# The timing of adaptation to high- and low-quality ketogenic diets: a parallel-arm randomized controlled feasibility study

by

Alissa Nicole Towsley

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Approved by:

Major Professor
Sara K Rosenkranz, PhD

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# Abstract

**Background:** With ketogenic diets gaining popularity among individuals who are considered healthy, there is controversy regarding the time necessary for adaptation to this dietary pattern. In addition, little is known about the effects of ketogenic diets on health outcomes in this population. The current study aimed to test the feasibility of short-term, high- (HQKD) and low-quality ketogenic dietary (LQKD) interventions, after both 7–10 days, and four weeks.

**Methods:** Participants (18–35yrs) were recruited and randomized to one of three 4-week interventions: HQKD, LQKD, or a Westernized-dietary pattern control group (CG). One-week (seven days) menus were created, standardized, and repeated over the 4-week intervention period. Dietary quality (DQ) was calculated using the Healthy Eating Index 2015 and was used to differentiate menus (HQKD 76/100, LQKD 45/100). Feasibility outcomes included adherence, dropout, ketone body production, ketogenic induction symptoms, compliance with dietary patterns, and ketogenic diet self-efficacy. In addition, anthropometrics, metabolic assessments, diet adaptation assessments (resting respiratory quotient (RQ), exercise efficiency), physical activity assessments, and dietary intake assessments (ASA-24, 3-day food records) were conducted. Descriptive statistics were determined using SPSS software version 28.0.

**Results:** Participants (n=11) were recruited, completed the screening visit, and passed eligibility criteria. Six participants dropped out (55%). Five participants completed the study (20–34yrs, 73% female, 73% white). No serious adverse events were reported. Total Mood Disturbance increased in HQKD (80.5±3.5 to 90.5±0.7) and LQKD (87±4.2 to 95±0) from week 1 to week 3 and decreased from week 3 to week 7 (HQKD: 87±9.9; LQKD:80±0). Three participants adhered to the 4-week dietary intervention for an average of 26 out of 28 days (94.1%), and the

remaining participant adhered only 35.7%. Ketone body levels did not fluctuate for the CG (0–5 mg/dL); however, there was some fluctuation in the ketogenic diet conditions, which reached higher levels in the LQKD (80 mg/dL) as compared to the HQKD (40 mg/dL). Ketogenic induction symptoms included mild-to-severe lightheadedness and moderate muscle weakness (100% HQKD), and mild-to-moderate headaches and difficulty concentrating (100% LQKD). Ketogenic diet participants (n=4, 100%) reported that they were "very sure" they could follow a ketogenic diet the first week; however, at follow up, all ketogenic diet participants (n=4) were "not at all" confident that they could maintain a ketogenic diet as a lifestyle. There were decreases in fasting blood glucose (HQKD: 77.5±19.1 to 69.5±3.5 mg/dL; LQKD: 92.0± 1.4 to 83.5± 2.1 mg/dL) and triglyceride (HQKD: 103.5±48.8 to 90.5±19.1 mg/dL) levels.

**Conclusions:** This small feasibility trial suggested that adaptation to a ketogenic diet may require two to three weeks, with no differences between high-quality and low-quality diets. Due to a small sample size, and the feasibility nature of the current study, hypothesis testing could not be conducted; however, the current results indicate that high dietary quality may be efficacious for cardiometabolic health outcomes, even in healthy individuals. Future fully powered studies that provide pre-determined menu items to participants are warranted to elucidate time requirements for adaptation to ketogenic diets as well as the role of DQ on the cardiometabolic health outcomes when complying with this dietary pattern.

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# List of Abbreviations

American College of Sports Medicine (ACSM)

Adequate Intake (AI)

Automated Self-Administered 24-hour recall (ASA24)

Beta-Hydroxybutyrate (BHB)

Bioelectrical Impedance Analysis (BIA)

Blood Pressure (BP)

Body Mass Index (BMI)

Carbohydrate (CHO)

Control Group (CG)

Cardiovascular Disease (CVD)

Dietary Quality (DQ)

Dietary Quality Index (DQI)

Dietary Reference Intake (DRI)

Dual-energy X-ray Absorptiometry (DXA)

Healthy Eating Index (HEI)

Healthy Diet Indicator (HDI)

High-Quality Ketogenic Diet (HQKD)

High Density Lipoprotein cholesterol (HDL-c)

International Physical Activity Questionnaire – Short Form (IPAQ – SF)

Institutional Review Board (IRB)

Low Density Lipoprotein cholesterol (LDL-c)

Low-Quality Ketogenic Diet (LQKD)

Mediterranean Diet Score (MDS)

National Health and Nutrition Examination Survey (NHANES)

National Institute for Health Research (NIHR)

Oral Glucose Tolerance Test (OGTT)

Physical Activity and Nutrition Clinical Research Consortium (PAN-CRC)

Power of Food Scale (PFS)

Profile of Mood States (POMS)

Resting Energy Expenditure (REE)

Resting Metabolic Rate (RMR)

Respiratory Quotient (RQ)

Satiety Labeled Intensity Magnitude (SLIM)

Total Cholesterol (TC)

Total Daily Energy Expenditure (TDEE)

Triglycerides (TRG)

United States Department of Agriculture (USDA)

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# Dedication

Two wise men once said, “Gather and absorb all information from everyone you encounter — you can always learn something new from them.” Those two wise men just so happen to be my dad, Greg Towsley, and my uncle, Harold Calkins. I’ve kept that quote with me throughout my time as a graduate student at Kansas State University and it has held just as much truth today as it did when I first heard it. Not a single conversation or opportunity has been taken for granted and I’ve flourished because of it. Thus, I dedicate this work to my parents, Greg and Julie, and my aunt and uncle, Susan and Harold, who have made a great impact on the entirety of my life, so that I can go make a greater impact on those I encounter each and every day.

# Chapter 1 - Introduction

## Ketogenic Dietary Pattern

It is well established that carbohydrates play an essential role in fueling the body. However, the human body is able to use a variety of macronutrients and derivatives as energy sources. For instance, a ketogenic diet is a low-carbohydrate (<50 grams of carbohydrates per day), high-fat diet that alters the balance of energy use toward higher amounts of fat and ketone bodies (Feinman et al., 2015). A ketogenic diet primarily consists of high amounts of fats (55–60%), moderate amounts of proteins (30–35%), and very low amounts of carbohydrates (5–10%) (Masood et al., 2022). Specifically, for a 2000 kcal per day diet, carbohydrates are limited to 50 grams per day (Masood et al., 2022). On a ketogenic diet, the body produces ketone bodies in large amounts due to the lack of carbohydrate-derived Krebs cycle (fuel sources for energy metabolism) intermediates, thereby helping to process the excess load of circulating fatty acids not oxidized via typical metabolic pathways. Most organs and tissues can use ketone bodies as an alternative source of energy when carbohydrate stores are significantly decreased (Dhillon & Gupta, 2022). Ketogenesis is primarily initiated by insulin, and a state of low insulin triggers many key enzymes, resulting in an upregulated breakdown of free fatty acids, thus increasing the amount available to be used in the ketogenic pathway (Dhillon & Gupta, 2022).

The ketogenic diet has been controversial, with ongoing disagreement between proponents of high-fat ketogenic diets and detractors. This controversy is based, in part, on the idea that in the short-term, people might experience negative consequences (i.e., fatigue, hunger, flu-like symptoms), yet the longer term, people may adapt and may experience positive health outcomes, particularly regarding metabolic health (C. Harvey et al., 2019).

According to the 2017–2018 data from the National Health and Nutrition Examination Survey (NHANES), more than 42.4% of U.S. adults are characterized as obese (2021). Obesity is significantly associated with increased risk for cardiovascular and metabolic diseases (cardiometabolic) such as type II diabetes, hypertension, dyslipidemia, hyperinsulinemia, and impaired glucose intolerance (Weihrauch-Blüher et al., 2019). In addition, these obesity-related comorbidities are associated with increased morbidity and mortality in midlife, due to cardiovascular and metabolic disorders (Berenson, 2012). Low-carbohydrate diets that comprise healthy choices for fats and proteins may confer other beneficial effects with regard to the risk of developing type 2 diabetes mellitus, coronary heart disease, and some cancers, particularly if attention is paid to the quality as well as the quantity of carbohydrates (Mayo Clinic, 2020).

## Timing of Fat Adaptation

Both fats and carbohydrates are critical fuel sources for the human body; therefore, there can be reciprocal shifts in the substrates that are oxidized based on shifts in the dietary macronutrient composition (Spriet, 2014). The regulation of fat metabolism is complex, and involves many sites of regulation, including the transport of fatty acids into the muscle cell, the binding and transport of fats in the cytoplasm, the regulation of fatty acid synthesis, and ketone body production (Cantrell & Mohiuddin, 2022; Jeukendrup, 2002; Spriet, 2014). It is known that short-term (1–3 days) adherence to a high-fat, low-carbohydrate (CHO) diet reduces muscle glycogen content (stored glucose in the body) and impairs capacity for prolonged submaximal exercise (Burke et al., 2000). During longer-term (>7 days) adherence, fat oxidation is enhanced during exercise to compensate for the reduced CHO availability (Burke et al., 2020; Lambert et al., 1994; Phinney et al., 1983). After chronic exposure to a high-fat, low-CHO diet, muscle adaptation and increases in enzymes involved in fat transport and oxidation occur (Helge &

Kiens, 1997; Phinney et al., 1983). The overall effects of these metabolic adaptations is uncertain; however, in the context of exercise performance, the key adaptations appear to be increased delivery, uptake, and subsequent oxidation of free fatty acids (Burke, 2021). A study conducted in 1999 reported significant increases in fat oxidation after 10 days of adherence to a high-fat, low-CHO diet that were continually present after five days (Goedecke et al., 1999). In addition, Burke et al. (2000), found that five days of exposure to a similar dietary pattern caused clear changes in fuel substrate utilization during submaximal exercise. However, fat-adaptation strategies did not provide clear benefit for subsequent aerobic time trial performance lasting more than 30 minutes (Burke et al., 2000).

## Dietary Quality

Dietary quality (DQ) is a measure of how healthful a meal or dietary pattern is, and is determined by comparing the pattern of dietary intake to established guidelines for a healthful diet (Wirt & Collins, 2009). Recently, this new concept of measuring DQ, based on recent changes in the Dietary Guidelines for Americans, has moved away from considering individual nutrients, and toward considerations of whole foods, dietary patterns, and health status (Tapsell et al., 2016).

The most frequently used and validated DQ scores include the Healthy Eating Index (HEI), the Dietary Quality Index (DQI), the Healthy Diet Indicator (HDI), and the Mediterranean Diet Score (MDS) (Gil et al., 2015). Gil et al. (2015), explained that the HEI includes a measure of diet variety within and across food groups, an indication of nutrient adequacy, a measure of foods to consume in moderation, and an overall balance of macronutrients. When determining DQ, the HEI uses a scoring system that is based on 13 individual components, reflecting recommendations from the *2015-2020 Dietary Guidelines for Americans*. The individual

component scores are assigned a standard to achieve a maximum score that can vary from 5 to 10 points. These component scores are summed and may achieve a maximal total HEI score of 100 points. According to the United States Department of Agriculture (USDA) Center for Nutrition Policy and Promotion (CNPP), HEI scores ranging from 0–51 are considered "poor" DQ, 51–80 "needs improvement", and scores ranging from 80–100 are considered "good" DQ (Food and Nutrition Services, 2021). According to USDA Food and Nutrition Services (2021), the average HEI-2015 score for Americans was 58 out of 100. This snapshot of overall DQ indicates Americans do not conform to dietary recommendations, and that there is room for substantive improvement. The closer the score gets to reaching 100, meaning it aligns with *Dietary Guidelines* recommendations, the greater the reduction in risk of developing diet-related chronic diseases and conditions such as heart disease, type 2 diabetes, cancer, and nutrient deficiencies (Food and Nutrition Services, 2022a).

The HEI comprises two groups of components: *adequacy components and moderation components*. The adequacy components represent food groups that Americans are encouraged to consume "more of"; a higher score reflects larger intakes, which are more beneficial. The moderation components represent recommended limits to consumption; higher scores reflect lower intakes because lower intakes are more protective (Food and Nutrition Services, 2022b). There are nine components in the adequacy group: 1) Total Fruits; 2) Whole Fruits; 3) Total Vegetables; 4) Greens and Beans; 5) Whole Grains; 6) Dairy; 7) Total Protein Foods; 8) Seafood and Plant Proteins; and 9) Fatty Acids. The remaining four components are part of the moderation group: 10) Refined Grains; 11) Sodium; 12) Added Sugars; and 13) Saturated Fats (Food and Nutrition Services, 2022b). To achieve a high HEI score, the dietary pattern must

include greater quantities within the adequacy component group and lower amounts of the moderation component group.

A previous study showed an association between poor DQ and depression; lower diet quality scores were associated with higher depression scores based on the Center for Epidemiological Studies-Depression Scale (CES-D) (Pagoto et al., 2009). Depression scores were not associated with BMI, caloric intake, or physical activity (Pagoto et al., 2009). A higher DQ has also been shown to be associated with a lower risk of obesity in children, adolescents, and adults (Ojeda-Rodríguez et al., 2018). Additionally, higher HEI scores were inversely related to serum cholesterol, low-density lipoprotein, impaired glucose tolerance, and body fat percentage (Wrobleski et al., 2018). Overall, improving DQ may play an important role in prevention of chronic diseases and promotion of positive health benefits.

When considering cardiometabolic health-related outcomes, it is possible that there is an interaction between the duration of ketogenic diet adaptation, energy balance, and the overall DQ. Therefore, the primary aim of the current study was to determine whether there were differences in the effectiveness of the ketogenic diet for improving cardiometabolic health outcomes after one week (7–10 days), and whether those outcomes were different after four weeks of a ketogenic diet. Overall, the aim of the current parallel-arm randomized controlled feasibility study was to determine the feasibility of these short-term high- and low-quality ketogenic dietary interventions for use in future trials that could determine the effectiveness of high- and low-quality ketogenic diets for improving cardiometabolic outcomes after both 7–10 days and four weeks.

# Chapter 2 - Literature Review

## Ketogenic Dietary Pattern and Chronic Diseases

The ketogenic diet is an established nutritional intervention for several clinical conditions, including seizure frequency, neurophysiological impairments following traumatic brain injury, type II diabetes, and obesity (D'Andrea Meira et al., 2019; Dashti et al., 2007; McGeown et al., 2021). This dietary pattern has been shown to be effective for treating adults and children who have epilepsy. However, the reason behind its effectiveness has not been completely elucidated (D'Andrea Meira et al., 2019).

Previous research has shown that the ketogenic diet is involved in multiple biochemical alterations, including increasing mediators of neuronal hyperexcitability (Lutas & Yellen, 2013). According to a previous systematic review, ketogenic diets have been shown to attenuate neurophysiological outcomes following traumatic brain injury; however, reductions in inflammation in the brain, improvements in outcomes after brain injury, and extension of lifespans have only been found in animal studies (McGeown et al., 2021).

Furthermore, blood lipid profiles may shift negatively initially, but often improve over time with increased levels of HDL cholesterol (HDL-c) and reduced triglycerides (TRG) (Feingold & Grunfeld, 2000). When adhering to a very low CHO diet as compared to a calorie-restricted diet, the very low CHO diet group, on average, experienced greater weight loss, more body fat loss, and significantly increased beta-hydroxybutyrate (BHB) levels (Brehm et al., 2003). Another longer-term study showed that in participants with obesity, a ketogenic diet reduced blood glucose levels by 5.6 mmol/l, body weight by 24.6 kg, total cholesterol (TC) by 1.9 mmol/l, LDL-cholesterol (LDL-c) by 1.8 mmol/l, and TRG by 3.7 mmol/l after 56 weeks (Dashti et al., 2007). In addition, beneficial HDL-c (1.0±0.3 mmol/l to 1.6±0.2 mmol/l) levels

were significantly increased. In opposition to these findings, it is possible that long-term high protein intake may lead to *new onset* chronic kidney disease (G.-J. Ko et al., 2020). Nonetheless, the quality of dietary protein may play a role in kidney health. Animal protein intake has been shown to be associated with an increased risk of End-Stage Kidney disease in several observational studies (Alvirdizadeh et al., 2020; Chen et al., 2016; Geng et al., 2021; G. J. Ko et al., 2017). The evidence from a recent systematic review of randomized controlled trials investigating the effects of a ketogenic diet on overall quality of life (QOL) on adults with chronic diseases was mixed (Abboud et al., 2021; Augustus et al., 2021; Cohen et al., 2018; Khodabakhshi et al., 2020). One study by Augustus et al.(2021), indicated significant improvement in overall QOL, whereas Cohen and colleagues (2018), reported improved QOL only for the physical component as compared to mental component. In addition, there were no significant differences in the QOL effects following a ketogenic diet versus a regular diet (Khodabakhshi et al., 2020). Across the board, higher-quality, long-term follow up studies are warranted to explore how the ketogenic diet influences chronic diseases, especially cardiometabolic conditions.

## Timing of Fat Adaptation to Ketogenic Dietary Patterns

While research studies have examined many performance and health effects of the ketogenic diet, there is limited research investigating the time course required for adaptation to the ketogenic diet (Burke, 2021; Cipryan et al., 2018). The question of adaptation to a high-fat ketogenic diet, especially for athletes, has been a question creating controversy and debate. It is known that substantial increases in fat oxidation occur within 3-4 weeks of adherence to a ketogenic diet (Burke et al., 2020). Fat oxidation or adaptation is a long-term metabolic adjustment to ketosis, a state in which your body burns fat for fuel instead of carbohydrates

(Burke et al., 2000). Furthermore, net fat oxidation increased substantially and reached a plateau while following a reduced CHO diet in six days as compared to a reduced fat diet, despite the diets being equivalent in calories (Hall et al., 2015). During this time symptoms of mild headaches, lethargy, and increased fatigue are often experienced with CHO restriction (Burke et al., 2002), although the generalized symptoms tend to decrease as the weeks progress.

In the context of exercise performance, the key adaptations appear to be increased delivery, uptake, and subsequent oxidation of free fatty acids (Burke et al., 2020). It has been noted that rigorously controlled studies have reported detriments to the real-life performances in high-intensity endurance events for elite athletes following 3–4 weeks of a low-CHO, high-fat diet, compared to a high-CHO diet (Bergström et al., 1967; Burke et al., 2017; Galbo et al., 1979; Hawley & Burke, 2010; Howard & Margolis, 2020; Starling et al., 1997). According to Burke (2000), adaptations of enhanced fat oxidation during exercise, independent, from CHO availability were achieved as a result of five days of high-fat intake; however, fat-adaptation and glycogen-restoration were not observed.

Previous studies have identified several factors that alter the rate of adaptation to high-fat, low-CHO diets. The first consideration is that adiposity may play a role. The ability of an individual to match fat intake and fat oxidation plays a key role in body-weight regulation (Thomas et al., 1992), especially when comparing lean individuals to individuals with obesity. After seven days on a high-fat diet, individuals with obesity had higher oxidation of CHO and lower oxidation of fat than lean individuals (Thomas et al., 1992). Lean individuals, however, had increased fat oxidation that matched their fat intake (Schrauwen et al., 1997; Smith et al., 2000). A second consideration is that in young women who were restrained eaters, following a high-fat short-term diet (three days) showed decreased fat oxidation compared to unrestrained-

eating participants, resulting in a positive fat balance in the restrained eaters, where an increase in fat intake may not stimulate fat oxidation (Smith et al., 2000). Participants were classified as restrained eaters based on two types of psychometric questionnaires: the Herman-Polivy (H-P) restraint scale, and the Three-Factor Eating Questionnaire (TFEQ) (Herman, 1978; Stunkard & Messick, 1985). Additionally, following five days of a high-fat diet, there were enhanced rates of fat oxidation during submaximal exercise, despite increased CHO availability before and during exercise, potentially indicating an impairment in the ability to use CHO for higher-intensity exercise performance (Burke et al., 2002).

## Healthy Eating Index and Chronic Diseases

Diets of the highest quality are associated with a significantly lower risk of non-communicable chronic diseases (cancers, diabetes, hypertension, cardiovascular diseases) (Schwingshackl et al., 2018). A systematic review and meta-analysis of cohort studies examined the role of DQ on health status (Schwingshackl et al., 2018). A total of 68 studies, including over 1.5 million participants were critically analyzed. The results of the meta-analysis indicated that diets of the highest DQ scores on the HEI, Alternate Healthy Eating Index (AHEI), and Dietary Approaches to Stop Hypertension (DASH) were associated with significant reductions in the risk for all-cause mortality (22%), cardiovascular diseases (22%), cancers (16%), type II diabetes (18%), neurodegenerative diseases (15%), and overall mortality among cancer survivors (12%) (Schwingshackl et al., 2018). Furthermore, a different systematic review and meta-analysis suggested that the highest level of adherence to the Mediterranean Diet was inversely associated with risk of cancer mortality in the general population, and all-cause mortality among cancer survivors (Morze et al., 2021). Finally, a prospective cohort study from the Nurses' Health Study (NHS) examined associations between DQ scores and risk of incident cardiovascular diseases

(Shan et al., 2020). Results indicated that higher DQ scores were associated with lower risk of both coronary heart disease and stroke, and were consistent in most subgroups of race and ethnicity (Shan et al., 2020).

## Gaps in the Literature

To our knowledge, no previous studies have considered the role that DQ may play on cardiometabolic health outcomes when following a ketogenic diet. Further, few studies have examined the effects of a ketogenic diet in individuals who are considered healthy, with no known diagnosis of chronic diseases or conditions. This population warrants study since the ketogenic diet is popular among athletes, young people, and individuals without obesity or other chronic conditions. With the ketogenic diet gaining popularity, it is essential to conduct high-quality clinical trials to elucidate the effects of ketogenic diets on health outcomes. The current feasibility trial attempts to close these gaps by considering the consumption of a high DQ ketogenic diet and a low DQ ketogenic diet in healthy adults on cardiometabolic outcomes. We hypothesize that in a fully powered trial, both treatment groups would adapt to the dietary patterns by the end of the first week and would be able to adhere to the assigned meal plans, such that they would experience similar side effects and similar reductions in water weight due to the diuretic effects of low-CHO consumption. A secondary hypothesis was that the HQKD group would have improved cardiometabolic outcomes (i.e., TC, HDL-c, LDL-c, TRG, fasting blood glucose) as compared to the LQKD group.

# Chapter 3 - Methodology

## Participant Recruitment

Recruitment was conducted via advertisement through university newsletters, university social media posts, electronic communication, and word of mouth in the Riley County, Kansas area. Eligible participants were aged 18 to 35 years, English-speaking, and healthy with no known diagnosed chronic diseases or conditions that might affect study outcomes. The inclusion criteria were intentionally minimal to best represent an appropriate sample from the target population. The advertisement included a link to an "interest screener" questionnaire to determine if the potential participants met the inclusion criteria. See Appendix A for the participant recruitment flyer used to advertise the research study and Appendix B for the Dietary Quality Interest Questionnaire. At the end of the questionnaire, an invitation to initiate email correspondence with the researcher was automated. Individuals who passed the interest screener were notified by the researcher, received additional information, confirmed eligibility requirements, and were asked to set up an in-person screening visit. The study protocol was explained thoroughly in writing, any questions were addressed and answered, and written informed consent was obtained prior to the study at the screening visit. Participants completed a medical history questionnaire to determine eligibility in the study. Participants were excluded for the following reasons: 1) individuals with two or more cardiovascular disease (CVD) risk factors according to American College of Sports Medicine's (ACSM) Guidelines (11$^{th}$ Edition, see Appendix C for details); 2) individuals who had been diagnosed with an acute or chronic disease; 3) individuals taking medications that impact lipid metabolism; 4) individuals who were currently pregnant or lactating; 5) individuals with diabetes mellitus, inflammatory disease, atherosclerotic disease, or other relevant chronic conditions; 6) individuals with heart failure; 7)

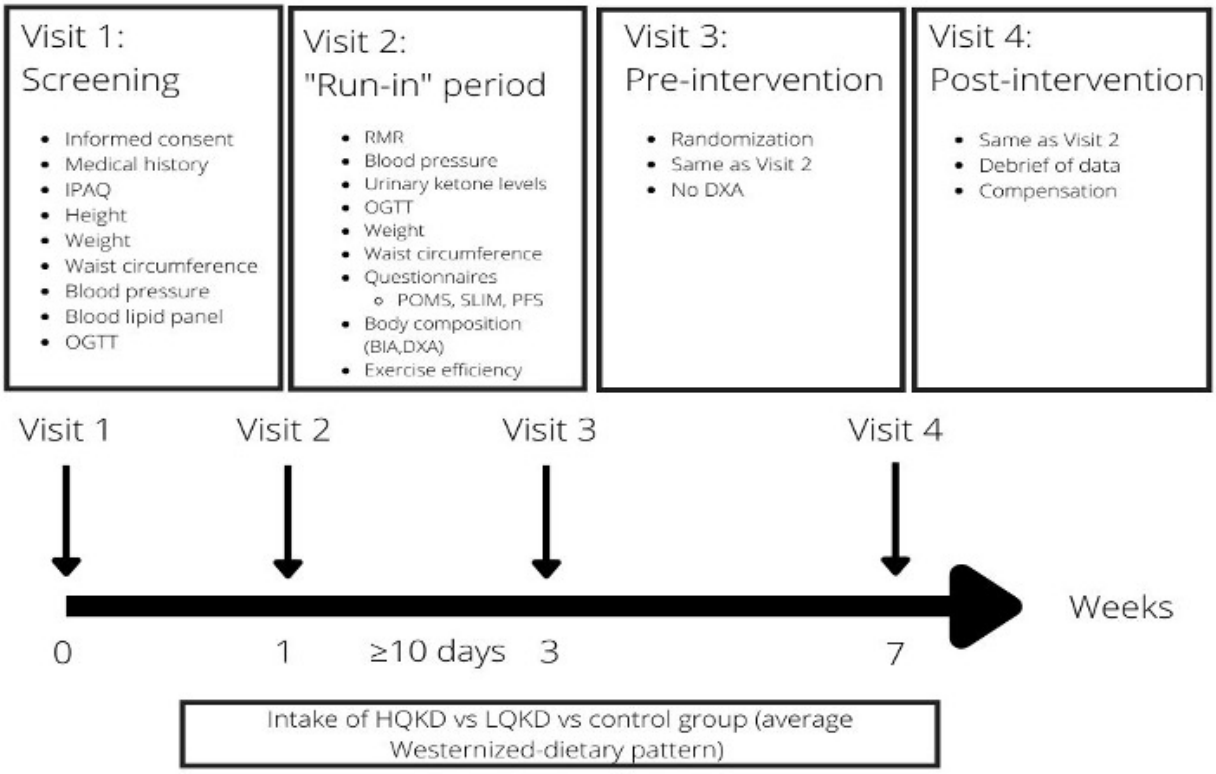
individuals who had a personal or family history of kidney stones; 8) individuals who had a personal or family history of abnormal serum lipids or strong family history of abnormal history; and 9) individuals with food allergies included in the dietary meal pattern. The study protocol was approved by the Kansas State University Institutional Review Board (IRB) Committee approval #10902.

## Study Design

The current study three-arm parallel-group randomized controlled trial was designed to compare the effects of a high-quality ketogenic diet (>70 out of 100 according to HEI score), a low-quality ketogenic diet (<50/100 HEI score), and a control group (CG) consuming an average Westernized-dietary pattern (not ketogenic). All testing sessions were performed at the Physical Activity and Nutrition Clinical Research Consortium (PAN-CRC) at Kansas State University, Manhattan, Kansas. All participants were asked to remain fasted for at least 10 hours prior to each visit. Participants who met inclusion criteria through the interest screener questionnaire came to the screening visit (Visit 1) and completed pre-trial assessments of height, weight, waist circumference, International Physical Activity Questionnaire – Short Form (IPAQ-SF); a blood lipid panel and resting blood pressure, followed by an oral glucose tolerance test (OGTT) protocol. Upon completion of the screening visit, a second visit (Visit 2) occurred following a "run-in" period for a minimum of ten days, where they consumed their typical dietary patterns in order to establish caloric needs for weight stability. This period was post-recruitment and pre-randomization. Following the run-in period, participants came back to the PAN-CRC three more times (Visit 2, Visit 3, and Visit 4) for approximately 3.5 hours each visit. At Visit 2, Resting Metabolic Rate (RMR) testing and resting blood pressure and assessment of urinary ketones, followed by an OGTT were completed. During the OGTT, the following questionnaires were

completed: Profile of Mood States (POMS); Satiety Labeled Intensity Magnitude (SLIM) scale; Power of Food Scale (PFS); and Automated Self-Administered 24-hour (ASA24®) dietary assessment tool. Subsequently, weight, waist circumference, and body composition via Bioelectrical Impedance Analysis (BIA) and Dual-energy X-ray Absorptiometry (DXA) were performed for the remaining period of the OGTT. Once the OGTT was completed, participants performed an exercise efficiency test on a cycle ergometer, where cadence was matched at each subsequent assessment period (Visit 3 and 4). At Visit 3, participants were randomly assigned to one of three treatment groups, a high-quality ketogenic diet (HQKD), a low-quality ketogenic diet (LQKD), or the CG, which consumed an average Westernized-dietary pattern for the duration of the study. The randomization process was blinded to the primary researcher and performed by another researcher using an Excel spreadsheet (Matthew Lavery, 2017). In Excel, participants were assigned at random to each arm of the study, using the function (=rand). The primary investigator of this study remained blinded until Visit 3, when participants were assigned their intervention. Participants were blinded to their diet condition by removing all documents and words used by researchers to describe the interventions. They remained blinded until all data were entered, the dataset was secured, and the statistical analyses were performed. The study was conducted over a 6-week period. The remaining two visits were similar to Visit 2, except Visit 3 did not include the DXA scan due to unnecessary radiation-related risk. Figure 3.1 depicts an overview of the current study.

**Figure 3.1. Overview of Study Design.**




## Experimental Meal Plans

### Ketogenic Diet Nutrition Standards

The ketogenic diet typically includes a total CHO intake of less than 50 grams per day (Feinman et al., 2015), which was considered when calculating the baseline 2000 kcal/day ketogenic meal plan. Sample 1-day menus were constructed by a Registered Dietitian Nutritionist for a 2000 kcal ketogenic diet for high DQ (HEI 70-80/100) and low DQ (HEI 30-40/100). The daily menus were broken down into breakfast, lunch, dinner, and two snacks. The macronutrient distribution for the 2000- kcal diet was in a three to one ratio of fat:CHO as 75% fat, 15% protein, and 10% CHOs (Masood et al., 2022; President and Fellows of Harvard College, 2018). When portioning out the total amount of calories that should correspond with each macronutrient, calculations indicated that 1500 kcals (166g) should come from fat, 300

kcals (75g) from protein, and 200 kcals (50g) from CHOs. The amount of CHOs calculated was a net total, meaning fiber was subtracted from the total CHOs value. After determining macronutrient needs, meal plans were developed using Diabetes Exchanges, and MyPlate, and translating macronutrients into food groups (American Diabetes Association & American Dietetic Association, 2011; USDA, 2022). Food groups for the HQKD and LQKD included starch, non-starchy vegetables, fruit, dairy (full-fat/whole), meat/meat alternates, and fats. Restrictions on types of foods included, varied depending on the DQ condition. The HQKD diet included 100% whole grain, minimized added sugar, at least one serving of dark green vegetables, at least three servings of fish/seafood or two plant-based meat alternates with no breading, fresh or plain frozen fruits and vegetables, and no more than two servings of unsaturated fat, each day. Conversely, the LQKD included 26g of added sugar per day, canned vegetables, no dark green vegetables, fruit canned in heavy syrup or non-100% fruit juice, no seafood or plant-based meals, and mostly saturated fats (i.e., butter, cream cheese, or coconut oil). See Appendix D for sample 1-day HQKD and LQKD menus and the Diabetes Exchanges used to develop meal plans. Recipes and meal plans were developed by an RDN (JJ) along with a dietetics graduate student with a culinary background and were based on these loose guidelines to maximize (HQKD) or lower (LQKD) HEI scores for DQ. Seven different daily menus with different meals were created resulting in a 1-week menu and repeated each week for the 4-week study duration. Uniformity of recipes and ingredients was intentional to result in minimal food waste and cost of food.

## Nutrient Analysis

Nutrient analysis was performed to ensure the meal plans met ketogenic nutrition standards. Nutrient analysis was conducted using ESHA's Food Processor® Nutrition Analysis

software, which combines an extensive and precise food and ingredient database (ESHA Research, 2022). The 1-week meal plans were inputted into ESHA for analysis. Reports of all macro- and micronutrient values for each ingredient were generated. Macronutrient distribution was verified by dividing the total of each macronutrient by the total calories per day.

Once meal plans were finalized, they were scaled to various calorie levels ranging from 1600 kcal to 2600 kcal, with further modification on portion sizes when determining participants' total daily energy expenditure (TDEE) determined at visit 2. See Appendix H for an example of one day of a scaled meal plan.

## Nutrient Deficiencies

The nutrient analyses determined using ESHA for the HQKD and LQKD were compared with the Dietary Reference Intakes (DRIs) and Adequate Intakes (AI) of all macronutrients and micronutrients. Recommended intakes for males and females were determined based on the average age group of 19 to 50 years.

## Dietary Quality

Following menu portioning and standardization using the HEI 2015, DQ was calculated (NIH & NCI, 2022). Methods and procedures were modified based on previous research from our research team (Joyce et al., 2020). An Excel calculator was created to calculate the HEI 2015 scores for both the HQKD and LQKD. The HEI 2015 is a valid and reliable measure of diet quality to reflect adherence to the Dietary Guidelines for Americans (Guenther et al., 2014). The HEI 2015 calculation instructions and equations are included in Appendix F (Joyce, 2018).

Daily DQ was computed for each DQ condition (EGRP et al., 2022). Once total portion sizes were summed for each day, they were multiplied by 1000 calories and then divided by the total calories for that day to scale the amount consumed to be per 1000 calories and thus

standardized to calories. This amount was then compared to the HEI component scoring standard amount to determine the score out of 5 or 10 total points per component. For sample calculations, see Appendix G. The total average HEI score for HQKD was 76 out of 100; whereas the total average HEI score for LQKD was 44.5 out of 100.

### Food Availability

Before menus were finalized, food access and availability of all ingredients and food items were confirmed in the Manhattan, Kansas area. Food availability was determined by factors including affordability, quality of food sellers, and distribution of products (The European Food Information Council, 2006). After verifying food availability, a grocery list was created for participant convenience, to minimize participant burden, and to improve participant retention. All costs were estimated from foods that could be purchased at the local Walmart — a store that sells all generic brand grocery items. The grocery list included four domains: *Item name; Amount needed to purchase* (quantity, unit, and price)*; Quantity food was sold in (*quantity, unit, and price); and the *Generic Walmart brand.* Cost analysis was performed and presented as individual ingredient costs, daily costs, costs for one week, and the total cost for the 4-week intervention. This cost analysis was performed using the 2000 kcal diet menu. Prior to Visit 3, menus, grocery lists, and costs were adjusted based on each participant's estimated daily caloric needs for weight stability. Sample grocery lists for HQKD and LQKD can be seen in Appendix E.

## Measures

### Adherence/Compliance Tools

#### *Compliance Checklist*

Compliance, regarding the consumption of the investigational dietary patterns, was measured via a checklist created for the current study. Items included agreement with "Did I Exceed the Daily Grams of Carbohydrates?" The checklist is included as Appendix I. The estimated grams of CHOs consumed was indicated for participants each day, which corresponded with the number of total grams of CHOs per day provided on the 7-day meal plan. Every day, participants checked a box indicating how well they had adhered to the diet plan regarding CHO consumption. The boxes indicated *less than, exact,* and *more than*. If the participant selected "more than", they were required to indicate the amount of CHOs (g) they consumed in addition to the planned diet through MyFitnessPal or Cronometer (Davidson, 2022; Evenepoel et al., 2020). To encourage adherence to the dietary conditions, a grocery list was developed and provided to the participants based on their individual estimated daily caloric needs. The food items on the grocery list were reviewed with each participant to determine food preferences and dislikes.

### *Ketone Body Levels*

Ketone body levels were tracked throughout the 4-week interventions for participants who were assigned to a ketogenic diet condition. A log was provided to participants during the run-in period to determine signs of ketosis that might have occurred prior to the start of the intervention period. Participants were provided 10 test strips during the run-in period and an additional 28 test strips for the 4-week intervention. Measurements were performed every morning prior to breakfast in a fasted state. Ketostix® (Bayer, Germany) ketone test strips and a color chart were used to determine the presence or absence of ketones in the urine by comparing the color of the strip after urination to the corresponding color indicated on the chart. The colors ranged from tan (negative; 0 mg/dL) to dark purple (large amounts; 160 mg/dL), with increasing

concentrations of ketone bodies. Adherence to the ketogenic diet conditions was observed through differences in colors and corresponding values indicated throughout the 4-week intervention. The log sheet provided to participants is shown in Appendix J.

### *Ketogenic Diet Perceived Self-Efficacy*

Participants who were randomized to the ketogenic diet conditions completed a Ketogenic Diet Confidence Scale, displayed in Appendix K. This scale defined the ketogenic diet and listed short-term and long-term potential outcomes. Questions determined the level of confidence when following the ketogenic diet for a set duration; 1 week, 4 weeks, 6 months, and as a lifestyle. The degree of confidence was recorded based on the scale as follows: *not at all; somewhat sure*; and *very sure*. Participants also listed open-ended answers to common barriers they might experience while following the dietary pattern. During Visit 2 and 3, participants received an initial "Ketogenic Diet Confidence" scale. Subsequently, during Visit 4, participants received a "Follow Up Ketogenic Diet Confidence" scale. In addition to the original scale questions, participants were asked, "*What were some common barriers you came across while following this diet?"* and *"Why do you think these barriers occurred?"* These items were open-ended questions. *"Is the ketogenic diet something you would want to continue following?"* Participants answered this item with "*yes*" or "*no*".

## Anthropometric Measurements

Height (cm) was measured using a standard stadiometer (Charder HM200P, Taiwan). Accurate and reproducible measurements of height were recorded, following the National Institute for Health Research (NIHR) procedures (NIHR, 2016). An average of two measurements was recorded and used for data analysis. If the measurements were more than 0.5 cm apart, a third measurement and the closest two measurements were averaged. Weight (kg)

was measured using a digital scale (Health-O-Meter 349KLX, McCook, IL). An average of two measurements were recorded and a third was documented if they were more than 0.5 kilograms (kg) apart. Waist circumference was determined using a standard tape measure (Healthy Hands™, generic). Measurements were determined by finding the "natural" waistline between the bottom of the ribs and the iliac crest. An average of two measurements was used for data analysis, and if the measurements were more than 0.5 cm apart, a third measurement was taken, and the closest two measurements were averaged. Body Mass Index (BMI) was determined using height and weight measurements. The following formula was used: kilograms/(meters squared) ($kg/m^2$).

### Resting Blood Pressure

Blood pressure was measured using an automated blood pressure cuff (Omron HEM-907XL, Japan). Resting heart rate and mean systolic and diastolic blood pressure were measured and recorded. Participants were asked to remain seated for five minutes after the indirect calorimetry testing with their arm at heart level and both feet flat on the floor to ensure consistent and accurate measurements.

### Blood Lipid Panel

Fasting blood samples were determined using finger sticks, collected via a safety lancet, capillary tube, and capillary plunger. The blood samples were inserted into a Cholestech LDX™ lipid profile and glucose cassette that measured TC, HDL-c, LDL-c, TRG, and glucose. The Lipid Profile-Glucose panel also calculates the TC/HDL ratio and non-HDL cholesterol.

### Oral Glucose Tolerance Test

Participants fasted overnight for 10–12 hours before every visit. Blood samples were collected at baseline and serially for two hours following consumption of a 75g glucose beverage

(Fisherbrand). Insulin assessments were determined only at baseline via venous sampling and collected using a BD Vacutainer Serum Separator Tube (SST). The SST tube was centrifuged (Ample Scientific Campion F-330, Norcross, GA). Serum was pipetted in two microcentrifuge tubes and stored in a -80°F freezer for further data analysis. Insulin results have not been analyzed, and therefore will not be reported.

## Indirect Calorimetry

Resting metabolic rate (RMR) was determined using indirect calorimetry with a metabolic cart (Parvo Medics TrueOne 2400, Salt Lake City, UT). Gas and flowmeter calibrations were performed every morning before a visit. A hood (canopy) was used to cover the head and face of the participant while they were in a supine position. The RMR testing was performed in the morning, with the exception of one participant who could not accommodate an early time. Proper positioning of the hood was ensured so that there was no leakage for accurate measurement of expired gases. The RMR assessment was 30 minutes in duration with the first 5 to 10 minutes of data discarded and the remaining 15 to 20 minutes used to determine estimated calorie needs at rest. From the RMR assessment, resting energy expenditure (REE) (kcal/day) and respiratory quotient (RQ) were recorded. The RQ was determined as the volume of carbon dioxide expired over the volume of oxygen inhaled during respiration (RQ=Vol CO2 expired/Vol O2 inhaled) (Delsoglio et al., 2019). In addition to the energy estimates, RQ was used to determine substrate utilization at rest (i.e., CHOs, fat, and protein). An RQ of 1.0 would theoretically indicate 100% CHO oxidation and 0.7 for fat. The REE was averaged over the 15-20 minutes that remained following discarding of the first 5 to 10 minutes to determine total daily energy expenditure and then added to the estimated energy needs for daily activity including exercise.

## Exercise Efficiency

Participants performed a structured exercise session of light-to-moderate intensity protocol on a bicycle ergometer (Lode Corival cpet 960900, Netherlands). The structured session comprised of three 7-minute work periods, at 50, 75, and 100 W, performed in ascending order (Edwards et al., 2011). Cadence was free of choice during the run-in period testing, but with Visits 3-4 cadences matched Visit 2. Expired gases were analyzed breath by breath using the same metabolic system for RMR testing (Parvo Medics TrueOne 2400). Metabolic cost was calculated using the methods of Weir (Weir, 1949). Gross efficiency was calculated at each work rate as gross efficiency (%)=100% x (work done/metabolic cost) (Edwards et al., 2011). Results were not reported due to unforeseen equipment complications.

## Body Composition

A DXA scan was used to measure body composition, including body fat percentage and fat-free tissue. Participants removed all jewelry and shoes prior to lying in a supine position for approximately 6-12 minutes before completing the DXA scan. Body composition was measured before and after the 4-week intervention using the DXA. This study, as with all study IRBs including a DXA scan, was approved by the Kansas Department of Health and Environment before usage can began.

Body composition was also determined using BIA (RJL Systems, Quantum II, Clinton Township, MI) for the purpose of tracking changes over time. Proper guidelines were followed according to the RJL manufacturer instructions. Two consecutive measurements were determined where values were within one percentage point. Resistance and reactance values were entered into the RJL System Interactive Online calculator to determine the body composition estimates. BIA results were not reported in this manuscript.

## Dietary Intake

Participants completed the Automated Self-Administered 24-Hour (ASA24) Dietary Assessment Tool after each visit (Subar et al., 2012). This online dietary 24-hr recall tool collects information on all of the food and beverages consumed by an individual. Participants were given a unique ID and password so they could access the website to report the foods and beverages they consumed the following day after the visit. For participants randomized to a ketogenic diet condition, total calories (kcal) per 24-hour recall were compared with a three-day food record, developed by the STAR Family Health Team, to determine daily caloric needs.

Following the screening visit, each participant completed a paper copy three-day food record to determine their typical dietary patterns. Food and beverage instructions were provided with accurate measurements and examples of sample food records. In addition, participants completed a second three-day food record during the run-in period. After this period, only participants who were randomized to the CG were required to complete weekly 3-day food records. These records were used to determine the individual's daily average caloric intake. Results were not reported as the primary purpose was to determine daily caloric needs for participants randomized to a ketogenic treatment condition.

## Other Questionnaires

Scales provided during Visits 2-4 included the Satiety Labeled Intensity Magnitude (SLIM), the Power of Food Scale (PFS), the Profile of Mood States (POMS), and a ketogenic induction symptoms questionnaire.

### *Satiety Labeled Intensity Magnitude Scale*

Satiety was measured during each visit using the SLIM Scale, a quantitative assessment of perceived hunger and/or fullness (Cardello et al., 2005). The SLIM scale is a sensitive,

reliable, and easy-to-use scale for measuring perceived satiety. For the current study, the participants were asked about their perceived satiety before breakfast to acquire consistent measures. Eleven phrases are placed along a vertical line scale at positions corresponding to the mean magnitude estimates (Balbale et al., 2014). The phrases are labeled from an end-point anchor of 'greatest imaginable fullness' to 'greatest imaginable hunger'. The anchors in between these points include, 'extremely full', 'very full', 'moderately full', 'slightly full', 'neither hungry nor full', 'slightly hungry', 'moderately hungry', 'very hungry', and 'extremely hungry'. Participants were asked to mark an "X" on the vertical line that best represented their level of hunger/fullness.

### *Power of Food Scale*

The psychological relationship individuals have with food was determined using the Power of Food Scale (PFS). The scale measures appetite-related thoughts, feelings, and motivations in environments where enjoyable foods are always available (Lowe et al., 2009). Rather than measuring the consumption of highly palatable foods, appetite is measured at three domains of food proximity (food available, food present, and food tasted). Examples of PFS items include: *I find myself thinking about food even when I'm not physically hungry; If I see or smell a food I like, I get a powerful urge to have some; and when I know a delicious food is available, I can't help myself from thinking about having some.* Respondents are instructed to indicate the extent to which each item describes how they feel based on a 5-point Likert scale. This scale ranges from (1) *don't agree at all* to (5) *strongly agree.* The measure is represented by three domain scores and an aggregate score (Cappelleri et al., 2009). Domain scores are calculated as the mean of the items representing food available, food present, and food tasted. The aggregate score is calculated as the mean of the three domains.

### *Profile of Mood States Questionnaire*

The Profile of Mood States (POMS) contains 40 adjectives designed to measure the present emotional condition of individuals using seven different mood states: fatigue, anger, tension, esteem-related affect, confusion, and depression (Grove & Prapavessis, 1992). In the current study, participants were instructed to respond according to how they are feeling "right now". Responses were made on a 0-4 scale with (0) indicated not at all, (1) a little, (2) moderately, (3) quite a lot, and (4) extremely. The POMS questionnaire was completed at visits 2-4 to determine the overall mood state of the study participants as an indicator of adaptation to the ketogenic diets and the symptoms developed.

### *Ketogenic Induction Symptoms Questionnaire*

Participants were instructed to complete a ketogenic induction symptoms questionnaire (Symptom-Q). This questionnaire is based on symptoms commonly observed in individuals who have followed ketogenic diets in previous studies (C. J. Harvey et al., 2018). Participants completed this questionnaire one week after beginning the diet, and asked, "In the past 24 hours to what extent have you experienced the following symptoms?". Scoring was based on a 5-point Likert-type scale where (1) indicated not at all, (2) mild, (3) moderate, (4) severe, and (5) indicated that the symptom was intolerable. The symptoms/effects included: headache, constipation, nausea, diarrhea, stomach or intestinal pain, intestinal bloating, change in breath odor, muscle cramps, muscle weakness, skin rash, difficulty concentrating, and lightheadedness. Participants were also asked to keep additional records of symptoms they experienced throughout the 4-week intervention.

## Physical Activity

Physical activity levels were determined using an Actical accelerometry worn on the dominant wrist. The Actical® (Mini Mitter, A Respironics, Inc. Company, Bend, OR) is an accelerometer that accurately measures physical activity and step counts to estimate physical activity at various intensities and to estimate energy expenditure. Analyses were performed using Actical® software version 3.12. Set up for each participant included information regarding biological sex, age (years), height (cm), weight (kg), start date, and epoch length. For the current study, the epoch length was set to 15 seconds. Participants wore the Actical® for 4-5 days during the first week of the intervention and repeated that wear time during the fourth week of the intervention to ensure at least three full days of data. The non-REE estimates from accelerometers were added to the REE estimates from the metabolic cart to obtain the TDEE for the 4-week assigned meal plan.

The IPAQ-SF was also used to assess physical activity levels for each participant (Lee et al., 2011). This questionnaire assesses the intensity, frequency, and the time spent performing various activities including sitting, walking, and moderate and vigorous intensity physical activity. Physical activity domains included work-related, household/yard work, transportation, and leisure activities.

## Glucose Control

Continuous glucose monitoring (CGM) was intended to provide valuable information to help push the body of research forward in terms of how a ketogenic diet might affect glucose excursions from the regulated range of glucose (70-180 mg/dL) (DiaTribe, 2022). The Dexcom G6 CGM was used by two participants at the beginning of intervention diet for 4-5 days. Glucose control was determined using the Dexcom G6 CGM (San Diego, CA), where data were

collected every five minutes, for a total of about 288 readings per day. The data provided included blood glucose patterns, time-in-range statistics, and hourly percentages of blood glucose outside of the normal range (very high or very low). There were no data from Visit 4 due to participant dropout and no results are shown.

## Data Analysis

Descriptive statistics were run on the data to obtain means and standard deviations for each treatment condition at pre- (Visits 1–3) and post-intervention (Visit 4). Descriptive analyses of the cardiometabolic outcomes determined at Visits 1-4 were conducted by treatment condition (CG; HQKD; LQKD). In addition, the same measurement variables were analyzed for non-completers at Visits 1-3, where one participant dropped out after visit one and the remaining four participants dropped out after Visit 3. Statistical analyses were performed using SPSS analytic software (version 28.0, IBM Corporation).

# Chapter 4 - Results

## Participant Characteristics

Twenty-five participants indicated interest in the current study, with eleven (40%) completing the screening visit (Visit 1) and passing eligibility criteria. During screening, fourteen participants were excluded due to food allergies, not responding to initial screening emails, current chronic diseases or conditions, lack of availability during follow-up visits, and family history of kidney stones. Of the eleven eligible participants, one dropped out due to the time required for follow-up visits. Ten participants were randomized to the treatment conditions. All ten participants were fairly active at baseline with regard to combined total activity per week including walking, moderate activities, and vigorous activities (CG Mean = 185 min/wk, HQKD Mean = 131.25 min/wk, LQKD Mean = 117.5 min/wk). In addition, all participants were at a moderate–high intensity level of physical activity according to the IPAQ-SF scoring. Further details of these scoring guidelines are shown in Table 4.3. Of the ten remaining participants, six did not complete the study (55% dropout rate) (Table 4.1). Dropouts occurred in all three arms of the study. One participant in the CG dropped out due to pregnancy during the study. In the HQKD group, two participants dropped out due adverse symptoms while adhering to the diet (i.e., nausea, GI distress, headaches). In addition, this diet affected one of the two participant's mental well-being (i.e., greater temptation toward CHOs) in the HQKD group. In the LQKD group, one participant could not adhere to the diet due to lack of time, while one participant could not afford the cost of groceries. Demographic characteristics of participants are shown in Table 3.1. Data analyses were performed for participants who completed the study protocol (n=5), and a diagram of the phases of this current randomized trial is presented in Figure 4.1.

Participants were randomly assigned to control (not ketogenic) (n=2), high-quality ketogenic diet (HQKD) (n=4), or low-quality ketogenic diet (LQKD) (n=4) groups.

**Figure 4.1. CONSORT Flow Diagram.**

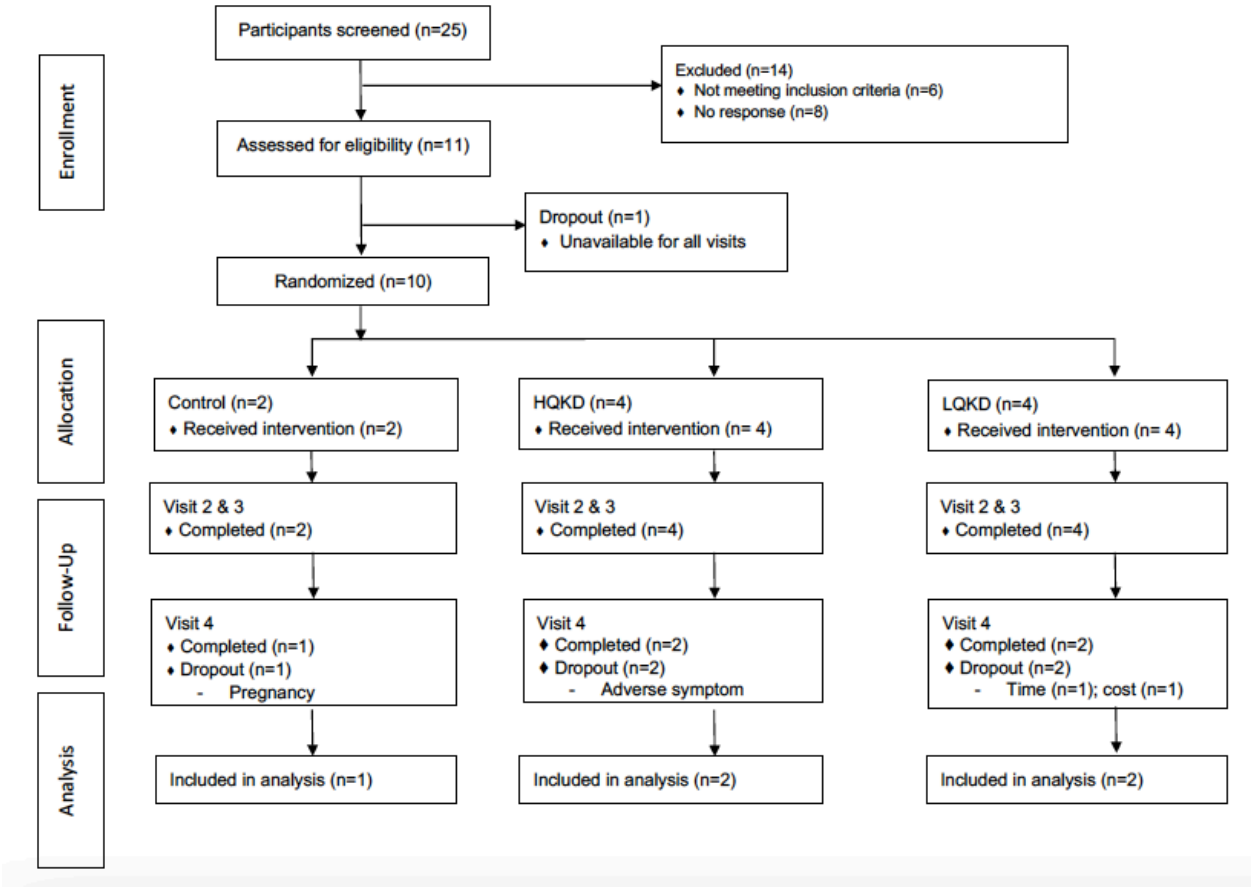



**Table 4.1. Characteristics of Participants.**

| | | All KD Participants (n=5) | HQKD Group (n=2) | LQKD Group (n=2) | CG (n=1) | Non-completers (n=6) |
|---|---|---|---|---|---|---|
| **Variable** | | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** |
| **Biological Sex** | **Female** | 2 (40) | 1 (20) | 1 (20) | 0 (0) | 6 (100) |
| | **Male** | 3 (60) | 1 (20) | 1 (20) | 1 (20) | 0 (0) |
| **Ethnicity** | **White** | 4 (80) | 2 (40) | 1 (20) | 1 (20) | 4 (67) |
| | **Hispanic/Latino** | 1 (20) | 0 (0) | 1 (20) | 0 (0) | 2 (33) |
| **Years (Range)** | | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Age (years); mean (range)** | 24 (20 to 34) | 21 (20 to 21) | 32 (29 to 34) | 21 | 23 (20 to 30) |
| **Anthropometrics (Mean ± Standard Deviation)** | | | | | |
| **BMI (kg/m$^2$)** | 24.2 ± 1.2 | 23.8 ± 1.1 | 24.8 ± 1.7 | 23.6 | 23.2 ± 5.1 |
| **Baseline Height (cm)** | 177.2 ± 9.5 | 178.7 ± 5.9 | 172.2 ± 14.9 | 184.1 | 163.8 ± 6.5 |
| **Baseline Weight (kg)** | 75.4 ± 6.2 | 76.2 ± 8.8 | 73.5 ± 7.7 | 80.5 | 62.0 ± 11.9 |

*KD: ketogenic diet

# Feasibility

Overall, the current study suggested several feasibility indicators. The dropout rate was 55%, a total of five out of eleven participants completed the study. The HEI scores for ketogenic diets could not be reached above 79.89, whereas the original goal was to reach a score above 80. Estimated costs of groceries per week ranged from $44.26–$52.39, with the high-quality diet costing more than the LQKD and no provision of food. Further, participant support from a dietitian via telephone and flexibility of scheduling would be beneficial for recruitment and retention. In addition, compliance with dietary patterns, fat-adaptation measured through ketosis, perceived self-efficacy, and ketogenic induced symptoms may also contribute towards feasibility.

## Compliance

Compliance with assigned dietary condition was observed through reporting grams of CHOs consumed each day during the 4-week intervention. Results showed on average, on 23 out of 28 days (82.1%) CHO amounts were met and did not exceed. Of the four participants assigned to the ketogenic dietary interventions, three complied on 26 out of the 28 days (94.1%), while the remaining participant, HQKD02, only complied on 10 out of 28 days (35.7%). In addition, allowances to food items were agreed upon to increase treatment acceptability. Food items

included items that had zero added sugar or calories such as coffee, tea, sugar-free coffee creamer, propel, and sprite zero.

## Fat Adaptation and Ketosis

Ketone body levels remained around 0mg/dL in the CG, as shown in Figure 4.2. In participant LQKD01, an increase in ketone bodies (80mg/dL) occurred at day 19 and 20 while adhering to the ketogenic diet, whereas in participant LQKD02 the ketone body levels range from 0 to 5mg/dL. When observing changes in participant HQKD01, an increase in ketone bodies (40mg/dL) occurred on days 12 to 15. In participant HQKD02, levels increased to 15mg/dL at day 21 but decreased to 0mg/dL by the end of the 4-week intervention. Due to the small sample size, and the nature of a feasibility study, statistical significance could not be determined.

## Perceived Self-Efficacy

Of the eight participants who were randomized to a ketogenic dietary treatment condition (excluding CG), 100% reported that they were "very sure" that they could maintain a ketogenic diet for 1 week prior to starting the treatment condition; however, 50% dropped out before the first week ended. In the LQKD group, participants listed the following barriers that may occur while adhering to this dietary pattern: *taste and texture of the food; headaches; convenience; motivation; and cost*. While the HQKD group listed barriers such as lack of *accountability, unable to leisurely eat, convenience, and sudden mood changes.* At the final visit (Visit 4), participants who completed the full 4-week intervention were asked follow-up questions based on their confidence and barriers. From both groups, 100% stated that they were "not at all" confident that they could maintain a ketogenic diet as a lifestyle. In addition, 75% reported that the ketogenic diet is not something they will continue to follow. Some barriers that were

common across both groups were *time, social gatherings, impaired athletic performance/exercise intensity, and tantalizing food.*

### Symptoms

No serious adverse events were reported during the intervention. In the LQKD group, 100% reported mild-to-moderate headaches and difficulty concentrating, and 50% reported lightheadedness, change in breath odor, and constipation during the first week of adherence to the diet. In the HQKD group, 100% reported mild-to-severe lightheadedness and moderate muscle weakness in the same period. It was also noted that 50% of the HQKD group experienced nausea, diarrhea, moderate intestinal bloating, and severe difficulty concentrating. In contrast, 100% of all ketogenic diet participants verbally reported suppressed hunger throughout the day, reduced athletic performance, whereas 50% of all ketogenic diet participants experienced reduced bloating. All symptoms were experienced within 7 to 10 days of beginning the dietary intervention and subsided after an additional 1 to 2 days.

## Cardiometabolic Outcomes

Measurement variables included weight, waist circumference (WC), average blood pressure (systolic/diastolic), resting heart rate, TC, HDL-c, TRG, LDL-c, fasting glucose, LDL/HDL ratio, blood glucose level after an OGTT, RQ, REE, and body composition via DXA (only Visit 2 and Visit 4).

Table 4.2 shows cardiometabolic outcomes data for participants who completed all visits. At baseline (Visit 1), all completers had an average weight of 75.4 ± 6.2 kg, blood pressure below 120/80 mmHg, a BMI categorized as normal (24.2±1.2), TC at optimal levels (<200 mg/dL), LDL-c above optimal levels (100 mg/dL), TRG at normal levels (<150 mg/dL), HDL-c

levels at borderline risk (40-45 mg/dL) of CVD, normal fasting blood glucose (<100 mg/dL), and normal OGTT glucose levels (< 155 mg/dL) after 2 hours.

From pre- (Visit 3) to post-intervention (Visit 4), the KD participants showed weight loss (HQKD: 77.2± 8.7 to 75.3 ± 12.6 kg; LQKD: 73.23± 7.5 kg to 70.8 ± 8.0 kg), increase in TC (HQKD: 159.5± 40.3 to 163.5± 24.7 mg/dL; LQKD: 136.5±14.8 to 154.5±12 mg/dL), increase in LDL-c (HQKD: 87.5±21.9 to 90.5±23.3 mg/dL; LQKD: 77.5±2.1 to 93.5±12 mg/dL) and in HDL-c (HQKD: 51±28.3 to 55±5.7 mg/dL; LQKD: 42±5.7 to 43±2.8 mg/dL) and a decrease in fasting blood glucose (HQKD: 77.5±19.1 to 69.5±3.5 mg/dL; LQKD: 92.0± 1.4 to 83.5± 2.1 mg/dL). In addition, a decrease in TRG was shown in the HQKD (103.5±48.8 to 90.5±19.1 mg/dL), whereas the LQKD showed an increase (86.0±33.9 to 89.0±15.6). The changes in RQ values were minimal to report any changes. Generally, the HQKD treatment performed better than the LQKD, showing smaller increases in blood lipid values that may increase risk for CVD (TC and LDL-c), along with deceases in TRG and fasting blood glucose levels.

Cardiometabolic health outcomes data, for non-completers at Visits 1-3 are found in Table 4.3. At baseline (Visit 1), all non-completers had an average weight of 62.0±11.9 kg, blood pressure below 120/80 mmHg, a BMI categorized as normal (23.2±5.1), TC below optimal levels (141.7±34.6 mg/dL) , LDL-c at optimal levels (76.5±8.9 mg/dL), TRG at optimal levels (66.3±23.9 mg/dL), HDL-c levels at acceptable levels (56.8±13.2 mg/dL) for CVD, normal fasting blood glucose (88.0±10.0 mg/dL), and normal OGTT glucose levels (76.8±16.0) after 2 hours.

**Table 4.2. Cardiometabolic Outcomes at Visits 1-4 for CG, HQKD, and LQKD.**

| | Visit 1 | | | Visit 2 | | | Visit 3 | | | Visit 4 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Variables** | **CG (n=1)** | **LQKD (n=2)** | **HQKD (n=2)** | **CG (n=1)** | **LQKD (n=2)** | **HQKD (n=2)** | **CG (n=1)** | **LQKD (n=2)** | **HQKD (n=2)** | **CG (n=1)** | **LQKD (n=2)** | **HQKD (n=2)** |
| **Weight (kg)** | 80.5 | 73.5 ± 7.7 | 76.2 ± 8.8 | 79.3 | 72.8 ± 6.5 | 75.9 ± 7.9 | 79.7 | 73.23 ± 7.5 | 77.23 ± 8.7 | 78.5 | 70.8 ± 8.0 | 75.3 ± 12.6 |
| **WC (cm)** | 84.9 | 79.6 ± 2.7 | 83.3 ± 4.2 | 85.1 | 80.3 ± 0.7 | 81.8 ± 3.6 | 83 | 79.1 ± 3.0 | 82.4 ± 5.1 | 81.2 | 76.4 ± 2.4 | 81.3 ± 6.6 |
| **Avg. BP (mmHg)** | 116/58 | 118.5/74.5 ± 14.8/10.6 | 108.5/58 ± 2.1/1.4 | 122/62 | 121/69.5 ± 21.2/0.7 | 111.5/54 ± 12/2.8 | 118/70 | 115.5/64 ± 7.8/7.1 | 111/60.5 ± 4.2/2.1 | 120/70 | 121/69.5 ± 11.3/6.4 | 109.5/59 ±6.4/2.8 |
| **Resting HR (bpm)** | N/A | 62.5 ± 10.6 | 55.5 ± 9.2 | 66 | 66.5 ± 0.7 | 46 ± 0 | 57 | 59.5 ± 12.0 | 42 ± 0 | 58 | 69.5 ± 4.9 | 47.5 ± 6.4 |
| **TC (mg/dL)** | 162 | 123.5 ± 14.8 | 171.5 ± 33.2 | 163 | 128.5 ± 14.8 | 179.5 ± 55.9 | 167 | 136.5 ± 14.8 | 159.5 ± 40.3 | 159 | 154.5 ±12 | 163.5 ±24.7 |
| **HDL-c (mg/dL)** | 43 | 42.5 ± 7.8 | 63.5 ± 24.7 | 39 | 45.5 ± 2.1 | 67 ± 25.5 | 44 | 42 ± 5.7 | 51 ± 28.3 | 39 | 43 ± 2.8 | 55 ±5.7 |
| **TRG (mg/dL)** | 61 | 88 ± 22.6 | 77.5 ± 31.8 | 50 | 84.5 ± 40.3 | 78.5 ± 30.4 | 110 | 86 ± 33.9 | 103.5 ± 48.8 | 120 | 89 ±15.6 | 90.5 ±19.1 |
| **LDL-c (mg/dL)** | 106 | 63 ± 2.8 | 92.5 ± 14.8 | 114 | 66 ± 4.2 | 97 ± 24.0 | 100 | 77.5 ± 2.1 | 87.5 ± 21.9 | 96 | 93.5 ±12 | 90.5 ±23.3 |
| **Fasting Glucose (mg/dL)** | 82 | 90.5 ± 0.7 | 83.5 ± 0.4 | 80 | 89.5 ± 7.8 | 84.5 ± 3.5 | 87 | 92 ± 1.4 | 77.5 ± 19.1 | 91 | 83.5 ±2.1 | 69.5 ±3.5 |
| **LDL/HDL Ratio (mmol/L)** | 118 | 1.5 ± 0.1 | 1.55 ± 0.4 | 2.9 | 1.45 ± 0.1 | 1.45 ± 0.2 | 2.3 | 1.9 ± 0.2 | 1.9 ± 0.6 | 2.5 | 2.2 ±0.1 | 1.7 ±0.2 |
| **OGTT (mg/dL)** | 95.5 | 90 ± 5.7 | 91.5 ± 30.4 | 119 | 126.8 ± 18.7 | 97.8 ± 1.8 | 80 | 113.8 ± 37.1 | 87.3 ± 7.4 | 119 | 128.5 ± 42.4 | 101 ± 36.8 |
| **RQ** | — | — | — | 0.94 | 0.82 ± 0 | 0.77 ± 0.08 | 0.88 | 0.78 ± 0 | 0.85 ± 0.03 | 0.94 | 0.78 ± 0.1 | 0.80 ± 0.11 |
| **REE (kcal/D)** | — | — | — | 1722 | 1369 ± 398.8 | 851 ± 113.1 | 2162 | 1689.5 ± 319 | 1501.5 ±130.8 | 1909 | 1499.5 ± 316.1 | 1656.5 ± 320.3 |
| **DXA (% Body Fat)** | — | — | — | 15.6 | 28.2 ± 18.9 | 19.7 ± 15.1 | — | — | — | 13.7 | 26.4 ± 20.9 | 19.4 ± 15.3 |

*Data are shown as mean ± standard deviation in the high-quality ketogenic diet group (HQKD) and low-quality ketogenic diet group (LQKD), but not for the control group (CG).

**Table 4.3. Cardiometabolic Outcomes at Visits 1-4 for Non-completers.**

| Non-completers (n=6) | | | | |
|---|---|---|---|---|
| | **Visit 1 (n=6)** | **Visit 2 (n=5)** | **Visit 3 (n=5)** | **Visit 4** |
| **Weight (kg)** | 62.0 ± 11.9 | 62.6 ± 13.1 | 63 ± 13.1 | Missing Data |
| **WC (cm)** | 76.3 ± 9.3 | 76.6 ± 11.2 | 76.2 ± 11.0 | |
| **Avg. BP (mmHg)** | 108.3/66.3 ± 5.5/8.0 | 111.2/69.2 ± 10.5/8.6 | 106.4/67.0 ± 9.9/3.5 | |
| **Resting HR (bpm)** | 67.8 ± 8.8 | 64.2 ± 8.4 | 65.0 ± 4.5 | |
| **TC (mg/dL)** | 141.7 ± 34.6 | 150.2 ± 37.0 | 144.4 ± 31.7 | |
| **HDL-c (mg/dL)** | 56.8 ± 13.2 | 56.0 ± 15.3 | 54.4 ± 15.9 | |
| **TRG (mg/dL)** | 66.3 ± 23.9 | 63.6 ± 28.3 | 65.4 ± 25.3 | |
| **LDL-c (mg/dL)** | 76.5 ± 8.9 | 86.8 ± 15.9 | 82.0 ± 16.9 | |
| **Fasting Glucose (mg/dL)** | 88.0 ± 10.0 | 91.4 ± 7.5 | 85.6 ± 3.8 | |
| **LDL/HDL Ratio (mmol/L)** | 1.2 ± 0.3 | 1.5 ± 0.3 | 1.6 ± 0.6 | |
| **OGTT (mg/dL)** | 76.8 ± 16.0 | 84.5 ± 21.5 | 89.0 ± 14.6 | |
| **RQ** | — | 0.85 ± 0.1 | 0.84 ± 0.1 | |
| **REE (kcal/D)** | — | 1519 ± 171.7 | 1478.6 ± 231.3 | |
| **DXA (% Body Fat)** | — | 23 ± 11.2 | 24.4 ± 9.3 | |

*Data are shown as mean ± standard deviation.

## Physical Activity

The IPAQ-SF categorical scoring was performed using an automated scoring Excel spread sheet (Cheng, 2016). A combination of raw data provided by the IPAQ, intermediary calculations, and MET-minutes were used to determine the physical activity category for each participant. Comparison of the total days of activity, total activity (minutes/week), and physical activity category for each treatment condition and participant are presented in Table 4.4.

**Table 4.4. IPAQ-SF Categorical Scoring**

| Completers | | | |
|---|---|---|---|
| **Participant** | **Total Days of Activity** | **Total Activity (min/wk)** | **Physical Activity Category** |
| **CG01** | 15 | 260 | High |
| **HQKD01** | 15 | 90 | Moderate |
| **HQKD02** | 14 | 180 | High |
| **LQKD01** | 10 | 105 | High |
| **LQKD02** | 6 | 100 | High |
| **Non-completers** | | | |
| **Participant** | **Total Days of Activity** | **Total Activity (min/wk)** | **Physical Activity Category** |
| **CG02** | 11 | 110 | High |
| **HQKD03** | 13 | 70 | Moderate |
| **HQKD04** | 14 | 185 | High |
| **HQKD05** | 8 | 75 | High |
| **LQKD03** | 9 | 75 | High |
| **LQKD04** | 12 | 190 | High |

*The IPAQ-SF categorical scoring guidelines are comprised as low, moderate, and high. The low category is based on “If neither moderate nor vigorous”. The moderate category indicates a) 3 or

more days of vigorous-intensity activity of at least 20 minutes per day or b) 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day. The high category must achieve vigorous-intensity activity on at least 3 days with 20 minutes minimum.

## Satiety

Table 4.5 shows the level of satiety reported at Visits 2-4. The CG indicated no changes in hunger/fullness throughout the study (0). The HQKD group indicated increased levels of "slight hunger" from Visit 3 to Visit 4 (-17.5). The LQKD group reported increased levels of "moderate hunger-very hungry" (-47.5) during this period as well. Overall, all participants who completed the ketogenic treatment condition had increased levels of hunger (-26).

**Table 4.5. Level of Satiety at Visits 2-4.**

| | Visit 2 | Visit 3 | Visit 4 |
|---|---|---|---|
| **CG (n=1)** | 0 ± 0 | 0 ± 0 | 0 ± 0 |
| **HQKD (n=2)** | -7.5 ± 17.68 | -7.5 ± 17.68 | -17.5 ± 3.54 |
| **LQKD (n=2)** | -10 ± 14.14 | -7.5 ± 17.68 | -47.5 ± 17.68 |
| **All Completed Participants (n=5)** | -7 ± 12.04 | -6 ± 12.94 | -26 ± 22.75 |
| **Non-Completers (n=5)** | -20 ± 26.22 | -32 ± 12.55 | Missing Data |

*Data are shown as mean ± standard deviation in the high-quality ketogenic diet group (HQKD) and low-quality ketogenic diet group (LQKD), but not for the control group (CG).

## Scoring of Power of Food Scale

The PFS has three domains: food available; food present; and food tasted. Scores for each domain are shown in Table 4.6 for all participants who completed the study. Overall, the average score did not change from pre-intervention (Visit 3) to post-intervention (Visit 4) for the HQKD

(13.8 ± 2.1 to 13.7 ± 2.3) and CG (10.7± 0 to 10.3 ± 0); however, scores increased among the LQKD group (12.5 ± 1.7 to 17.2 ± 0.2). PFS scores for non-completers are shown in Table 4.7.

**Table 4.6. Power of Food Scores at Visits 2-4 for Completers.**

| Completers (n=5) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Visit 2 | | | Visit 3 | | | Visit 4 | | |
| | CG (n=1) | HQKD (n=2) | LQKD (n=2) | CG (n=1) | HQKD (n=2) | LQKD (n=2) | CG (n=1) | HQKD (n=2) | LQKD (n=2) |
| **Factor 1** | 11 ± 0 | 13.5 ± 0.7 | 17 ± 4.2 | 10 ± 0 | 14 ± 1.4 | 16 ± 0 | 10 ± 0 | 13.5 ± 3.5 | 20 ± 1.4 |
| **Factor 2** | 13 ± 0 | 12.5 ± 0.7 | 8.5 ± 0.7 | 9 ± 0 | 14 ± 0 | 10.5 ± 2.1 | 9 ± 0 | 15 ± 1.4 | 12 ± 1.4 |
| **Factor 3** | 17 ± 0 | 13.5 ± 3.5 | 12 ± 0 | 13 ± 0 | 13.5 ± 4.9 | 13 ± 0 | 12 ± 0 | 12.5 ± 2.1 | 19.5 ± 2.1 |
| **Aggregate Score** | 13.7 ± 0 | 13.2 ± 0.7 | 12.5 ± 1.7 | 10.7± 0 | 13.8 ± 2.1 | 13.2 ± 0.7 | 10.3 ± 0 | 13.7 ± 2.3 | 17.2 ± 0.2 |

* Factor 1 = food available; Factor 2 = food present; Factor 3 = food tasted. Data are shown as mean ± standard deviation in the high-quality ketogenic diet group (HQKD) and low-quality ketogenic diet group (LQKD), but not for the control group (CG).

**Table 4.7. Power of Food Scores at Visits 2-4 for Non-completers.**

| Non-completers (n=5) | | | |
|---|---|---|---|
| | Visit 2 | Visit 3 | Visit 4 |
| **Factor 1** | 11.2 ± 2.2 | 12.4 ± 2.9 | Missing Data |
| **Factor 2** | 11.2 ± 3.0 | 11.4 ± 4.2 | |
| **Factor 3** | 13.2 ± 2.9 | 12.8 ± 3.1 | |
| **Aggregate Score** | 11.9 ± 2.1 | 12.2 ± 3.0 | |

*Factor 1 = food available; Factor 2 = food present; Factor 3 = food tasted

## Total Mood Disturbance

A Total Mood Disturbance (TMD) score was calculated by adding the raw scores for tension, depression, anger, fatigue, and confusion, and then subtracting the vigor score. The

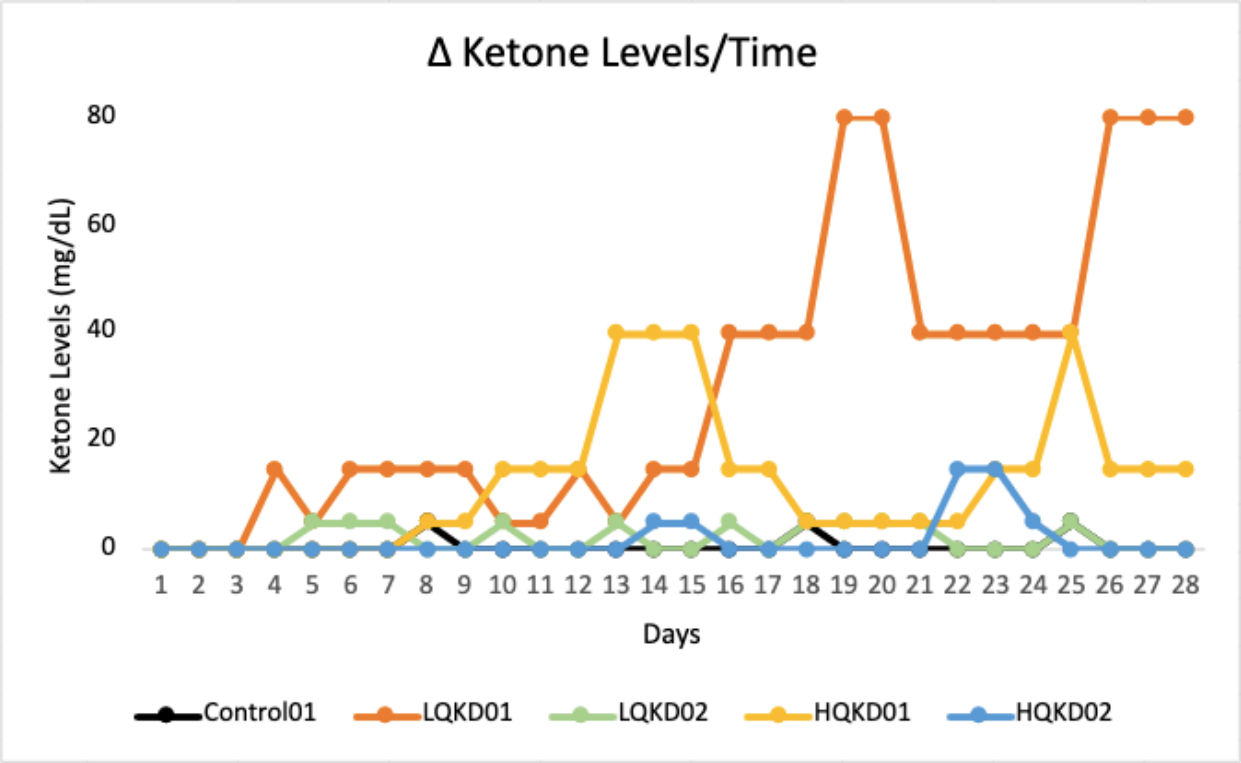
lower scores indicate more stable mood profiles. As indicated in Table 4.8, the CG was the most stable throughout the study. At Visit 3, both HQKD and LQKD had increased TMD scores, indicating that they were less stable as compared to Visit 2. TMD scores decreased in all dietary treatment conditions from Visit 3 to Visit 4.

**Table 4.8. Total Mood Disturbance Averages at Visits 2-4.**

| | **Visit 2** | **Visit 3** | **Visit 4** |
|---|---|---|---|
| **CG (n=1)** | 77 | 76 | 71 |
| **HQKD (n=2)** | 80.5 ± 3.5 | 90.5 ± 0.7 | 87 ± 9.9 |
| **LQKD (n=2)** | 87 ± 4.24 | 95 ± 0 | 80 ± 0 |
| **All Completed Participants (n=5)** | 82.4 ± 5.22 | 86.4 ± 9.71 | 81 ± 8.25 |
| **Non-Completers (n=5)** | 84.6 ± 9.24 | 84.6 ± 2.88 | Missing Data |

*Data are shown as mean ± standard deviation in the high-quality ketogenic diet group (HQKD) and low-quality ketogenic diet group (LQKD), but not for the control group (CG). Scores are out of a possible total of 200. The lowest score possible is a 56.

**Figure 4.2. Change in Ketone Body Levels over Visits 1-4.**



# Chapter 5 - Discussion

The aim of the current study was to test the feasibility of short-term high- and low-quality ketogenic dietary interventions after both 7–10 days, and four weeks. Because there are limited published studies and existing data investigating DQ while observing a ketogenic dietary intervention, the current feasibility study population is critical, as more healthy adults choose ketogenic diets for weight loss and health outcomes.

Feasibility indicators suggest that 1) sample size estimates for future studies should assume high dropout, 2) participants must be willing to be randomized to any treatment condition, 3) ketosis status should be monitored closely for appropriate health outcome determination, 4) cost analysis should be provided to participants during informed consent, 5) HEI ceiling scores for ketogenic diets need to be <80; whereas the original goal was to reach a score above 80, 6) and compensation is necessary in future studies due to high participant burden.

If we consider the DQ achieved in the meal planning as an element of effectiveness, achieving optimal DQ while following a ketogenic diet appears unrealistic based on the menu creation process used for the current study. A DQ score between 80 and 100 is considered "good" DQ, and due to the requirements of a ketogenic diet for a 3:1 ratio of fat:CHO which limits the ability to maximize fruits, vegetables, whole grains, and dairy intake, it cannot be considered a "good" DQ pattern. Since that is the case, we opted to maximize the DQ to the extent possible, and as a result created a high-quality ketogenic diet where the HEI score was 76 out of 100, which is in the "needs improvement" category. Completers and non-completers of the current study were all willing to be randomized to any treatment condition and seemed motivated to participate. Perceived self-efficacy for following the ketogenic diet showed that participants

were motivated to maintain a ketogenic diet for one week prior to starting the study; however, those who completed the full 4-week intervention stated that they were not at all confident they could maintain a ketogenic diet as a lifestyle. Further, three of the four participants reported that the ketogenic diet was not something they would continue to follow, which may suggest that this dietary pattern is not sustainable for the study population. Finally, the dropout rate for the current study was 55%. While this level of attrition seems quite high, previous research indicates that similar attrition rates are common in high-intensity dietary intervention studies ranging in duration from 6 weeks to over a year (Appel et al., 2005; Dansinger et al., 2005; Sacks et al., 2009).

The question of adaptation to a high-fat ketogenic diet, especially for athletes, has been a question of controversy and debate. It is known that substantial increases in fat oxidation occur within 3–4 weeks of adherence to a ketogenic diet, but may occur even sooner (Burke et al., 2000). In the current study, the sample size did not allow for detection of changes in RQ values that would have elucidated timing of adaptation. However, fully powered trials that examine changes in substrate utilization and the time course of those changes, are important to improve understanding of the potential benefits and detriments to following a ketogenic diet, and may help to bridge the gap in the research literature for athletes and the general public.

Additionally, a further novel aspect of the current feasibility study was the inclusion of a subsample of participants who agreed to undergo continuous glucose monitoring. The intention behind using a CGM along with physical activity monitoring was to better understand the relationship between ketogenic diet adaptation, glucose regulation, and exercise efficiency. These data are not shown, given the extremely small sample and the dropout of both of these participants before study completion. However, future trials should include glucose monitoring

during adaptation to ketogenic diets to elucidate the regulation of glucose during the alteration of substrate utilization.

All participants adhering to the ketogenic diet conditions, both high- and low-quality, lost weight and verbally expressed suppressed hunger throughout the day, although increased hunger levels were reported prior to each visit. Interestingly, similar results were shown in a meta-analysis of 12 randomized and non-randomized studies ranging from 4 to 12 weeks in duration, (Gibson et al., 2015). This study determined that participants on a ketogenic diet, when compared to participants who followed a very-low-energy diet, experienced less hunger and a reduced desire to eat, even as they lost weight. Normally, weight loss is reported to increase appetite, and authors indicated that there are limited available ketogenic diet studies that provide any clear evidence regarding appetite regulation, warranting further investigation (Gibson et al., 2015). The unintentional weight loss may be principally a result of changes in body water and coincide with phases of ketosis (Frigolet et al., 2011; Gomez-Arbelaez et al., 2017). These observations are consistent with previous studies (Gomez-Arbelaez et al., 2017; Kephart et al., 2018). In addition to weight loss, the results of this feasibility study suggest that there may be differences in other cardiometabolic health outcomes when comparing HQKD and LQKD from pre- to post-intervention, which is consistent with previous literature. According to Yuan and colleagues, a meta-analysis comprised of 13 studies showed that after following a ketogenic diet intervention for durations ranging from one to 56 weeks, fasting blood glucose levels decreased by 23.22 mg/dL (95% CI: - 1.78 to -0.79) on average, and TRG decreased by 0.72mg/dL (95% CI: -1.01 to -0.43) on average (Yuan et al., 2020). Another study showed that a low-CHO, high-fat diet with 78% of energy from fat, decreased fasting glucose levels significantly (5.4 mg/dL)

after three weeks (Valsdottir et al., 2019). In this very small sample size, there was a decrease in fasting blood glucose and TRG levels for the HQKD group.

## Strengths and Limitations

This feasibility trial included a very small sample size, and while feasibility studies should not include inferential statistics, even with larger sample sizes, the current study was further limited in its ability to determine feasibility appropriately given the very limited sample size. In addition, there are tradeoffs with any study with regard to use of invasive methods or methods that place a large burden on participants. In the current feasibility study, we sought to strike a balance between burden and use of the gold standard methods that would potentially be invasive or time consuming. Two major limitations of the current study were the lack of oversight of dietary compliance, and the lack of provision of food. Given the very high dropout rate, steps would need to be taken when designing fully powered trials to maximize adherence and minimize dropout. Participants should be compensated monetarily, and food should be provided. While we attempted to minimize costs to the extent possible, some participants indicated that the cost of food led to their decision to drop out of the study.

Further, there are several outcomes that we intended to measure that were problematic and would need to be improved when developing fully powered trials. Exercise efficiency could not be calculated due to unexpected equipment issues with metabolic cart calibration, therefore expired gases were not collected during cycle ergometry. Similarly, the use of continuous glucose monitoring was problematic, as most participants opted not to wear the monitors.

## Future Directions

This feasibility study provides future directions for studies that examine the importance of DQ for overall health and wellbeing, particularly in the context of following popular dietary

patterns. A fully powered trial would allow for inferential statistical analyses to be conducted in order to better determine the time course for adaptation to ketogenic diets, and the potential differences in cardiometabolic outcomes when adhering to high-quality or low-quality ketogenic diets. Inclusion of DQ measures is necessary to provide a better understanding of the potential beneficial and detrimental short- and long-term effects of nutritional ketosis. Future research should continue to investigate the effects DQ can have on health outcomes, not only when following the ketogenic diet, but within the context of other popular diets currently being consumed by Americans.

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# Appendix A - Participant Recruitment Flyer

## Participants Needed for Nutrition Research Study

**WHO:**

- Individuals between 18 to 35 years of age
- Motivated individuals that will adhere to a weekly meal plan for 4 weeks.
- Individuals who are able to commit to 4 separate visits,
  - 3 hours/visit
  - 4-5 week duration, consecutively
- Healthy individuals with no known chronic diseases or conditions that might affect study outcomes.

**WHAT:** K-State researchers are recruiting participants for a study examining the effects of three different diets on health.

**WHEN:** Starting after finals week with ongoing enrollment.

**WHERE:** 3rd floor of Lafene Health Center building in the Physical Activity and Nutrition Clinical Research Consortium (PAN-CRC)

Interested? Link to sign up:
**https://kstate.qualtrics.com/jfe/form/SV_ehCPF13szJxzNCm**

**For more info, contact:**
**Alissa Towsley**
**—**
**Atows@ksu.edu**

### Benefits/Opportunities

to learn about your health:

- Body composition (DEXA)
- Blood lipid levels
- Fasting glucose level
- Receive a suitable meal plan
- Additional information on your metabolic health
- $25 upon completion

This study has been approved by the Institutional Review Board at Kansas State University
**IRB Approval #10902**

# Appendix B - Dietary Quality Interest Screener

1. Do you have the ability to prepare your own meals? (i.e., do you have a kitchen?)**
    a. Yes
    b. No
2. Do you have a known food allergy? *
    a. Yes
    b. No
3. Do you have a known diagnosis of an acute or chronic disease? *
    a. Yes
    b. No
4. Do you have the presence of diagnosed diabetes mellitus, inflammatory disease, atherosclerotic disease, or other relevant chronic conditions that may affect metabolic processes?*
    a. Yes
    b. No
5. Are you currently taking medication for chronic disease including anti-inflammatory, anti-hypertensive, glucose controlling, or steroidal inflammation?
    a. Yes
    b. No
6. Are you taking any supplements that may affect metabolism?*
    a. Yes
    b. No
7. Do you have a history of kidney stones or do you have a family history of kidney stones?*
    a. Yes
    b. No
8. Do you have a history of abnormal serum lipids or a strong family history of abnormal lipids?*
    a. Yes
    b. No

9. Are you currently pregnant or lactating, or planning to become pregnant during the intervention?*
    a. Yes
    b. No
10. Please select all of the following that apply to you: (If two or more were selected, participants were ineligible to participate).
    a. Current cigarette smoker OR quit smoking within the last 6 months
    b. Have participated in less than 30 minutes of moderate-intensity exercise on less than 3 days/week during the past 3 months
    c. BMI > 30
    d. Blood pressure: > 140/90 OR on antihypertensive medication
    e. LDL cholesterol: >130 mg/dL
    f. HDL cholesterol: <40 mg/dL
    g. Total cholesterol: >200 mg/dL
    h. None of these apply to me
11. Based on these initial criteria, it looks like you may be eligible to participate. After reviewing the study details, are you still interested in participating and learning more about this nutrition research study?**
    a. Yes
    b. No

I. The next step will be to schedule an in-person screening visit. At this visit, you will complete a paper copy of the informed consent, fill out a medical history questionnaire, measure anthropometrics (height, weight, waist circumference, blood pressure) and collect 5mL of blood for insulin sensitivity.

We will review any medications to make sure they are compatible with the study. We will have you perform an Oral Glucose Tolerance Test, which consists of consuming a glucose beverage, then 7 finger pricks to measure your blood glucose levels. We will also be able to answer any questions that you might have. If you pass the screening based on our measurement criteria, you will have the option to officially enroll in this study.

* If any of these questions are marked “Yes”, the individual was thanked for their interest in the study. They were asked to email the lead researcher if they thought this was an error and to discuss eligibility.
** If any of these questions are marked “No”, the individual was thanked for their interest in the study. They were asked to email the lead researcher if they thought this was an error and to discuss eligibility.

***Questions were input in an online survey distributor that collects, organizes, and understands data (Qualtrics XM).

# Appendix C - ACSM Risk Stratification Screening Questionnaire



**Assess your health status by marking all *true* statements**

***History***

You have had:

_____ a heart attack
_____ heart surgery
_____ cardiac catheterization
_____ coronary angioplasty (PTCA)
_____ pacemaker/implantable cardiac defibrillator/rhythm disturbance
_____ heart valve disease
_____ heart failure
_____ heart transplantation
_____ congenital heart disease

***Symptoms***

_____ You experience chest discomfort with exertion
_____ You experience unreasonable breathlessness
_____ You experience dizziness, fainting, or blackouts
_____ You take heart medications.

***Other health issues***

_____ You have diabetes
_____ You have asthma or other lung disease
_____ You have burning or cramping sensation in your lower legs when walking short distances
_____ You have musculoskeletal problems that limit your physical activity
_____ You have concerns about the safety of exercise
_____ You take prescription medications
_____ You are pregnant

*If you marked any of these statements in this section, consult your physician or other appropriate health care provider before engaging in exercise. You may need to use a facility with a medically qualified staff.*

***Cardiovascular risk factors***

_____ You are a man older than 45 years
_____ You are a woman older than 55 years, have had a hysterectomy, or are postmenopausal
_____ You smoke, or quit smoking within the previous 6 months
_____ Your blood pressure is >140/90 mm Hg
_____ You do not know your blood pressure
_____ You take blood pressure medication
_____ Your blood cholesterol level is >200 mg/dL
_____ You do not know your cholesterol level
_____ You have a close blood relative who had a heart attack or heart surgery before age 55 (father or brother) or age 65 (mother or sister)
_____ You are physically inactive (i.e., you get <30 minutes of physical activity on at least 3 days per week)
_____ You are >20 pounds overweight

*If you marked two or more of the statements in this section you should consult your physician or other appropriate health care provider before engaging in exercise. You might benefit from using a facility with a professionally qualified exercise staff[a] to guide your exercise program.*

_____ None of the above

*You should be able to exercise safely without consulting your physician or other appropriate health care provider in a self-guided program or almost any facility that meets your exercise program needs.*

[a]Professionally qualified exercise staff refers to appropriately trained individuals who possess academic training, practical and clinical knowledge, skills, and abilities commensurate with the credentials defined in Appendix D.

**FIGURE 2.2.** AHA/ACSM Health/Fitness Facility Preparticipation Screening Questionnaire (Modified from American College of Sports Medicine Position Stand and American Heart Association. Recommendations for cardiovascular screening, staffing, and emergency policies at health/fitness facilities. *Med Sci Sports Exerc.* 1998;30(6):1009–18.)

# Appendix D - Dietary Quality Sample Menus

**2000 kcals, Ketogenic, High Dietary Quality (HEI 70-80/100)**

**Breakfast**

1 fruit
1 dairy
4 fats
*Example: 1c vanilla Greek yogurt, 1c thawed frozen berries, 8 whole pecans (chopped)*

**Lunch**

1 non-starchy vegetable
4oz medium-fat meat
5 fats
*Example: 1c romaine salad (free food) with 4oz ground beef (with sodium-free taco seasoning), 1c pico de gallo, 3/8 medium avocado, 2 Tbsp ranch dressing*

**Dinner**

1 non-starchy vegetable
5oz lean meat
5 fats
*Example: 5oz sautéed cod with 1 Tbsp olive oil and garlic, 1c sautéed spinach (in same 1 Tbsp olive oil and garlic, free food), 1/2c baked yellow squash (tossed in 2 tsp canola oil before baking)*

**Snack 1**

½ starch
5 fats
*Example: 1 Tbsp peanut butter on ½ slice 100% whole grain toast sprinkled with 2 whole walnuts (chopped)*

**Snack 2**

½ starch
5 fats
*Example: other half of toast with 1 Tbsp PB sprinkled with 2 whole walnuts (chopped)*

---

**Macronutrient Distribution for 2000 kcals diet:**

3:1 ratio of fat to carbs in macronutrient distribution → 75% fat, 15% protein, 10% carbs
Fat: 75% energy = 1500cal = 166g
Protein: 15% energy = 300cal = 75g
Carbs: 10% energy = 200cal = 50g (net carbs)

**Diabetes Exchanges for 2000 kcals HQKD Meal Plan**

| Food Group | # of Servings | Carbs (g, goal 50g, 10% of energy) | Protein (g, goal 75g, 15% of energy) | Fat (g, goal 166g, 75% of energy) | Calories (goal 2000) |
|---|---|---|---|---|---|
| Starch (no starchy vegetable, whole grain) | 1 | 15 | 2 | 0 | 80 |
| **No starchy vegetables, only grain-based foods, always 100% whole grain, minimize added sugar* | | | | | |
| *Subtotals* | | *15* | *2* | *0* | *80* |
| Non-starchy vegetables | 2 | 10 | 4 | 0 | 50 |
| **Must be plain frozen or fresh, make 1 serving dark green daily* | | | | | |
| *Subtotals* | | *25* | *6* | *0* | *130* |
| Fruit | 1 | 15 | 0 | 0 | 60 |
| **Must be fresh or plain frozen* | | | | | |
| *Subtotals* | | 40 | 6 | 0 | 190 |
| Dairy (full fat/ whole) | 1 | 12 | 8 | 8 | 150 |
| **Can be flavored, but must minimize added sugar* | | | | | |
| *Subtotals* | | *52* | *14* | *8* | *340* |
| Meat/meat alternates (lean) | 5 | 0 | 35 | 15 | 275 |
| Meat/meat alternates (medium-fat) | 4 | 0 | 28 | 20 | 300 |
| **At least 3 fish/seafood or 2 plant-based daily, no breading* | | | | | |
| *Subtotals* | | *52* | *77* | *43* | *915* |
| Fats | 24 | 0 | 0 | 120 | 1080 |
| **At least 22 servings as unsaturated fat, no more than 2 servings from saturated fat* | | | | | |
| **Totals** | | **52g** | **77g** | **163g** | **1995cal** |
| **% of Energy** | | **10.4%** | **15.4%** | **73.5%** | |

* Limit added salt.

**2000 kcals, Ketogenic, Low Dietary Quality (HEI 30-40/100)**
**Breakfast**

1 fruit
1 dairy
4 fats

**Lunch**

1 non-starchy vegetable
4oz medium-fat meat
4 fats

**Dinner**

1 non-starchy vegetable
5oz lean meat
4 fats

**Snack 1**

½ starch
4 fats

**Snack 2**

½ starch
3 fats

---

**Macronutrient Distribution for 2000 kcals diet:**
3:1 ratio of fat to carbs in macronutrient distribution → 75% fat, 15% protein, 10% carbs
Fat: 75% energy = 1500cal = 166g
Protein: 15% energy = 300cal = 75g
Carbs: 10% energy = 200cal = 50g (net carbs)

**Diabetes Exchanges for 2000 kcals LQKD Meal Plan**

| Food Group | # of Servings | Carbs (g, goal 50g, 10% of energy) | Protein (g, goal 75g, 15% of energy) | Fat (g, goal 166g, 75% of energy) | Calories (goal 2000) |
|---|---|---|---|---|---|
| Starch (no starchy vegetable, whole grain) | 1 | 15 | 2 | 0 | 80 |
| **Can do starchy vegetable in place of grain if it is fried or has added butter and salt, NOT 100% whole grain, go for grains with added sugar (need 26g per day added sugar)* | | | | | |
| *Subtotals* | | *15* | *2* | *0* | *80* |
| Non-starchy vegetables | 2 | 10 | 4 | 0 | 50 |
| **Ideally canned, do not do dark green, can be fried, ideally add butter and salt* | | | | | |
| *Subtotals* | | *25* | *6* | *0* | *130* |
| Fruit | 1 | 15 | 0 | 0 | 60 |
| **Not fresh or plain frozen, ideally canned in heavy syrup or non-100% fruit juice only, alternate between the canned and juice* | | | | | |
| *Subtotals* | | 40 | 6 | 0 | 190 |
| Dairy (full fat/ whole) | 1 | 12 | 8 | 8 | 150 |
| **Should be flavored with added sugar* | | | | | |
| *Subtotals* | | *52* | *14* | *8* | *340* |
| Meat/meat alternates (high-fat) | 5 | 0 | 35 | 40 | 275 |
| Meat/meat alternates (medium-fat) | 4 | 0 | 28 | 20 | 300 |
| **No seafood or plant-based meals* | | | | | |
| *Subtotals* | | *52* | *77* | *68* | *1140* |
| Fats | 19 | 0 | 0 | 95 | 855 |
| **Mostly saturated fats (butter, cream cheese, coconut oil)* | | | | | |
| **Totals** | | **52g** | **77g** | **163g** | **1995cal** |
| **% of Energy** | | **10.4%** | **15.4%** | **73.5%** | |

*Limit added salt.

# Appendix E - Dietary Quality Grocery List

## High Dietary Quality, 2000 kcals

| Grocery List | Amount to Purchase (1wk) | | | Amount Food is Sold | | |
|---|---|---|---|---|---|---|
| Item Name | Quantity | Measure | Price /Item | Quantity | Measure | Walmart Brands |
| Apple, fresh, sliced | 0.5 | Cup | $0.59 | 1 | each | Gala |
| Asparagus, boiled, drained | 0.5 | Cup | $1.78 | 1 | bunch | Produce |
| Avocado, fresh | 4.875 | Each | $0.57 | 1 | each | Hass Small |
| Beef flank steak, broiled, 0" trim | 2 | Oz | $8.32 | 1 | lb | Beef Choice Angus Flank Steak |
| Beef strip steak, top loin, broiled, choice, lean, 1/8" trim, | 3 | Oz | $10.46 | 1 | lb | Beef NY Strip Steak |
| Beef, ground, baked, 20% fat | 6.5 | Oz | $3.98 | 1 | lb | All Natural |
| Bell pepper, green, fresh, chopped | 1/8 | Cup | $0.78 | 1 | each | Produce |
| Bell pepper, red, fresh, medium, 2 3/4" x 2 1/2" | 1 | Each | $1.38 | 1 | each | Produce |
| Blackberries, fresh | 0.25 | Cup | $3.84 | 6 | oz | Produce |
| Blueberries, fresh | 1.08 | Cup | $3.63 | 11 | oz | Produce |
| Bread, multigrain, whole grain | 4 | Slice | $2.98 | 10 | slices | Oroweat Multi-grain bread |
| Broccoli florets, fresh | 3/4 | Cup | $1.14 | 1 | lb | produce |
| Broth, beef, low sod, cnd | 1.5 | Cup | $0.80 | 14.5 | oz | Swanson 50% less Na |
| Broth, chicken, canned, low sodium | 0.25 | Cup | $0.80 | 15 | can | Swanson lower Na |
| Cabbage, boiled, drained, shredded | 1.25 | Cup | $2.04 | 9 | cups | Produce (1 head) |
| Carrots, fresh, medium strips | 0.25 | Cup | $0.82 | 1 | lb | Produce (whole carrots) |
| Cashews, dry roasted, unsalted | 5 | Tbsp | $4.96 | 10 | oz | Walmart |
| Cauliflower florets, fresh | 0.5 | Cup | $2.44 | 1 | head | produce |
| Celery stalk, fresh, medium, 7 1/2" to 8" | 2 | Each | $1.98 | 10 | celery | Produce (1 stalk) |
| Cheese, feta, crumbled | 2 | Tbsp | $2.54 | 5 | oz | Frigo feta |
| Cheese, mozzarella, low moisture part skim, shredded | 2.5 | Oz | $2.38 | 8 | oz | Great Value |
| Cheese, parmesan, grated | 2 | Tbsp | $2.36 | 8 | oz | Great Value |
| Chicken breast, grilled, skinless | 4 | Oz | $3.40 | 1 | lb | Tyson All Natural Boneless |
| Cod, atlantic, baked, fillet | 4 | Oz | $11.97 | 2 | lb | Great Value Frozen |
| Corn, yellow, microwaved, from frozen, whole kernel | 1/8 | Cup | $0.78 | 12 | oz | Great Value |
| Cucumber, fresh, with skin, sliced | 1 | Cup | $0.68 | 1 | each | Produce |
| Egg, cooked, large | 5 | Each | $1.08 | 12 | each | Great Value |
| Garlic cloves, fresh | 9 | Tsp | $0.45 | 12 | cloves | Produce (1 bulb) |
| Juice, lime, fresh | 1/8 | Cup | $1.00 | 15 | oz | Great Value |
| Lemon juice, fresh | 1 | Tsp | $0.88 | 5 | oz | Concord Foods |

| | | | | | | |
|---|---|---|---|---|---|---|
| Lettuce, romaine, fresh, shredded | 3.5 | Cup | $1.87 | 1 | head | Produce |
| Lima beans, baby, boiled, from frozen, drained | 0.25 | Cup | $1.72 | 16 | oz | Great value |
| Milk, whole, 3.25%, with vitamin D | 1.875 | Cup | $2.28 | 16 | cups | Great Value (1 gallon) |
| Mushrooms, cooked, from fresh | 0.375 | Cup | $1.88 | 8 | oz | Produce |
| Oil, canola | 36 | Tsp | $1.88 | 48 | oz | Great value |
| Oil, olive | 32.5 | Tsp | $2.52 | 17 | oz | Great value |
| Oil, sesame, salad or cooking | 17 | Tsp | $1.84 | 48 | oz | Great value vegetable oil |
| Onion, red, fresh, chopped | 0.375 | Cup | $0.78 | 1 | each | produce |
| Onion, white, fresh, sliced | 0.1875 | Cup | $0.78 | 1 | each | produce |
| Peanut butter, creamy, natural, unsalted | 4.5 | Tbsp | $2.20 | 16 | oz | Natural low sodium Jif |
| Peanuts, dry roasted, unsalted | 10 | Each | $1.98 | 16 | oz | Great value |
| Pecans, dry roasted, unsalted | 56 | Each | $5.46 | 8 | oz | Great value pecan halves |
| Popcorn, oil popped, unsalted | 2 | Cup | $1.84 | 32 | oz | Jolly time white popcorn kernels |
| Pork chop, top loin, broiled, lean, | 3 | Oz | $4.78 | 1 | lb | Pork chop center cut loin chops |
| Quinoa, cooked | 0.5 | Cup | $2.97 | 16 | oz | Great value tri-color |
| Raspberries, fresh | 0.58 | Cup | $2.70 | 6 | oz | produce |
| Salad dressing, asian sesame | 2 | Tbsp | $1.72 | 16 | oz | Kraft Asian Toasted Sesame Lite |
| Salad dressing, italian, light | 3 | Tbsp | $1.72 | 16 | oz | Kraft zesty italian lite |
| Salad dressing, ranch | 2 | Tbsp | $1.72 | 16 | oz | Kraft Classic ranch |
| Salad dressing, vinaigrette, raspberry, light | 2 | Tbsp | $1.72 | 16 | oz | Kraft Raspberry Vinaigrette Lite |
| Salmon, pink, baked, fillet | 10 | Oz | $4.52 | 16 | oz | Great value wild caught pink salmon |
| Scrambled egg whites | 3 | Oz | $3.87 | 32 | oz | Great value liquid egg whites |
| Seasoning mix, taco, original | 1 | Tsp | $0.44 | 1 | oz | Great value original |
| Shrimp, raw, medium | 2 | Oz | $5.53 | 12 | oz | Frozen Raw Medium peeled deveined |
| Soy sauce, lite | 1 | Teaspoon | $1.62 | 15 | oz | Great value less sodium |
| Spinach, boiled, from frozen, drained, 10 oz | 4 1/8 | Cup | $1.97 | 10 | oz | Great value frozen chopped |
| Spread, buttery, with omegas | 21.5 | Tbsp | $2.72 | 13 | oz | Smart balance EVOO |
| Squash, summer, yellow, cooked, from fresh | 0.5 | Cup | $0.89 | 1 | each | Produce |
| Strawberries, fresh, sliced | 3.58 | Cup | $2.22 | 16 | oz | Produce |
| Taco shell, baked, 5", unsalted | 2 | Each | $1.98 | 18 | ct | La Tiara |
| Tilapia, baked | 4 | Oz | $3.88 | 1 | lb | Great Value tilapia skinless & boneless |
| Tomatoes, fresh, year round average, medium, 2 3/5" | 2.5 | Each | $0.91 | 1 | each | Produce |
| Vinegar, white, distilled | 1 | Tsp | $0.80 | 32 | oz | Great Value |
| Walnuts, english, dried, halves | 64 | Each | $3.98 | 8 | oz | Great value |

| | | | | | | |
|---|---|---|---|---|---|---|
| Yogurt, greek, vanilla, lowfat | 1.413 | Cup | $1.22 | 5 | oz | Two Good lowfat lower sugar |
| Zucchini, boiled, from frozen, with skin, drained | 1.25 | Cup | $1.48 | 10 | oz | Great value Zucchini blend |

**Estimated Total for 1 Week:** $52.39
**Estimated Total for 4 Weeks:** $209.55

## Low Dietary Quality, 2000 kcals

| Grocery List | Amount to Purchase (1wk) | | | Amount Food is Sold | | |
|---|---|---|---|---|---|---|
| **Item Name** | **Quantity** | **Measure** | **Price /Item** | **Quantity** | **Measure** | **Walmart Brands** |
| Alfredo sauce | 1 | Cup | $2.12 | 15 | oz | Bertolli |
| Applesauce, canned, sweetened, with salt | 0.75 | Cup | $2.14 | 24 | oz | Musselman's cinnamon |
| Bacon, brld, med slice | 24 | Slice | $3.47 | 18 | slices | Great value hicory smoked |
| Beef strip steak, top loin, broiled, prime, 1/8" trim, URMIS 1404 (Meas Raw Boneless) | 5 | Oz | $10.46 | 1 | lb | Beef NY Strip Steak |
| Beef, ground, raw, 20% fat | 14.5 | Oz | $3.98 | 1 | lb | All Natural |
| Bell pepper, red, fresh, medium, 2 3/4" x 2 1/2" | 1 | Each | $1.38 | 1 | each | Produce |
| Bread, soft white | 2.5 | Thin slice | $0.88 | 22 | slice | Great value |
| Butter, salted | 62 | Tsp | $0.94 | 1 | stick | Land o lakes |
| Cabbage, fresh, shredded | 1 | Cup | $2.04 | 1 | head | Produce |
| Carrots, fresh, medium strips | 1 | Cup | $0.82 | 1 | lb | Produce (whole carrots) |
| Cheese, cheddar, shredded | 1.5 | Oz | $2.38 | 8 | oz | Great value |
| Cheese, mozzarella, whole milk, shredded | 1 | Oz | $2.38 | 8 | oz | Great value |
| Chicken thigh, raw, skinless | 13 | Oz | $5.44 | 1.8 | lb | Tyson All Natural b/s less |
| Coleslaw | 0.25 | Cup | $1.76 | 15 | oz | Freshness Guaranteed |
| Corned beef, cooked, brisket, cured | 5 | Oz | $0.68 | 2 | oz | Buddig original |
| Egg, cooked, large | 8 | Each | $1.08 | 12 | each | Great value |
| Chicken drumstick, baked, with skin | 2 | Each | $7.97 | 4 | lb | Great value (NOT BREADED) |
| Fruit cocktail, canned, in heavy syrup | 0.5 | Cup | $1.84 | 29 | oz | Great Value |
| Garlic, minced | 1 | Tbsp | $1.74 | 8 | oz | Great value |
| Gravy, beef, canned | 0.5 | Cup | $0.86 | 10.5 | oz | Great value |
| Green beans, canned, drained | 1 | Cup | $0.50 | 14.5 | oz | Great value |
| Hash browns, pan fried, prepared from frozen, in Canola oil (AP Uncooked) | 3 | Oz | $1.76 | 32 | oz | Great value sourthern hash browns |
| Lemon juice, fresh | 1 | Tsp | $0.88 | 4.5 | oz | Concord Foods |
| Lettuce, iceberg, fresh, shredded | 3.5 | Cup | $1.68 | 12 | oz | Marketside |
| Mashed potatoes | 0.5 | Cup | $1.00 | 9 | oz | Great value instant mashed potatoes |
| Milk, whole, chocolate | 8.5 | Oz | $1.12 | 1 | pint | Hiland |
| Mixed nuts | 62 | Each | $4.23 | 10.3 | oz | Planters |
| Mushrooms, canned, sliced, drained | 0.5 | Cup | $0.98 | 4 | oz | Great value |
| Oil, sesame, salad or cooking | 9 | Tsp | $1.84 | 48 | oz | Great value Veggie oil |
| Onion, white, fresh, sliced | 0.5 | Cup | $0.78 | 1 | each | produce |

| | | | | | | |
|---|---|---|---|---|---|---|
| Pasta, spaghetti, cooked, not packed, enriched | 2/3 | Cup | $1.00 | 16 | oz | greeat value half-length |
| Peached, Canned, in heavy syrup | 0.25 | Cup | $1.38 | 8.5 | oz | Del monte sliced |
| Peanuts, salted, oil roasted | 20 | Each | $1.83 | 16 | oz | Great value dry roasted |
| Peas & carrots, canned, in liquid | 0.5 | Cup | $0.84 | 8.5 | oz | Del Monte Harvest selects |
| Pecans, salted, dry roasted | 8 | Oz | $4.47 | 7 | oz | Great value |
| Pork chop, blade loin, broiled, with bone, lean (Meas Raw Boneless) | 5 | Oz | $4.78 | 1 | lb | Pork chop center cut loin chops bonless |
| Salad dressing, caesar | 4 | Tbsp | $1.72 | 16 | oz | Kraft classic ranch |
| Salad dressing, ranch | 9 | Tbsp | $1.72 | 16 | oz | Kraft classic ranch |
| Sausage patty, beef & pork, cooked | 4 | Oz | $4.54 | 32 | oz | Banquet brown n serve |
| Seasoning, italian, Essence | 1 | Tbsp | $0.98 | 0.95 | oz | Great value |
| Soup, baked potato, Chunky, canned, with cheddar & bacon bits | 1 | Cup | $1.52 | 18.8 | oz | Campbell's |
| Sour cream, cultured | 2 | Tbsp | $1.38 | 8 | oz | Daisy Pure & natural |
| Soy sauce | 2 | Tbsp | $1.62 | 15 | oz | Great value naturally brewed |
| Squash, butternut, baked, cubes | 0.25 | Cup | $1.48 | 10 | oz | Great value canned |
| Tomato paste, canned, 6 oz | 0.5 | Tbsp | $0.42 | 6 | oz | Great value |
| Tomatoes, fresh, year round average, medium, 2 3/5" | 0.5 | Each | $0.91 | 1 | each | produce |
| Vegetables, stir fry, canned | 0.5 | Cup | $2.28 | 28 | oz | La Choy |

**Estimated Total for 1 Week:** $44.26
**Estimated Total for 4 Weeks:** $177.03

# Appendix F - HEI Calculator Instructions and Equations for DQ Analysis

Accredited to: (Joyce, 2018), with updated modifications.

HEI Calculator Instructions:

1. Sum all nutrients for each day to obtain a daily total for each nutrient.
2. Copy and paste HEI equations at the end of those sums.
3. Fill in the amounts at beginning of calculator – total fruit (c), whole fruit (c), total veg (c), dark green veg (c), whole grain (oz.), dairy (c), total protein (oz), seafood/ plant protein (oz.).
4. Score amounts at end of calculator using scoring scale below for fatty acid ratio, sodium, saturated fat, added sugar, and refined grains.

| FA Ratio | FA Score | Sodium | Na Score | Sat Fat | SF Score | Add. Sugar | AS Score | Refined Grain | RG Score |
|---|---|---|---|---|---|---|---|---|---|
| 2.5 | 10 | 1.1 | 10 | 8 | 10.0 | 6.5 | 10 | 1.8 | 10 |
| 2.4 | 9.1 | 1.2 | 9 | 8.5 | 9.0 | 7.5 | 9.5 | 2 | 9 |
| 2.3 | 8.4 | 1.3 | 8 | 9 | 8.4 | 8.5 | 9 | 2.25 | 8 |
| 2.2 | 7.7 | 1.4 | 7 | 9.5 | 7.8 | 9.5 | 8.5 | 2.5 | 7 |
| 2.1 | 7.0 | 1.5 | 6 | 10 | 7.2 | 10.5 | 8 | 2.75 | 6 |
| 2.0 | 6.3 | 1.6 | 5 | 10.5 | 6.6 | 11.5 | 7.5 | 3 | 5 |
| 1.9 | 5.6 | 1.7 | 4 | 11 | 6.0 | 12.5 | 7 | 3.25 | 4 |
| 1.8 | 4.9 | 1.8 | 3 | 11.5 | 5.4 | 13.5 | 6.5 | 3.5 | 3 |
| 1.7 | 4.2 | 1.9 | 2 | 12 | 4.8 | 14.5 | 6 | 3.75 | 2 |
| 1.6 | 3.5 | 2.0 | 1 | 12.5 | 4.2 | 15.5 | 5.5 | 4 | 1 |
| 1.5 | 2.8 | | | 13 | 3.6 | 16.5 | 5 | 4.25 | 0 |
| 1.4 | 2.1 | | | 13.5 | 3.0 | 17.5 | 4.5 | | |
| 1.3 | 1.4 | | | 14 | 2.4 | 18.5 | 4 | | |
| 1.2 | 0.7 | | | 14.5 | 1.8 | 19.5 | 3.5 | | |
| | | | | 15 | 1.2 | 20.5 | 3 | | |
| | | | | 15.5 | 0.6 | 21.5 | 2.5 | | |
| | | | | 16 | 0.0 | 22.5 | 2 | | |
| | | | | | | 23.5 | 1.5 | | |
| | | | | | | 24.5 | 1 | | |
| | | | | | | 25.5 | 0.5 | | |
| | | | | | | 26.5 | 0 | | |

5. Check that no scores at end of calculator (cell columns CN-CZ) are over the max HEI score for that component.
    a. Max scores = total fruit 5, whole fruit 5, total vegetable 5, dark green/ legume 5, whole grain 10, dairy 10, total protein foods 5, seafood/ plant proteins 5, fatty acid ratio 10, refined grain 10, sodium 10, added sugar 10, saturated fat 10
6. Check that HEI score (cell column BM) is not over 100.

HEI Calculator Equations:

*The Excel calculator requires three sets of cells to transform input data from nutrient analysis and menu into the HEI score. The three cells are consecutively linked and build off of each other.

General Cell Rationale:

1. First cell = amount of that nutrient of food group in the day
2. Second cell = (first cell)*1000/(cell with total calorie data from nutrient analysis)
    a. The HEI score is per 1000 calories, so the first cell must be standardized to 1000 calories using a ratio
3. Third cell = (second cell)/(amount to receive max score per HEI-2015)*(max score for the component)
    a. This is the actual score the day received for this HEI scoring component. Because we were unable to put a maximums or minimums on this equation, researchers needed to check all third cells to ensure that they did not exceed that HEI scoring components' max score (instructions #4 and #5 above).

Total Fruit:

1. First cell =  amount of total fruit served in the day in cups
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/0.8*5

Whole Fruit:

1. First cell = amount of whole fruit served in the day in cups
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/0.4*5

Total Vegetable:

1. First cell = amount of total vegetables served in the day in cups
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/1.1*5

Dark Green/ Legumes:

1. First cell = amount of dark green/ legume served in the day in cups
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/0.2*5

Whole Grain:

1. First cell = amount of whole grain served in the lunch in ounces
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/1.5*10

Dairy:

1. First cell = amount of dairy served in the day in cups
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/1.3*10

Total Protein:

1. First cell = amount of total protein served in the day in ounces
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/2.5*5

Seafood/ Plant Protein:

1. First cell = amount of seafood/ plant protein served in the day in ounces
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = (second cell)/0.8*5

Fatty Acid Ratio:

1. First cell = [(cell with amount of PUFA from nutrient analysis) + (cell with amount of MUFA from nutrient analysis)]/(cell with amount of saturated fat from nutrient analysis)
2. Second cell = (first cell)
3. Third cell = hand scored based on second cell value and table score (instruction #4 above)

Refined Grain:

1. First cell = (cell with amount of refined grains based on MyPlate guidelines, converted to oz)
2. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
3. Third cell = hand scored based on second cell value and table score (instruction #4 above)

Sodium:

4. First cell = (cell with amount of sodium from nutrient analysis)
5. Second cell = (first cell)*1000/(cell with calorie data from nutrient analysis)
6. Third cell = hand scored based on second cell value and table score (instruction #4 above)

Added Sugar:

1. First cell = (cell with amount of sugar added from nutrient analysis)*4/(cell with calorie data from nutrient analysis)*100
2. Second cell = (first cell)
3. Third cell = hand scored based on second cell value and table score (instruction #4 above)

Saturated Fat:

4. First cell = (cell with amount of saturated fat from nutrient analysis)*9/(cell with calorie data from nutrient analysis)*100
5. Second cell = (first cell)

6. Third cell = hand scored based on second cell value and table score (instruction #4 above)

# Appendix G - Samples of HEI Score Calculations

**1 Week, High Dietary Quality Meal Plan, 2000 kcals**

| HEI Component | Scoring Criteria | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---|---|---|---|---|---|---|---|---|
| **Calories** | | 2063.41 | 2043.72 | 1990.74 | 2006.22 | 2006.24 | 2009.63 | 2040.33 |
| **Total Fruit** | ≥ 0.8c/1000kcal | 3 | 3.06 | 4.71 | 2.01 | 2.34 | 2.33 | 3.06 |
| **Whole Fruit** | ≥ 0.4c/1000kcal | 5 | 5 | 5 | 3.12 | 4.67 | 4.67 | 3.06 |
| **Total Vegetables** | ≥1.1c/1000kcal | 5 | 5 | 5 | 5 | 5 | 3.64 | 5 |
| **Greens & Beans** | ≥0.2c/1000kcal | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Whole Grains** | ≥1.5oz/1000kcal | 4.46 | 4.50 | 0 | 10 | 4.82 | 1.92 | 0 |
| **Dairy** | ≥1.3c/1000kcal | 1.23 | 1.88 | 3.86 | 1.28 | 0.96 | 1.91 | 3.30 |
| **Total Protein Foods** | ≥2.5oz/1000kcal | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Seafood & Plant** | ≥0.8oz/1000kcal | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Fatty Acids** | (MUFA+PUFA) /SFA≥2.5 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **Refined Grains** | ≤1.8oz/1000kcal | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **Sodium** | ≤1.1g/1000kcal | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **Added Sugars** | ≤6.5% of energy | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **Saturated Fats** | ≤8% of energy | 4.2 | 3.6 | 1.8 | 3.0 | 3.6 | 2.4 | 1.8 |
| **Total Score** | 100 | 79.89 | 78.04 | 75.37 | 79.41 | 76.39 | 71.87 | 71.22 |

**1 Week, Low Dietary Quality Meal Plan, 2000 kcals**

| HEI Component | Scoring Criteria | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---|---|---|---|---|---|---|---|---|
| **Calories** | | 1928.33 | 2029.11 | 1994.68 | 2034.28 | 2019.75 | 1928.33 | 1969.81 |
| **Total Fruit** | ≥ 0.8c/1000kcal | 0.81 | 0.77 | 0.78 | 0.83 | 0.77 | 0.81 | 0 |
| **Whole Fruit** | ≥ 0.4c/1000kcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Vegetables** | ≥1.1c/1000kcal | 52.36 | 2.80 | 2.85 | 1.26 | 5 | 2.36 | 5 |
| **Greens & Beans** | ≥0.2c/1000kcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Whole Grains** | ≥1.5oz/1000kcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Dairy** | ≥1.3c/1000kcal | 1 | 0.95 | 1.93 | 0.95 | 1.90 | 1 | 1.95 |
| **Total Protein Foods** | ≥2.5oz/1000kcal | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Seafood & Plant** | ≥0.8oz/1000kcal | 5 | 0 | 5 | 5 | 5 | 5 | 5 |
| **Fatty Acids** | (MUFA+PUFA) /SFA≥2.5 | 0.7 | 0.7 | 2.1 | 5.6 | 6.3 | 0.7 | 7.7 |
| **Refined Grains** | ≤1.8oz/1000kcal | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **Sodium** | ≤1.1g/1000kcal | 10 | 5 | 10 | 0 | 10 | 10 | 2 |
| **Added Sugars** | ≤6.5% of energy | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **Saturated Fats** | ≤8% of energy | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Score** | 100 | 44.86 | 35.22 | 47.66 | 38.63 | 53.98 | 44.86 | 46.65 |

# Appendix H - Sample of a Scaled Standardized Menu

**Day 2 for the High Dietary Quality Meal Plan**

| Food item | Measure | 1600cal | 1800cal | 2000cal | 2200cal | 2300cal | 2400cal | 2800cal |
|---|---|---|---|---|---|---|---|---|
| zucchini, boiled, from frozen | Cup | 0.8 | 0.9 | 1 | 1.1 | 1.15 | 1.2 | 1.4 |
| walnuts, english, dried, halves | Each | 12.8 | 14.4 | 16 | 17.6 | 18.4 | 19.2 | 22.4 |
| strawberries, fresh, sliced | Cup | 0.8 | 0.9 | 1 | 1.1 | 1.15 | 1.2 | 1.4 |
| spread, buttery, with omegas | Tbsp | 2.4 | 2.7 | 3 | 3.3 | 3.45 | 3.6 | 4.2 |
| salmon, pink, baked, fillet | Oz | 2.4 | 2.7 | 3 | 3.3 | 3.45 | 3.6 | 4.2 |
| salad dressing, asian sesame | Tbsp | 1.6 | 1.8 | 2 | 2.2 | 2.3 | 2.4 | 2.8 |
| peanut butter, creamy, natural, unsalted | Tbsp | 0.8 | 0.9 | 1 | 1.1 | 1.15 | 1.2 | 1.4 |
| oil, sesame, salad or cooking | Tsp | 4 | 4.5 | 5 | 5.5 | 5.75 | 6 | 7 |
| oil, olive | Tsp | 1.6 | 1.8 | 2 | 2.2 | 2.3 | 2.4 | 2.8 |
| oil, canola | Tsp | 5.6 | 6.3 | 7 | 7.7 | 8.05 | 8.4 | 9.8 |
| mushrooms, cooked, from fresh | Cup | 0.2 | 0.225 | 0.25 | 0.275 | 0.2875 | 0.3 | 0.35 |
| milk, whole, 3.25%, with vitamin D | Cup | 0.4 | 0.45 | 0.5 | 0.55 | 0.575 | 0.6 | 0.7 |
| lettuce, romaine, fresh, shredded | Cup | 1.2 | 1.35 | 1.5 | 1.65 | 1.725 | 1.8 | 2.1 |
| egg, cooked, large | Each | 0.8 | 0.9 | 1 | 1.1 | 1.15 | 1.2 | 1.4 |
| cucumber, fresh, with skin, sliced | Cup | 0.2 | 0.225 | 0.25 | 0.275 | 0.2875 | 0.3 | 0.35 |
| celery stalk, fresh, medium, | Each | 0.8 | 0.9 | 1 | 1.1 | 1.15 | 1.2 | 1.4 |
| cabbage, boiled, drained, shredded | Cup | 0.4 | 0.45 | 0.5 | 0.55 | 0.575 | 0.6 | 0.7 |
| Broth, beef, low sod | Cup | 1.2 | 1.35 | 1.5 | 1.65 | 1.725 | 1.8 | 2.1 |
| bread, multigrain, whole grain | Slice | 1.2 | 1.35 | 1.5 | 1.65 | 1.725 | 1.8 | 2.1 |
| beef flank steak, broiled, 0" trim | Oz | 1.6 | 1.8 | 2 | 2.2 | 2.3 | 2.4 | 2.8 |
| avocado, fresh | Each | 0.2 | 0.225 | 0.25 | 0.275 | 0.2875 | 0.3 | 0.35 |

# Appendix I - Ketogenic Diet Compliance Checklist

**4 Weeks, High Dietary Quality Meal Plan, 2000 kcals**

# Did I Exceed the Daily Grams of Carbohydrate?

Subject ID: _____

| Week 1: _____ | | Week 2: _____ | | Week 3: _____ | | Week 4: _____ | |
|---|---|---|---|---|---|---|---|
| **Day 1 (72.52g)** | | **Day 1 (72.52g)** | | **Day 1 (72.52g)** | | **Day 1 (72.52g)** | |
| | Less than | | Less than | | Less than | | Less than |
| | Exact | | Exact | | Exact | | Exact |
| | More than | | More than | | More than | | More than |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ |
| **Day 2 (70.41g)** | | **Day 2 (70.41g)** | | **Day 2 (70.41g)** | | **Day 2 (70.41g)** | |
| | Less than | | Less than | | Less than | | Less than |
| | Exact | | Exact | | Exact | | Exact |
| | More than | | More than | | More than | | More than |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ |
| **Day 3 (66.13g)** | | **Day 3 (66.13g)** | | **Day 3 (66.13g)** | | **Day 3 (66.13g)** | |
| | Less than | | Less than | | Less than | | Less than |
| | Exact | | Exact | | Exact | | Exact |
| | More than | | More than | | More than | | More than |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ |
| **Day 4 (75.78g)** | | **Day 4 (75.78g)** | | **Day 4 (75.78g)** | | **Day 4 (75.78g)** | |
| | Less than | | Less than | | Less than | | Less than |
| | Exact | | Exact | | Exact | | Exact |
| | More than | | More than | | More than | | More than |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ |
| **Day 5 (75.08g)** | | **Day 5 (75.08g)** | | **Day 5 (75.08g)** | | **Day 5 (75.08g)** | |
| | Less than | | Less than | | Less than | | Less than |
| | Exact | | Exact | | Exact | | Exact |
| | More than | | More than | | More than | | More than |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ |

| Day 6 (72.24g) | | Day 6 (72.24g) | | Day 6 (72.24g) | | Day 6 (72.24g) | | |
|---|---|---|---|---|---|---|---|---|
| | Less than | | Less than | | Less than | | Less than | |
| | Exact | | Exact | | Exact | | Exact | |
| | More than | | More than | | More than | | More than | |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | |
| | | | | | | | | |
| **Day 7 (87.31g)** | | **Day 7 (87.31g)** | | **Day 7 (87.31g)** | | **Day 7 (87.31g)** | | |
| | Less than | | Less than | | Less than | | Less than | |
| | Exact | | Exact | | Exact | | Exact | |
| | More than | | More than | | More than | | More than | |
| | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | | Over by how much?: _____ | |

Resources: chronometer, myfitnesspal, myplate.com

# Appendix J - Ketone Level Log Sheet

## Ketone Log

Week:_____ Participant ID: _____

Procedure: Urine Test for Ketones ***Measure in the Morning***

1. Remove the strip from bottle. Do not touch the test area of the strip.
2. Pass the test end of the strip through a stream of urine.
3. Begin timing.
4. At EXACTLY 15 SECONDS, match the test area to the ketone color chart, ignore color changes that occur after 15 seconds. **Record the result.**

| Date: | Time: | Ketone Level: | Notes |
|---|---|---|---|
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# Appendix K - Ketogenic Diet Confidence Scale

Ketogenic Diet Confidence Scale

**INSTRUCTIONS:** Read this information on following a diet, then answer all questions by filling in the circle that goes with your answer.

**A ketogenic diet** is a low-carbohydrate (<50 g CHO per day), high-fat diet that alters the balance of energy use toward higher amounts of fat and ketone bodies. (Feinman et al., 2015)

**In short term**, people following a **ketogenic diet** might experience negative consequences (fatigue, hunger, flu-like symptoms).
**In the longer term**, people will adapt, and health outcomes will be positive, particularly regarding metabolic health. (Harvey et al., 2019)

| | Not at all Sure | Somewhat Sure | Very Sure |
|---|---|---|---|
| **A.** How sure are you that you can maintain a ketogenic diet for 1 week? | ○ | ○ | ○ |
| **B.** How sure are you that you can maintain a ketogenic diet for 4 weeks? | ○ | ○ | ○ |
| **C.** How sure are you that you can maintain a ketogenic diet for 6 months? | ○ | ○ | ○ |
| **D.** How sure are you that you can maintain a ketogenic diet as a lifestyle? | ○ | ○ | ○ |

What are some common barriers you think may occur while following this diet?
*For example: I don't think I will be able to follow this diet because I will lose motivation.*

Follow Up Ketogenic Diet Confidence Scale

**INSTRUCTIONS:** Read this information on following a diet, then answer all questions by filling in the circle that goes with your answer.

**A ketogenic diet** is a low-carbohydrate (<50 g CHO per day), high-fat diet that alters the balance of energy use toward higher amounts of fat and ketone bodies. (Feinman et al., 2015)

**After completing this 4-week intervention, how confident are you to maintain a ketogenic diet?**

| | **Not at all Sure** | **Somewhat Sure** | **Very Sure** |
|---|---|---|---|
| **E.** How sure are you that you can maintain a ketogenic diet for 1 week? | ○ | ○ | ○ |
| **F.** How sure are you that you can maintain a ketogenic diet for 4 weeks? | ○ | ○ | ○ |
| **G.** How sure are you that you can maintain a ketogenic diet for 6 months? | ○ | ○ | ○ |
| **H.** How sure are you that you can maintain a ketogenic diet as a lifestyle? | ○ | ○ | ○ |

What were some common barriers you came across while following this diet?

Why do you think these barriers occurred?

Is the ketogenic diet something you would want to continue following?
Yes No