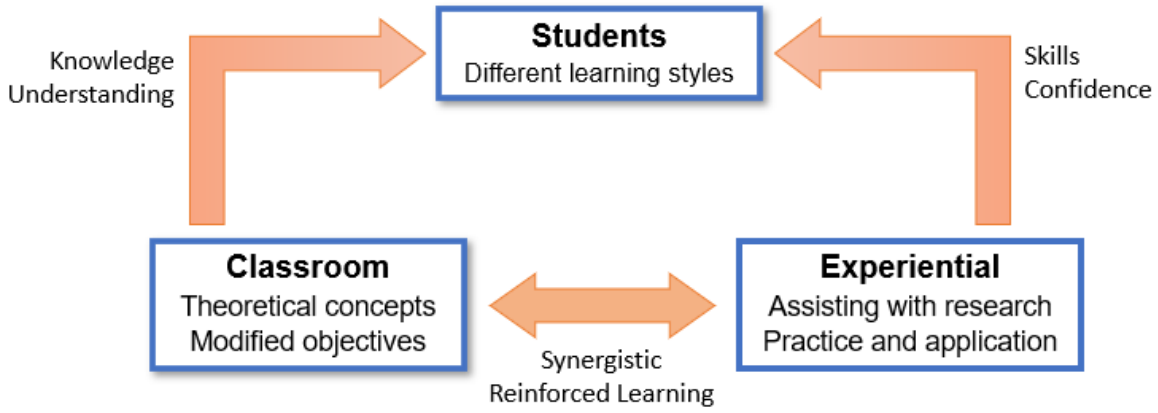

Figure 5.1 Conceptual Model Using Research as an Experiential Learning Activity

The primary limitation of this study is the inability to suggest the adoption of this model for other programs if the research participant cohort differs. Since our participant research cohort was mostly healthy, young adults without any significant health problems, this effectively reduced the risks during interactions and no therapeutic recommendations or decisions were required of the students. Although likely a valuable experience, working with medically compromised participants could pose a greater risk from the student interactions and education. Under these parameters, additional faculty supervision of students would be needed, more external training, and greater recruitment and screening efforts of participants to ensure no harm is done on a more vulnerable population.

CONCLUSION

Integrating research assistant work into an undergraduate dietetics course demonstrated an increase in students' perceived knowledge and confidence for dietetics related concepts and skills used in direct patient care. These findings suggest that undergraduate students can perform some of the basic skills that would be expected of an entry level RDN. Earlier patient or participant practice in healthcare training programs may improve practitioner comfortability, communication skills, and ability to provide patient-centered care.

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APPENDICES

Appendix A1 Student Participant Consent Form

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Evaluation of a Home Visiting Nutrition Education Program with Food Delivery on Patient Fruit and Vegetable Consumption and Student Learning

CONCISE SUMMARY

The purpose of this research study is to determine the effectiveness of an interdisciplinary student-run nutrition education program on improving student knowledge of and comfort engaging in nutrition counseling. Duke Outpatient Clinic patients will be enrolled in a program where graduate level medical and nutrition students will visit the patient's home to deliver food and provide nutrition education over the course of six months. Each visit will take between 1-2 hours. Students will engage in motivational interviewing, SMART goal, and curriculum preparation orientations. Participants will be asked to complete surveys before the program starts, after the program ends, and six months after their last nutrition education session. They will also complete recorded reflections on a monthly basis during their monthly food drop off. Information from the electronic medical record will also be collected including height, weight, HbA1c, blood pressure, cholesterol, and changes in medications. Total study duration is about 6 and one-half months.

The greatest risk of this study is the loss of confidentiality.

You are being asked to take part in this research study because you are a MD/PA student or dietetic intern interested in participating in conducting home-based nutrition education. Research studies are voluntary and include only people who choose to take part. Refusal to participate in this study involves no penalty or loss of benefits. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Larry Greenblatt will conduct the study and it is funded by the Schweitzer Fellowship.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Greenblatt will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to determine

1. The effectiveness of a home based nutrition program in increasing fruit and vegetable consumption in patients with diabetes and other chronic diet related illness who are also experiencing food insecurity
2. The effectiveness of an interdisciplinary student-run nutrition education program on improving student knowledge of and comfort engaging in nutrition counseling.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 28 students will take part in this study at Duke School of Medicine and NCCU.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will be paired with a medical student or dietetic intern who will partner with you to conduct home visits. You and your partner will be paired with a Duke Outpatient Clinic patient to conduct home visits on a monthly basis to deliver food and provide nutrition education. You will also work with the patient to create health related goals and you will follow up with the patient on a weekly basis via test, call, or email. You will be asked to complete surveys and recorded interviews. Surveys will be completed before your begin the program, shortly after you complete the program, and six months after your last session. Recorded interviews will be completed on a monthly basis during your monthly food bag drop off. These surveys and interviews can be completed over the phone if we are unable to complete them in person. The interview conversation will be audio-recorded, and later will be transcribed, though names and identifiers will be removed.

HOW LONG WILL I BE IN THIS STUDY?
If you choose to be a part of this study, you will actively be engaged in the program for six months. A follow-up survey will be conducted six months after your last session.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the PI, Dr. Greenblatt, first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time. During the interview, if you would like us to turn off audio-recording you may request to

do that; we will then ask you if you would like to continue the conversation with the research team, unrecorded. You may choose not to.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefit to you. You will have the opportunity to engage in an additional educational experience. We hope that in the future the information learned from this study will benefit other students in your position.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. To maintain confidentiality, you will be assigned a unique code number, and the key to the code will be kept securely. All the information we collect from you will be kept in locked files and encrypted, secured computer servers.

WHAT ARE THE COSTS TO YOU?

Costs will include travel expenses and time spent participating in nutrition education and completing surveys.

WHAT ABOUT COMPENSATION?
There is no compensation for participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Larry Greenblatt at ***(insert PI's number here with area code)*** during regular business hours and at ***(insert PI's 24-hour number here with area code)*** after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be

collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Greenblatt and let him know that you are withdrawing from the study. His email is larry.greenblatt@duke.edu.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Larry Greenblatt

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

(Optional)

_____	_____	_____
Signature of Principal Investigator	**Date**	**Time**

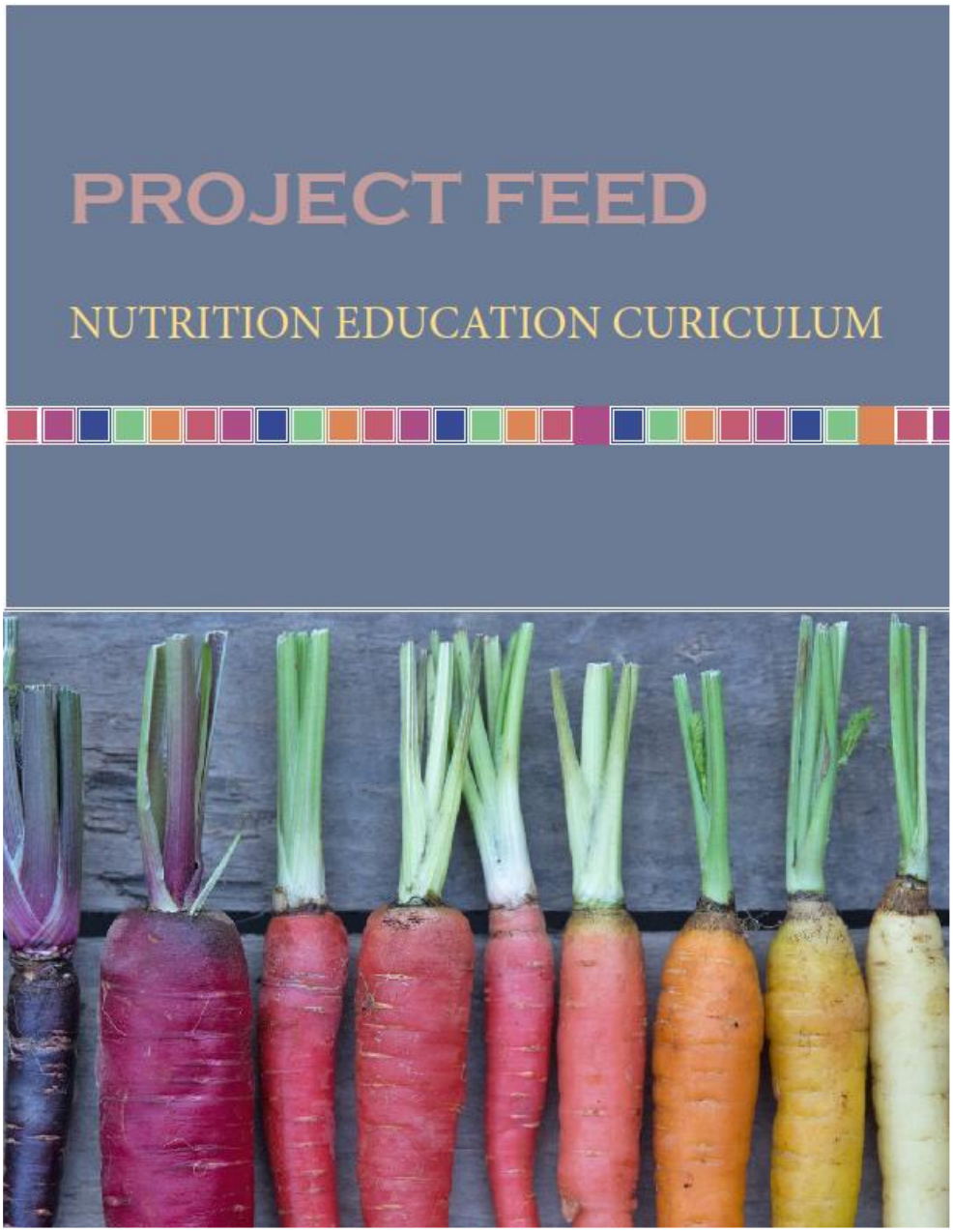
(If applicable, add or substitute any of the following:)

_____	_____	_____
Signature of Legal Representative	Date	Time

_____

Relationship to Subject

Appendix A2 Project FEED Nutrition Education Curriculum



All of the content in this book is adopted from other sources. This booklet is used solely for the purpose of providing education to patients. This book is not being distributed for profit.

The information was adapted from the following sources:

USDA

US FDA

CDC

National Institute of Diabetes and Digestive and Kidney Diseases - patient resources

American Diabetse Association - patient resources

Medline plus - How to Read Food Labels

Diabetes Forecast - Diabetes Healthy Plate

UNIT 1. VEGETABLES

Today we will learn about why vegetables are good for you and how many vegetables should be included in a healthy meal

Learning goals for today's lesson:

1. Understand that there are different types of vegetables.
2. Know which vegetables increase your blood sugar and which do not.
3. Strategize ways to increase your vegetable intake.

What Foods are in the Vegetable Group?

Any vegetable or 100% vegetable juice counts as a member of the Vegetable Group. Vegetables may be raw or cooked; fresh, frozen, canned, or dried. They may be whole, cut-up, or mashed.

Based on their nutrient content vegetables are organized into five categories:

1. dark-green vegetables
2. starchy vegetables
3. red and orange vegetables
4. beans and peas

Can you sort the vegetables in your produce pack into different categories?

PRO TIP:
Make sure to eat different types of vegetables. Each vegetable has different nutrients that make you healthy. Try to make plates that are extra colorful! Try eating more green, red, and orange vegetables. Many Americans do not get enough of those in their diet.

How many vegetables do I need to eat?

Eating a lot of vegetables is good for you! We should always be trying to incorporate more vegetables into our diet, especially the big leafy greens. Experts recommend that men and women eat at LEAST 2-3 cups per day.

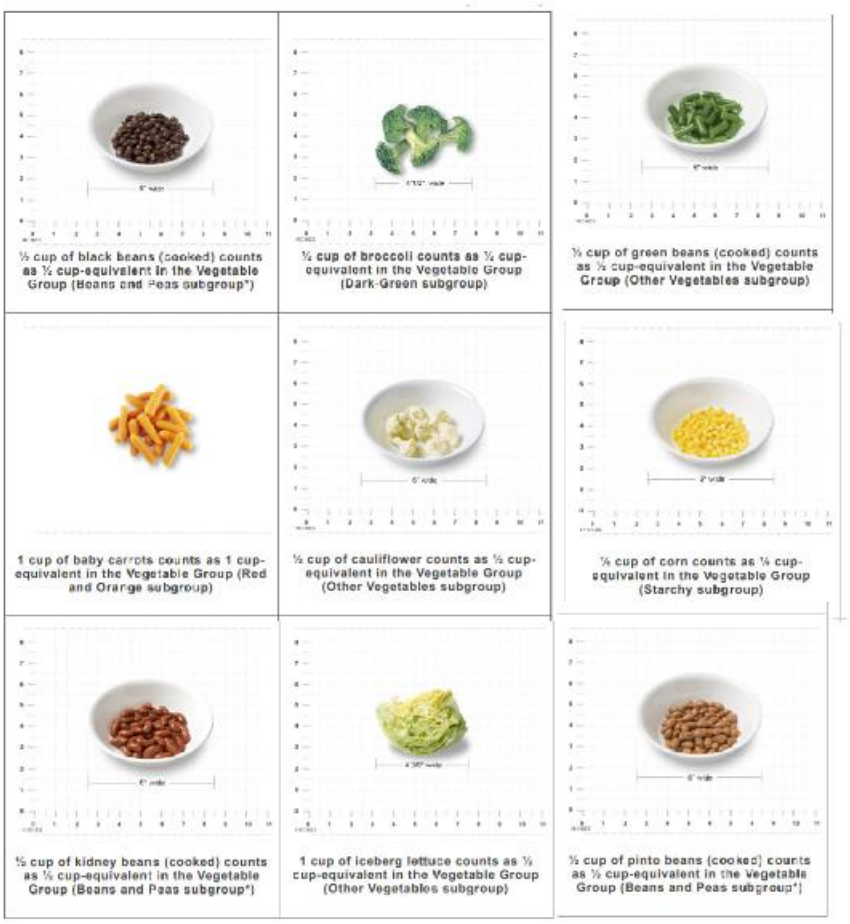
DAILY VEGETABLE TABLE		
Daily recommendation		
WOMEN	31-50 years old	2 1/2 cups
	51+ years old	2 cups
MEN	31-50 years old	3 cups
	51+ years old	2 1/2 cups

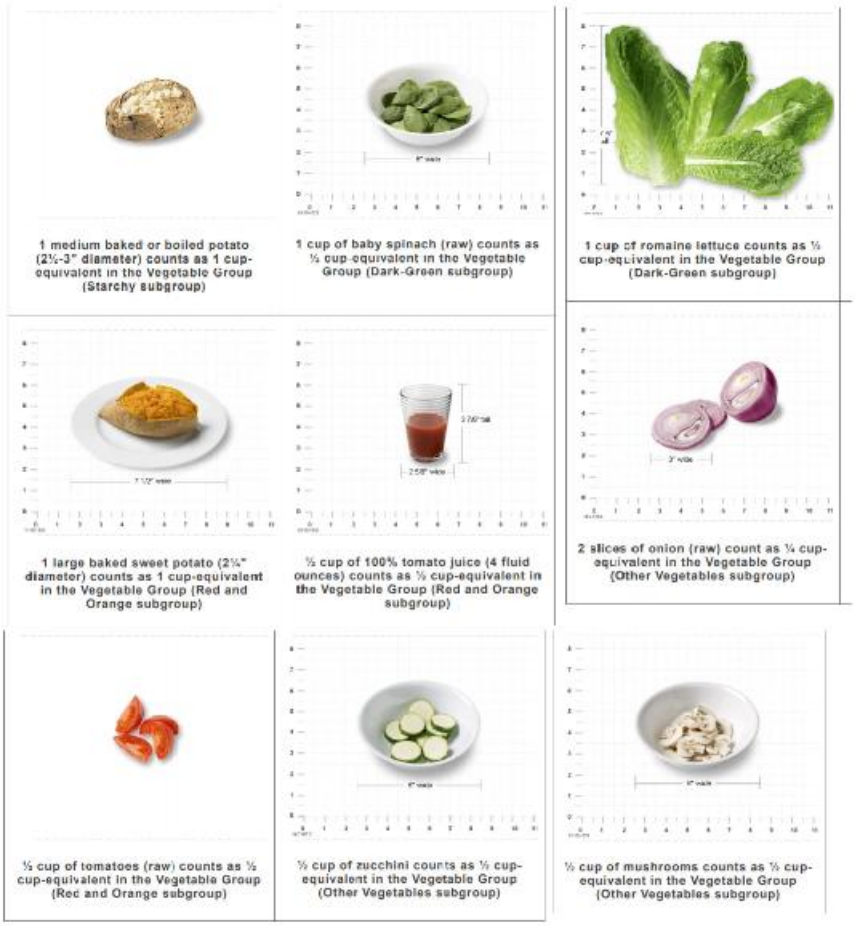
I eat _____ cups of vegetables a day

My goal is to eat _____ cups of vegetables a day.

My goal is to eat _____ cups of vegetable a week.

What counts as a serving of vegetables?





How many servings of vegetables are in your produce pack?

Why is it important to eat vegetables?

Most vegetables are naturally low in fat and calories and NONE have cholesterol

Vegetables are important sources of many **nutrients**:

Potassium and diets rich in potassium help maintain healthy blood pressure

Fiber in vegetables help reduce blood cholesterol and may lower risk of heart disease. it can also help regulate your bowel function. Fiber helps you feel full with less calories

Vitamin A keeps eyes and skin healthy and helps to protect again infection

Vitamin C makes sure your body can recover from cuts and wounds and it keeps teeth and gums healthy

Eating diets rich in vegetables can reduce risk for.....
heart disease, including heart attack and stroke
obesity
diabetes
hypertension
bone loss
kidney stones
and can be protective against certain types of cancers

Potassium and Chronic Kidney Disease:

As your kidneys slow down, you may need to eat foods that are lower in potassium. Your healthcare provider will use lab tests to watch those values. If you think this applies to you, there is more information on eating with CKD in the back of this book!

Beans and Peas are unique foods

Quick Tip:

Substitute beans and meats to reduce cost!

Beans and peas include kidney beans, pinto beans, black beans, lima beans, black-eyed peas, garbanzo beans, split peas, and lentils

These food are excellent sources of PROTEIN. They also provide other nutrients such as iron and zinc. Therefore, they are similar to meats, poultry, and fish. They are considered part of the "protein foods goup". Many people consider beans and peas as vegetarian alternatives for meat.

Because they are also part of the plant group, they are also excellent sources of dietary fiber and nutrients such as folate and potassium.

Green peas, lima beans, and green (string) beans are not considered to be part of the beans and peas subgroup.
Green Peas and Lima beans are in the starchy vegetables subgroup
Green beans are grouped with other vegetables such as onions, lettuce, and celery.

Starchy Vegetables and Diabetes

Remember, starchy vegetables include potatoes, corn, lima beans, butter beans, and green peas. These vegetables are different from other kinds of vegetables because they contain a lot of starch. Starch is a long chain of sugars. When you eat starch it gives you energy. However, it can also raise your blood sugar.

Other foods that raise your blood sugar include grains and beans. Refer to the plate method for more info about how to eat healthy with diabetes. (You can try carb counting if you are up for the challenge!) Both are at the back of the book.

The big picture with starchy vegetables is that they are good in moderation. They contain vitamins, minerals, and fiber. They give you energy.

However, choose starchy vegetables that are prepared in a more healthy way. For example, limit starchy vegetables with lots of added salt or fat, things like French fries and creamed potatoes.

Also, pay attention to your portions of starchy foods. Try to choose just one portion of starch at each meal. Instead of having corn, potatoes, and bread all at once, just choose one, and have a moderate portion.

And remember that non starchy vegetables (like the vegetables in the orange and red vegetable group and the green vegetable group) do not raise your blood sugar. You can enjoy those in larger amounts.

USDA
United States Department of Agriculture

MyPlate MyWins

Dietary Guidelines for Americans

Add more vegetables to your day

It's easy to eat more vegetables! Eating vegetables is important because they provide vitamins and minerals and most are low in calories. To fit more vegetables in your day, try them as snacks and add them to your meals.

1 Discover fast ways to cook

Cook fresh or frozen vegetables in the microwave for a quick-and-easy dish to add to any meal. Steam green beans, carrots, or bok choy in a bowl with a small amount of water in the microwave for a quick side dish.

2 Be ahead of the game

Cut up a batch of bell peppers, cauliflower, or broccoli. Pre-package them to use when time is limited. Enjoy them in a casserole, stir-fry, or as a snack with hummus.

3 Choose vegetables rich in color

Brighten your plate with vegetables that are red, orange, or dark green. They are full of vitamins and minerals. Try acorn squash, cherry tomatoes, sweet potatoes, or collard greens. They not only taste great but are good for you, too.

4 Check the freezer aisle

Frozen vegetables are quick and easy to use and are just as nutritious as fresh veggies. Try adding frozen vegetables, such as corn, peas, edamame, or spinach, to your favorite dish. Look for frozen vegetables without added sauces, gravies, butter, or cream.

5 Stock up on veggies

Canned vegetables are a great addition to any meal, so keep on hand canned tomatoes, kidney beans, garbanzo beans, mushrooms, and beets. Select those labeled as "reduced sodium," "low sodium," or "no salt added."

6 Make your garden salad glow with color

Brighten your salad by using colorful vegetables such as black beans or avocados, sliced red bell peppers or onions, shredded radishes or carrots, and chopped red cabbage or watercress. Your salad will not only look good but taste good, too.

7 Sip on some vegetable soup

Heat it and eat it. Try tomato, butternut squash, or garden vegetable soup. Look for reduced- or low-sodium soups. Make your own soups with a low-sodium broth and your favorite vegetables.

8 While you're out

If dinner is away from home, no need to worry. When ordering, ask for an extra side of vegetables or a side salad instead of the typical fried side dish. Ask for toppings and dressings on the side.

9 Savor the flavor of seasonal vegetables

Buy vegetables that are in season for maximum flavor at a lower cost. Check your local supermarket specials for the best in-season buys. Or visit your local farmers market.

10 Vary your veggies

Choose a new vegetable that you've never tried before.

UNIT 2. FRUIT

Today we will learn about fruits and we will introduce food nutrition labels

Learning goals for today's lesson:

1. Understand that fruit can be a healthy treat
2. Understand that fruit has sugar, and you should be especially cautious with fruit juice
3. Know where to find serving size on a nutrition label and how to use serving size to make healthy decisions

But first, lets review from last month...

1. Name one vegetable that increases blood sugar.

2. Name one vegetable that does not increase blood sugar.

3. Name one trick you can use to add more vegetables to your diet. (Please share if you have practiced anything this past month!)

Why is it important to eat fruits?

Eating fruit provides health benefits — people who eat more fruits and vegetables as part of an overall healthy diet are likely to have a reduced risk of some chronic diseases. Fruits provide nutrients vital for health and maintenance of your body.

Health benefits

- Most fruits are naturally low in fat, sodium, and calories. None have cholesterol.
- Fruits contain essential nutrients that many Americans don't get enough of, including potassium, dietary fiber, vitamin C, and folate (folic acid).
- Eating vegetables and fruits may reduce risk for heart disease, including heart attack and stroke and certain types of cancers.
- Diets rich in foods containing fiber, such as some vegetables and fruits, may reduce the risk of heart disease, obesity, and type 2 diabetes.
- Eating vegetables and fruits rich in potassium as part of an overall healthy diet may lower blood pressure, and may also reduce the risk of developing kidney stones and help to decrease bone loss.
- Eating foods such as fruits that are lower in calories per cup instead of some other higher-calorie food may be useful in helping to lower calorie

What foods are in the Fruit Group?

Any fruit or 100% fruit juice counts as part of the Fruit Group. Fruits may be fresh, canned, frozen, or dried, and may be whole, cut-up, or pureed.

Daily Fruit Table

	Age Group	Daily Amount Recommended
Women	31+ years old	1.5 cups
Men	31+ years old	2 cups

Avoid sugar sweetened beverages!

Drink (12-ounce serving)	Teaspoons of Sugar	Calories
Bottled Water	0 teaspoons	0
Diet Cola	0 teaspoons	0
Sugar Free Drink Mix	0 teaspoons	0
Sugar Free Lemonade	0 teaspoons	0
Unsweetened Tea	0 teaspoons	0
Sports Drink	2 teaspoons	75
Lemonade	6¾ teaspoons	105
Orange Juice	7½ teaspoons	160
Sweet Tea	8½ teaspoons	120
Powdered Drink Mix (with sugar)	9 teaspoons	145
Cola	10¼ teaspoons	150
Fruit Punch	11½ teaspoons	195
Root Beer	11½ teaspoons	170
Grape Juice	12 teaspoons	200
Orange Soda	13 teaspoons	210

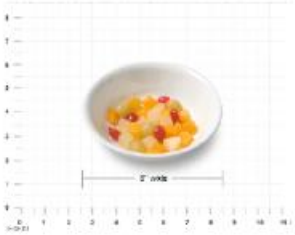
In general it's recommended that people with diabetes have no more than four ounces of fruit juice per day. It's recommended to choose whole fruit instead of juice, because fruit contains fiber. The fiber helps fill up your belly and also reduces how high your blood sugar goes up after you eat fruit.

What counts as a serving of fruit?

Fruit Image Gallery

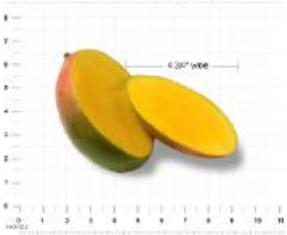
1 small apple (2¼" diameter) counts as 1 cup-equivalent in the Fruit Group

1 large banana (8-9" long) counts as 1 cup-equivalent in the Fruit Group



½ cup of fruit cocktail counts as ½ cup-equivalent in the Fruit Group

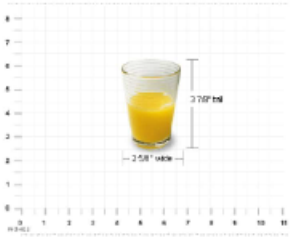
½ medium grapefruit (4" diameter) counts as ½ cup-equivalent in the



1 medium bunch of grapes (about 50 grapes) counts as 1½ cup-equivalents

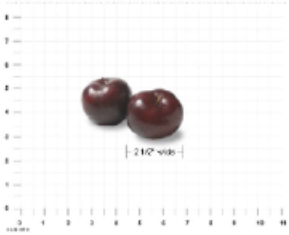
1 medium mango counts as 1 cup-equivalent in the Fruit Group

1 small orange (approx. 2½" diameter) counts as ½ cup-equivalent



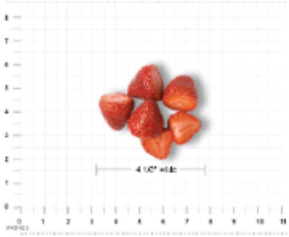
½ cup of 100% orange juice (4 fluid ounces) counts as ½ cup-equivalent in

½ large peach (2¾" diameter) counts as ½ cup-equivalent in the Fruit



2 large plums (2½" diameter each) count as 1 cup-equivalent in the Fruit

¼ cup of raisins counts as ½ cup-equivalent in the Fruit Group



½ cup of strawberries counts as ½ cup-equivalent in the Fruit Group

How many servings of fruits are in your produce package?

Fruits and Diabetes

Wondering if you can eat fruit? Yes! Fruits are loaded with vitamins, minerals and fiber just like vegetables.

Fruit contains carbohydrate so you need to count it as part of your meal plan. Having a piece of fresh fruit or fruit salad for dessert is a great way to satisfy your sweet tooth and get the extra nutrition you're looking for.

The best choices of fruit are any that are fresh, frozen or canned without added sugars.

Choose canned fruits in juice or light syrup
Dried fruit and 100% fruit juice are also nutritious choices, but the portion sizes are small so they may not be as filling as other choices.

Try to replace your candy craving with some sweet fruit for extra nutrients!

Refer to the Plate Method for more info on how to eat healthy with diabetes. (You can try carb counting if you are up for the challenge!) Both are in the back of the book.

Intro to reading Nutrition Facts Labels

Notice the size of the soft drink container and the number of servings in the container. Many containers have more than one serving, even though they are sold to look like single-serving containers. The container shown on this slide lists the serving size as the entire bottle, but that is not always the case.

The sugar content is listed in grams. Every 4 grams is equal to approximately 1 teaspoon.

How many grams of sugar do you think you consume a day just through your drinks?

Lets take a look at the Nutrition Facts label on some fruit juice!

UNIT 3. GRAINS

Today we will learn about grains and the importance of hydration.

Learning goals for today's lesson:

1. Understand that some grains have more nutrients than others
2. Understand that grains can increase blood sugar and the limit of grains to include in your diet.
3. Know how much water you need a day to be healthy

But first, lets review from last month...

1. Name a fruit that you like to eat as a healthy treat. How many of that fruit would be healthy to eat in one day?
2. We recommend having whole fruit over fruit juices. If you have diabetes, you should have no more than ____ ounces of fruit juice per day.
3. Find a drink and look at the Nutrition Label. Where can you find serving size? How many servings are in the bottle?

What are grains?

Any food made from wheat, rice, oats, cornmeal, barley or another cereal grain is a grain product. Bread, pasta, oatmeal, breakfast cereals, tortillas, and grits are examples of grain products.

There are two types of grains

Whole Grains	Refined Grains
Whole Grains - Whole grains contain the entire grain kernel (the bran, germ, and endosperm). Examples of whole grains include: - Whole-wheat flour - Bulgur (cracked wheat) - Oatmeal - Whole cornmeal - Brown rice	Refined Grains - Refined grains have been milled, a process that removes the bran and germ. This is done to give grains a finer texture and improve their shelf life, but it also removes dietary fiber, iron, and many B vitamins. Examples of refined grain products are: - White flour - De-germinated cornmeal - White bread - White rice

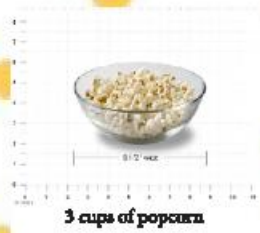
Try to eat whole grains instead of refined grains for more dietary fiber, iron, and B vitamins.

How many servings of grains do I need a day?		
Men	31-50 years old	7 servings
	50+ years old	6 servings
Women	31-50 years old	6 servings
	50+ years old	5 servings

Examples of what would count as 1 serving

1 slice of wheat bread

1 cup of whole grain or corn flake cereal



3 cups of popcorn

7 saltine crackers

5 whole grain crackers

1/2 a cup of cooked oatmeal

1 small quesadilla (warning a lot are sold larger)

1/2 cup of brown rice

1 small hamburger bun

Examples of what would count as 2 servings

1 cup of white rice

1 small (2 inch by 2 inch) piece of cornbread

A bagel can be about 6 servings of grain!

Why eat whole grains instead of refined grains

Consuming whole grains as part of a healthy diet may reduce the risk of heart disease. Consuming foods containing fiber, such as whole grains, as part of a healthy diet, may reduce constipation.

Eating whole grains may help with weight management.

Grains also contain other essential nutrients:

B vitamins: thiamin, riboflavin, niacin, and folate

Minerals: iron, magnesium, and selenium

Dietary fiber from whole grains or other foods, may help reduce blood cholesterol levels and may lower risk of heart disease, obesity, diverticulosis and type 2 diabetes.

Grains are an important source of fiber.

A serving size tells you how much of a food or a liquid is in 1 serving.

This number tells you how many grams (g) of fiber are in 1 serving.

Nutrition Facts

Serving Size ½ cup (130g)
Serving Per Can 3½

Amount Per Serving	
Calories 140	Calories from Fat 0
	% Daily Value*
Total Fat 0.5g	1%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 510g	21%
Total Carbohydrates 28g	9%
*Dietary Fiber 6g	24%
Sugars 11g	
Protein 6g	
Vitamin A 2% •	Vitamin C 0%
Calcium 6% •	Iron 10%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily values may be higher or lower depending on your calorie needs.

How much fiber should I eat	
MEN	
18-50 years old	50+ years old
38 grams	30 grams
WOMEN	
18-50 years old	50+ years old
25 grams	21 grams

Grains and Diabetes

Grains increase your blood sugar. So if you are going to eat a grain, you should opt for the more nutritious version, whole grains!

Leave the processed white flour-based products, especially the ones with added sugar, on the shelves or use them only for special occasion treats.

For more information on eating healthy with diabetes refer to the Plate Method in the back of the book. (You can read about carb counting as well!)

Staying hydrated!

You should be drinking 90-125 ounces of water a day!

(or about 3 L of water a day - so imagine a 2L bottle of soda and drink one and a half of those of water!)

There are many calorie-free alternatives to plain, noncarbonated water. Some examples:

- Carbonated water: seltzer, club soda
- Hot herbal tea
- UNSWEETENED Iced tea
- Coffee
- "Spa water": water infused with herbs, cucumbers, citrus fruits
- Flavored sparkling water

PRO TIP:

Put an alarm to remind yourself to hydrate!

Lets take a look at the cup or water bottle you usually drink from.
Based on the size of your bottle or cup, lets see if we can figure out how many times you have to finish a full cup of water to meet your water goal.

UNIT 4. PROTEIN

Today we will learn about how much protein we should be eating and what are healthy plant based protein sources

Learning goals for today's lesson:

1. **Learn how to identify healthy animal and plant based protein sources.**
2. **Understand that some proteins can be bad for your heart health.**

But first, lets review from last month...

1. **Can you name an example of a grain that is more nutritious than refined grains?**
2. **What portion of your plate should grains cover?**
3. **Do you remember how much water you should be drinking to be most healthy?**

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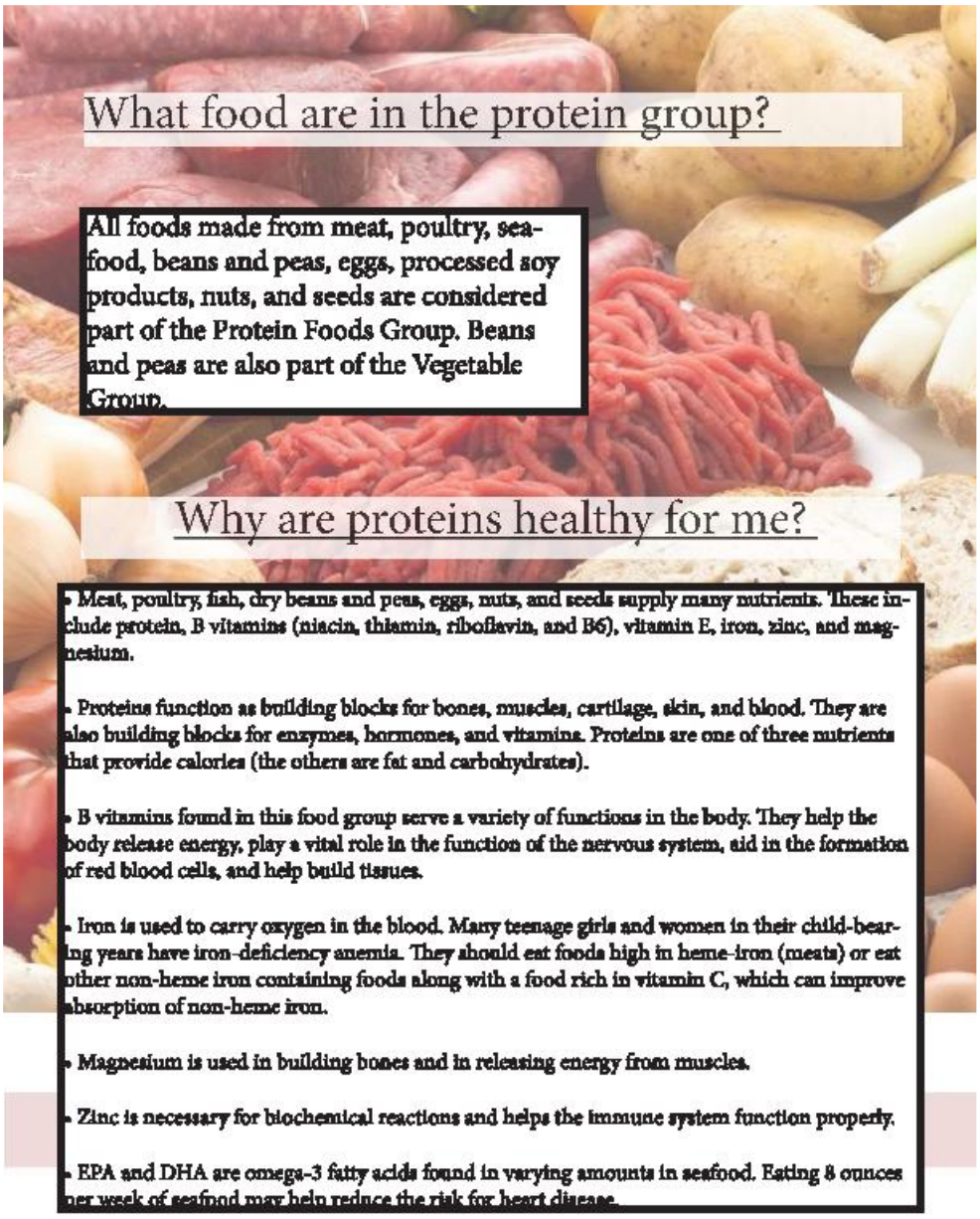


What food are in the protein group?

All foods made from meat, poultry, seafood, beans and peas, eggs, processed soy products, nuts, and seeds are considered part of the Protein Foods Group. Beans and peas are also part of the Vegetable Group.

Why are proteins healthy for me?

- Meat, poultry, fish, dry beans and peas, eggs, nuts, and seeds supply many nutrients. These include protein, B vitamins (niacin, thiamin, riboflavin, and B6), vitamin E, iron, zinc, and magnesium.

- Proteins function as building blocks for bones, muscles, cartilage, skin, and blood. They are also building blocks for enzymes, hormones, and vitamins. Proteins are one of three nutrients that provide calories (the others are fat and carbohydrates).

- B vitamins found in this food group serve a variety of functions in the body. They help the body release energy, play a vital role in the function of the nervous system, aid in the formation of red blood cells, and help build tissues.

- Iron is used to carry oxygen in the blood. Many teenage girls and women in their child-bearing years have iron-deficiency anemia. They should eat foods high in heme-iron (meats) or eat other non-heme iron containing foods along with a food rich in vitamin C, which can improve absorption of non-heme iron.

- Magnesium is used in building bones and in releasing energy from muscles.

- Zinc is necessary for biochemical reactions and helps the immune system function properly.

- EPA and DHA are omega-3 fatty acids found in varying amounts in seafood. Eating 8 ounces per week of seafood may help reduce the risk for heart disease.

How many servings of protein do I need a day?		
Men	31-50 years old	6 servings
	50+ years old	5.5 servings
Women	31+ years old	5 servings

In general, 1 serving = 1 ounce of meat, poultry or fish, ¼ cup cooked beans, 1 egg, 1 tablespoon of peanut butter, or ½ ounce of nuts or seeds can be considered as 1 ounce-equivalent.

1 ounce of nuts = 2 servings of protein

1/2 cup of beans = 2 servings of protein

6 thin slices of lunch meat = 2 servings of protein

2 ounces of shrimp = 2 servings of protein

1 small chicken breast = 3 servings of protein

5 ounces of steak = 5 servings of protein

When it comes to meat and fish, number of ounces equals number of servings

Watch out for proteins that are high in saturated fats!

• Diets that are high in saturated fats raise "bad" cholesterol levels in the blood. The "bad" cholesterol is called LDL (low-density lipoprotein) cholesterol. High LDL cholesterol increases the risk for coronary heart disease.

• A high intake of fats also makes it difficult to avoid consuming more calories than are needed.

o The following proteins are high in saturated fat:

Fatty cuts of beef, pork, and lamb

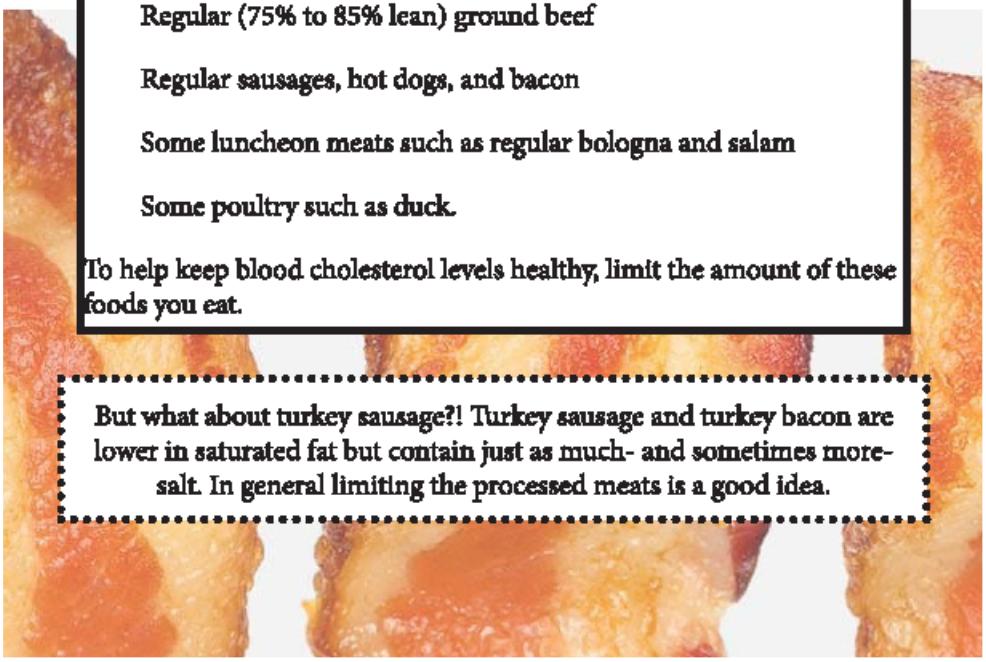
Regular (75% to 85% lean) ground beef

Regular sausages, hot dogs, and bacon

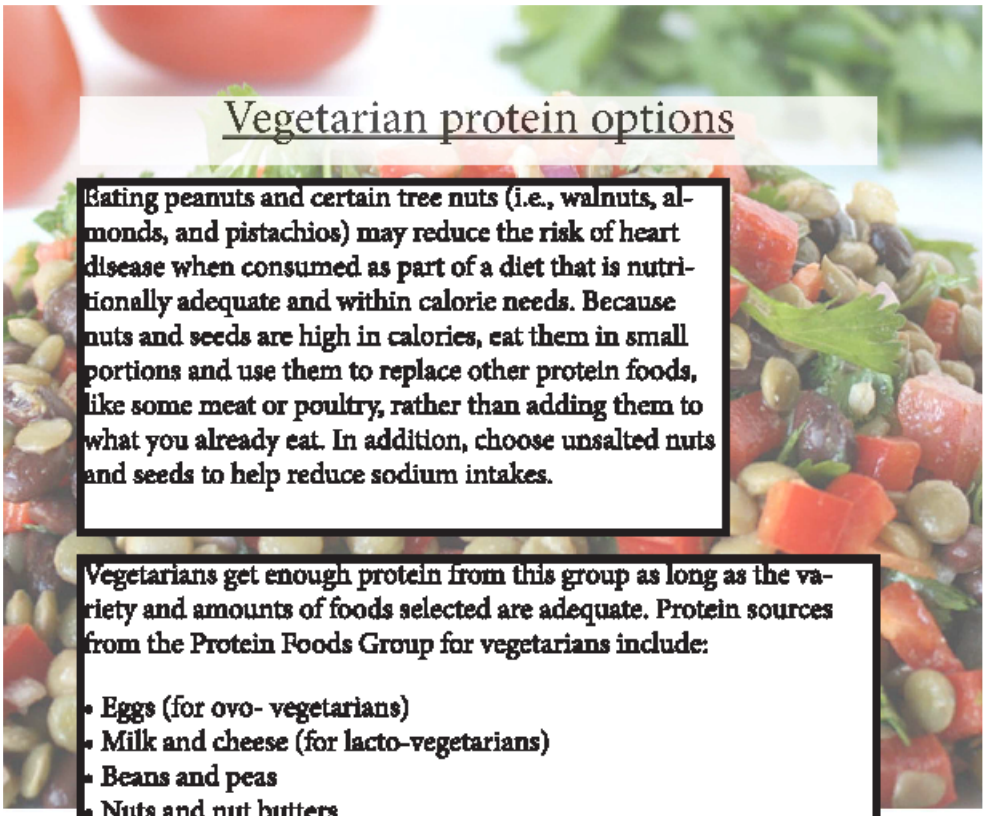
Some luncheon meats such as regular bologna and salam

Some poultry such as duck.

To help keep blood cholesterol levels healthy, limit the amount of these foods you eat.



But what about turkey sausage?! Turkey sausage and turkey bacon are lower in saturated fat but contain just as much- and sometimes more- salt. In general limiting the processed meats is a good idea.



Vegetarian protein options

Eating peanuts and certain tree nuts (i.e., walnuts, almonds, and pistachios) may reduce the risk of heart disease when consumed as part of a diet that is nutritionally adequate and within calorie needs. Because nuts and seeds are high in calories, eat them in small portions and use them to replace other protein foods, like some meat or poultry, rather than adding them to what you already eat. In addition, choose unsalted nuts and seeds to help reduce sodium intakes.

Vegetarians get enough protein from this group as long as the variety and amounts of foods selected are adequate. Protein sources from the Protein Foods Group for vegetarians include:

- Eggs (for ovo- vegetarians)
- Milk and cheese (for lacto-vegetarians)
- Beans and peas
- Nuts and nut butters
- Soy products (tofu, tempeh, veggie burgers)

Nutrients that vegetarians may need to focus on include protein, iron, calcium, zinc, and vitamin B12.

Animal protein includes all of the building blocks that your body needs. Plant proteins need to be combined to get all of the building blocks that your body needs. For more tips on eating like a vegetarian, refer to the section in the back of the book!

Why is protein important for people with CKD?

When you body uses protein it produces waste. This waste is removed by the kidneys. Took much protein can make the kidneys work harder, so people with CKD may need to eat less protein.

How do I eat the right amount of protein?

A dietitian will tell you what amount and types of protein are right for you. Here is some general information about protein types and serving sizes.

Eat smaller portions of meat and dairy. This will help you also lower the amount of phosphorus in your diet because phophorus is found in meat and diary.

- Meat, poultry, and fish: a cooked portion should be about 2-3 ounces or about the size of a deck of cards
- Dairy foods: a portion is 1/2 cup of milk or yogurt or one slice of cheese

Plant proteins should make up the rest of the protein that you eat. A serving is:

- 1/2 a cup of cooked beans
- 1/4 a cup of nuts
- a slice of bread
- 1/2 a cup of cooked rice or noodles

UNIT 5. FATS

Today we will learn about fats, meal planning, and shopping

Learning goals for today's lesson:

1. Understand that there are healthy and unhealthy fats
2. Learn ways to decrease unhealthy fats in your diet
3. Pick up some new tricks regarding meal planning and food shopping

But first, lets review from last month...

1. Name one example of a healthy animal based protein?
2. Name one example of a healthy plant based protein?
3. What is an example of a protein high in saturated fats?

Most food contain several different kinds of fat. Some are better for your health than others. It is wise to choose healthier types of fat, and enjoy them in moderation. Keep in mind that even healthier fats contain calories and should be used sparingly for weight management. Here is some information about healthy and harmful dietary fats.

For major types of fats are:
1. Monounsaturated fats
2. Polyunsaturated fats
3. Saturated fats

Monounsaturated and polyunsaturated fats are known as "healthy fats" because they are good for your heat, cholesterol levels, and overall health. These fats tend to be "liquid" at room temperature. Consider trying beneficial polyunsaturated fats containing Omega-3 fatty acids found in fatty fish, flaxseed, and walnuts.

Monounsaturated Fat	Polyunsaturated Fat
Olive oil	Soybean oil
Canola oil	Corn oil
Sunflower oil	Safflower oil
Peanut oil	Walnuts
Olives	Sunflower, sesame, and pumpkin seeds; flaxseed
Nuts (almonds, peanuts, hazelnuts, macadamia nuts, pecans, cashews)	Fatty fish (salmon, tuna, mackerel, herring, trout, anchovies, sardines, and eel)
Avocados	Soymilk
Peanut butter	Tofu

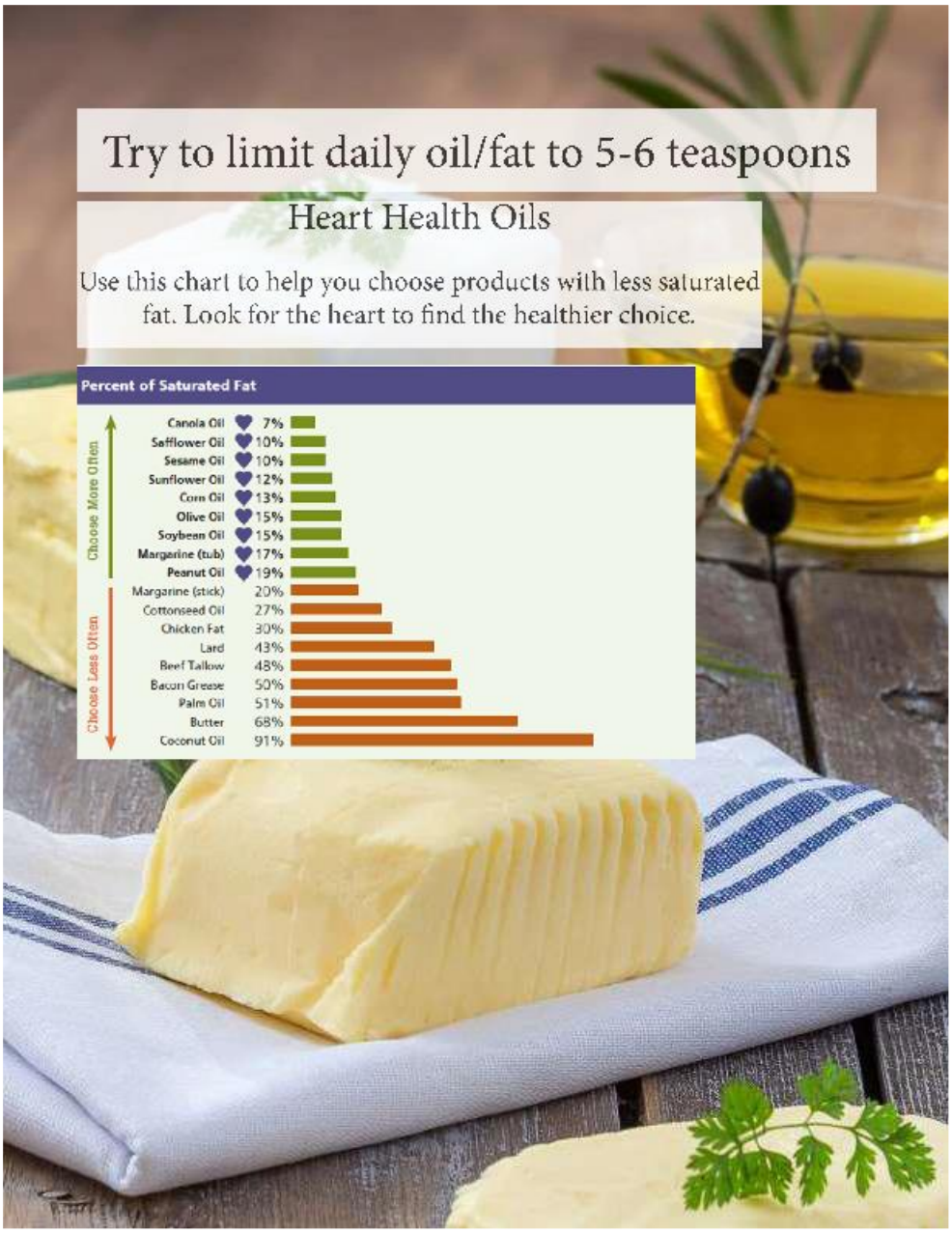
Tips for increasing healthy fats in your diet:
1. Cook with olive oil
2. Plan snacks of nuts or olives
3 Eat more avocados
4. Dress you own salads instead of using commercial dressings

Saturated fats and trans fats are known as the "harmful fats." They increase your risk of disease and elevate cholesterol. Saturated fats tend to be solid at room temperature, but they are also found in liquid tropical oils (palm and coconut). Trans fats (partially hydrogenated or hydrogenated fats) are oils that have been modified for a longer shelf life. Trans fats are very bad for you. No amount of trans fats is healthy.

Saturated Fat	Trans Fat
High-fat cuts of meat (beef, lamb, pork)	Commercially baked pastries, cookies, doughnuts, muffins, cakes, pizza dough, pie crusts
Chicken with the skin	Packaged snack foods (crackers, microwave popcorn, chips)
Whole-fat dairy products (cream/milk)	Stick margarine
Butter	Vegetable shortening
Palm and coconut oil (snack foods, non-dairy creamers, whipped toppings)	Fried foods (French fries, fried chicken, chicken nuggets, breaded fish)
Ice cream	Candy bars
Cheese	Pre-mixed products (cake mix, pancake mix, chocolate drink mix)
Lard	

Tips for decreasing harmful fats in your diet:

1. Read food labels and avoid trans fats and hydrogenated/partially hydrogenated oils
2. Avoid fried products
3. Avoid fast food
4. When eating out, ask that food be prepared with olive oil


Try to limit daily oil/fat to 5-6 teaspoons
Heart Health Oils
Use this chart to help you choose products with less saturated fat. Look for the heart to find the healthier choice.
Percent of Saturated Fat
Choose More Often
Choose Less Often
Canola Oil 7%
Safflower Oil 10%
Sesame Oil 10%
Sunflower Oil 12%
Corn Oil 13%
Olive Oil 15%
Soybean Oil 15%
Margarine (tub) 17%
Peanut Oil 19%
Margarine (stick) 20%
Cottonseed Oil 27%
Chicken Fat 30%
Lard 43%
Beef Tallow 48%
Bacon Grease 50%
Palm Oil 51%
Butter 68%
Coconut Oil 91%

Meal Planning and Shopping

1. Plan Meals
   - Avoid stress at mealtime by planning a weekly menu and posting it in a location for everyone to see, like a chalkboard in the kitchen.
   - Vary your vegetables.

2. Prep Ahead
   - Have ingredients for the week ready. After you shop, cut vegetables and measure ingredients in advance for easier meals.
   - Use herbs and spices.

3. Make Mealtime a Priority
   - Make time for family meals when planning your household's schedule each week. Try to cook, eat up, and clean up together!
   - Know how much to eat.

4. Think Beyond Dinner
   - If evenings are too hectic at your house, consider other meals for family time such as a weekend brunch or even afternoon snack time.
   - Drink plenty of water and often.

5. Keep Meals Fun and Focused
   - Keep the family table a media- and stress-free zone. Use your valuable family time to "unplug," interact, and focus on each other.
   - Make eating a social event.

Smart shopping tips:

1. Celebrate the season

Use fresh vegetables and fruits that are in season. They are easy to get, have more flavor, and are usually less expensive. Your local farmer's market is a great source of seasonal produce.

2. Don't pay full price

Get the best price, check the local newspaper, online, and at the store for sales, coupons, and specials that will cut food costs. Often, you can get more for less by visiting larger grocery stores (discount grocers if available).

3. Stick to your list

Plan, plan, plan out your meals ahead of time and make a grocery list. You will save money by buying only what you need. Don't shop when you're hungry. Shopping after eating will make it easier to pass on the tempting snack foods. You'll have more of your food budget for vegetables and fruits.

4. Try canned or frozen

Compare the price and the number of servings from fresh, canned, and frozen forms of the same veggie or fruit. Canned and frozen items may be less expensive than fresh. For canned items, choose fruit canned in 100% fruit juice and vegetables with "low sodium" or "no salt added" on the label.

5. Buy small amounts frequently

Some fresh vegetables and fruits don't last long. Buy small amounts more often to ensure you can eat the foods without throwing any away.

6. Buy in bulk when items are on sale

For fresh vegetables or fruits you use often, a large size bag is the better buy. Canned or frozen fruits or vegetables can be bought in large quantities when they are on sale, since they last much longer.

7. Utilize store brands

Choose store brands when possible. You will get the same or similar product for a cheaper price. If your grocery store has a membership card, sign up for even more savings.

8. Keep it simple

Buy vegetables and fruits in their simplest form. Pre-cut, pre-washed, ready-to-eat, and processed foods are convenient, but often cost much more than when purchased in their basic forms.

9. Plant your own

Start a garden—in the yard or a pot on the deck—for fresh, inexpensive, flavorful additions to meals. Herbs, cucumbers, peppers, or tomatoes are good options for beginners. Browse through a local library or online for more information on starting a garden.

10. Plan and cook smart

Beware of the "convenience cost". Convenience foods like frozen dinners, pre-cut fruits and vegetables and take-out meals cost more than the home prepared versions.

Prepare and freeze vegetable soups, stews, or other dishes in advance. This saves time and money. Add leftover vegetables to casseroles or blend them to make soup. Overripe fruit is great for smoothies or baking.

UNIT 6. SNACKS AND SODIUM

Today we will learn about sodium and snacking

Learning goals for today's lesson:

1. Understand which foods have a lot of sodium
2. Learn about seasoning alternatives to salt.
3. Learn ways to be a healthy snacker.

But first, lets review from last month...

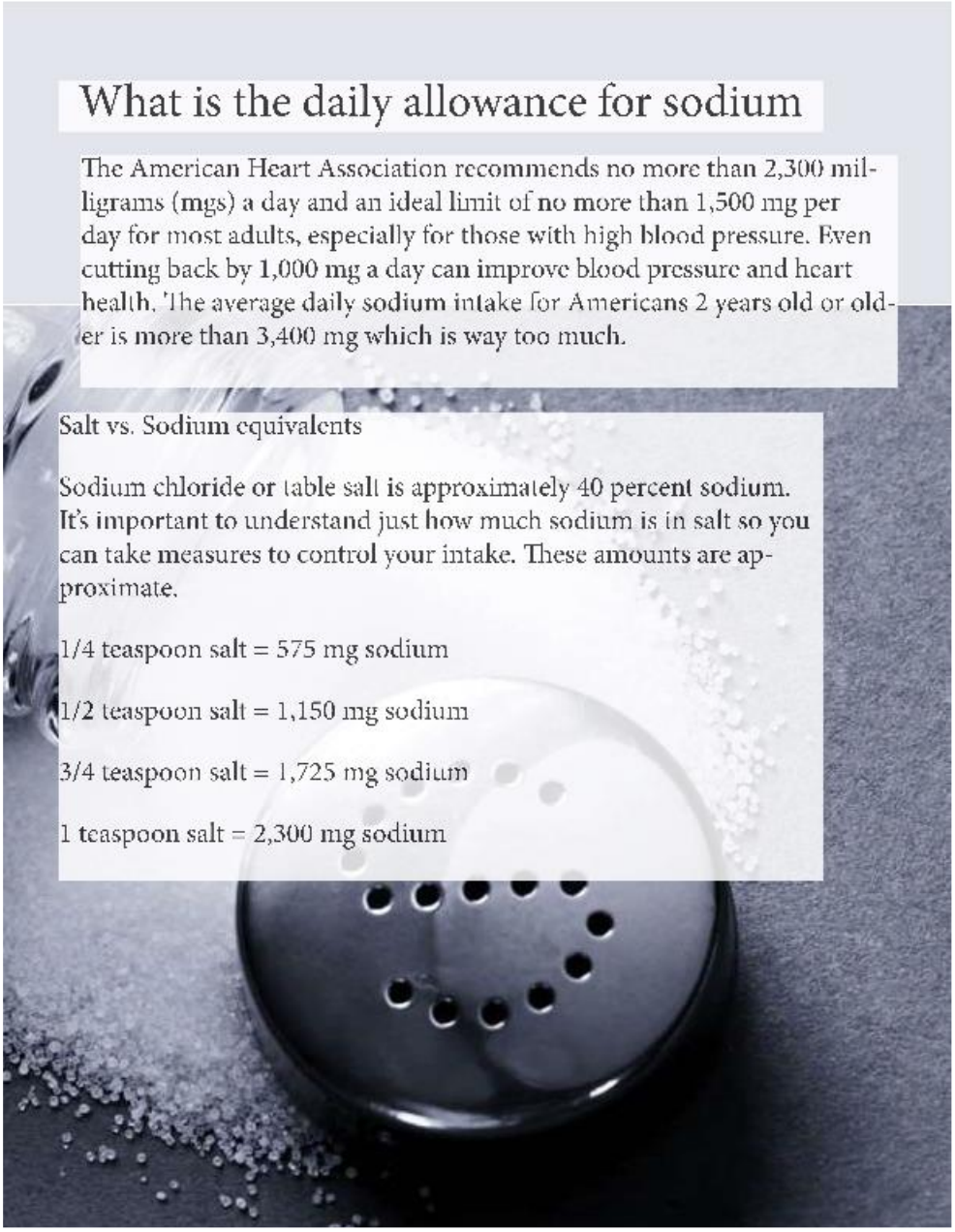
1. What is an example of a healthy fat?
2. What is an example of an unhealthy fat?
3. What is one way you can decrease unhealthy fats in your diet?
4. What is one thing you found useful around meal planning and food shopping?

What is sodium?

The body needs a small amount of sodium to function, but most Americans consume too much sodium. High sodium consumption can raise blood pressure, and high blood pressure is a major risk factor for heart disease and stroke. Heart disease and stroke are the nation's first and fifth leading causes of death.

How does sodium affect your heart health

When there's extra sodium in your bloodstream, it pulls water into the blood vessels, increasing the total amount (volume) of blood inside your blood vessels. With more blood flowing through your blood vessels, blood pressure increases. This puts an extra burden on your heart and blood vessels. In some people, this may lead to or raise high blood pressure. Having less sodium in your diet may help you lower or avoid high blood pressure. People with high blood pressure are more likely to develop heart disease or have a stroke.


What is the daily allowance for sodium
The American Heart Association recommends no more than 2,300 milligrams (mgs) a day and an ideal limit of no more than 1,500 mg per day for most adults, especially for those with high blood pressure. Even cutting back by 1,000 mg a day can improve blood pressure and heart health. The average daily sodium intake for Americans 2 years old or older is more than 3,400 mg which is way too much.
Salt vs. Sodium equivalents
Sodium chloride or table salt is approximately 40 percent sodium. It's important to understand just how much sodium is in salt so you can take measures to control your intake. These amounts are approximate.
1/4 teaspoon salt = 575 mg sodium
1/2 teaspoon salt = 1,150 mg sodium
3/4 teaspoon salt = 1,725 mg sodium
1 teaspoon salt = 2,300 mg sodium

Where is sodium found?

The Salty Six

Most of the sodium Americans eat comes from packaged, processed, store-bought, and restaurant foods. Only a small amount comes from salt added during cooking or at the table. In fact, most Americans already get more daily sodium than recommended before they ever pick up a salt shaker. Many Americans have acquired a taste for a high salt diet. One way to cut back is to skip the table salt. Eating these foods less often can help reduce your sodium intake, lower your blood pressure and/or prevent high blood pressure (HBP or hypertension) from developing in the first place.

Seasoning Alternatives to Sodium

How do I cook with less sodium and more flavor?

1. Avoid adding table salt to foods
2. Flavor foods with herbs, spices, lemon, lime, vinegar, or salt-free seasoning blends (see table below)
3. Use fresh poultry, fish, and lean meat, rather than canned, smoked, or processed types
4. Choose unsalted nuts and low-sodium canned foods. Cook dried peas and beans
5. Use products made without added salt
6. Try low sodium bouillon and soups and unsalted broth
7. Rinse canned vegetables and beans to reduce sodium.

Here are some seasonings to add some variety

Allspice	Cinnamon	Onion powder (not onion salt)
Almond extract	Curry powder	Paprika
Basil	Dill	Parsley
Bay leaves	Garlic (not garlic salt)	Rosemary
Caraway seeds	Ginger	Sage
Chives	Lemon juice	Thyme
Cider vinegar	Mustard (dry)	Turmeric
	Nutmeg	

Hacking your Snacking

Planning for healthy snacks can help satisfy hunger in between meals and keep you moving towards your food group goals.

Tips for Healthy Snacking

1. BYOS (Build Your Own Snacks)
   Make your own trail mix with unsalted nuts and add-ins such as seeds, dried fruit, popcorn, or a sprinkle of chocolate chips.
2. Prep Ahead
   Portion snack foods into baggies or containers when you get home from the store so they're ready to grab-n-go when you need them.
3. Make it a Combo
   Combine food groups for a satisfying snack—yogurt and berries, apple with peanut butter, whole-grain crackers with turkey and avocado.
4. Eat Vibrant Veggies
   Spice up raw vegetables with dips. Try dipping bell peppers, carrots, or cucumbers in hummus, tzatziki, guacamole, or baba ghanoush.
5. Snacks on the Go
   Bring ready-to-eat snacks when you're out. A banana, yogurt (in a cooler), or baby carrots are easy to bring along and healthy options.

EXTRA INFORMATION:

Diets for patients with CKD

Tips for eating like a vegetarian

The Diabetes Plate Method

Carbohydrate Counting

THE FIRST STEPS TO EATING RIGHT

STEP 1 Choose and prepare foods with less salt and sodium.

- Buy fresh food more often. Sodium (a part of salt) is added to many packaged foods.
- Use spices, herbs, and sodium-free seasonings in place of salt.
- Check the Nutrition Facts label on food packages for sodium. A Daily Value of 20% or more means the food is high in sodium.
- Try lower-sodium versions of frozen dinners and other convenience foods.
- Rinse canned vegetables, beans, meats, and fish with water before eating.

Look for Food Labels that Say
• Sodium free • Salt free • Very low sodium • Low sodium • Reduced or less sodium • Light in sodium • No salt added • Unsalted • Lightly salted

STEP 2 Eat the right amount and right types of protein.

- Eat small portions of protein foods.
- Protein is found in foods from plants and animals. Talk to your dietitian about how to choose the right combination for you.

Animal-protein Foods	Plant-protein Foods
• Chicken • Fish • Meat • Eggs • Dairy	• Beans • Nuts • Grains

STEP 3 Choose foods that are healthy for your heart.

- Grill, broil, bake, roast, or stir-fry foods, instead of deep frying.
- Cook with nonstick cooking spray or a small amount of olive oil instead of butter.
- Trim fat from meat and remove skin from poultry before eating.

Heart-healthy Foods
• Lean cuts of meat, like loin or round • Poultry without the skin • Fish • Beans • Vegetables • Fruits • Low-fat milk, yogurt, cheese

THE NEXT STEPS TO EATING RIGHT

As your kidneys slow down, you *may* need to eat foods that are lower in phosphorus and potassium. Your health care provider will use lab tests to watch your levels.

STEP 4 Choose foods with less phosphorus.

Why? To help protect your bones and blood vessels.

- Many packaged foods have added phosphorus. Look for phosphorus—or for words with "PHOS"—on ingredient labels.
- Deli meats and some fresh meat and poultry can have added phosphorus. Ask the butcher to help you pick fresh meats without added phosphorus.

Foods *Lower* in Phosphorus	Foods *Higher* in Phosphorus
• Fresh fruits and vegetables • Breads, pasta, rice • Rice milk (not enriched) • Corn and rice cereals • Light-colored sodas/pop	• Meat, poultry, fish • Bran cereals and oatmeal • Dairy foods • Beans, lentils, nuts • Colas

STEP 5 Choose foods that have the right amount of potassium.

Why? To help your nerves and muscles work the right way.

- Salt substitutes can be very high in potassium. Read the ingredient label. Check with your provider about using salt substitutes.
- Drain canned fruits and vegetables before eating.

Foods *Lower* in Potassium	Foods *Higher* in Potassium
• Apples, peaches • Carrots, green beans • White bread and pasta • White rice • Rice milk (not enriched) • Cooked rice and wheat cereals, grits	• Oranges, bananas • Potatoes, tomatoes • Brown and wild rice • Bran cereals • Dairy foods • Whole wheat bread and pasta • Beans and nuts

CKD (Chronic Kidney Disease)

If you have CKD and depending of the stage, your doctor may have advised you to limit the amount of potassium you consume from foods or supplements. A person may prevent or delay some health problems from CKD by eating the right foods and avoiding foods high in sodium, potassium, and phosphorus.

As CKD progresses, nutritional needs change. A health care provider may recommend that a patient with reduced kidney function choose foods carefully.

High Potassium Foods	Low Potassium Alternatives	High Phosphorus Foods	Low Phosphorus Alternatives
Oranges/Orange Juice	Apples and apple juice	Dairy foods (milk, cheese, yogurt)	Liquid non-dairy creamer
Melons	Cranberries and cranberry juice	Beans (baked, kidney, lima, pinto)	Sherbert
Apricots	Canned pears	Nuts and peanut butter	Cooked rice
Bananas	Strawberries, blueberries, raspberries	Processed meats (hot dogs, canned meat)	Rice, wheat, and corn cereals
Potatoes	Plums	Cola	Popcorn
Tomatoes	Pineapple	Canned iced teas and lemonade	Lemon-lime soda
Sweet potatoes	Cabbage	Bran cereals	Root beer
Cooked spinach	Boiled Cauliflower	Egg yolks	Powderd iced tea and lemonade mexes
Cooked broccoli			
Beans (baked, kidney, lima, pinto)			
Potassium containing salt substitute			

Tips for eating like a vegetarian!

Build meals around protein sources that are naturally low in fat, such as beans, lentils, and rice. Don't overload meals with high-fat cheeses to replace the meat. Many foods that typically contain meat or poultry can be made vegetarian. This can increase vegetable intake and cut saturated fat and cholesterol intake.

Micronutrients that may be low in vegetarian diets:

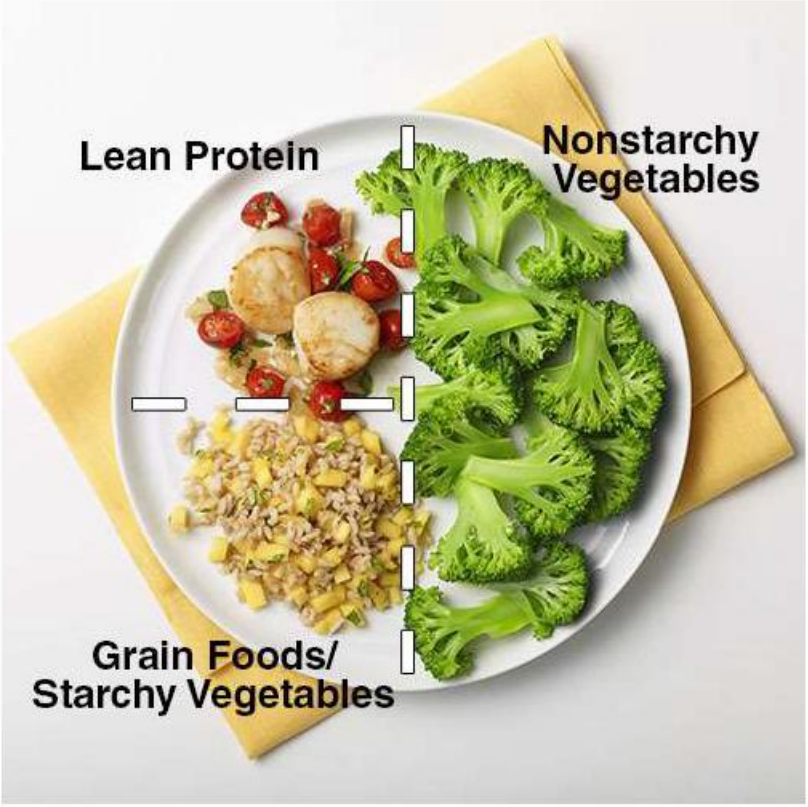
- Iron functions primarily as a carrier of oxygen in the blood. Iron sources for vegetarians and vegans include iron-fortified breakfast cereals, spinach, kidney beans, black-eyed peas, lentils, turnip greens, molasses, whole wheat breads, peas, and some dried fruits (dried apricots, prunes, raisins).

- Calcium is used for building bones and teeth and in maintaining bone strength. Sources of calcium for vegetarians and vegans include calcium-fortified soymilk, calcium-fortified breakfast cereals and orange juice, tofu made with calcium sulfate, and some dark-green leafy vegetables (collard greens, turnip greens, bok choy, mustard greens). Milk products are excellent calcium sources for lacto vegetarians.

- Zinc is necessary for many biochemical reactions and also helps the immune system function properly. Sources of zinc for vegetarians and vegans include many types of beans (white beans, kidney beans, and chickpeas), zinc-fortified breakfast cereals, wheat germ, and pumpkin seeds. Milk products are also a source of zinc.

- Vitamin B12 is found in animal products and some fortified foods. Sources of vitamin B12 for vegetarians include milk products, eggs, and foods that have been fortified with vitamin B12. These include breakfast cereals, soymilk, veggie burgers, and nutritional yeast.

The Plate Method



The Diabetes Plate Method is based on a 9-inch-diameter plate and helps keep portion sizes in check. Plates have been getting larger over the years, so make sure you're using the right size plate.

Fill Your Plate

1/2 Nonstarchy Vegetables

Fill half your plate with nonstarchy vegetables, such as broccoli, cabbage, carrots, cauliflower, green beans, salad, and zucchini.

1/4 Grain Foods/Starchy Vegetables

Fill one-quarter of your plate with whole grain or starchy foods, such as brown rice, bulgur, green peas, sweet potatoes, and whole wheat bread. Beans, which are both starchy and a good source of protein and fiber, can fit here, as well.

1/4 Lean Protein

Fill the remaining one-quarter of your plate with lean protein foods, such as fish, chicken, eggs, and lean beef or pork, and soy products such as tofu.

Fruit and/or Dairy on the Side

Add a serving of fruit, such as a small apple, or a serving of low-fat dairy, such as nonfat yogurt, or both as your meal plan allows.

Healthy Fats

Choose healthy fats in small amounts. For cooking, use healthy oils, such as olive oil. Other healthy fats that can be used in meals include nuts, seeds, and avocados.

Carbohydrate Counting

Carbohydrates are foods that when broken down (digested) become glucose and this glucose is absorbed into the blood stream. Depending on the type and amount of carbohydrates, this can happen in minutes to hours after a consuming a meal or a beverage. When blood glucose is high or consistently elevated, damage can be done to kidneys, eyes, heart, and fingers and toes among other organs and tissues.

What are the carbohydrate containing foods?

The major carb-containing food group categories are fruits, vegetables, grains, dairy (milk) and sweets/snacks/beverages. Carbohydrates are not bad, and therefore do not have to be avoid; however, they can be consumed in excess rather easily depending on the combination and amounts.

One carbohydrate serving = 15 g of carbohydrates

Most diabetic diets are designed to allow no more than 2-3 (females) or 3-4 (males) carbohydrate servings per meal and 1-2 per snack. This equals 30-45 grams of carbs for females and 45-60 grams for males.

This is just a brief overview of carbohydrate counting. If this is something you would like to learn more about then you can schedule an appointment with a dietitian!

Non-starchy vegetables don't count towards your carbohydrate count!

Starchy vegetables

- Corn/peas (½ cup)
- Potato, baked (1 small or ¼ large, 3 oz)
- Potatoes, mashed (½ cup)
- Pumpkin, cooked (1 cup small cubes)
- Squash, acorn, butternut (1 cup)
- Sweet potato or yam (½ cup)

Fruits

- Apple or orange (1 small)
- Banana, extra small (1 or 4 oz)
- Blueberries (¾ cup)
- Canned fruit in juice (½ cup)
- Cantaloupe (1 cup cubes)
- Cherries (12)
- Dried fruit (2 tbsp)
- Grapefruit, large (½)
- Grapes, small (17)
- Mango (½ small or ½ cup)
- Peach (1 medium)
- Pear (½ large)
- Pineapple (¾ cup)
- Plum (2 small) or 3 dried plums
- Raspberries (1 cup)
- Strawberries (1¼ cup)

Dried beans, peas, and lentils

- baked beans (¼ -1/3 cup)
- black, garbanzo, kidney, lima (½ cup)
- peas and lentils (½ cup)

Breads, cereals, and grains

- 1/3 large bagel
- ½ biscuit
- 1 slice or 1 oz of bread
- ½ bun
- ½ english muffin
- 4" pancake
- cold cereal (½ - ¾ cup)
- granola (¼ cup)
- pasta (1/3 cup)
- rice (1/3 cup)
- 4-6 crackers

Milk and yogurt (1 cup)

Sweets, desserts, and regular soda

- Brownie, unfrosted (1¾-inch square—1 oz)
- Cake, unfrosted (2-inch square—1 oz)
- Cookies (2 small, sandwich type)
- Ice cream (½ cup)
- Jam/jelly (1 tbsp)
- Muffin (¼ of 4-oz muffin)
- Pancake syrup (1 tbsp)
- Regular soda (½ cup)
- Sports drinks (1 cup)
- Doughnut, glazed (½)
- Milk, chocolate (½ cup)
- Pie, pumpkin (1/16 pie)
- Pudding (¼ cup)

Appendix A3 Participant Consent Forms

You are being asked to take part in this research study because you have diabetes, other diet related chronic illness, and are experiencing food insecurity. Research studies are voluntary and include only people who choose to take part. Refusal to participate in this study involves no penalty or loss of benefits. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Larry Greenblatt will conduct the study and it is funded by the Schweitzer Fellowship.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Greenblatt will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to determine the effectiveness of a home-based nutrition program in increasing fruit and vegetable consumption in patients with diabetes and other chronic diet related illness who are also experiencing food insecurity.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 14 people will take part in this study at the Duke Outpatient Clinic.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will be paired with a medical student and a dietetic intern who will visit your home on a monthly basis to deliver food and provide nutrition education. They will also work with you to create health related goals and follow up with you on a weekly basis via texts, calls, or emails. You will be asked to complete surveys and recorded interviews. Surveys and interviews will be completed before your begin the program, shortly after you complete the program, and six months after your last session. Much shorter surveys will be completed on a monthly basis during your monthly food bag drop off. These surveys and interviews can be completed over the phone if we are unable to complete them in person. The interview conversation will be audio-recorded, and later will be transcribed, though names and identifiers will be removed.

HOW LONG WILL I BE IN THIS STUDY?
If you choose to be a part of this study, you will actively be engaged in the program for six months. A follow-up survey will be conducted six months after your last session.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the PI, Dr. Greenblatt, first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time. During the interview, if you would like us to turn off audio-recording, you may request to do that; we will then ask you if you would like to continue the conversation with the research team, unrecorded. You may choose not to.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefit to you. You will have fruits and vegetables delivered to your home over the course of six months and nutrition education may improve management of your diabetes. We hope that in the future the information learned from this study will benefit other people with your condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research.

As part of this study, we will also access and gather information from your electronic medical record. Information we will look at includes height, weight, HbA1c, blood pressure, cholesterol, and changes in medications.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. To maintain confidentiality, you will be assigned a unique code number, and the key to the code will be kept securely. All the information we collect from you will be kept in locked files and encrypted, secured computer servers.

WHAT ARE THE COSTS TO YOU?

There are no monetary costs to participate in this study. Costs will include time spent participating in nutrition education and completing surveys.

WHAT ABOUT COMPENSATION?
There is no compensation for participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Larry Greenblatt at 919-280-2236.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Greenblatt and let him know that you are withdrawing from the study. His email is larry.greenblatt@duke.edu.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Larry Greenblatt at 919-280-2236.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

(Optional)

_____	_____	_____
Signature of Principal Investigator	**Date**	**Time**

(If applicable, add or substitute any of the following:)

_____	_____	_____
Signature of Legal Representative	Date	Time

_____

Relationship to Subject

Appendix A4 Project FEED Coding Manual

Coding Manual:

Healthy Eating Barriers, Motivations and Perspectives of Project FEED Participants

Project FEED (Feeding Empowerment and Educational Delivery)

Purpose:

The purpose of this coding manual is to analyze transcripts of Project FEED participant interviews. Participants were selected for this program based on the following inclusionary criteria of: difficulty managing diabetes, food insecurity, limited transportation, and interest in receiving weekly fresh produce through the Durham Outpatient Clinic's Fresh Produce Program.

This coding manual is designed to highlight areas related to:

- Dietary Habits
- Barriers to healthy eating (real vs perceived)
- Motivations
- Various Social Determinants of Health

Transcripts of each participant's interview a found in a Google Drive document. A copy of the code book will be provided to each research assistant performing transcription coding.

Codes:
The codes listed in the manual are organized by major code categories identified during the first phase of analysis. Use the definitions to appropriately determine the subject of the quote you are analyzing.

Overlapping Codes:
Some passages may contain more than one code.

Process of Coding:
Familiarize yourself with the broader code categories and read through each code. While reading through text passages, look for the related meaning and/or references as described in the code and code definition. Keep an out for good quotes. Insert comments with a brief memo to highlight good

General Precautions:
Think about the entire passage not just a single word. Consider the context and the meaning behind the subjects' responses.

Dietary Habits

Food Decisions – Healthy [***#foodhealth***]
Definition: The subject describes thoughtful intent to prepare, substitute, acquire or purchase a healthy or healthier food item, ingredient or meal.
Example: The participant states that they chose baked over fried foods or purposefully consume smaller portions of a food or food ingredient.

Food Decisions – Unhealthy [***#foodunhealth***]
Definition: The subject describes preparing, substituting, acquiring or purchasing unhealthy or less-healthy food items, ingredients or meals.
Example: The participant purposefully or unwittingly consumes unhealthy foods (e.g. ultra-processed foods)

Undesirable Food Choice Compromises [***#foodsubs***]
Definition: Intentionally choosing less favorable food items, food preparation techniques or shopping locations due to personal, physical or environmental barriers.
Example: The participant may reluctantly shop at the convenience store because of a lack of transportation or purchase white bread because it's cheaper.

Skipping Meals [***#skip***]
Definition: Any instance where the subject describes intentionally skipping or missing meals.
Example: The participant may skip breakfast or other meals.

Ability to Prepare Meals [***#cook***]
Definition: Describes cooking techniques, food preparation and balanced meals.
Example: The participant does not rely solely on convenience foods, can cook and include foods from multiple food groups in the same meal.

Nutrition Facts Panel Reading [***#nutlabel***]
Definition: The participant describes reading a food label or health messaging on the food product package.
Example: The participant references the nutrition content, nutrition messaging (e.g. from food manufacturer or FDA approved statements/claims) or describes specific ingredients for non-whole food items.

Barriers to Eating Healthy

Barriers to Healthy Eating – Financial [***#barriermoney***]
Definition: The participant describes barriers to obtaining or consuming healthy foods due to lack of economic resources
Example: Participant states or describes compromises in purchases ability due to limited financial resources. They may also describe conscientiously budgeting practices that limit acquisition to resources. Stress may or may not be attributed.

Barriers to Healthy Eating – Miscellaneous [***#barriermisc***]
Definition: The participant describes barriers to obtaining or consuming healthy foods
Example: Participant acknowledges limited transportation, poor dentition, poor appetite, or anything other than money.

Barriers to Healthy Eating – Perceived [***#barrierper***]
Definition: The participant thinks they would be unable to accomplish a proposed action.
Example: Perceives eating new foods as difficult.

Barriers to Healthy Eating – Environmental [***#barrierenviro***]
Definition: The participant thinks the environment in which they reside limits their ability to eat healthy.
Example: The participant describes environment conditions that may be unsafe, have low access to healthy foods or poor housing quality.

Motives and Actions

Belief in Higher Power *or* God [***#motiveGod***]
Definition: The participant refers to an innate motivation or support from a religious institution, faith in God, or prayer
Example: Finds comfort relying on or engaging in a relationship with a religious institution and/or God

Coping Strategies [***#cope***]
Definition: Engaging in an activity or thought-process to reduce stress or anxiety.
Example: The participant describes utilizing a meditation, walking, listening to music, exercising, etc. to reduce or manage stress.

Engages in Physical Activity [***#exercise***]
Definition: Purposeful movement or activity not associated with activities of daily living.
Example: The participant describes walking, an exercise routine, swimming, etc

Requests for Assistance [***#help***]
Definition: Participant seeks help or assistance from government organization, healthcare professional, family/friend, etc.
Example: The participant discloses the need for or states previously requesting assistance

Social Determinants of Health

Adverse Health Conditions [***#SDHcomorbid***]
Definition: The participant describes an unfavorable health condition or chronic disease
Example: The participant refers to their high cholesterol, diabetic ulcer, etc

Prior Exposure to Crime, Violence or Social Disorder [***#SDHviolence***]
Definition: The participant describes prior experiences with abuse, crime, violence or social disorder.
Example: The participant has experienced physical, verbal or sexual abuse. The participant describes issues of social disorder such as lack of cooperation in their community or disrespect.

Concern for Crime or Violence [***#SDHworry***]
Definition: The participant describes an imminent concern or threat of violence.
Example: The participant may be fearful or concerned that crime or violence is imminent and may be taking precautionary actions.

Health Literacy [***#SDHknowsmgmt***]
Definition: The participant demonstrates and understanding of their disease, proper disease management and/or physiology
Example: The participant describes techniques or behaviors that will improve or worsen a given disease state or chronic condition (e.g. carbohydrate counting, making food decisions based on blood glucose measurement).

Language and Literacy [***#SDHliteracy***]
Definition: The participant answers or responds to a question in a non sequitur manner
Example: The participant has a difficult time answering questions. Responses to questions are not plausible answers. Responses are inconsistent or contradictory.

Discrimination [***#SDHunjust***]
Definition: The participant describes an unjust or prejudicial treatment.
Example: The participant believes they were treated differently or unfairly because of their gender, weight or health condition.

Racism [***#SDHracism***]
Definition: The participant describes discrimination believed to be substantiated by motives based on race or skin color.
Example: A racial epithet was directed at the participant or services were unavailable to them but available to others.

Appendix B1 Project FEED Student Surveys

How confident do you feel about the following:
The following questions will be assessed at the beginning of the project, and then at the end 6 months later.

How confident do you feel about obtaining an accurate diet history from a patient?

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Counseling a patient about healthy eating?

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Your motivational interview skills?

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

When and how to refer a patient to someone within the specialty of your teammate (physician, if respondent is nutrition student; nutritionist/dietician if respondent is medical student)?

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Please rate your agreement with the following statement: it is important that I encourage my patients/clients to seek support from other health professionals if I am unable to meet their nutrition-related needs

- ❑ Strongly agree
- ❑ Agree

- ❑ Unsure
- ❑ Disagree
- ❑ Strongly disagree

2. How confident are you that you could CURRENTLY demonstrate a good understanding of key nutritional issues in the management of patients with:
Elevated LDL cholesterol

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Impaired renal function

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Type 2 diabetes chronic

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Coeliac disease

- ❑ Not confident at all
- ❑ Not very confident
- ❑ Unsure
- ❑ Somewhat confident
- ❑ Completely confident

Where have you gained the MOST RELEVANT knowledge on nutrition during your education?
Please select the most appropriate response.

1. lecture content
2. tutorial discussions
3. through assessment tasks, for example, assignments and examination preparation
4. problem-based learning cases
5. not gained relevant information on nutrition

Appendix C1 CGM-Exercise Recruitment Flier

Appendix C2 CGM Exercise Informed Consent Forms

North Carolina Central University
INFORMED CONSENT FORM for RESEARCH

Title of Study: Effects of short-interval, multiple bout exercise on postprandial glucose response
IRB Approval Number: 1201461
Principal Investigator: Jason O'Briant, jobrian1@nccu.edu, 919.530.7139
Co-investigators: Kimberly Powell, kpowel34@nccu.edu, 919.530.6359

What are some general things you should know about research studies?
You are being asked to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate or to stop participating at any time without penalty.

You are not guaranteed any personal benefits from being in study. Research studies may also pose risks to those that participate. In this consent form, you will find specific details about the research in which you are being asked to participate. If you do not understand something in this form, it is your right to ask the researcher for clarification or for more information. A copy of this consent form will be provided to you. If at any time you have questions about your participation, do not hesitate to contact the researcher(s) named above.

What is the purpose of this study?
The purpose of research studies is to gain a better understanding of your blood glucose responses after consuming a standard meal with or without a short bout of exercise.

What is the expected duration of this study?
You will be asked to fill out a survey and meet with the researchers for about an hour the week before and after the trial. The length of the trial is 7 days.

What will happen if you take part in the study?
If you agree to participate in this study, you will be asked to:
1. Fill out a diet and exercise questionnaire at the beginning and end of the study.
2. Schedule an appointment to create a meal plan that will be repeated twice for a total of 4 days. You will be asked to consume meals on a schedule suitable for you within an hour window for each. We will also measure height, weight and body fat percent.
3. A continuous glucose monitoring system (CGM) will be inserted into the back of your upper arm on the day before the first day of the scheduled meal plan. The CGM will measure your blood glucose every five minutes for the duration of the wear (7-days tota*l)***.***
The CGM device should not be used during magnetic resonance imaging (MRI), x-rays, computed tomography (CT) scans, intensity modulated radiation therapy (IMRT), or other treatments that generate strong magnetic fields or ionizing radiation.
4. Download the Medtronic app on your cellular phone. Create a username and password for the application, access the app 3-4 times daily to enter blood glucose values obtained from finger sticks.
5. If you are asked to exercise, you will perform the bouts of exercise three times a day before meals for two consecutive days. Do not exercise on the non-exercise days.
6. You will obtain four finger sticks each day and record on a log sheet.
7. Return all CGM, glucometer and log sheet supplies in one week back.

Potential Risks for Participating

(A). Repeated finger sticks for blood sampling often results in soreness on the fingertips that goes away within a day. There is a remote risk of infection if you do not clean the blood collection site well before lancing. If you have irritation on the fingertips, we can escort you to the NCCU Student Health Center for a more detailed evaluation.
(B). The continuous glucose transmitter can cause irritation. This is a small, lightweight device that attaches to the glucose sensor, gathers glucose data, and stores it for downloading to a computer at the end of each week. The glucose sensor is inserted with a needle, which is removed after the glucose sensor is in place. The most common place to wear a glucose sensor is in the abdomen. There is a remote risk of infection if you do not clean the blood collection site well before insertion. Pain can occur when the tape holding the device in place is

removed if there is hair on the site. The sites for the glucose monitors and blood collection will be thoroughly cleaned with alcohol wipes to prevent infections. Some people experience irritation from the medical tape that adheres the CGM device to the skin. Pain upon its removal is comparable to removing a Bandaid. The sterilized sensing probe of the CGM device remains below the skin for several days at a time, creating a small risk of infection. Data generated by this device in this study should not be used for medical diagnoses. Bleeding, swelling, irritation or infection at the insertion site are possible risks associated with inserting the sensor and may result from improper insertion and maintenance of insertion site. If sensor is not securely placed in Sen-serter® prior to insertion, pain or minor injury may occur. If you develop inflammation, redness, soreness or tenderness at insertion site, or if you experience unexplained fevers, remove sensor. Check site often for these conditions and to ensure sensor is still in place, especially before going to bed and upon waking. Always make sure the sensor is firmly attached so that it does not come out of your body. Factors that may increase the likelihood of the sensor falling off include increased physical activity (particularly for younger patients) and improper taping technique. We will provide additional tape if the device becomes loose.

(C). Exercise may cause an increase in blood pressure, a decrease in blood glucose, and short-term exhaustion. For untrained individuals beginning a new exercise routine may cause muscular soreness and tenderness that usually goes away within a day or two. Perspiration and shortness of breath are two common side effects of exercise. Participants will be encouraged to wear clothing that does not restrict mobility and is comfortable. If an exercise at any point is perceived by the participant to be painful, it will be eliminated.

(D). There may also be unexpected or unforeseeable risks if you decided to participate.

Potential Benefits for Participating

As a participant of this research you will have the opportunity to learn about your glycemic response to both food and exercise and will gain better nutritional knowledge about food choices and the effects of a specific exercise regimen. You will have the option for a Registered Dietitian to review this information with you or to bring a copy of your blood glucose report to your PCP or managing physician.

Maintenance of Confidentiality

The information in the study records will be kept confidential. Data that can be linked to your identity will be stored securely in … locked filing cabinets in our locked lab or office. Data that will be collected after the enrollment period will only have an ID code that will be used in our working files prior to statistical analysis. These files will be password protected and encrypted on the Principle Investigator's computer. No reference will be made in oral or written reports that could link you to the study.

Voluntary Participation

You are free to decide not to participate in this study or to withdraw at any time without adversely affecting your relationship with the investigator(s), academic standing, employment or enrollment at North Carolina Central University.

Rights to Withdrawal

Your decision regarding whether or not to participate in this study will not result in any loss of benefits to which you are otherwise entitled. You have the right to refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Compensation

For participating in this study, you will receive $100.00 at the completion of the study. Requirements for study completion includes answering two surveys, participating in two consecutive days of exercise and consuming the foods as specified on the meal plan. You will not be paid if you withdraw from this research, do not participate or are terminated. Your complete participation is very important.

Termination of Participation

You will be removed from the study if you are unable or unwilling to attempt the research protocol to a reasonable extent.

Emergency Medical Treatment

If you are hurt or injured during the study session(s), the researcher will contact the University's emergency medical services at 530-6317 for necessary care. There is no provision for free medical care for you if you are injured as a result of this study.

What if you are a NCCU student?
Participation in this study is not a course requirement and your participation or lack thereof, will not affect your class standing or grades at NCCU.

What if you are a NCCU employee?
Participation in this study is not a requirement of your employment at NCCU, and your participation or lack thereof, will not affect your employment.

What if you have questions about this study?
If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Jason O'Briant by phone at 919.530.7139.

What if you have questions about your rights as a research participant?
This study has been approved by the Institutional Review Board (IRB) at North Carolina Central University. If you have questions about your rights as a research participant, or if you have complaints or concerns about this study, you may contact the Director of Research Compliance & Technology Transfers, Undi Hoffler at uhoffler@nccu.edu or 919-530-5140.

Acknowledgment of Protocol and Risks

1. I am willing to check my blood glucose four times a day while wearing the CGM device. _____(Initial)

2. I do not have any medical restrictions from exercise. _____(Initial)

3. If I am scheduled to exercise, I am willing and able to complete a bout of exercise before each meal.

_____(Initial)

4. I am willing to prepare and consume the same daily menu for four days. _____(Initial)

5. The CGM device should not be worn during magnetic resonance imaging (MRI), x-rays, computed tomography (CT) scans, intensity modulated radiation therapy (IMRT), or other treatments that generate strong magnetic fields or ionizing radiation.

_____(Initial)

Consent To Participate

"I have read and understand the above information. I have received a copy of this form. I agree to participate in this study with the understanding that I may choose not to participate or to stop participating at any time without penalty or loss of benefits to which I am otherwise entitled."

Subject's signature_____ **Date** _____

Investigator's signature_____ **Date** _____

Appendix C3 Exercise Instructions and Routines

Exercise Requirements for CGM-Exercise Trail

Overview

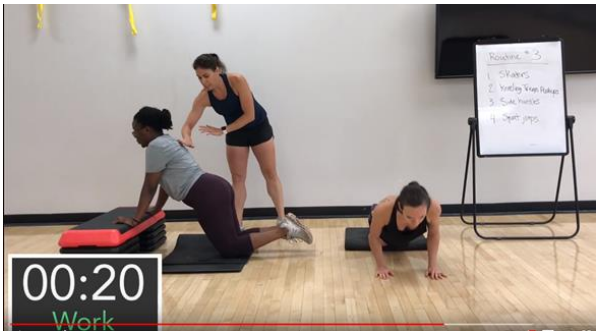
Participants will exercise before each meal for a total of 3 times during each exercise day. Complete a different routine before each meal. Exercises will be performed at max intensity for 20 seconds with a 10 second rest between exercises. Each exercise has a modified option for participants experiencing any mobility restrictions, pain, or excessive fatigue.

Instructions

1. Load up exercise routine on YouTube.
2. Perform a different routine before each meal.
3. Warm up for 1-3 min independently. Do light jogging in place, slow high knee steps, or side shuffles.
4. If pain or fatigue is present, perform the modified version of that particular exercise.
5. Cool down if desired.

Exercise Routines

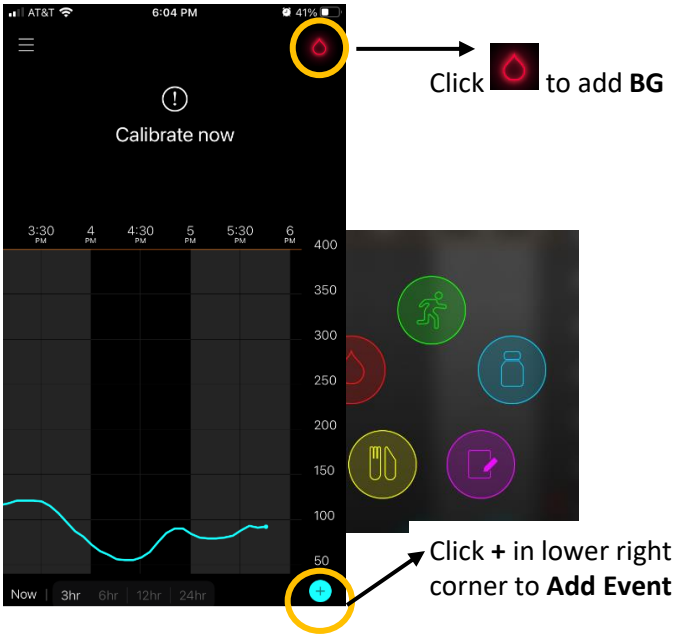
- Routine 1: https://youtu.be/bF5n62G5XcU
    - High knees
    - Triceps dips
    - Side shuffle
    - Wall sit
- Routine 2: https://youtu.be/5N4IlJ8aiPU
    - Jumping jacks
    - Push-ups
    - Mountain Climbers
    - Alternating Lunges
- Routine 3: https://youtu.be/5FofZNR0T04
    - Skaters
    - Kneeling Triceps Push-ups
    - Side Hurdles
    - Squat Jumps



Appendix C4 Participant Orientation Packet and Reference Guide

Participant Orientation and Guide

Thank you for agreeing to participate in this research trial. Your full participation is very important since there are many steps to ensure we are collecting the best data possible on you. The researchers can help you accomplish your daily tasks, but we also want to provide you with the training and knowledge so this study is not too intrusive. Along with our assistance and guidance, you will be responsible for the following daily tasks which we will cover in detail below. Feel free to ask any questions at any time. We want you to be comfortable and understanding of what we need from you. If you think at any time you are unable to accomplish these tasks, please inform us as soon as possible.



Daily Participant Tasks

I. Participant Log Sheet
II. Finger Sticks
III. Exercise
IV. Sensor Care

I. Participant Log Sheet (Food, exercise and blood glucose journal)

a. Record all blood glucose (**BG**) measurements, meals, snacks and exercise bouts on the *Participant Log Sheet*
a. Record the times of meals, BG and exercise bouts
b. Provided detailed food ingredients and amounts

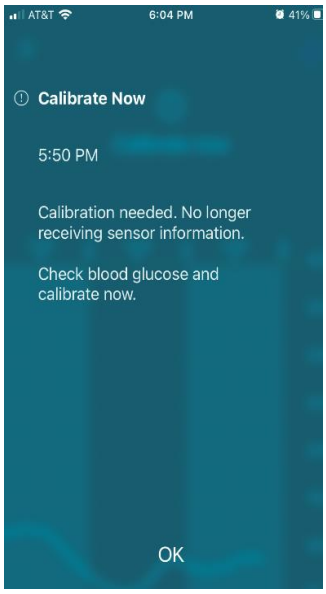
<u>Other Important Info about the Food Journal/Participant Log Sheet</u>

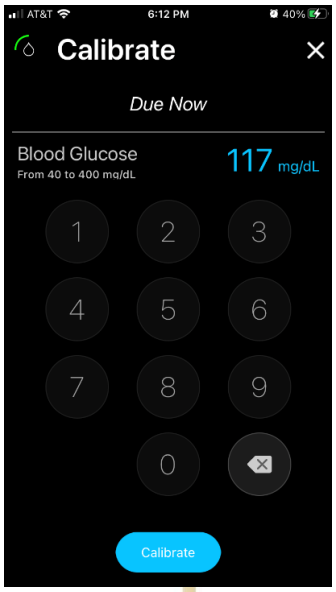
- Record as you go. Do NOT try and wait until the end of the day to record all food items.
- Take the sheets with you everywhere you go.
- Provide more detail, especially about your food, not less.

Participant Meal Plan for Monday, Tuesday, Thursday, and Friday

Meal	Food and Amounts
Breakfast	

Obtain 4 Finger Sticks Every Day





II. Finger Sticks and Calibration (Blood Glucose Meter Readings)

a. It is important to obtain at least **<u>four</u> blood glucose measurements per day** (aka "finger sticks") so the CGM (Continuous Glucose Monitor) will calibrate appropriately.
b. Record Blood Glucose values on the Medtronic app to calibrate.

On Day 1, the transmitter will take about 2 hours to synch with your phone. You must obtain a finger stick at this time to complete the set up.

<u>Other Important Info about checking blood glucose</u>

- Use the same glucose meter and the same lot of strips for the entire study.
- Do not let anyone else use the meter during the study.
- Do not change any settings on the meter during the study

III. Exercise

Perform the prescribed bouts of exercise on the exact days and times as prescribed by the researchers.

My exercise days are

_____ – _____

a. Exercise ONLY on designated days and times
b. Exercise **3 times per day** for **2 consecutive days**
c. Exercise **before meals**
d. Each exercise bout will consist of:
    - 1-3 minute warm up (not on video) – light jogging in place, slow high knee steps or side shuffles
    - 5 minutes high intensity interval training (see workout videos which will be emailed to you)
e. Do NOT exercise on non-exercise days
f. Try to maintain a normal schedule

The 1-3 minute warm up is to ease you into the exercise, get your heart rate up, and prepare muscles for the higher intensity movements. During the 5 minutes of high intensity interval training, you will perform a total of 8 exercises for 30 seconds each with a 10 second rest between each exercise.

Exercise Routines to Follow Along

- **Routine 1**: before breakfast
  https://youtu.be/bF5n62G5XcU
- **Routine 2**: before lunch
  https://youtu.be/5N4IlJ8aiPU
- **Routine 3**: before dinner
  https://youtu.be/5FofZNR0T04

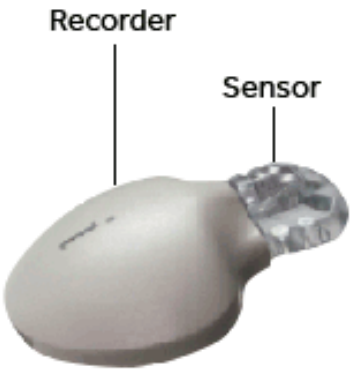
Other Important Info about Exercise

- Do NOT perform any exercises that cause you pain, distress or are very uncomfortable.
- If you feel dizzy or light-headed, stop exercising immediately and let the researchers know.

IV. Sensor Care

The *Sensor* (see pic) component contains the hair-thin filament that remains below the skin and takes the blood glucose measurements.

The *Recorder* is also called the transmitter or Guardian Connect (GC). CGMS or continuous glucose monitor system is the whole system together.



a. Do not expose the **Recorder** to MRI, x-ray, CT scans, diathermy devices or strong magnetic fields. Remove prior to undergoing any of these procedures.
b. Try to avoid taking acetaminophen (this will cause an elevated reading)
c. Do not pull on either the Recorder or Sensor since this could remove the measuring sensor.

Other Important Info about Wearing the CGM

- Wear the CGM continuously while following normal daily activities or as directed by the researchers.
  - Avoid rigorous movement to sensor site.
  - Avoid wearing overly tight or constraining clothing over the sensor.
  - Do not move, adjust, or remove sensor from insertion site.
- Record meals, blood glucose, exercise or strenuous activities, and medications on the Participant Log Sheet.
- The participant can shower and swim without removing the CGM or sensor. The transmitter and sensor are watertight for up to 30 minutes, up to a depth of 8 feet (2.4 meters). There is no time limit for swimming on the surface of the water or showering.

- Keep the **Participant LOG** sheets accessible at all times so that information can immediately be written down after each event. Record the time and date within five minutes of each BG meter reading.

RETURN

My equipment and log return date is

DATE		LOCATION
_____	@	_____

Return the following items:

a. Sensor & Transmitter (or we can remove in the office)
b. Glucose meter and any unused materials
c. Participant Log sheet

During your return visit plan to stay for about 30 mins. You will complete a final survey and be eligible to receive a $100 Visa gift card.

Appendix C5 Pre and Post Survey Questions - Research Subjects

PRE

I. Demographics

a. Which best describes your race?
   - Black or African-American
   - American Indian or Alaskan Native
   - Asian
   - Hispanic
   - White
   - Multiple races
   - Some other race (please specify)

b. Which gender are you?
   - Male
   - Female

c. Which category includes your age?
   - 18-20
   - 21-23
   - 24-29
   - 30-39
   - 40-49
   - 50 or older

d. What is your current collegiate class standing?
   - 1st year
   - 2nd year
   - 3rd year
   - 4th year
   - 5th year or more undergraduate
   - graduate student

e. Which category best describes your employment status?
   - Unemployed
   - Employed, On campus
   - Employed, Off campus

f. [links to e.] How many hours per week do you work on average?
   - 0-10
   - 11-30
   - 31-40
   - 40+

g. Which best describes your current living situation?
   - On campus
   - Off campus, apartment
   - Off campus, lives with family member
   - Off campus, single-family residence

II. Anthropometric Measurements – these measurements will be obtained by researchers and research assistants while participants are competing surveys.

a. Height – obtained using a stadiometer
b. Weight – measured using a digital scale
   a. BMI = kg/m^2
c. Body fat % - obtained by an Omron, hand-held, bioelectrical impedance device
d. Waist circumference – using flexible measuring tap, abdominal circumference will be measured

III. Medical History

a. Do you have any of the following diseases, illnesses, or conditions (check all that apply)?
   - High blood pressure (hypertension)
   - High cholesterol
   - Heart (cardiovascular) disease
   - Asthma
   - Other respiratory disease (Not asthma)
   - Kidney disease (Chronic kidney disease)
   - Gastrointestinal disorders
     - i. Celiac disease
     - ii. Crohn's disease

iii. Ulcerative colitis
iv. Gastroporesis (slow stomach emptying)
v. IBS (irritable bowel syndrome)
vi. Food/dietary

- Neuropathy
- Arthritis
- Osteoporosis or osteopenia
- Cancer

b. What medications are you currently taking?
   - List all:

c. Do you have any food allergies or intolerances?
   - Describe:

IV. Exercise History

a. Which best describes your weekly exercise habits? Exercise is defined as an intentional physical bout beyond normal daily activities. Normal daily activities such as *house work*, *chores*, *walking to class* or *shopping* should <u>not</u> be counted as exercise.
   - Never
   - Rarely (couple times per month)
   - 1-2x/week
   - 3-4x/week
   - 5-6x/week
   - Every day

b. [links from IV. a.] How long does one typical exercise session last for you?
   - less than 5 minutes
   - 6-15 mins
   - 16-30 mins
   - 31-45 mins
   - 46-60 mins
   - more than 1 hour

c. [links from IV. a.] What types of exercise(s) do you most commonly perform?
   - Aerobic machines (i.e. treadmill, elliptical, stair machine)
   - Walking
   - Hiking
   - Jogging, running or sprints
   - Biking
   - Strength training (i.e. free weights, kettle bells, weight machines, elastic resistance bands)
   - Group exercise classes
   - Dancing (Zumba, group or individual)
   - Pilates or yoga
   - Swimming
   - Team sports (i.e. basketball, soccer, baseball, football)
   - Individual sports (i.e. tennis, track and field, bike/running races)

V. Diet History

a. On average how many meals do you consume per day?
   - 0
   - 1
   - 2
   - 3
   - 4 or more

b. On average how many snacks do you consume per day?
   - 0
   - 1
   - 2
   - 3

- 4 or more

c. Where do you typically consume meals and snacks? Check up to two choices

Location	Breakfast	Lunch	Dinner	Snack
Don't usually consume				
Pearson Cafeteria (dine in)				
Pearson Cafeteria (take out)				
Subway				
Chick-fil-a				
Student Union				
Nineteen 10 Convenience Store				
Pizza Hut				
WOW Café Grill & Wingery				
Jazzmans Brew and Bakery				
Starbucks				

d. On average, how many alcoholic beverages do you drink in a week?
   - 0
   - 1-3
   - 4-6
   - 7-9
   - 10 or more

POST

I. Demographics

NONE

II. Anthropometric Measurements

Height and waist circumference will not be remeasured---only weight and BF%.

e. Weight – measured using a digital scale
    a. BMI = kg/m^2
f. Body fat % - obtained by an Omron, hand-held, bioelectrical impedance device

III. Medical History

NONE

IV. Exercise History

d. During this trial, how did the *amount* of exercise compare to your normal exercise habits?
    - The trial exercise was significantly more
    - The trial exercise was slightly more
    - The trial exercise was neither more or less
    - The trial exercise was slightly less
    - The trial exercise was significantly less
e. During this trial, how did the *intensity* (amount of effort required) of exercise compare to your normal exercise habits?
    - The trial exercise was significantly more intense
    - The trial exercise was slightly more intense
    - The trial exercise was neither more or less intense
    - The trial exercise was slightly less intense
    - The trial exercise was significantly less intense
f. During this trial, how did the *type* (amount of effort required) of exercise compare to your normal exercise habits?
    - The type of exercise during the trial was significantly different
    - The type of exercise during the trial was slightly different
    - The type of exercise during the trial was about the same

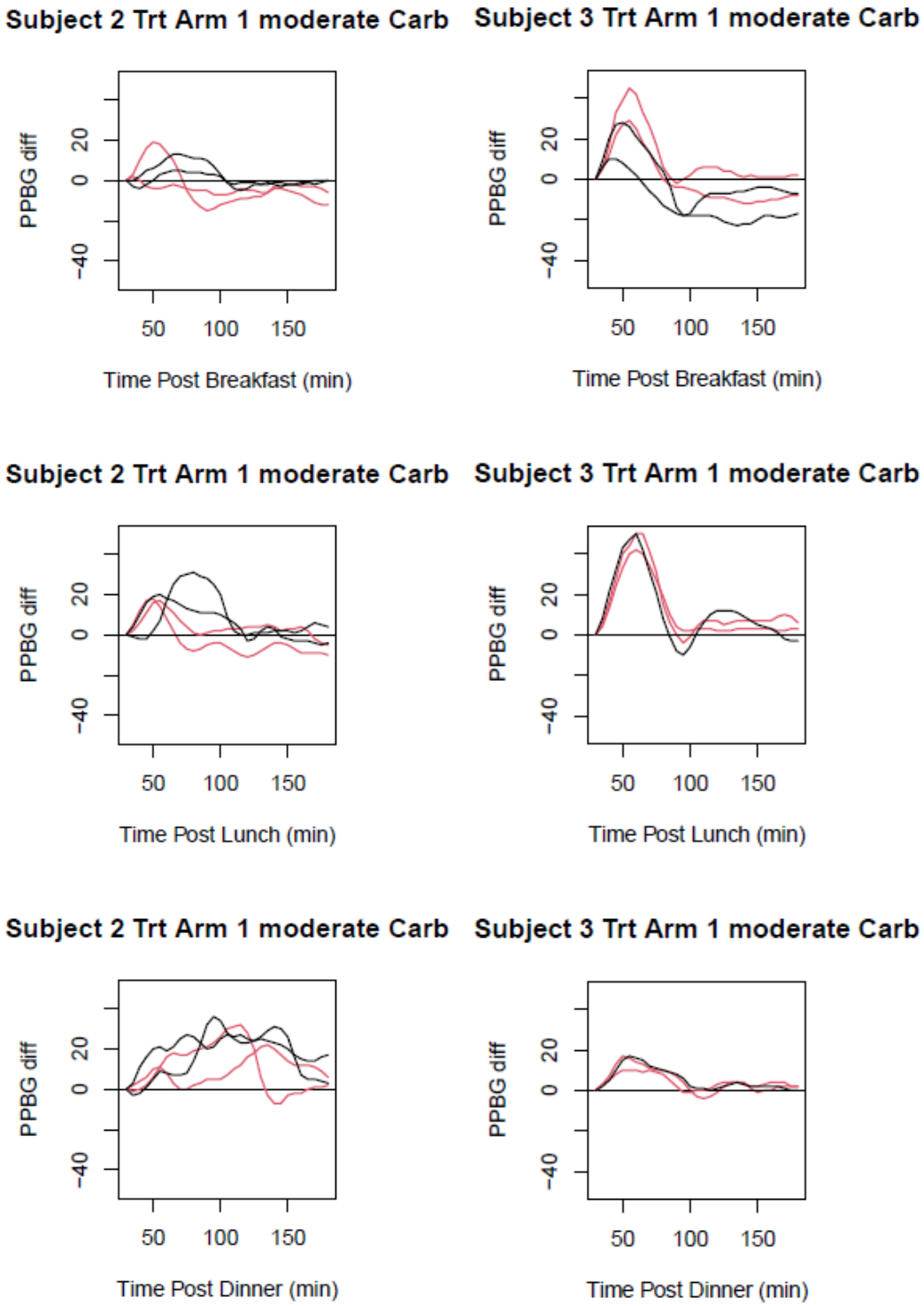
V. Diet History

e. Please rate your hunger while on the trial.
    - Significantly more hungry
    - Slightly more hungry
    - My hunger was about the same as normal
    - Slightly fuller (satiated)
    - Significantly fuller (satiated)
f. The overall dietary pattern (meals and snacks) during the trial was typical for you.
    - Strongly agree
    - Slightly agree
    - Neither agree or disagree
    - Slightly disagree
    - Strongly disagree
g. The types of foods you consumed during the trial were typical for you.
    - Strongly agree
    - Slightly agree
    - Neither agree or disagree
    - Slightly disagree
    - Strongly disagree
h. The amount of food you consumed during the trial was typical for you.
    - Strongly agree
    - Slightly agree
    - Neither agree or disagree
    - Slightly disagree
    - Strongly disagree

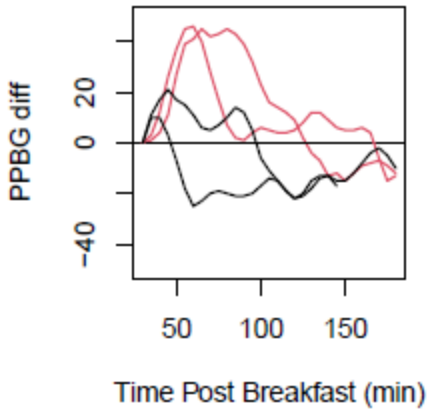
i. How often did you deviate from the trial meal plan that was issued to you?
    - Never
    - 1-2 times/week
    - 3-4 times/week
    - 5-6 times/week
    - Daily
    - Nearly every meal

Appendix C6 PPBG Overlay Plots by Meal

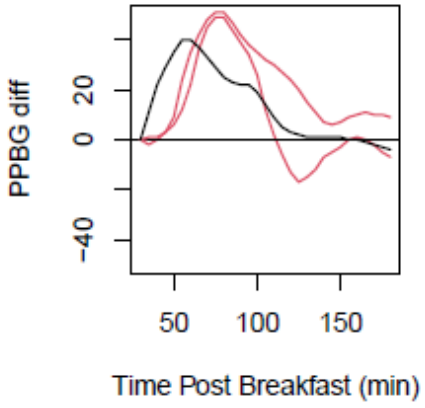
Red lines – intervention meal; Black lines – control meal



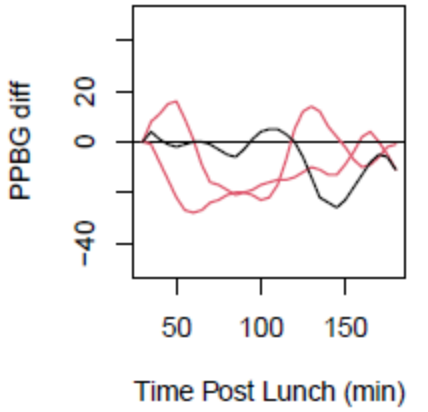
Subject 4 Trt Arm 1 moderate Carb



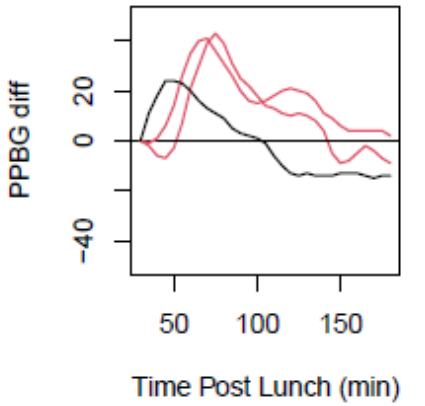
Subject 5 Trt Arm 1 high Carb



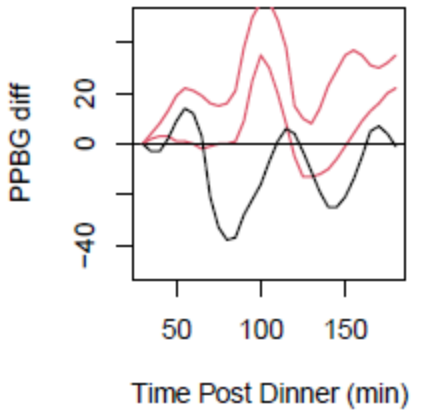
Subject 4 Trt Arm 1 moderate Carb



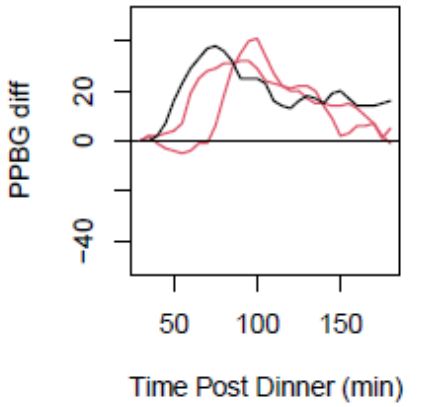
Subject 5 Trt Arm 1 high Carb

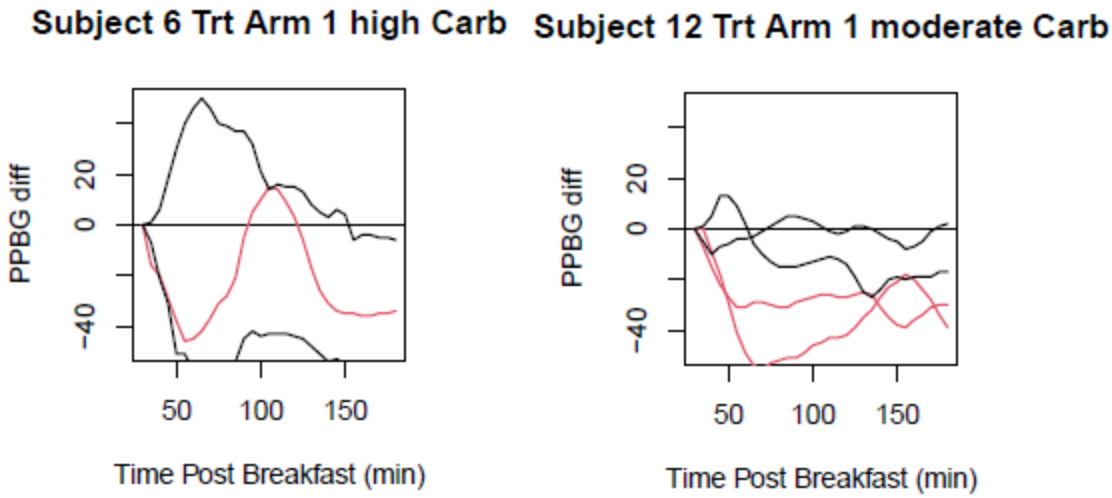


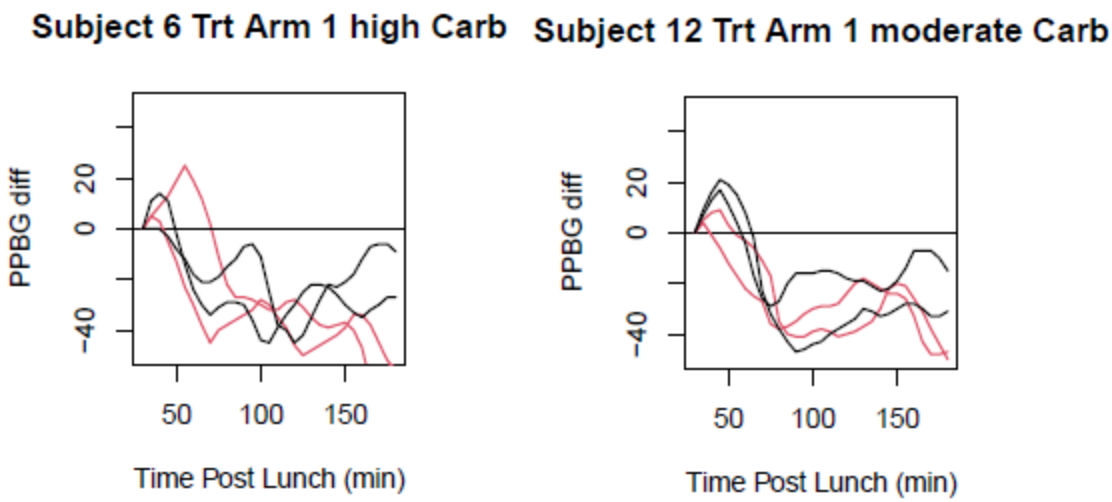
Subject 4 Trt Arm 1 moderate Carb

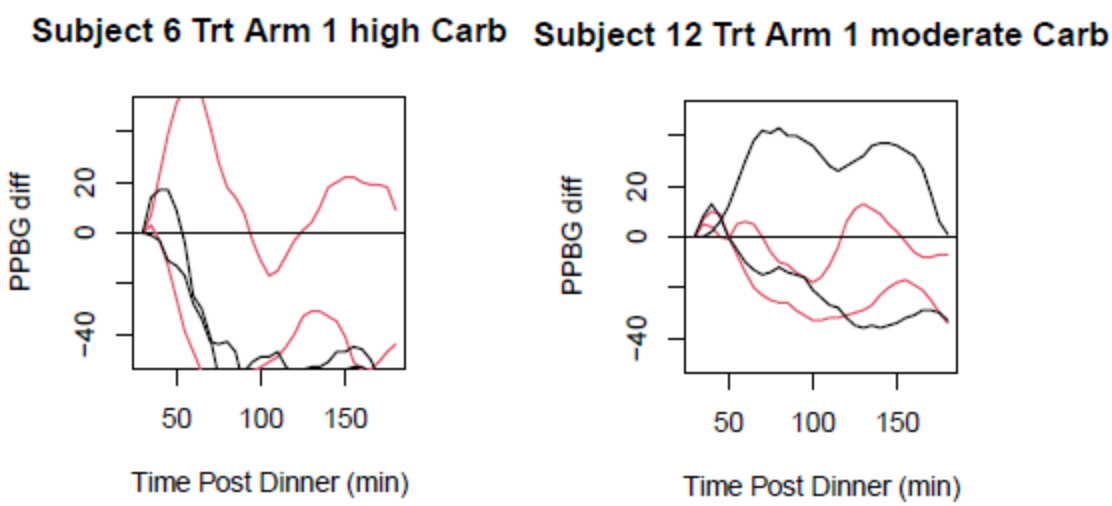


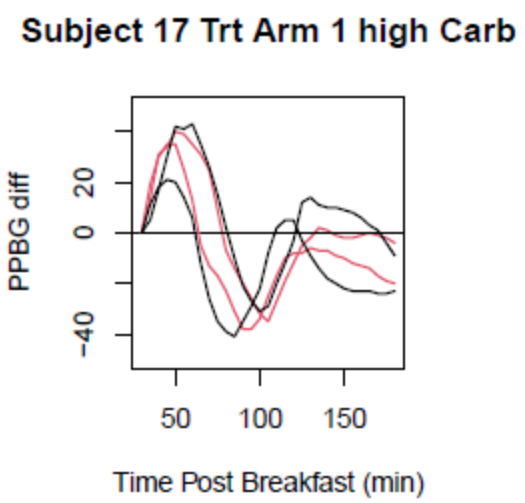
Subject 5 Trt Arm 1 high Carb

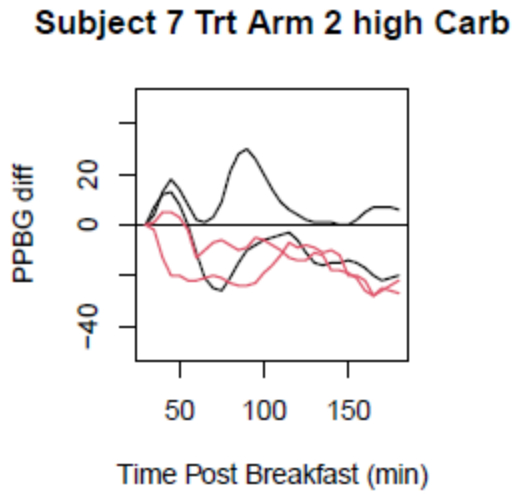


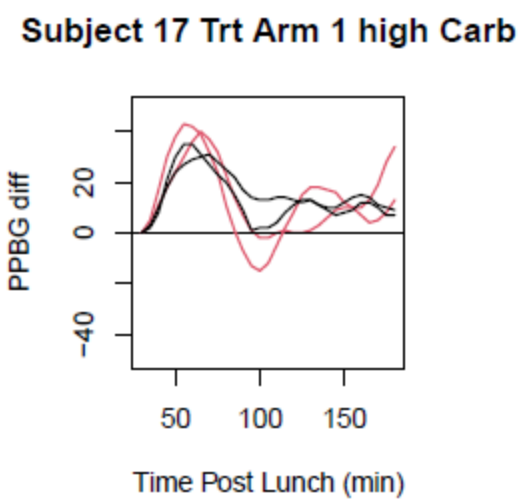

Subject 6 Trt Arm 1 high Carb
Subject 12 Trt Arm 1 moderate Carb
PPBG diff
20
0
−40
50
100
150
Time Post Breakfast (min)

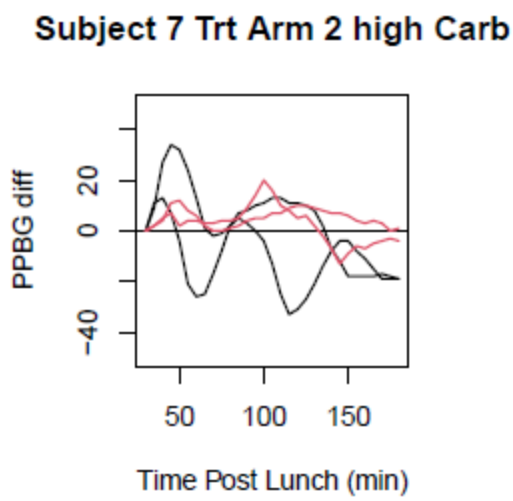

Subject 6 Trt Arm 1 high Carb
Subject 12 Trt Arm 1 moderate Carb
PPBG diff
20
0
−40
50
100
150
Time Post Lunch (min)

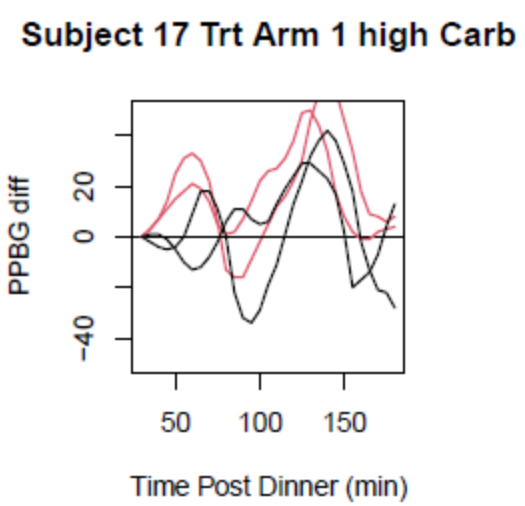

Subject 6 Trt Arm 1 high Carb
Subject 12 Trt Arm 1 moderate Carb
PPBG diff
20
0
−40
50
100
150
Time Post Dinner (min)

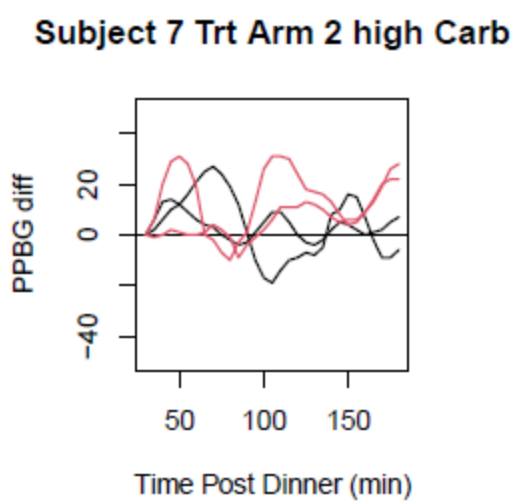

Subject 17 Trt Arm 1 high Carb
PPBG diff
20
0
−40
50
100
150
Time Post Breakfast (min)


Subject 7 Trt Arm 2 high Carb
PPBG diff
20
0
−40
50
100
150
Time Post Breakfast (min)

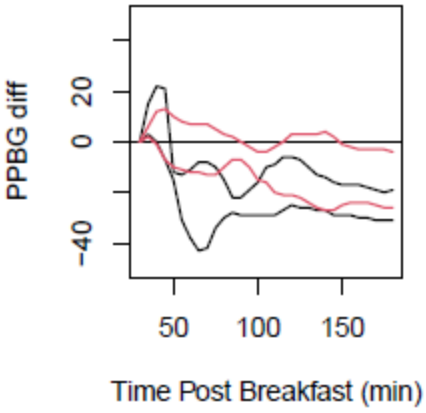

Subject 17 Trt Arm 1 high Carb
PPBG diff
20
0
−40
50
100
150
Time Post Lunch (min)


Subject 7 Trt Arm 2 high Carb
PPBG diff
20
0
−40
50
100
150
Time Post Lunch (min)

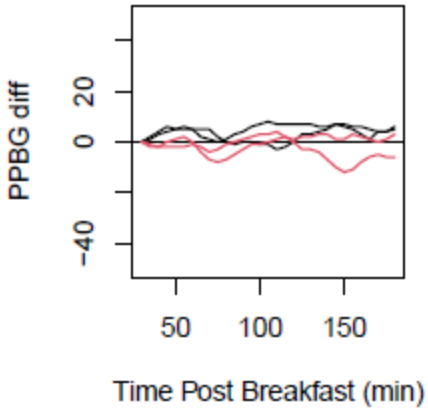

Subject 17 Trt Arm 1 high Carb
PPBG diff
20
0
−40
50
100
150
Time Post Dinner (min)


Subject 7 Trt Arm 2 high Carb
PPBG diff
20
0
−40
50
100
150
Time Post Dinner (min)

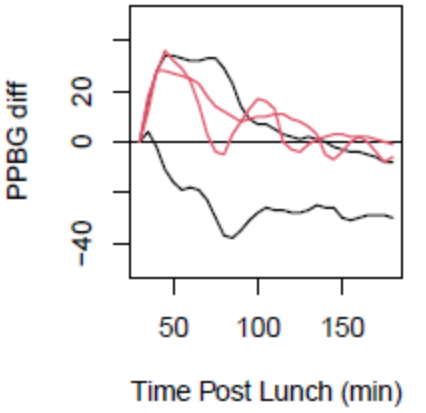
Subject 10 Trt Arm 2 high Carb



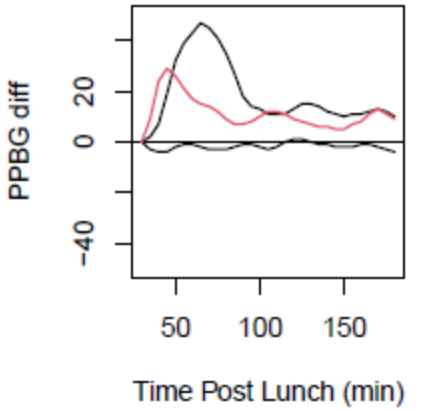
Subject 11 Trt Arm 2 moderate Carb



Subject 10 Trt Arm 2 high Carb



Subject 11 Trt Arm 2 moderate Carb



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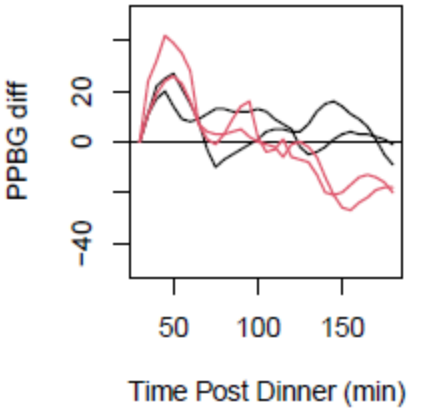

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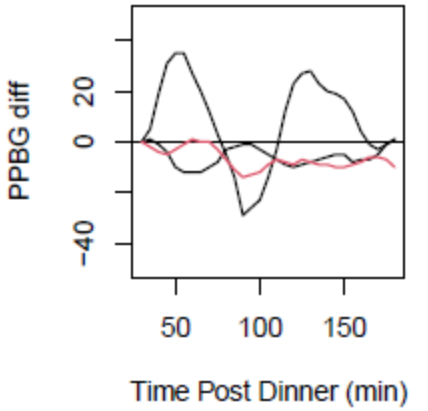
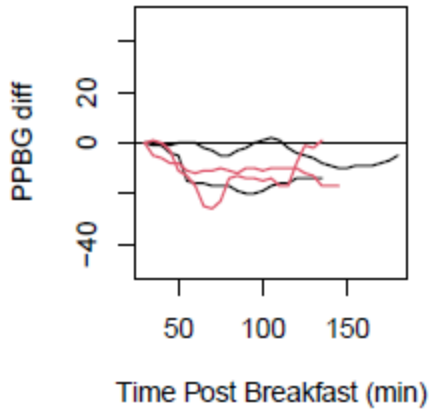
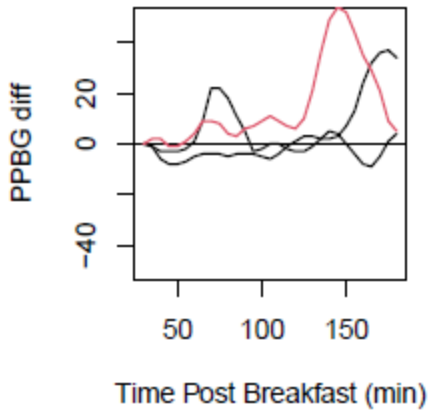


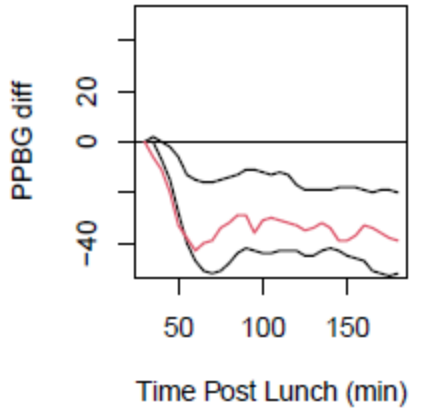
Subject 13 Trt Arm 2 moderate Carb



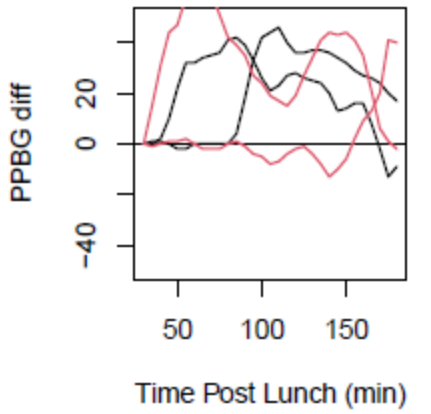
Subject 14 Trt Arm 2 high Carb



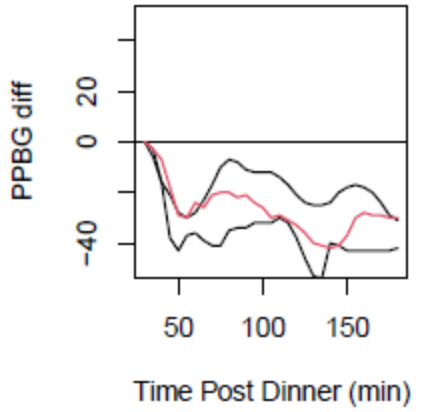
Subject 13 Trt Arm 2 moderate Carb



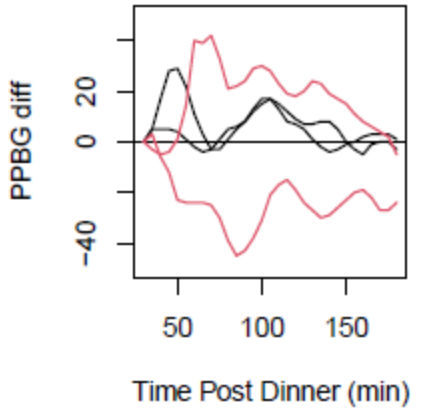
Subject 14 Trt Arm 2 high Carb



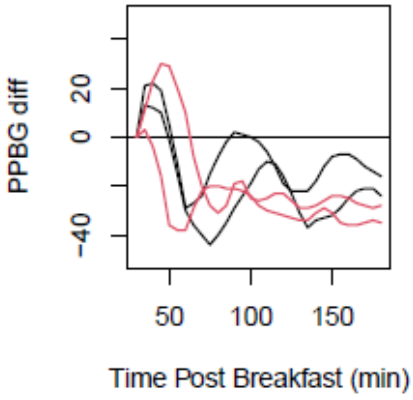
Subject 13 Trt Arm 2 moderate Carb



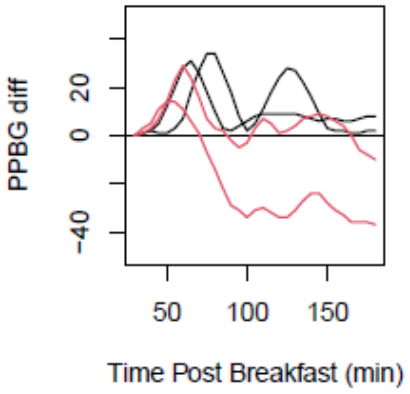
Subject 14 Trt Arm 2 high Carb



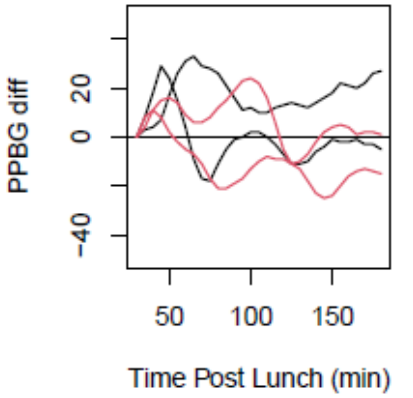
Subject 15 Trt Arm 2 moderate Carb



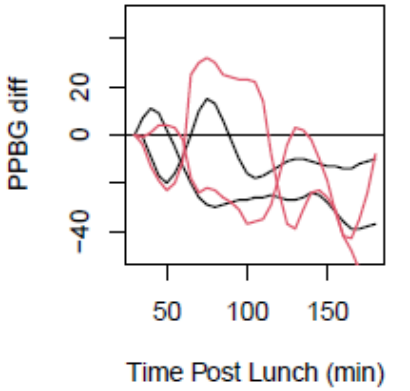
Subject 16 Trt Arm 2 moderate Carb



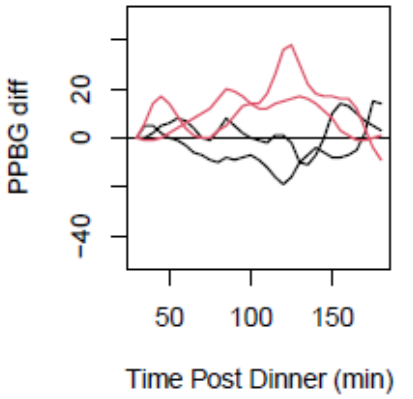
Subject 15 Trt Arm 2 moderate Carb



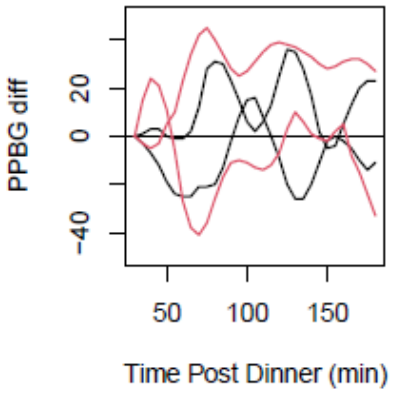
Subject 16 Trt Arm 2 moderate Carb



Subject 15 Trt Arm 2 moderate Carb



Subject 16 Trt Arm 2 moderate Carb



Appendix D1 Student Perceived Knowledge and Confidence Pre and Post-Participation Surveys

Students (Baseline)

I. Demographic Information

a. Which best describes your race/ethnicity?
   - Black or African-American
   - American Indian or Alaskan Native
   - Asian
   - Hispanic
   - Non-Hispanic White
   - Multiple races
   - Some other race (please specify)

b. What is your sex?
   - Male
   - Female

c. Which category includes your age?
   - 18-20
   - 21-23
   - 24-29
   - 30-39
   - 40-49
   - 50 or older

d. What is your current collegiate class standing?
   - 1st year
   - 2nd year
   - 3rd year
   - 4th year
   - 5th year or more undergraduate
   - 2nd degree seeking undergraduate
   - graduate student

e. Which best describes your enrollment in FOOD 4500 Nutritional Biochemistry?
   - Required course
   - Elective

f. What is your identifying number (will be provided to you?

g. What are your initials?

II. Perceived Knowledge

Respond to the following statements as honestly as possible. There are no right or wrong responses (no grading consequence!). These statements allow you to evaluate your current perceived knowledge about various topics in diabetes and dietetics patient care.

Diabetes and Glucose Control

a. I am knowledgeable about diabetes
b. I am knowledgeable about glucose diagnostic devices.
c. I am knowledgeable about insulin.
d. I understand how glucose metabolism is regulated in the human diabetic model.
e. Diagnostic medical devices are important tools for managing glucose in persons with diabetes.

Exercise and Diabetes

f. I understand how exercise can improve health outcomes in persons with diabetes.
g. Exercise can significantly lower blood glucose.
h. I understand the metabolic changes that occur at the cellular level on insulin and glucose when an individual has performed a bout of exercise.

Treating Individuals with Diabetes

i. I am confident taking anthropometric measurements from patients.
j. I would feel comfortable planning meals for patients with diabetes
   a. I am comfortable assessing patient's diets using food records.

k. I would feel comfortable making lifestyle (i.e. exercise, meal timing, meal composition, sleep, etc) recommendations for patients with diabetes
l. I am comfortable and have experience using diagnostic medical devices, interpreting reports and making therapeutic recommendations.

Clinical Research

m. I am aware how to conduct human clinical research.
    a. I am aware of ethical consideration in human research.
    b. I am aware of privacy issues for research participants.
n. I think clinical research is important to help understand ways to improve adverse human conditions.
    1. Strongly agree
    2. Agree
    3. Agree somewhat
    4. Undecided
    5. Disagree somewhat
    6. Disagree
    7. Strongly disagree
    8. Unsure of don't understand

Students (Follow-Up)

POST PARTICIPATION SURVEY

I. Perceived Knowledge

Respond to the following statements as honestly as possible. There are no right or wrong responses (no grading consequence!). These statements allow you to evaluate your current perceived knowledge about various topics in diabetes and dietetics patient care.

Diabetes and Glucose Control

a. I am knowledgeable about diabetes
b. I am knowledgeable about glucose diagnostic devices.
c. I am knowledgeable about insulin.
d. I understand how glucose metabolism is regulated in the human diabetic model.
e. Diagnostic medical devices are important tools for managing glucose in persons with diabetes.

Exercise and Diabetes

f. I understand how exercise can improve health outcomes in persons with diabetes.
g. Exercise can significantly lower blood glucose.
h. I understand the metabolic changes that occur at the cellular level on insulin and glucose when an individual has performed a bout of exercise.

Treating Individuals with Diabetes

i. I am confident taking anthropometric measurements from patients.
j. I would feel comfortable planning meals for patients with diabetes
k. I would feel comfortable making lifestyle (i.e. exercise, meal timing, meal composition, sleep, etc) recommendations for patients with diabetes
l. I am comfortable and have experience using diagnostic medical devices, interpreting reports and making therapeutic recommendations.

Clinical Research

m. I am aware how to conduct human clinical research.
n. I think clinical research is important to help understand ways to improve adverse human conditions.

II. Evaluation of Program

a. Working on the CGM Exercise research project helped me apply and better understand certain concepts from FOOD 4500 Nutritional Biochemistry.
b. After working on the CGM Exercise project, I am more confident working with diagnostic medical devices.
c. After working on the CGM Exercise project, I am more confident with meal planning and dietary assessments.
d. After working on the CGM Exercise project, I am more confident working on research projects that involve human subjects.
e. I am more knowledgeable about diabetes diagnostic devices.
    1. Strongly Agree
    2. Agree
    3. Agree somewhat
    4. Undecided
    5. Disagree somewhat
    6. Disagree
    7. Strongly disagree

f. What did you find the most helpful about working with the CGM Exercise project?
g. What was the most challenging aspect about working with the CGM Exercise

h. Which aspect of the CGM Exercise project could have been explained better?