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Nutritional Adequacy Comparison of Paleo and Healthy U.S. Dietary Patterns Followed by
Athletic Adults

by

Emily L. Sherwood

Thesis

Submitted to the Department of Health Sciences

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in

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Thesis Committee:

John Carbone, Ph.D., RD, Chair

Stefan M. Pasiakos, Ph.D.

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Abstract

The Paleo diet has become popular for promoting good health, but there is little available research on its nutritional adequacy or its long-term effects. The present literature review explores the strengths and limitations of the research on health-related outcomes and nutritional adequacy derived from following a Paleo dietary pattern. An original pilot study is also presented which uses survey and diet journal data to qualitatively explore the nutritional adequacy of the Paleo diet and the Healthy U.S.-style Pattern (HUS) recommended within the Dietary Guidelines for Americans as followed through self-adherence in an American population. Analysis of week-long diet journals of six healthy, physically active, young adults (HUS, $n = 4$; Paleo, $n = 2$) showed similar dietary quality between the groups with sub-optimal intake of several micronutrients. Nutritional adequacy for the Paleo participants could be improved with increased vegetable and fruit intake, daily inclusion of calcium fortified nut-milks, and leaner protein sources.

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Chapter 1: Introduction and Background

Introduction

Diet-related chronic diseases and the epidemic of obesity continue to plague the United States and burden the health-care system. Additionally, the growing global population combined with the environmental effects of mass food production presents the challenge of finding sustainable production methods. The Dietary Guidelines for Americans Committee addressed these problems in the currently implemented 8th edition of the *Dietary Guidelines for Americans* (DGA) by recommending actions on the individual and community levels to shift toward more healthful and sustainable eating patterns. Among the suggested actions for individuals are to gradually adjust eating habits towards one of the recommended healthy and sustainable dietary patterns; engage in physical activity to balance energy for weight-maintenance within a healthy range; and utilize the services of health, exercise, behavioral, and nutritional interventions as needed to make positive lifestyle changes.¹ On the community level, it is recommended that policy and initiatives be put in place to make healthcare and healthful foods more accessible to people in need, to support ecologically sustainable food systems, and to shift the healthcare model to one of prevention with special emphasis on evidence-based nutrition services.¹ Registered dietitians (RDs) should play an integral part in delivering evidence-based nutrition services to the American population under the DGA recommendations, which requires a full understanding of the nutritional adequacy, health outcomes, and sustainability of the DGA recommended dietary patterns. However, RDs must also maintain competency of other common dietary patterns and trends that pique public interest in order to effectively address their clients' questions about popular diets, make scientifically sound recommendations to mitigate gaps between individual dietary preferences and DGA objectives, and continue to research alternative

dietary patterns that may sufficiently meet these objectives so that they may be considered for review in future editions of the DGA. The Paleo diet is one such dietary pattern that has generated public interest and may potentially meet some DGA objectives.

The Paleo Diet

The Paleolithic Diet, alternately called the Caveman diet, the Stone Age diet, or simply the Paleo diet, has been popular in recent years, especially among the athletic community. The ideological principle behind the Paleo Diet is that humans are experiencing evolutionary discordance, meaning that the human genome evolved under very different conditions than those experienced today, and post-Neolithic eating patterns are not compatible with this genome.² Proponents of the Paleo diet claim that this dietary incompatibility is the root cause for the epidemics of chronic diseases in Westernized countries and that better health can be achieved by eating a diet similar to hunter-gatherer groups that lived prior to the Neolithic revolution.² The foods that are promoted in the Paleo dietary pattern include meats from naturally grazed animals, fish/seafood, fresh fruits and vegetables, eggs, seeds, tree nuts, and unrefined oils. Foods that are to be avoided on this diet are all cereal grains, legumes, dairy, potatoes, salt, processed foods, and refined sugars and oils.³ Though the evolutionary approach to formulating dietary recommendations is unique to the Paleo diet, the foods it promotes and the underlying goal of reducing the risk of developing chronic disease are analogous to the DGA-recommended dietary patterns.

Recommended Dietary Patterns

The 2015 DGA committee reviewed data from the *What We Eat in America*/National Health and Nutrition Examination Survey (WWEIA NHANES) 2009-10 to identify trends in nutritional intake. The committee compared nutritional analyses of reported intake on these

surveys against standards such as estimated average requirement (EAR) and adequate intake (AI), established by the Food and Nutrition Boards of the Institute of Medicine (IOM), to identify and categorize nutrients of public health concern into two groups: (a) nutrients at risk of being under consumed and (b) nutrients at risk of being over consumed. Representative foods from these surveys were also used to determine weighted averages of nutrient content of food groups so that recommendations for consumption of each food group more accurately reflect the nutrient density of the foods that Americans are eating.⁶ For instance, the required serving size of vegetables to meet recommended dietary allowances (RDAs) would be quite different if the vegetables consumed are relatively nutrient-sparse such as iceberg lettuce, corn, and celery as opposed to nutrient-dense selections such as kale, broccoli, and carrots.

Clinical studies were reviewed by the DGA committee to find dietary patterns with strong evidence for reducing risk factors and occurrence of major chronic diseases. Additionally, factors such as sustainability and physical activity as well as eating behaviors, such as meal skipping and supplementation, were reviewed and considered. The major limitation of the review was that the *WWEIA* NHANES surveys rely heavily on food frequency questionnaires and 24-hour recalls, which are not completely accurate methods for reflecting actual intake due to self-reporting bias and forgetting some foods or serving sizes. Another limitation is that many of the dietary intervention studies that were reviewed to determine good health outcomes used methods to increase compliance such as supplying food or coaching participants, so they do not represent typical free-living dietary patterns.

The compilation of the committee's review resulted in choosing three distinct eating patterns to be recommended in the 8th edition of the DGA as nutritionally adequate, supportive of good health outcomes, and sustainable: "Healthy U.S.-style Pattern," "Healthy Mediterranean-

style Pattern,” and “Healthy Vegetarian Pattern.” Guides for consumption within each food group were developed for each of these eating patterns for 12 caloric levels.⁵ There are differences in the proportion of foods recommended within each food group across the three dietary patterns. For instance, the Healthy Vegetarian Pattern does not include foods from the meat/poultry or seafood groups, but it does include more portions of legumes, soy products, nuts and seeds, and whole grains. The Healthy-Mediterranean Style Pattern includes fewer portions of dairy foods but more fruit and seafood. The Healthy U.S.-style Pattern is similar to the previous 2010 USDA recommended diet in that it does not exclude any food groups, but this pattern is also modeled after the Dietary Approaches to Stop Hypertension (DASH) diet with emphasis on consuming less-processed and more nutrient-dense options within each food group.⁶

Comparison between the Paleo diet and DGA diets. There are some interesting similarities and differences between the Paleo dietary pattern and those recommended in the DGA. The most significant similarity is that the Paleo diet and the DGA dietary patterns all emphasize consumption of nutrient-dense, minimally processed foods. Like the Healthy Vegetarian Pattern, the Paleo diet is defined by which foods are excluded as much as by which foods are included. However, the exclusion pattern in the Paleo diet is reversed from the Healthy Vegetarian Pattern; most of the foods that are increased (whole grains, legumes, and soy) to make up for the exclusion of protein from animal sources are excluded on the Paleo diet with a direct increase in calories from meat, poultry, and seafood. The Paleo diet has some similarities to the Healthy-Mediterranean Style Pattern in that they both encourage higher consumption of fruit and seafood than other diets; however, the Paleo diet encourages a greater amount of these two foods with about 15% of total calories recommended from fruit and 27.5% of calories from seafood.⁶ The Paleo diet’s macronutrient and food group recommendations are based on dietary

intake patterns from modern hunter-gatherer groups,⁷ meaning contemporary societies around the world who presently practice hunting and gathering for food acquisition, as opposed to ancient groups that lived prior to the Neolithic revolution. Conversely, the food group proportions for the DGA diets were designed with the underlying goal of keeping nutrients within the IOM recommendations using consumption and purchasing data from the *WWEIA* NHANES as a guide. Micronutrient goals in the three DGA dietary patterns are mostly met, but as with previously recommended USDA diets the projected intake of potassium, vitamin D, vitamin E, and choline fall short of RDA and AI levels. Additionally, the Healthy-Mediterranean Style Pattern provides adequate calcium at 2000 calories per day to meet the RDA for younger adults, but it would not meet the recommended intakes for adolescents and adults over 50 years of age.^{4,6} Very limited data is currently available for the nutritional adequacy of the Paleo diet, as no large observational studies have yet been conducted to assess consumption trends for people following this diet. See Table 1 for a summary of characteristics and nutrient quality of the three DGA recommended dietary patterns and the Paleo diet. Some of the nutrients with projected intake values below the RDA and AI levels on these diets are associated with deficiency symptoms following long-term low intake. For instance, one possible consequence of long-term low intake of vitamin D, calcium, and potassium is decreased bone density, since vitamin D and calcium are necessary for healthy bone-remodeling and low potassium intake increases bone turnover and calcium excretion.⁸⁻¹⁰ Certain age groups of females and elite female athletes are at higher risk of decreased bone density, especially those at risk of the female athlete triad.⁹ Athletes of both sexes benefit from adequate thiamin, folate, and iron intake due to these nutrients' roles in energy metabolism and red blood cell formation.¹¹⁻¹³ Many of these nutrients have implications for reproductive health as well; pregnancy complications or impaired fetal and

neonatal development have been associated with low intakes of choline, iodine, iron, and folate.¹²⁻¹⁵ Regular inclusion of foods that are high in these key nutrients is advisable for most individuals, but may be especially important for women of child-bearing age and athletes. See Table 2 for a summary of deficiency symptoms and high content foods sources of these nutrients.

Table 1: Summary of Dietary Patterns

Dietary Pattern	Included Food Groups	Reduced or Excluded Food Groups	Nutrients of Concern for Deficiency*
Healthy U.S.-style Pattern ⁴ (Used as base of comparison for other diet patterns.)	Nutrient dense options from all food groups included, at least half of all grain products whole grain.	Minimizes processed/ refined foods.	Potassium ~71% AI, Vitamin E ~68% RDA, Vitamin D ~6% RDA, Choline ~82% AI
Healthy Mediterranean Pattern ^{6, 18}	Nutrient dense options from all food groups included, at least half of all grain products are whole grain. Increased inclusion of fruit and seafood.	Reduced inclusion of dairy. Minimizes processed/ refined foods.	Potassium ~71% AI, Vitamin E ~70% RDA, Vitamin D ~42% RDA. Choline ~81 % AI. Calcium may be insufficient for adolescents and adults older than 50 years.
Healthy Vegetarian Pattern ^{6, 19}	Vegetables, fruits, dairy or dairy alternatives, and eggs (optional). Increased inclusion of legumes, soy products, nuts and seeds, and whole grains.	Excludes meat, poultry, and seafood. Minimizes processed/ refined foods.	Potassium ~70% AI, Vitamin E ~37 % RDA, Vitamin D ~42% RDA. Choline ~66% AI.
Paleo Pattern ³	Meat, poultry, seafood, fruit, vegetables, eggs, seeds, tree nuts, and unrefined oils.	Excludes cereal grains, legumes, dairy, potatoes, and salt. Minimizes processed/refined sugars, oils, and foods.	Vitamin D, Calcium, and Iodine. Very limited data available. Unknown values for choline, copper, manganese, selenium, and Vitamin K. [†]
RDA: Recommended Dietary Allowance, the level at which 97-98% of healthy people will meet nutrient needs.			
AI: Adequate Intake, a level which is assumed to be nutritionally adequate, set when RDA cannot yet be established with current evidence.			
† See "Nutritional Adequacy of the Paleo Diet" section in Chapter 2.			
*Based on nutrient needs of females aged 19-50 years on a 2000 kcal/day diet. ¹⁷			

Table 2: Deficiency Symptoms and Dietary Sources of Key Nutrients⁸⁻¹⁶

Nutrient	Insufficiency Symptoms	Deficiency Symptoms	High Content Food Sources
Potassium	Increase blood pressure, kidney stone risk, bone turnover, urinary calcium excretion	Mild hypokalemia: constipation, fatigue, muscle weakness, and malaise. Severe hypokalemia rare in health individuals	Dried fruit, fresh fruits and vegetables, lentils, beans, soy, milk, yogurt, chicken breast, salmon, beef
Vitamin E	Not observed in healthy people even with low dietary intake	People with fat malabsorption: peripheral neuropathy, ataxia, skeletal myopathy, retinopathy, impaired immune response	Wheat germ, seeds, nuts, peanuts, oils, spinach, broccolis, kiwi, mango, tomato
Vitamin D	Low bone density, inflammation, impaired immune response, glucose metabolism, cell proliferation	Rickets in children, osteomalacia in adults, hypocalcemic seizures, tetanic spasms, cardiomyopathy, dental abnormalities	Fatty fish, beef liver, fortified milk/dairy alternatives, mushrooms, egg yolk
Choline	Rare even with low dietary intake except among pregnant or lactating women	Neurological disorders, hepatic abnormalities in conditions of impaired absorption. Toxicity risk with excess.	Beef liver, egg, soybeans, chicken, beef, codfish, potatoes, wheat germ, milk, quinoa, kidney beans, cruciferous veggies
Calcium	No short term symptoms due to bone reabsorption. Adequate intake crucial if risk of "female athlete triad"	Long term: osteopenia, osteoporosis	Dairy/fortified dairy alternatives, fish canned with bones, tofu, leafy greens
Iodine	Impaired immune response and thyroid hormone production, increased risk in pregnancy/lactation	Goiter, miscarriage, Irreversible neurodevelopmental deficits in fetuses or newborns	Seaweed, cod, breads w/iodated dough conditioner, oysters, milk, iodized salt, eggs, shrimp
Thiamin	Muscle weakness, weight loss, anorexia, confusion, short-term memory loss	Beriberi, Wernicke-Korsakoff syndrome with chronic alcohol abuse	Fortified/enriched grains, black beans, pork, trout, tuna, mussels, acorn squash, rice, oats, barley, corn, sunflower seeds, beef steak,
Iron	Common, especially in women. Bone marrow depletion, reduced erythrocyte production, transferrin saturation decline	Hematocrit and hemoglobin decline resulting in microcytic, hypochromic anemia. Pregnancy complications, impaired growth/development	Fortified/enriched grains, beans, lentils, tofu, stewed canned tomatoes, beef, potato, chicken, cashew, broccoli, spinach, peas, raisins, eggs
Folate	Weakness, fatigue, difficulty concentrating, irritability, headache, heart palpitations, and shortness of breath	Megaloblastic anemia, increased risk neuro-tube defects/preterm birth/low birth weight	Beef liver, leafy greens , enriched grains, rice, black-eyed peas, asparagus, Brussels sprouts, avocado, broccoli, peas, crab

A very significant difference between the Paleo diet and the DGA dietary patterns is the distribution of calories across macronutrients. Though there is no consensus Paleo diet, the macronutrient distribution ratios recommended by Cordain³ are commonly referenced in academic articles; the energy from protein and fat are much higher and the energy from carbohydrates much lower on the Cordain-defined Paleo diet than the acceptable macronutrient

distribution range (AMDR) set for the three DGA recommended dietary patterns. See Table 3 for a comparison of the projected macronutrient values of these dietary patterns.

Table 3: Macronutrient Intake Recommendations by Dietary Pattern

	RDA & AMDR Goals	Healthy Vegetarian	Healthy Med-Style	Healthy US-Style	Paleo
Kcal	2200	2202	2203	2198	2203
Total Protein (g)	56 g	76 g	98 g	100 g	217 g
% of RDA	100%	136%	175%	179%	388%
% of Energy	10-35%	13%	17%	18%	38%
Total Carbohydrate (g)	130 g	306 g	289 g	286 g	129 g
% of RDA	100%	235%	222%	220%	99%
% of Energy	45-65%	54%	52%	51%	23%
Total Fat (g)	48-85 g	82 g	78 g	78 g	100 g
% of Energy	20-35%	33%	31%	31%	39%
Saturated Fat DGA Limit	<10% energy	8%	8%	8%	7%
Total Dietary Fiber (g)	30.8 g	40 g	36 g	35 g	42.5 g
% of Goal (14 g/1000kcal)	100%	130%	117%	114%	138%
Values for Healthy Vegetarian, Healthy Med-Style, and Healthy US-Style Patterns from RDA for 2200 calorie level. RDA & AMDR for a male 31-50 years of age. ¹⁷⁻¹⁹ Paleo values obtained from Cordain. ³					

Due to its recent popularity, there has been a surge of research and literature assessing the Paleo diet from a variety of approaches.^{7, 20-31} The questions of whether there was a “typical” Paleolithic diet, what that diet was comprised of, and whether eating in that way is feasible for people in the modern world are all topics of academic articles and reviews. Additionally, there have been trials comparing the results of following a Paleo style diet against other therapeutic diets in reducing various chronic disease markers, inflammation, and achieving weight loss.³²⁻⁴⁴ In spite of the academic interest that the Paleo diet has generated, there has been very little research assessing its nutritional adequacy. More specifically, no research has been conducted comparing the nutritional adequacy of the Paleo diet to the DGA recommended diets. The limitations of the existing data and how it relates to the current study are summarized below, and

a detailed description of the cumulative body of information on the Paleo diet follows in the literature review.

Statement of the Problem

The existing research has assessed the Paleo diet in a variety of ways to include both observational studies of modern hunter-gatherer groups and controlled trials in Westernized-civilizations. Many of the formative articles on the Paleo diet focus on arguing for or against the application of evolutionary discordance theory,^{28,29} developing a macronutrient energy ratio based on modern hunter-gatherer diets,⁷ and comparing chronic disease occurrence in Westernized society against that of hunter-gatherer groups.³⁰ Though these studies are interesting academically, they do not help with the practical application of identifying trends for nutrient excesses and deficiencies or making food group recommendations. More recent clinical studies have compared results of the Paleo diet as a dietary intervention against other therapeutic diets for obesity and bioindicators of chronic disease.³²⁻⁴⁴ These studies are useful for determining health outcomes of the Paleo diet, but they have the limitation that intervention methods to increase compliance, such as providing meals or education, do not accurately represent anticipated intakes without such methods. If the Paleo diet is to ever be considered as a dietary pattern recommended by health officials, or contrariwise to be dismissed as nutritionally inadequate, then there must be more observational studies, surveys, and food frequency questionnaires reviewing intake trends of free-living, self-identified Paleo followers. Such data could be used to assess the nutritional adequacy of the diet and formulate appropriate dietary recommendations.

Purpose of the Study

This study examines the Paleo diet in a way that is lacking in the existing literature by comparing the nutritional adequacy of this eating pattern against a current DGA-recommended diet as they are followed by healthy, physically active people in their everyday lives without intervention. The study compares the nutrition analyses of seven-day intake histories for healthy, athletic adults who regularly follow a Paleo diet pattern against those who follow a Healthy U.S.–style Pattern. Comparing these data against the dietary reference intake (DRI) standards set by the Institute of Medicine will help to establish an understanding of whether nutritional adequacy of the Paleo diet deviates significantly from that of dietary patterns recommended in the DGA when followed by self-adherence without intervention methods.

Significance and Justification of the Study

This study is important to the discipline of dietetics because it provides a foundation on which nutrition professionals can make evidence-based recommendations for clients who wish to follow a Paleo dietary eating pattern. The Paleo diet has become a popular diet for weight loss, general wellness, and athletic performance; and though clients may have questions about which foods to include and in what proportions, there is little available research on which nutrient deficiencies and excesses may become present on this diet. Nutrient analyses of people who follow the Paleo diet through self-adherence may provide a point of reference on its nutritional adequacy until larger observational studies and surveys are conducted. Lastly, this study aims to initiate the question as to whether specified food group recommendations for a Paleo diet pattern should be considered for review in future editions of the DGA.

Chapter 2: Review of Related Literature

The purpose of this review is to present an understanding of the existing research on the Paleo diet's effect on chronic disease risk factors and nutrient intake. An overview of the literature arguing for and against evolutionary discordance is also provided. The present literature review was conducted using Medline and PubMed databases. Reviewed articles include metabolically or diet-controlled trials published in academic journals which compare the effects of the Paleo diet on health outcomes against those at baseline or those achieved on healthful diets recommended by the DGA or by similar foreign dietary committees for their respective countries. The literature was also reviewed for dietary analyses that determined average macro- and micronutrient consumption of study participants following the Paleo diet, and though this was not the primary objective of any of the reviewed studies, some did provide a minimal nutrition analysis of their participants' diet logs.

Evolutionary Rationale for the Paleo Diet

Evolutionary discordance occurs when a species' genome is well adapted to their environmental conditions and an abrupt, permanent change in that environment disrupts the stability, often resulting in increased morbidity, mortality, and impaired reproductive success.² The ideological concept of the Paleo diet invokes evolutionary discordance to affirm that humans have adapted to thrive on a dietary pattern characteristic of the hunter-gatherer period of their evolution, and dietary changes that have occurred since the Neolithic revolution are the primary cause for the increased prevalence of chronic diseases in Westernized cultures compared to that of modern hunter-gatherer societies. If this position is correct, then there could be little room for argument that to achieve good health outcomes people must conform to a dietary pattern specific to the time and place that they evolved for. However, this argument is primarily theoretical, there

is limited evidence to substantiate the conclusions, and some of the rhetoric used to support it is logically flawed. For instance, in one criticism of post-agricultural diets, Cordain et al. state, “Although dairy products, cereals, refined sugars, refined vegetable oils, and alcohol make up 72.1% of the total daily energy consumed by all people in the United States, these types of foods would have contributed little or none of the energy in the typical preagricultural hominin diet.”² This statement is used to emphasize the necessity of eliminating agriculturally derived food groups by erroneously implying that a highly processed, energy-dense, nutrient-sparse diet is synonymous with an agriculturally based diet. Taking a position that humans are not adapted to include any post-Neolithic food groups is very different from stating that humans are not adapted to consume a majority of their calories from highly refined nutrient-sparse foods. So there needs to be a distinction between food of varying nutrient quality when discussing the possibility of evolutionary discordance, rather than relying on examples of overconsumption of the least nutritious foods to justify eliminating entire food groups. Another logical flaw is that ascribing evolutionary discordance to agriculture ignores evidence that the Neolithic revolution improved reproductive success among humans. One commonality observed by anthropologists across societies that adopted agricultural methods is population growth and reduced mortality.⁴⁵ If agriculturally derived foods were at odds with the human genome, the opposite effect would be expected. Cultivation of crops was implemented in diverse ways on every continent that held ancient societies with the exception of Australia,⁴⁵ and how this adaptation subsequently affected nutritional quality and life expectancy is dependent on many genetic, societal, technological, environmental, and occupational variables. Without research to control for these variables, ascribing evolution discordance with agricultural food groups as the primary cause of chronic diseases is speculative and an over simplification of diversity in humans and agriculture.

Finally, if it were true that humans are experiencing evolutionary discordance and should revert to eating in accordance with pre-Neolithic patterns, then the diets of ancient hunter-gatherers rather than modern hunter-gatherers should be emulated. Many anthropological studies have been conducted to gather data on the dietary habits of early hominins and pre-Neolithic humans.^{20-22, 46-61} These studies primarily use carbon isotopes to trace nutrient sources in bone, scarring on mandible fossils, and assessment of pre-Neolithic tool fossils for clues about the hunting and food preparation capabilities of early humans. The logical method for formulating a Paleo diet would utilize this data to recommend foods that were being consumed during that phase in human evolution. However, the Paleo diet is primarily based on average macronutrient distribution ratios derived from modern hunter-gatherer diets, translated into foods that can be easily purchased in Western societies.^{3, 7, 30} The anthropological evidence shows that the modern interpretation of the Paleo diet is not an accurate portrayal of ancient dietary habits or nutrient composition.

An alternative perspective to evolutionary discordance is that humans have adapted for dietary flexibility rather than for a specific time, place, and lifestyle in the course of human evolution. Turner and Thompson point out that evolutionary discordance theory erroneously relies on the assumption that there was a fairly universal diet at some point in humanity's past. It also presupposes that the universal diet was selected through genetic or instinctual mechanisms, and that any evolutionary changes that have occurred within the past twelve-thousand years since the Neolithic revolution are not significant enough to warrant change in this diet.³¹ Anthropological and genomic evidence do not support these assumptions. Though some eating preferences such as aversion to bitter tastes are genetically based, these preferences are often overridden by social and environmental factors. Food selection is strongly influenced by social

learning and even influenced *in utero* by maternal food choices.^{31, 62} Several studies have shown that fetal nutrition also alters gene expression relating to metabolism.⁶³⁻⁶⁵ Through these mechanisms, hunter-gatherer groups occupied a variety of dietary niches, expressing biological adaptation even within individual lifetimes to match availability of food within their environment. Additionally, humans have evolved in significant ways since the Neolithic revolution such as the number and variation of genes that code for lactase and amylase.⁶⁶⁻⁶⁸ These data are more supportive of niche construction theory, which proposes that humans influence their evolutionary change by altering their environments and behavior.³¹ Niche construction seems to better explain the variation that can be observed in modern hunter-gatherer groups than evolutionary discordance. For instance, Cordain et al. attempted to define a standard Paleo diet macronutrient distribution ratio by averaging the intake patterns of modern hunter-gatherer groups,^{7, 30} but the variation between the reviewed groups undermines the starting premise that it is necessary to adopt a uniform dietary pattern characteristic of pre-Neolithic evolution to achieve good health. The majority of pre-Neolithic human evolution took place in Africa, where five out of six of the reviewed hunter-gatherer populations consumed the majority of their calories from plants.³⁰ However, dietary data from specialized population groups in extreme temperatures such as the Eskimo of Greenland and the Nunamiut of Alaska, who consume 96% and 99% of their calories from animal food, respectively, were also included in the review because of their similarly low incidence of cardiovascular disease. The fact that these groups were able to migrate to such a vastly different environment than the one they initially evolved to, adopt a new dietary niche, and have good health under these conditions supports niche construction theory and discredits evolutionary discordance.

In the existing literature, arguments for niche construction and evolutionary discordance

as they pertain to dietary adaptation are presented as if these concepts are mutually exclusive. In actuality, the two concepts can be partially true simultaneously, and together they may represent human evolution better than either could individually. Humans may have evolved to be highly adaptive, occupy a variety of environmental and dietary niches, and influence their own evolution through culture, learned behavior, and tools while also experiencing evolutionary discordance when the severity and/or speed of an environmental change surpassed their high adaptability. When dietary evolution is considered through this perspective, prescribing a dietary pattern specific to one time and place in human evolution for everyone is not desirable. Instead, dietary habits should be evaluated individually for how they affect nutrition goals and health outcomes with the understanding that results may be different from one population to another based on the evolutionary trajectory and dietary niches represented in each group. Evolutionary discordance may be present with a diet or lifestyle condition in one population group while another group could thrive under the same conditions. A variety of dietary patterns may yield good health outcomes, but they may not have interchangeable results for all population groups, and food group recommendations may have to be calibrated for metabolic and genetic differences. So, for the purpose of this literary review and study, the Paleo diet will be discussed as one of many possible dietary patterns that may be conducive to good health in some populations. It will also be assessed through the evidence of its health outcomes and nutritional quality as a modern diet plan, rather than in the way it has been conventionally presented as a representation of the ancient eating pattern that humans evolved to thrive on.

Effect of the Paleo Diet on Chronic Diseases

The initial formation of the Paleo diet was primarily based on observational studies suggesting that modern hunter-gatherer groups experience lower incidence of chronic disease

than industrialized societies. In one such study, Cordain et al.³⁰ attempted to define the macronutrient distribution of the Paleo diet and demonstrate that it is more heart-healthy than a typical Western diet. The average calories from animal sources and calories from plant sources across many modern hunter-gatherer groups throughout the world were combined to show that the average hunter-gatherer derives about 66-75% of its calories from animal sources and the remaining 26-36% from plants. Using this estimate and the average fat mass of various wild game, it was estimated that hunter-gatherers consume around 36-43% of calories from fat. The virtually non-existent occurrence of cardiovascular disease (CVD) in hunter-gatherer groups was then compared against the statistics of Western society to form the conclusion that a diet of high protein and high fat accompanied by high antioxidant foods may be more effective for treating and preventing CVD than the traditional therapeutic diet of higher carbohydrate and lower fat. There are some noticeable flaws with the study; for instance, it makes very little consideration of lifestyle variations between hunter-gatherer and Westernized populations such as activity level, smoking, and environment, and it does not mention these differences in the conclusions. Additionally, it's erroneous to use incidence rates of CVD in Western societies as evidence that therapeutic diets are ineffective, as the general population are not following therapeutic diet recommendations. Lastly, the inclusion of outliers such as the Eskimo and Nunamiut who almost exclusively eat food from animal sources skewed the data to show a greater caloric contribution from fat and protein in hunter-gatherer diets. It is unclear why these groups were included in an analysis to formulate standard Paleo macronutrient distribution ratios since modern specialized hunter-gatherer groups in extremely cold temperatures have very few dietary commonalities with groups of Paleolithic Africa where most of human evolution took place. Lastly, the fact that there are low rates of CVD across all of the hunter-gather groups while there were significant

variations in macronutrient distribution across these groups seems to discredit the conclusion that higher fat and protein are the common cardiac protecting factor, especially since some of the groups consumed a macronutrient distribution similar to Western diets while enjoying low occurrence of CVD. The conclusion that higher energy from fat and protein and lower energy from carbohydrates is the cardio-protective factor of hunter-gatherer diets only holds up if the macronutrient averages of these groups are used; when the diversity of hunter-gatherer diets is considered and the groups are looked at individually, it suggests that there is either some common factor other than macronutrient distribution that is cardio-protective, or different factors that are not common across the diets are cardio-protective. For instance, one potentially cardio-protective factor that is common to all of the hunter-gatherer groups is an energy and physical activity balance that promotes a healthy body weight; alternately, the African hunter-gatherer groups may be benefiting from a diet high in fiber and polyphenols from minimally processed fruits and vegetables, whereas the Eskimo and Nunamiut have the benefit of high intake of anti-inflammatory omega-3 fatty acids from fish.

Various clinical studies have since been conducted to compare the Paleo diet against other healthy eating patterns for treating cardiac disease factors, diabetes, obesity, and metabolic syndrome. These studies mostly show more beneficial or similarly beneficial outcomes for the Paleo diet test groups when compared to control groups following diets based on established healthy eating guidelines. However, it is difficult to determine the strength of the body of evidence supporting the Paleo diet as an intervention to chronic disease because most of these trials have had small sample sizes, have been short in duration, and impose varying levels of control to ensure compliance to the assigned diets. Another factor that makes it difficult to compile data from multiple studies is a lack of consensus in the definition of the Paleo diet.

Some trials defined the Paleo diet as including meat, poultry, fish, eggs, fruits, vegetables, nuts, and seeds *ad libitum* without instruction on portion sizes or macronutrient distribution,⁶⁹ some put daily restriction on certain foods such as white potatoes, eggs, nuts, oils, wine, or dried fruit,^{32-35, 41, 43, 70} and others defined the diet by the inclusion and exclusion of food groups in addition to designating macronutrient distributions.^{36-41, 71, 72} When macronutrient distribution ratios were specified, they were often, though not always, based on the Cordain et al.⁷ plant/animal subsistence ratios, so even this characteristic varied widely with 18.5% of energy from protein (PRO), 58.2% from carbohydrates (CHO), and 27.0% from fat at one end of the spectrum³⁹ and 30% energy from PRO, 30% from CHO, and 40% from fat at the other end.^{36, 37, 42, 72} Applying these trials to an American population is also difficult since only two trials found in this review were conducted with American subjects and control diets based on recommendations by American organizations.^{39, 41} Two uncontrolled studies,^{69, 70} one cross-sectional study that used food-frequency questionnaire data rather than dietary intervention,⁷³ and one preliminary study published as an extended abstract⁷⁴⁻⁷⁶ were also found with American subjects. Regional availability and cultural food preferences affect selection of foods within recommended food groups, so these variables could possibly change the nutritional adequacy and salubrious effects of a diet. Finally, some of the trials did not have a control diet group for comparison⁶⁹⁻⁷² and some controlled for weight loss^{39, 41} while others did not. Thus, the compounding variables in the Paleo clinical trials make it difficult to draw clear conclusions on the mechanisms of action and degree of beneficial effects of this diet. However, these trials cumulatively build a case to consider the Paleo diet as a dietary intervention for several chronic conditions which will be discussed individually.

Obesity/overweight. Of all health outcomes assessed in this literature review, the

evidence of the Paleo diet's effectiveness for achieving weight loss is the most convincing, at least in short-term. When compared to control groups, Paleo diet groups typically lost more weight with this difference reaching statistical significance in some instances.^{32, 33, 44} In some trials the Paleo groups lost weight even when caloric intake was being controlled to prevent it.^{39.}

⁴⁴ Multiple factors such as higher fiber content or fiber density,^{32, 39} higher water content from foods,⁴⁰ higher percent energy intake from protein,^{32, 40} and a tendency toward lower energy intake^{40, 43} were cited in these articles as possible contributors to weight loss. These factors support the recurring explanations that the foods most frequently consumed on the Paleo diet increase satiety, have a high thermodynamic effect, and may affect hormones such as leptin and glucocorticoids that influence appetite and adipose tissue deposition. For example, Jönsson et al.³⁴ conducted a trial of 29 male participants with ischemic heart disease, diabetes mellitus type II (DMII) or impaired glucose tolerance, and a waist circumference greater than 94 cm. The participants were randomized to either a Paleo or Mediterranean diet for 12 weeks *ad libitum* and received individual dietary counseling on their respective diets. The Paleo group was advised on which food groups to include and exclude but were not instructed to adhere to specific macronutrient distributions ratios. Serum leptin was one of the outcomes measured because of its potential relationship to obesity. In healthy normal weight people leptin signals to the brain that energy is available and thus decreases appetite, but obese subjects have increased levels of circulating leptin without the anorectic effect, leading some researchers to consider leptin resistance a potential contributor to obesity.⁷⁷ In order to measure the effects of the two test diets on leptin resistance, Jönsson et al.³⁴ measured both leptin and soluble leptin receptor (sLR) which potentiates the action of leptin when the two are bound. The ratio between leptin and sLR, called the free leptin index (FLI), is close to 1:1 in lean subjects,⁷⁷ but it is strongly related to

body composition as serum sLR is inversely correlated both with body fat percentage and serum leptin concentration in overweight and obese individuals.⁷⁸⁻⁸⁰ After twelve weeks, Jönsson et al. observed no significant difference between changes in FLI between the Paleo (28% decrease) and Mediterranean (30% decrease) groups.³⁴ However, the mechanism for the change was inverse between the diets, as the Paleo group had a 31% decrease in leptin and a 17% increase in sLR, whereas the Mediterranean group had an 18% decrease in leptin and a 33% increase in leptin receptor. This difference may be attributable to macronutrient distribution in the diets since total leptin and free-leptin levels have been positively correlated with diet carbohydrate content,^{81,82} which was significantly higher on the Mediterranean diet, and negatively correlated with dietary fat intake, which was significantly lower on the Mediterranean diet.³⁴ However, since sLR and leptin work synergistically to regulate appetite, one result does not seem to be superior to the other between the Jönsson et al. diet groups, as the decrease in FLI was nearly the same. A positive correlation has been observed between resting energy expenditure and bound leptin,⁸¹ so even though the mechanism of change in FLI was different between the diet groups the metabolic consequences were likely similar. Jönsson et al. had only male participants, and results might vary with female subjects since sex differences have been observed for serum sLR and bound-leptin to free-leptin ratios, which is likely due to the difference in typical subcutaneous fat mass between males and females.^{79,81} Additional research to explore which independent variables might have influenced the mechanisms for change in FLI ratio could potentially be useful for advancing dietary therapy for obesity.

A secondary analysis of Jönsson et al.'s work³⁴ was conducted by Lindeberg et al.,⁴³ which compared the intervention diets for their effect on blood sugar regulation and weight loss. Both groups lost a similar amount of weight, but the group on the Paleo diet lost more fat off of

their waist. Interestingly, waist circumference had a strong negative correlation with fruit intake, consumption of which was about twice as high in the Paleo group than the Mediterranean group as reported in 4-day weighted food logs. This correlation was independent of diet assignment, total energy intake, and total carbohydrate intake. Conversely, there was a strong positive association between waist circumference and cereal grain intake.

Changes in serum leptin and weight loss similar to those observed by Jönsson et al.³⁴ and Lindeberg et al.⁴³ were found in a small crossover study conducted by Fontes-Villalba et al.³³ Participants were given oral and written instruction individually before starting each diet period. Dietary counseling for the Paleo diet included a description of the evolutionary rationale and which types of foods to include, exclude, and minimize, but no recommendations for proportions were given. The Paleo diet intervention resulted in greater reduction of fasting leptin levels compared with the recommended diabetes diet when the diets were consumed *ad libitum* for two consecutive 3-month periods. However, the participants lost significantly more body fat on the Paleo diet than the recommended diabetes diet, and due to the small sample size it was not possible to adjust for weight loss, so it could not be determined whether the changes in serum leptin levels were due to weight loss alone or the dietary changes *per se*. Fasting plasma concentrations were measured for other hormones associated with appetite regulation, but none besides leptin displayed significant differences between the diets.

Secondary analyses of the Fontes-Villalba et al.'s work³³ were conducted by Jönsson et al.^{35, 40} to study the level of subjective satiety of the Paleo diet against the control diabetes diet and the diets' comparative effects on cardiovascular risk factors. Participants kept a 4-day weighed food record for each diet period, ranked their level of subjective satiety on a 7-point equal-interval, bipolar visual analogue scale at meal initiation and 30 minutes following, and

answered three open-ended questions about both diets to be analyzed for recurrent opinions. Meal spacing and frequency were similar on both diets as were the levels of satiety reported at meal initiation and 30 minutes after; thus there was no significant difference between the diets in the satiety quotient, calculated as the change in satiety during the meal.³⁵ However, the participants reported lower total energy intake and lower energy density on the Paleo diet,⁴⁰ so it was more satiating per calorie.³⁵ In the exploratory analysis, change in energy density was correlated with change in both weight and waist circumference, which both had greater reductions during the Paleo half of the intervention period.⁴⁰ Water from food was correlated with satiety quotients for energy density in post hoc analysis of within-subject differences,³⁵ but it is unlikely that differences in macronutrient content impacted satiety in this study. The percent of dietary energy from protein was slightly higher on the Paleo diet than the diabetes diet (24 ± 3 vs $20 \pm 4\%$) while the percent energy from carbohydrate and fiber were lower (32 ± 7 vs $42 \pm 7\%$ and 2.5 ± 0.7 vs $2.7 \pm 0.7\%$, respectively) but none of these values had any correlation with satiety quotients.^{35, 40} The participants consumed nearly 80% more fruit on the Paleo diet than the diabetes diet,⁴⁰ and though differences in sources of carbohydrates did not correlate directly to satiety quotients, fruit was a major contributor of water content which was strongly correlated with satiety quotient for energy density.³⁵ In the open ended survey data, there was no difference between distribution of positive and negative comments for the diets, but there were significantly more reoccurring comments of the Paleo diet contributing to weight loss and being satiating. There were also more comments relating to difficulty adhering to the Paleo diet.

Bligh et al.³⁸ also explored the relationship of the Paleo diet and appetite regulation in a randomized cross-over trial on 21 healthy males in which serum concentrations of anorectic gut hormones were measured by venous blood samples throughout the consumption of three sample

mixed meals following a 12 hour fast. Questions relating to subjective satiety and liking were also measured in conjunction with the serum sampling. The reference meal (REF) was matched as closely as practical to the macronutrient recommendations from the World Health Organization (WHO) with 15% of energy from protein, 60% from carbohydrate, and 25% from fat and a total of 383 kcal. Two versions of a Paleo style meal (PAL1 and PAL2) were formulated using varying amounts of similar ingredients to test different macronutrient distributions. PAL1 had a higher percent of energy from protein (29%), lower energy from carbohydrate (43%), slightly higher fat (28%), and greater total energy (556 kcal) than the REF diet to represent the higher animal-to-plant subsistence ratios suggested in the Cordain papers,^{3, 7, 30} whereas PAL2 was matched to the REF diet for total energy and macronutrient distribution ratios. Both PAL meals received significantly greater scores for subjective satiety than the REF meal at all survey points, which may have been associated with significantly higher levels of some anorectic gut hormones secreted during the PAL meals; however, the liking scores for both PAL meals were significantly lower than those for the REF meal, so lower palatability may have also affected satiety by reducing the participants' desire to eat. The difference of PAL1 being more satiating than PAL2 only reached significance at the final time point, which is surprising considering the higher energy and protein content of PAL1. When satiety quotient per unit of energy was calculated from the final collection point, PAL2 provided the greatest level of satiety per kJ.

This study design would have been a very effective way of addressing the question of whether the animal to plant subsistence ratios recommended by some proponents of the Paleo diet are actually contributing to its positive effects, specifically relating to the immediate post-prandial metabolic responses and appetite regulation, or if the benefits can be attributed to some other characteristic of the diet. However, the researchers introduced some unnecessary variables

in their meal design that make it difficult to draw clear conclusions when comparing the results of the Paleo meals against the reference WHO macronutrient diet. Firstly, though the research team expressed the aim to create Paleo meals from ingredients that are readily available to modern consumers, they decided to include more variety of plant foods and choose plants that are higher in polyphenol for PAL1 and PAL2 than for REF. The REF diet had carrots and mango as the only vegetable and fruit ingredients, while the Paleo meals included strawberries, apples, peppers, onions, eggplant, mushroom, raisins, and courgettes. Additionally, the Paleo meals included 5 g each of cinnamon and capers to increase phytochemical content, which was not included in the REF meal. The rationale for these differences is that it was hypothesized that wild ancestral plants would be higher in polyphenols and phytochemicals than modern commercially grown plants. However, the modern consumer has the same level of access to diversity in their food choices regardless of which dietary lifestyle they follow, and there is no evidence-based reason to believe that someone following the WHO recommendations is less likely to consume a variety of fruits and vegetables or use phytochemical rich seasonings than a follower of the Paleo diet. Unfortunately, introducing these variables creates the possibility that the differences in metabolic effects were caused by the phenolic content or diverse micronutrient composition rather than the exclusion of cereal grains, which is the defining characteristic of the Paleo diet. There are many studies on animal subjects that show anti-obesity effects from consuming phenolic compounds,⁸³ so until testing is conducted with humans, there will be uncertainty about how phenolic content affected these results. To reduce these compounding variables, the meals should have been assembled from the same ingredients and seasonings with only the quantities adjusted to account for the addition of rice in the REF meal and different macronutrient ratios between the PAL meals. Additionally, if the researchers meant for their trial

to be indicative of results that are likely to be achieved by modern consumers following these diets, their results would have been more pertinent if they had made their vegetable and fruit selections based on purchase data, cultural preferences, and regional/seasonal availability, which are more likely considerations in consumer selections than polyphenol content. There were a few other minor differences between the meals' compositions. The PAL meals included flax seed oil rather than the olive oil used for the REF meal, which is another unnecessary variable since olive oil can be included in the Paleo diet. Also, the PAL1 meal included blanched almonds and fewer strawberries than the PAL2 meal, which was needed to normalize available carbohydrates to the goal of 50 g across the three diets. PAL1 also included 90 g haddock fish, in addition to the 39 g of salmon which was included in all three meals, in order to increase the protein content of PAL1 while keeping fat content relatively consistent to the other meals; however, this adds support to the criticism that the meals were too engineered to compare to those in a free-living population as it seems unlikely that most consumers would include two different types of finfish in the same meal. Lastly, normalizing the carbohydrate and fat content across all three diets but increasing total calories in PAL1 with additional protein introduces the question of whether its higher subjective satiety scores relative to REF are the result of higher energy content or some other characteristic of the meals. Total energy could be normalized across the meals while varying the energy distribution ratios, and formulating the test meals in this way may yield a more accurate assessment of the effects of macronutrient energy distribution on subjective satiety.

Though these variables present problems for extrapolating expected outcomes to a free-living population or for comparing the results from the PAL meals to those of the REF meal, the data are still of value in displaying possible results from very well-planned Paleo diets.

Comparing the results of the two PAL meals is also valuable as there is less variance between the

composition of these two meals, with additional calories from protein in PAL1 being the primary difference. The fact that subjective satiety scores of PAL1 and PAL2 were so similar in spite of PAL1 having 173 kcal more energy and 25 g more protein than PAL2 supports the hypothesis that some characteristic besides macronutrient distribution ratios or total caloric content is responsible for the satiating qualities of the Paleo diet.

There is currently very little data on long-term effects of the Paleo diet on weight loss as there has only been one long-term trial which resulted in four publications.^{36, 37, 42, 84} The primary trial conducted by Mellberg et al.³⁷ compared risk markers for the development of heart failure throughout a randomized, investigator-blinded 24-month intervention of *ad libitum* adherence to a Paleo or Nordic Nutrition Recommendation (NNR) diet in seventy healthy postmenopausal women with a body mass index (BMI) of ≥ 27 kg/m². One strength of this study is that adherence was entirely *ad libitum* rather than through meal delivery. Since written materials, recipes, and group educational sessions/cooking classes with a dietitian were the only means to impose dietary control, the results are more indicative of those which can be achieved through dietary counseling in a free-living population. Both groups had significant weight loss compared to baseline throughout the study, and there was a tendency for more weight loss in the Paleo group compared to the control diet, which was significant at all follow-up check points except at 24 months. Waist circumference also decreased significantly in both groups throughout the whole study period with a significantly greater decrease in the Paleo group at 6 months. Target macronutrient energy ratios for the Paleo diet were set at 30% energy from protein, 30% from carbohydrates, and 40% from fat (preferentially selecting from monounsaturated and polyunsaturated sources), but 4-day estimated food journals and nitrogen excretion tests gathered at intervals throughout the trial determined that consumption consistently fell short of those

targets in spite of pronounced changes from baseline (17% PRO: 46% CHO: 33% Fat) to 6 months (23% PRO: 29% CHO: 44% Fat) and 24 months (22% PRO: 34% CHO: 40% Fat).

Reported energy intake decreased significantly on both diets with a 19% and 20% lower reported intake on the Paleo diet at 6 and 24 months, respectively, and 18% and 12% lower intake for the NNR group, but the differences between the groups did not reach significance.

Stomby et al.³⁶ conducted a secondary analysis of Mellberg et al.³⁷ to study the effects of long-term weight loss on glucocorticoid metabolism. The same group of post-menopausal women were used excluding 21 participants who missed either a urine sample, cortisone test, or subcutaneous adipose tissue biopsy at baseline, 6 months, or 24 months. The long-term weight loss achieved by both diet groups caused significant normalizing effects on glucocorticoid metabolism, without significant difference between the Paleo and NNR diet groups. Production of the enzyme 11 β hydroxysteroid dehydrogenase type 1 (11 β HSD1) in subcutaneous adipose tissue and urinary output of glucocorticoid metabolites were both observed. Normally 11 β HSD1 converts cortisone into cortisol, but in obesity it is over-expressed in adipose tissues while selective inhibitors reduce its activity in the liver, leading to decreased cortisol levels.⁸⁵ This dysregulation has been associated with increased visceral adiposity, hyperlipidemia, inflammation, and insulin resistance.^{36, 85} Urinary glucocorticoid metabolites can be used to analyze glucocorticoid production and the global activity of 11 β HSD1.⁸⁵ Both diet groups in the Stomby et al. trial had reduced expression of 11 β HSD1 in adipose tissues and increased urinary output of glucocorticoid metabolites, suggesting that inhibitory factors for 11 β HSD1 action were reduced. The results from Mellberg and Stomby et al. show that the Paleo diet can be used successfully as a long-term weight loss intervention with a moderate increase in protein and fat and concomitant reduction in carbohydrates. However, though the Paleo intervention achieved

greater reductions to anthropometric measurements than the control diet throughout the trial, these differences lost significance at 24 month, and there were no significant differences in glucocorticoid metabolism between the diet groups. So the Paleo diet is not necessarily better for long-term weight loss maintenance or for normalizing obesity-related changes to glucocorticoid metabolism than traditionally recommended higher carbohydrate/lower fat diets.

Other Paleo studies also showed decreased weight, waist circumference, and reduced caloric intake in spite of *ad libitum* consumption. Genoni et al.³² observed significantly greater changes in body composition in their Paleo group. Weight loss and reduced waist circumference were observed in 39 healthy women randomized to either the Paleo diet or Australian Guide to Healthy Eating (AGHE) *ad libitum* for four weeks, though these reductions were significantly greater in the Paleo group compared to the AGHE group. Weight loss was associated with increased energy intake from protein. This study also analyzed 3-day weighed food records taken prior to and after dietary intervention so that mean macro- and micronutrient intakes could be compared between the test diets and baseline; this provided the most thorough nutrition assessment of an *ad libitum* Paleo diet in free-living adults found in this review and will be discussed in the Nutrition Adequacy section.

In a two-phase study of 20 hypercholesterolemic male and female participants serving as their own control, Pastore et al.⁴¹ observed dramatically greater weight loss after a 4-month Paleo phase compared to the 4-month dietary intervention based on recommendations by the American Heart Association (AHA), with a noted diet-by-sex interaction ($p < .05$) of men losing more weight in both phases than women. There was also significantly lower energy intake during the Paleo intervention compared to the AHA control intervention even though no caloric restriction was imposed during the Paleo diet phase, but a caloric maximum based on the AHA's

age/sex/height/weight recommendations were incorporated in the AHA diet phase. All participants completed the AHA phase prior to the Paleo phase, so there is a possibility of order bias. This study is of particular importance because of its longer trial period, American participants, both sexes being represented, and truly *ad libitum* design. It also deserves extra consideration because the macronutrient intake ratios in this study are closer to the low-carbohydrate, high-protein ratios recommended by Cordain,⁷ whereas many of the other studies in this review represent a more moderate carbohydrate to protein ratio in spite of referencing the Cordain subsistence ratios. This study will be discussed in greater detail in the Cardiovascular Disease Outcomes section.

Ryberg et al.⁷² also observed weight loss and reduced waist circumference compared to baseline values after a 5-week Paleo intervention, but there was no control group for comparison in this study so it cannot be determined whether another healthy diet plan with meals provided and weekly meetings with a dietitian would have yielded similar results. One novel observation was a decrease in hepatic lipid content with a 49% reduction in liver triglyceride (TG) levels, implying that the Paleo diet may be an effective dietary therapy for nonalcoholic fatty liver disease. However, the sample size was small and only female, consisting of 10 non-smoking, healthy postmenopausal women with BMI > 27 kg/m². Longer term studies with both sexes will be needed to explore the effect of the Paleo diet on liver health. As with other studies in this review, analysis of the participants' weighed food records showed a significant decrease in caloric intake (-22% decrease) from baseline as well as a reduction in percent energy from carbohydrates with a concomitant increase in percent energy from protein and fat. However, these participants were provided all of their meals along with instruction for additional foods to

include *ad libitum*, which likely increased compliance, so it is difficult to predict if these results would be repeated in the general population who must plan and prepare all of their own meals.

Two other non-controlled studies showed beneficial body composition changes in healthy, young (20-40 years) men and women after a Paleo diet intervention.^{69,70} Both of these studies imposed less control over the subjects' *ad libitum* consumption than the Ryberg et al.⁷² design, as neither supplied meals for participants, specified macronutrient requirements, or provided dietary education/coaching beyond the initial dietary assignment; these designs aligned with the goal of emulating adherence of a free-living population. Österdahl et al.⁷⁰ noted a mean decrease in weight by 2.3 kg and waist circumference by 0.5 cm ($p < .001$) in 14 Swedish medical students after a 3-week Paleo intervention that excluded all dairy, grains, legumes, and canned food (except tomatoes with only citric acid for preservation), and restricting dried fruit (2 days/week), potatoes (two medium sized/day), honey (one serving/week), and salted seafood/cured meat/non-lean meat (one entrée per week of each). Smith et al.⁶⁹ observed a reduction in body fat percentage from $24.3 \pm 1.2\%$ to $20.7 \pm 1.2\%$ ($p < .05$) and body weight from 80.7 ± 2.6 kg to 77.5 ± 2.4 kg ($p < .01$) in 44 athletic American participants after a 10-week Paleo intervention with no limitations on intake beyond strict avoidance of all dairy, grain, and legumes. Aside from the lack of a control group, Österdahl et al. was underpowered due to dropout, and completed dietary intake records were available for only 6 of the 14 participants, so correlation analysis could not be conducted. Smith et al. also had low availability of intake data, with only 8 of the 44 participants returning their diet logs, so those data were not included in the write up. In spite of these limitations, these studies had some interesting preliminary findings that may be useful in the formulation of future Paleo trials, so they will be discussed in more depth within the Cardiovascular Disease Outcomes section and Nutritional Adequacy section.

Diabetes mellitus II and pre-diabetes outcomes. Significant weight loss is known to improve blood sugar regulation in DMII and prediabetes, so many of the studies that measured the effect of the Paleo diet on weight loss collected serum glucose and insulin data as well. At 12 weeks in the study by Lindeberg et al.,⁴³ the Paleo group had an average 26% decrease in post-prandial area under the curve (AUC) glucose over 120 minutes (0-120) as opposed to a 7% decrease in the Mediterranean group. Both groups had a significant decrease of 22% in AUC Insulin 0-120 at 6 weeks, and the Paleo group had a decrease at 12 weeks which lost significance after adjustment for loss in waist circumference. Macronutrient distribution ratios were not associated with changes in primary outcomes for either diet, but an overall 25% lower energy intake for the Paleo participants did account for the greater loss in waist circumference and larger decrease in AUC Insulin 0-120. As previously mentioned, fruit intake in the Paleo group was double that of the Mediterranean group, but fruit intake did not have any association with change in post-prandial AUC glucose or insulin following a 2-hour oral glucose tolerance test. The main limitations of this study were small sample size of 29, all male participants, and a short-term intervention period of 12 weeks.

The Bligh et al.³⁸ study showed some very interesting post-prandial insulin response data for the two Paleo model meals compared to the reference WHO meal. There was no significant difference between the three diets in post-prandial positive incremental area under the curve over 120 minutes (+iAUC₁₂₀) glucose or insulin. Likewise, the peak concentration in the serum (C_{\max}) glucose did not differ between the meals, but PAL2 had significantly lower insulin C_{\max} relative to REF. Both PAL1 and REF caused a drop in glucose levels that fell below baseline. With PAL1, glucose levels fell between 30 and 60 minutes post prandial and remained below baseline through 120 minutes, and REF had similar results except glucose rose gradually between 60 and

120 minutes back to baseline level. These results are indicative of an exaggerated insulin response which requires the release of counter regulatory hormones to achieve glycemic stability. However, following consumption of PAL2 there was a slower rate of glucose decline between 30 and 60 minutes and glucose remained stable at baseline level between 60 and 120 minutes. PAL2 had a significantly lower insulinogenic index relative to REF, which is normally a sign of impaired beta-cell function, but in this instance it demonstrates a more appropriate insulin response than was seen with the other two meals since baseline levels were achieved within the same time frame without the need for counter regulation. Lower insulinogenic index was a predictor of slower rate of decline in glucose levels in *post hoc* regression analysis, and in stepwise multivariate analysis PAL2 was the strongest independent predictor of insulinogenic index. It is important to note that this study was conducted on apparently healthy males with an average BMI of 23.4 kg/m^2 with a standard deviation of 2.67, so it is undetermined whether these results could be repeated with participants who have DMII, insulin resistance, or obesity.

There are interesting similarities in the AUC glucose and insulin response between the Bligh et al.³⁸ study and a small short term study by Frassetto et al.⁶² As with the Bligh et al. study, the subjects used by Frassetto et al. were healthy, non-obese adults, and all meals were prepared and provided by the research team. The trial period included 3 days of participants' usual diet in which a five-pass, 24-hour diet recall was conducted, followed by a 7-day ramp-up diet to gradually increase potassium and fiber intake, and a 10-day Paleo diet intervention. Energy distribution provided 30% kcal from protein, 38% from carbohydrate, and 32% from fat (mainly unsaturated). Following the Paleo intervention, fasting glucose and AUC glucose during a 2-hour oral glucose tolerance test (OGTT) did not change significantly from baseline measurements, but fasting insulin decreased by 68% and the AUC insulin decreased so that the

insulin/glucose ratio during the OGTT was about 40% lower. Interestingly, the greatest decreases in AUC insulin occurred in the subjects whose dietary potassium intake and urinary potassium excretion were most increased from their baseline. This implies that the increased fruit and vegetable content of the Paleo intervention was a major contributor to the change in glycemic control. There was also improvement in insulin sensitivity using the homeostatic model assessment (HOMA), with the most insulin resistant subjects showing the greatest increases in sensitivity. As with the Bligh et al. study, these results can not necessarily be extended to a diabetic or obese population since all participants were healthy and free of any prescription or over-the-counter medications. Also, as mentioned previously in this review, provision of prepared meals to ensure compliance may not represent *ad libitum* results in a free-living population. The other major limitation of this study is that there was no control group consuming a recommended consensus diet, instead the intervention results were measured against the subjects' baseline metabolic tests and 24-hour diet recall. An important feature of this study is that it is one of only five published Paleo studies that have American participants, but with only 9 participants and an intervention period of 10 days it is the smallest and shortest Paleo trial in this review.

The same American research team conducted another study, this time comparing the effects of a Paleo diet versus a diet based on the American Diabetes Association (ADA) recommendations on metabolic markers in patients with DMII.³⁹ The 24 participants were between 50 and 69 years of age, with a BMI < 40 kg/m², and excluded patients taking thiazolidinedione or glucocorticoids that affect insulin sensitivity. Both groups had meals and snacks prepared and provided by research staff for 14 days; the Paleo group started with a seven day ramp-up diet to gradually increase potassium before their trial period. Both diet groups lost

an average of about 2 kg despite portion adjustments to prevent weight loss. A reduction in glycated hemoglobin (HbA1c) at day 14 was similarly modest in both test groups, but a large decrease would not be expected for a two week intervention. Serum fructosamine is a better marker of short-term glycemic control, and it decreased significantly in the Paleo group ($-34 \pm 41 \mu\text{mol/L}$) compared to the ADA recommendation group ($-3 \pm 28 \mu\text{mol/L}$). Both groups saw an improvement for insulin sensitivity which was independent of weight loss with a statically insignificant trend for greater improvement in the Paleo group. One very important difference between this trial and other Paleo diet trials is that the average macronutrient distribution did not fit the higher protein and fat to carbohydrate ratio that is characteristic of the Cordain-defined Paleo diet. The average percent of calories derived from protein, fat, and carbohydrate in the Paleo meals were 18.5% PRO, 58.2% CHO, and 27.0% fat as opposed to 20.3% PRO, 54.4% CHO, and 28.8% fat in the ADA meals. The ADA meals in this study actually had a greater amount of energy from protein and fat and lower amount from carbohydrate than the Paleo meals, but the sources of carbohydrates in the Paleo meals were fruits and vegetables whereas the ADA meals relied more on grains. This provides supports for the hypothesis that some characteristic other than the higher protein and fat macronutrient distribution ratio are responsible for the Paleo diet's beneficial effects in DMII management. It should be noted that the subjects in this study all had well-controlled HbA1c, TG, and systolic blood pressure at baseline and continued on their regular cardiac and diabetes medications throughout the study, which may have attenuated the effects of the therapeutic diets; differences between diet results may have been more pronounced in subjects with less-controlled baseline values.

Likewise, the 13 participants in the aforementioned Jönsson et al.^{35, 40} cross-over study (see page 20-21 in Obesity/Overweight) were taking an average of four prescription medications

per day to include diabetic, lipid-lowering, and anti-hypertensive drugs, which also may have attenuated the effects of the therapeutic diets.⁴⁰ This group achieved lower mean HbA1c values on the Paleo diet than the control diabetes diet over their consecutive 3-month trial periods. Change in HbA1c was correlated with change in potassium intake, which was higher on the Paleo diet in part due to the 80% increase in fruit consumption versus the control consensus diabetes diet. The Paleo trial period also resulted in significant improvements in fasting plasma glucose, fasting plasma insulin, AUC glucose, HOMA for insulin sensitivity (as a percent of a normal reference population), and insulin sensitivity index (calculated from fasting and 120 minutes post-OGTT concentrations of insulin and glucose) compared to the baseline values but not significant compared to the control values achieved by the diabetes diet.

Cardiovascular disease outcomes. There have been mixed results for cardiovascular and serum lipid outcomes on the Paleo diet. Refer to Table 4 for a summary of cardiovascular and serum lipid outcomes in Paleo trials.

The Mellberg et al.³⁷ study is of particular importance since it is the only long-term Paleo intervention. In this trial, systolic blood pressure decreased in both the Paleo and NNR diet test groups at 6 months but returned to baseline at 24 months. Left ventricular mass, end diastolic volume, and stroke volume decreased in both diets from baseline to 24 months, and reduction in cardiac output reached significance for the NNR group but was not significant for the Paleo group. End systolic volume, ejection fraction, and myocardial TG accumulation did not change in either diet group. The NNR group had insignificant decreases in serum TG levels relative to baseline, but the decrease in serum TG for the Paleo group was significant relative to baseline values and changes in the NNR group at both 6 and 24 months. The main limitation with this study is that there was no observational control group to compare the natural progression of these

Table 4: Effects of Paleo Diet Intervention Trials on Cardiovascular Outcomes

Study category; author (ref)	Participants	Duration	Dietary intervention and macronutrient energy distribution ratios (EDR) when available	Paleo-group cardiac outcomes
Trials with control diets				
Genoni et al. ³²	39 healthy women, Paleo (<i>n</i> = 22) and AGHE (<i>n</i> = 17)	4 weeks	<i>Ad libitum</i> . Paleo EDR: 26.8% Pro, 27.8% CHO, 39.8% fat. Australian Guide to Healthy Eating (AGHE) EDR: 21.7% Pro, 40.6% CHO, 32.6% fat.	Reduction in TC, TG, and LDL significant to baseline but not significant to control AGHE group.
Mellberg et al. ³⁷	70 obese, postmenopausal women, Paleo (<i>n</i> = 35) and NNR (<i>n</i> = 35)	2 years	<i>Ad libitum</i> . Paleo EDR at 24 months: 22% Pro, 34% CHO, 40% fat. Nordic Nutrition Recommendation (NNR) EDR at 24 months: 17% Pro, 43% CHO, 34% fat.	Significantly greater reduction in TG at 6 and 24 months in Paleo group than NNR group. Diastolic BP, HR, CRP, LDL, and PAI-1 activity decreased at 6 and 24 months, SBP decreased at 6, and HDL increased at 24 months significant to baseline in both groups.
Masharani et al. ³⁹	24 participants with well controlled DMII, Paleo (<i>n</i> = 14) and ADA (<i>n</i> = 10)	14 days (following 7 day ramp-up for Paleo group)	Meals provided with energy adjustments to prevent weight-loss. Paleo EDR: 18.5% Pro, 58.2% CHO, 27.0% fat. American Diabetes Association (ADA) recommendations EDR: 20.3% Pro, 54.4% CHO, and 28.8% fat.	Decrease in TC, HDL, and LDL significant to baseline but not significant to ADA control.
Jönsson et al. ⁴⁰	13 men (<i>n</i> = 10) and women (<i>n</i> = 3) with DMII	Two consecutive 3-month cross-over periods	<i>Ad libitum</i> . Paleo EDR 24% Pro, 32% CHO, 39% fat. Diabetes Diet 19% Pro, 42% CHO, 35% fat.	Greater increase in serum HDL and greater reduction in diastolic BP and TG for Paleo trial significant to Diabetes Diet control and baseline.
Pastore et al. ⁴¹	20 men (<i>n</i> = 10) and women (<i>n</i> = 10) with hypercholesterolemia	Two consecutive 4-month periods, same order for all subjects	<i>Ad libitum</i> . Paleo EDR: 37% Pro, 23% CHO, 40% fat. American Heart Association (AHA) diet EDR: 21% Pro for men / 17% pro for women, 56% CHO for men / 60% for women, 23% fat.	Decrease in TC, LDL, TG, and increase in HDL significant to baseline and AHA control. Significantly greater HDL values in women compared to men.
Andersson et al. ⁴² (secondary analysis of Mellberg et al.)	68 obese, postmenopausal women	2 years	<i>Ad libitum</i> . Paleo EDR at 24 months: 22% Pro, 34% CHO, 40% fat. Nordic Nutrition Recommendation (NNR) EDR at 24 months: 17% Pro, 43% CHO, 34% fat.	Left ventricular mass significantly reduced from baseline in both groups, no significant difference between Paleo and NNR group
Boers et al. ⁴⁴	34 men (<i>n</i> = 9) and women (<i>n</i> = 25) with >2 MetS characteristics, Paleo (<i>n</i> = 18), DHC (<i>n</i> = 14), lost to follow-up (<i>n</i> = 2)	2 weeks	Meals and snacks provided, isoenergetic to baseline diet to prevent weight-loss. Paleo EDR: 24% Pro, 32% CHO, 41% fat. Dutch Health Council (DHC) guidelines EDR: 17% Pro, 50% CHO, 29% fat.	Significantly reduced systolic BP, diastolic BP, TC, TG, TC:HDL ratio, TG:HDL ratio, and increased HDL compared to control DHC group.
Trials without control diets				
Smith et al. ⁶⁹	44 healthy men (<i>n</i> = 24) and women (<i>n</i> = 20) following a high-intensity Cross-Fit program.	10 weeks	<i>Ad libitum</i> . No EDR recommended, no limitations imposed on any Paleo-qualifying food groups. EDR intake data not available due to low number of diet logs returned.	Non-HDL, LDL, and TC increased significantly from baseline following Paleo intervention with most deleterious effects observed in participants with optimal blood lipid levels at baseline.
Österdahl et al. ⁷⁰	14 men (<i>n</i> = 5) and women (<i>n</i> = 9) recruited from a medical student association	3 weeks	<i>Ad libitum</i> . Paleo EDR from 6 participants over entire trial period: 10-15% Pro, 55-65% CHO, and <30% from fat	Systolic BP and PAI-1 decreased significantly from baseline values following a Paleo intervention.
Frassetto et al. ⁶²	9 non-obese, sedentary men (<i>n</i> = 6) and women (<i>n</i> = 3)	10 days following a 7-day ramp up diet	Meals provided. Paleo EDR: 30% Pro, 38% CHO, 32% fat (mainly unsaturated)	TC, LDL, TG, and BP decreased significantly from baseline values following a Paleo intervention.
Ryberg et al. ⁷²	10 obese, postmenopausal women	5 weeks	Provided 3 meals per day, and instructed on additional foods that could be included <i>ad libitum</i> . Paleo EDR: 28% Pro, 25% CHO, 44% fat.	TC, LDL, TG, HDL, ApoA1, ApoB, and BP decreased significantly from baseline values following a Paleo intervention.
Abbreviations: ApoA1, apolipoprotein A1; ApoB, apolipoprotein B; BP, blood pressure; CHO, carbohydrate; EDR, energy distribution ratio; HDL, serum high-density lipoprotein; LDL, serum low-density lipoprotein; MetS, metabolic syndrome; PAI-1, plasminogen activator inhibitor-1; Pro, protein; TC, serum total cholesterol; TG, serum triglycerides.				

metabolic parameters. Also, it is unknown whether greater or lesser effects would be achieved in subjects with compounding health issues such as impaired glucose tolerance, since the subjects in this study were all healthy.

In the previously discussed short-term studies, some positive changes in cardiovascular health bioindicators were observed compared to the subjects' baseline values following their Paleo diet intervention, but in controlled trials, these changes were not significantly different from those of the control group. These changes include reductions in serum lipid values for TG,^{32, 71, 72} total cholesterol (TC), and LDL cholesterol.^{32, 39, 71, 72} Reductions in diastolic blood pressure,^{71, 72} systolic blood pressure,^{40, 70} and arterial pressure⁷² compared to baseline values were also observed. However, some negative short term changes in serum lipids compared to baseline values were also noted including decreases in HDL cholesterol^{39, 72} and percentage of the total serum cholesterol represented by HDL,⁷² which is an independent indicator of cardiovascular disease risk.⁸⁶ There is very little data for other serum proteins that effect cardiovascular risk; Osterdahl et al.⁷⁰ observed a 72% decrease in Plasminogen activator inhibitor-1, the reduction of which may be protective against thrombosis and atherosclerosis, and Ryberg et al.⁷² noted an undesirable decrease in Apolipoprotein A1 accompanied by a desirable decrease in Apolipoprotein B.

Fewer short-term studies had changes in serum lipid or cardiac health parameters compared to a healthy consensus control diet. Only Jönsson et al.⁴⁰ and Boers et al.⁴⁴ found significant reductions in diastolic blood pressure, TC, and TG, and an increase in HDL cholesterol compared to their control diets. Boers et al. also observed a significant reduction in systolic blood pressure compared to the control Dutch Health Council recommended diet. However, it is important to note that these two studies' results may have been affected by

selection bias, as there were differences between the outcome parameters of the Paleo group and control group at baseline.⁸⁷

The Pastore et al.⁴¹ study which was briefly discussed in the Obesity/Overweight section is especially relevant for the purpose of this review because it is one of only two Paleo trials that have an American population and a control diet based on guidelines from an American organization (the American Heart Association). This study, in which participants acted as their own control, showed increased HDL and significant reductions to mean TC, LDL, and TG in 20 subjects with hypocholesterolemia after following a Paleo diet *ad libitum* for four months compared to baseline and also compared to measurements taken after four months of following a heart-healthy diet based on recommendations by the AHA. Regression analysis showed that these changes were independent of weight loss. The main limitation for this study is that all participants followed the AHA diet for four months prior to following the Paleo eating pattern rather than utilizing a crossover design, so there is a possibility that order bias influenced results. The researchers were aware of this limitation, and noted within their discussion that their findings implied that a Paleo diet might be a good alternative for hypocholesterolemic individuals who have already implemented pharmaceutical and traditionally recommended dietary therapy without success.

In contrast to these findings, Smith et al.⁶⁹ observed deleterious effects on blood lipid levels in American participants after a 10-week Paleo diet intervention with concurrent participation in a CrossFit-based, high-intensity circuit training program. Non-high density lipoprotein (the TC value minus the HDL value, which may be a better predictor of CVD risk than LDL values),^{88, 89} LDL, and TC increased significantly from baseline values while there was a very small and insignificant increase in TG and decrease in HDL. There are several very

important differences between the study designs of Smith et al. and Pastore et al.⁴¹ that likely account for the variations between their findings. Firstly, the participants for Smith et al. were young, athletic, and had healthier weights and blood lipid values at baseline than the Pastore et al. participants. It is possible that healthy subjects are already practicing healthful dietary habits; so, the beneficial effects of replacing energy-dense, low-nutrient, highly processed foods with Paleo-approved choices would not be as pronounced in populations who generally avoid those less healthful options already. Smith et al. did observe some evidence to suggest that baseline health might be a determinant of the Paleo diet's effects. When the subjects were stratified into categories for baseline blood lipid values, optimal and near optimal levels at baseline were associated with negative changes post Paleo intervention, and sub-optimal levels were associated with improved positive changes post Paleo intervention, but these trends only reached statistical significance in a few stratifications. Secondly, Pastore et al. provided monthly nutrition counseling and reviewed diet journals bi-weekly to improve compliance, whereas Smith et al. did not provide support beyond the initial dietary assignment so as to better emulate self-adherence in a free-living population. One consideration is that partial compliance to a Paleo diet might be detrimental if adherence primarily entails *ad libitum* consumption of the least healthful Paleo-approved choices while practicing lax observation of other aspects that might normally off-set the diet's shortcomings. Unfortunately, so few of the Smith et al. participants returned their diet logs that assessing the level of compliance was not possible. Lastly, Smith et al. provided no dietary limitations for the Paleo diet beyond elimination of dairy, grains, and legumes, while Pastore et al. emphasized choosing lean animal proteins and put daily restrictions on dried fruit to no more than 1 ounce, potatoes to no more than ½ cup, and wine to no more than 4 ounces. It is possible that the Smith et al. participants displaced most of the energy they would

normally get from the excluded food groups with higher saturated fat options such as fatty meats and were more liberal with their consumption of the less nutrient dense/higher energy dense options such as alcohol, dried fruit, and starchy root vegetables. The findings of Smith et al. must be interpreted with care since there was no control group to compare the natural progression of the population. With that being said, it is noteworthy that these subjects had a significant ($p < .01$) decrease in body fat percentage and improved cardiorespiratory fitness (as measured by relative maximal oxygen and absolute oxygen consumption) from following the Paleo diet and a CrossFit training program for 10 weeks while also having undesirable changes in their blood lipid measurements. Such positive changes in body composition and fitness would normally be associated with improvements in blood lipid levels.

One preliminary study presents some interesting findings for how the Paleo diet may affect CVD. Talreja et al. compared the outcomes of 279 American adults with at least one CVD risk factor following one of four diet patterns for 60 days.⁷⁴⁻⁷⁶ The relatively large sample size of Americans is of particular importance, but this study is also meaningful because the trial diets are very similar to DGA recommended diet patterns. Fifty-eight participants followed a whole-food, plant-based vegan diet, which is similar in many aspects to the healthy vegetarian diet recommended by the DGA; 65 participants followed DASH, which is the primary basis for the Healthy U.S.-style pattern; 80 participants followed a Mediterranean diet, which is a DGA-recommended pattern; and 76 participants followed a Paleo diet. All of the diet groups had significant improvements in blood pressure and weight loss compared to their baseline, with the greatest weight loss observed in the vegan and Paleo groups. The changes in serum lipid risk factors were more variable across the diet groups with the greatest improvement seen in the vegan and Paleo groups compared to baseline⁷⁵ and the greatest improvements were observed in

the vegan group in between-group analysis.⁷⁴ In the 193 participants who returned for 6-month follow-up, those who regularly attended the diet support group meetings had the greatest and most sustained effects.^{75, 76} The availability of the methods and data is limited because this study has been published only as an extended abstract and through poster presentations summarized in supplement issues of academic journals. Also, results must be interpreted with caution since the subjects were not equally dispersed between study groups and had baseline imbalances, as participants were able to choose their intervention diet as part of an outpatient nutrition education program rather than being randomly assigned. In spite of these limitations, the preliminary findings may offer some insight for the differences between outcomes in Pastore et al.⁴¹ and Smith et al.⁶⁹ Attendance to the group support meetings was instrumental in the success of all diet groups in Talreja et al.,⁷⁵ which corroborates the explanation that the minimal support and education provided by Smith et al. may partially account for negative serum lipid outcomes observed in that study compared to those of Pastore et al. which provided support and nutrition counseling to the participants during the intervention. Additionally, Talreja et al.⁷⁴⁻⁷⁶ is the only study that compares the DASH diet and a whole-food, plant-based vegan diet against the Paleo diet, in addition to the Mediterranean diet which has been used as a control in other Paleo clinical trials. Mean percent of weight-loss, BMI reduction, and blood pressure reduction were very similar at both 60 days and 6 months between the vegan diet and the Paleo diet, out-performing the other two diets, and the vegan and Paleo groups had the best serum lipid changes. The similar outcomes between the vegan and Paleo interventions leads to the question of whether there is some underlying similarity between these dietary patterns that accounts for the beneficial outcomes of both, for instance the high emphasis on minimally processed plant-based foods. However, without the availability of diet logs and data assessment for correlations between

consumption trends and primary outcome measurements, it cannot be determined whether such similarities exist between these diet patterns, as implemented in this particular study.

So, though it seems that a Paleo diet designed with some restrictions and guidelines to emphasize food choices with a greater nutrient-to-energy density ratio may offer cardiovascular benefits at least in the short term compared to typical pre-intervention diets, it is unclear whether the Paleo diet is equally, more, or less cardio protective than established therapeutic diets. More long-term studies are required to determine if this diet should be generally recommended for people at risk of cardiovascular disease. Repeating the Talreja et al.⁷⁴ study design with randomized intervention groups, measured diet-logs, nutrient analyses for all participants, and publishing the results in a complete peer-reviewed article would contribute greatly to the understanding of the efficacy of the Paleo diet for achieving good health outcomes for Americans compared to diets recommended by U.S. health officials. Until such studies occur, considering the Paleo diet as an alternative after medication and recommended cardiac diets have been unsuccessful, as Pastore et al.⁴¹ suggested, could be a responsible way of incorporating the diet into clinical practice. Additionally, the Smith et al.⁶⁹ findings suggest that until controlled studies with completely unrestricted *ad libitum* versions of the Paleo diet are conducted, it would be wise to err on the side of caution by implementing the Paleo diet with restrictions similar to the ones used within the trials cited in this review.

Metabolic syndrome outcomes. Metabolic syndrome (MetS) is defined by the International Diabetes Federation as central obesity (measured as waist circumference with sex and ethnicity specific values) in addition to at least two of the following risk factors: elevated concentrations of fasting plasma glucose, elevated TG, reduced HDL cholesterol, and elevated blood pressure. MetS predisposes a person to developing DMII and/or cardiovascular disease.⁹⁰

Considering the study results for cardiovascular risk factors, DMII/pre-diabetes, and body composition, the Paleo diet seems promising as an intervention for MetS. As many of these risk factors were individually discussed in other sections of this review, they will only be discussed in this section from studies that specify MetS as a primary outcome measure. Boers et al.⁴⁴ found positive outcomes from a Paleo diet intervention on markers of MetS when compared against an isoenergetic healthy diet in a randomized controlled single-blinded pilot study. All meals were delivered to participants throughout the two-week study, and the macronutrient composition for the Paleo diet was based on Cordain's⁷ plant-animal subsistence ratios of hunter-gatherer societies. The Paleo group saw greater improvement in systolic blood pressure, cholesterol, TG, and fasting glucose than the reference group. Ultimately, the Paleo participants reduced their number of MetS risk factors by an average of 1.07 more ($p = .010$) than the control diet. However, it is important to note that the Paleo participants had an average of one more MetS characteristic at baseline than the control group participants, so the difference in improvement could possibly be attributable to baseline imbalance. The limitations of this study are small size, with 34 total participants, a very short duration of only two weeks, and food delivery to participants is a highly controlled intervention so it is not indicative of results from free-living adherence to the diets.

A systematic review and meta-analysis of the Paleo Diet's effects on MetS was conducted by Manheimer et al.⁸⁷ which compiled data from four of the trials included in this review (Mellberg,³⁷ Jönsson,⁴⁰ Lindeberg,⁴³ and Boers⁴⁴). The primary conclusion of the pooled evidence is that the Paleo diet resulted in greater short term improvements for waist circumference, TG, and blood pressure than the control diets, but improvements in HDL cholesterol and fasting blood glucose did not reach significance. However, the researchers noted

that the improvements to MetS risk factors can be credited to the reduction in carbohydrate, glycemic load, and salt with an improved omega-3 to omega-6 fatty acid ratio that resulted from the Paleo interventions, but it is not evident whether avoidance of whole grain or dairy products are essential to those improvements.⁸⁷ Lastly, Manheimer et al. pointed out that the validity of these trials can be questioned due to the possibility of performance bias, since it is difficult to double-blind nutrition studies, and possible selection bias as there is baseline imbalance in Boers et al., and possible imbalance in Jönsson et al. and Lindeberg et al. As already mentioned, the Paleo participants in the Boers et al. study had approximately one fewer MetS characteristics compared to their baseline measurements after a two-week intervention whereas the control group participants did not have a reduction in MetS characteristics. However, the Paleo participants had greater potential for improvement from a dietary intervention since they started with an average of one more MetS characteristic than the control participants and significantly (≤ 0.05) higher baseline values for bodyweight and BMI. Daily weight measurements were taken and adjustments were made to energy intake to prevent weight loss; however, reductions to weight and BMI were significantly greater in the Paleo group compared to the control group at the end of the intervention, which may have been attributable to their higher baseline values or could indicate biased intervention efforts by the researchers when adjusting energy to prevent weight loss. Baseline imbalances in Jönsson et al. and Lindeberg et al. are less apparent. Jönsson et al. utilized a cross-over design which is an effective method for improving the validity of a study, but baseline imbalances and carry-over effects could still impact outcomes. The group that started on the Paleo diet were on average older, had been diagnosed with diabetes more recently, and were taking more medications but required a lower dose of Metformin than the group that began on the diabetes diet. Carry-over effects were tested and two-sided t-tests measured

baseline differences for serum sample variables, but age, medications, and duration of diabetes were not included in those analyses. In Lindeberg et al. age was the only significant baseline difference between the diet groups, with a Paleo group of 65 ± 10 years and control group of 57 ± 7 years ($p = 0.01$). The group assignments in these studies were randomized, but perhaps it would have been beneficial to reassign some participants to create more uniformity between the groups. It is unclear to what degree, if any, that these baseline differences impacted these studies' results, so they should be interpreted cautiously until more controlled trials are conducted to test the effect of the Paleo diet on MetS.

Nutritional Adequacy of the Paleo Diet

No studies were identified in this review that assess the nutrient intake of self-identified Paleo diet followers in Westernized cultures. Some nutritional adequacy data is available from Paleo diet trials that performed nutrition analysis on their participants' food logs. Genoni et al.³² assessed 3-day weighed food records covering two weekdays and one weekend day during baseline and intervention for their 39 healthy female participants. Twenty-two participants were assigned to the Paleo diet and 17 to the control Australian Guide to Healthy Eating (AGHE). None of the micronutrients that changed from baseline to intervention reached significance within the AGHE group. However, the Paleo group had significant ($p < .01$) decreases in thiamin, riboflavin, iodine, sodium, and calcium and increases in vitamin C, beta-carotene, and vitamin A equivalents. There were also significant ($p < .05$) decreases in iron and folate equivalents and an increase in vitamin E. Mean intake values for thiamin, vitamin E, folate equivalents, iodine, sodium, potassium, calcium, and iron fell below the AI and RDA values in the Paleo diet logs. Since the participants were women, most of whom were within reproductive age, the lower levels of folate, iron, and calcium are of particular importance due to the

possibility of fetal neural-tube defects, anemia, and reduced bone density in this population, respectively. One interesting observation is that serum levels of red cell folate increased in the Paleo group in spite of a reduced intake of dietary folate equivalents. The researchers suggested that this may be indicative of limitations in the nutrition database for assessing fruits and vegetables that may have varying levels of some nutrients. Not all micronutrients were included in the assessment; all trace minerals, vitamin D, vitamin K, choline, biotin, pantothenic acid, vitamin B₆, and vitamin B₁₂ were absent. See Table 5 for a summary of observed micronutrient intake values in Paleo dietary trial groups.

Table 5: Observed Micronutrient Intakes from Paleo Participants in Trials

Source of Intake Values	Dietary Reference Intakes ⁷	Genoni et al. ³² (Mean ± SD)	Österdahl et al. ⁷⁰ (Mean ± SD)
Qualifiers for Recommended or Observed Values	Values for adults of 31-50 years	22 (F), mean age 47 ± 13 years	6 subjects (M & F), 20-40 years
Thiamin (mg)	1.1	0.96 ± 0.5	Not available
Riboflavin (mg)	1.1 (F), 1.3 (M)	1.47 ± 0.4	Not available
Niacin (mg)	14 (F), 16 (M)	43.76 ± 19.4	Not available
Vit-B6 Pyridoxine (mg)	2.4	Not available	4.4 ± 0.9
Vit-B12 Cyanobalamin (mcg)	2	Not available	16.3 ± 22.7
Folate equivalents (µg)	400	316.59 ± 84.9	Not available
Vitamin C (mg)	75 (F), 90 (M)	167.72 ± 84.2	354 ± 61
Total Vitamin A equivalents (µg)	700 (F), 900 (M)	2031.93 ± 1359.0	Not available
Vitamin E (mg)	15	14.25 ± 7.3	17.5 ± 3.7
Vitamin D (µg)	15	Not available	8.5 ± 2.7
Iodine (µg)	150	63.91 ± 22.7	Not available
Sodium (mg)	2300 (Upper Limit)	915.07 ± 448.8	1192 ± 181
Potassium (mg)	4700	3371.21 ± 891.2	5228 ± 745
Calcium (mg)	1000	355.42 ± 91.2	395 ± 81
Iron (mg)	18 (F), 8 (M)	11.08 ± 2.7	14.3 ± 3.2
Magnesium (mg)	320 (F), 420 (M)	327.88 ± 96.7	424 ± 51
Zinc (mg)	8 (F), 11 (M)	11.86 ± 3.4	Not available
Phosphorus (mg)	700	Not available	1300 ± 253
Notes: Female (F) and Male (M). Standard Deviation (SD)			

Österdahl et al.⁷⁰ only had complete diet logs for six of 14 participants (one man, five women) owing to a technical error, but the logs were kept through the full 3-week Paleo trial period, so the assessments should reflect the subjects' average intake fairly accurately. There was no control diet in this study, so the Paleo nutrition analysis was compared against participants' baseline diets; but, the report does not specify how long the pre-intervention diet logs were kept. Like Genoni et al.,³² this dietary assessment did not include values for any trace minerals, vitamin K, choline, biotin, or pantothenic acid, and it was also lacking values for folate, thiamine, riboflavin, and niacin. However, it did include vitamin B₆, vitamin B₁₂, and vitamin D which were absent in the Genoni et al. study. Significant (paired Wilcoxon, $p = .0277$) changes from normal intakes included increases in vitamin B₆, vitamin C, vitamin E, and potassium, and decreases in calcium and sodium with the Paleo intervention. Mean intakes for vitamin D, calcium, and iron (adequate for men but not for women) were below the RDAs on the Paleo intervention. One consideration when interpreting this study is that all of the participants were medical students, and may not accurately represent the general population since higher education on health outcomes may have influenced their dietary choices. No long-term studies on nutrient adequacy of the Paleo diet have been conducted; however, a secondary analysis of Mellberg et al.³⁷ did assess dietary iodine balance at 6 and 24 months post Paleo intervention.⁸⁴ The results suggest that following a Paleo diet increases the risk for developing iodine deficiency as evidenced by significant decreases in urinary iodine concentration/excretion and serum levels of free triiodothyronine after 6 months compared to the control diet group.⁸⁴ This finding is supported by the inadequate iodine intakes, significantly reduced from baseline diets, reported in the weighed food records analyzed by Genoni et al. So, presently, the only evidence-based

micronutrient recommendation that can be advised to long-term Paleo followers is to consider incorporating supplemental iodine.

Cordain³ presented a nutrition analysis of sample Paleo meal plans made to follow a distribution of about 55% of energy provided from animal sources and the remaining 45% from plant sources. The sample diet was designed for comparison with the standards for a 25 year old female consuming 2200 kcal per day. The major limitation with this article is that the meal plans were compiled specifically to fit Paleo food inclusion and exclusion patterns and the prescribed plant-animal subsistence ratios without regard for actual eating patterns of contemporary self-proclaimed Paleo diet followers; but, the methodology had the strength that the meal plans were comprised of foods that are most commonly consumed in the U.S., with the exclusion of those that do not fit the Paleo diet pattern. In spite of the foods being very commonplace, the portion sizes are so irregular that it could be suspected that quantities of foods were titrated within the nutrition software until they met specific nutrient parameters. Then, these quantities were presented in grams so that it is not immediately apparent that the portion sizes may not be realistic. For instance, the dinner in this menu is comprised of a vegetable, avocado, and almond salad served with steamed broccoli, lean sirloin steak, and strawberries for dessert. The combined weight of the salad ingredients and strawberries is 555 g which equals 1.22 lbs. of mixed plant matter, served with 235 g of sirloin (8.25 oz.) and 468 g steamed broccoli, which equals about 5 cups of broccoli if weighed raw or 3 cups if weighed cooked. The mass and volume of this meal may be excessive for some women. Even with a 2200 kcal budget and large volumes of produce, there are some nutritional shortcomings in the dietary analysis. Calcium consumption on the sample meal plan averaged 691 mg daily, meeting only 69% of the RDA. Cordain suggested that this amount may be adequate for maintaining calcium balance since the

net renal ionic load on this diet is slightly alkaline from high ingestion of fruits and vegetables. This is supported by a few other studies, as Boers et al.⁴⁴ and Masharani et al.³⁹ noted their Paleo group consumed significantly less calcium than the control group and Frassetto et al.⁷¹ observed an insignificant decrease in calcium consumption from the participants' usual diets, but urinary loss of calcium was lower during these Paleo interventions than during the control diets or baseline diet (these trials had meals provided by the research teams, so data on calcium intake should be accurate). However, in Cordain's meal plan broccoli appears to be the single greatest contributor to calcium intake, so it is concerning that this nutrient is deficient even when the prescribed portion seems unrealistically large. Likewise, though the 400-800 mcg folate recommendation for women of reproductive age is being met with this sample menu, eliminating the serving of broccoli from dinner reduces the provided folate to 387 mcg (assuming 3 cups weighed steamed is the correct portion), so there is reason for concern that folate would be deficient without deliberate inclusion of folate-rich vegetables. With the exception of calcium and sodium, average daily intake of all micronutrients listed in the Paleo diet analysis were greater than those of the projected intake on the 2200 kcal DGA Healthy U.S.-style Food Pattern plan.^{3,91} However, no data were presented for choline, copper, manganese, selenium, and Vitamin K in the Paleo diet analysis, so intakes for these nutrients could not be compared.

There was also no data provided for vitamin D intake, and Cordain³ offered the explanation that modern Paleo diets have no dietary sources of vitamin D and very few dietary sources were available in hunter-gatherer diets with synthesis from sunlight exposure being the primary source in these populations. This is an erroneous claim as some mushrooms, organ meats, and fish provide more vitamin D per serving than fortified milk. An apparent oversight in Cordain's nutrition analysis is the 333 g (11.75 oz.) of salmon included in the breakfast meal

plan, which is one of the best dietary sources of vitamin D and provides 55.6 µg, nearly four times the RDA, in that quantity.⁹² However, as with the aforementioned folate consideration, the serving size for the salmon is unusually large and it is the only significant source of vitamin D in the sample meal plan. This demonstrates that it is possible to consume adequate vitamin D on a Paleo diet, but this nutrient may be at risk of deficiency without deliberate inclusion of high vitamin D content foods. Relying on sunlight exposure for adequate vitamin D synthesis, as Cordain suggests, is not realistic for most people with indoor jobs, especially for those living at northern latitudes. One factor that should be taken into consideration while planning for dietary sources of vitamin D is preformed vitamin A content. Many of the fatty fish and organ meats that could provide vitamin D on a Paleo diet are also excellent sources of preformed vitamin A, which may be detrimental when overconsumed. Chronic elevated intake of preformed vitamin A has a negative association with bone density and vitamin D absorption; chronic excess vitamin A intake at levels as low as 1500 retinol equivalents (RE), was associated with increased incidence of osteoporosis or hip fracture in a review of four large, prospective, observational studies.⁹³ There have not been enough studies to determine how genetic and dietary variables may affect individual thresholds for preformed vitamin A, but since calcium and vitamin D are nutrients at risk of under consumption on the Paleo diet, minimizing factors that interfere with their absorption is advisable. Cordain's sample menu provided an average of 6386 RE, 798% of the RDA, but the majority of this was obtained from provitamin A carotenoids derived from plants, which are not associated with toxicity or reduced bone density. The preformed vitamin A in Cordain's meal plan was derived almost entirely from salmon, providing 191 RE,⁹² well under the level associated with impaired calcium and vitamin D absorption. Organ meats have a higher concentration of preformed vitamin A than fish; for example, a 1 oz. serving of beef liver

provides 1780 RE.⁹⁴ Therefore, it is advisable that Paleo followers incorporate fatty fish and mushrooms in their diets to obtain adequate vitamin D and limit consumption of organ meats.

Observational studies that assesses average intake of all macro- and micronutrients in long-term American followers of the Paleo diet against the intakes of recommended dietary patterns and IOM standards would greatly contribute to the understanding of the nutritional adequacy of this diet and be useful for assessing whether or not the Paleo diet should be considered for review in future editions of the DGA. The current study addresses this gap in the literature by comparing the nutritional adequacy of the Paleo diet against DGA recommended diets in a sample of healthy, athletic, self-adhering American adults.

Chapter 3: Research Design and Methodology

Research Design

This study is a prospective cohort study to assess the nutritional adequacy of dietary intakes in a population of healthy, athletic adults self-adhering to one of four different dietary patterns. Participants kept a one-week measured diet log and answered questions on a screening questionnaire about estimated intake of food groups and nutrition education (Appendices A and B). A nutrition assessment was conducted on all of the diet logs for comparison against DRI values to identify any intake levels of concern or trends in the dietary habits of participants within the self-administered diet groups.

Selection Criteria

The study population included healthy, athletic adults who self-report adhering to a Paleo, Healthy U.S., Healthy Mediterranean, or Healthy Vegetarian dietary pattern (Appendix C). Exclusion criteria were any health conditions that interfere with dietary intake, pregnancy, or adherence to a diet plan designed by a medical professional such that intake is representative of following a dietary intervention rather than self-imposed *ad libitum* eating habits. Qualifying participants were required to be between ages 18 and 40 years old, have a body fat percentage range of 10-24% for women and 2-17% for men, and report regularly performing at least 2.5 hours of moderate-intensity activity or 1.25 hours of vigorous-intensity activity per week. Body composition parameters were set to include physically fit individuals, excluding body fat percentages below maintenance of essential adipose tissue.

Recruiting healthy, athletic volunteers rather than a random sampling of the general population limits the applicability of the findings since it can be reasonably expected that athletes in good health, who engage in healthful behaviors such as regular physical activity, also have an

overall higher quality diet than many other population groups. This condition was imposed for several reasons:

1. The Paleo diet is especially popular with athletes, particularly in the CrossFit community, but not as commonly followed by non-athletic individuals. Conversely, the DGA recommended diets are promoted and marketed by the USDA and many healthcare providers, so they are likely to be followed by a variety of people with a wider range of fitness and baseline health. Athletes are typically more motivated than the general population to eat in a way that is conducive to good health and maintaining caloric balance because it improves their physical performance. Without imposing the condition that all study participants be athletes, it is likely that the individuals in the Paleo group would have been more nutritionally educated and adherent to their dietary lifestyle than the participants in the DGA diet groups. Requiring that all participants be athletes within a healthy body fat percent range reduced variables relating to lifestyle, nutritional education, energy balance, and motivation and increased the likelihood that participants in all four study diets self-adhere to their dietary patterns.
2. The Physical Activity Guidelines for Americans issued by the Department of Health and Human Services recommends that adults without a limiting health condition should engage in at least 150-300 minutes of moderate-intensity activity, or 75-150 minutes of vigorous-intensity aerobic activity per week, or an equivalent combination of moderate and vigorous activity; in addition, muscle strengthening activities involving all major muscle groups should be incorporated two or more days per week.⁹⁵ When a person regularly engages in physical activity they may consume more calories while maintaining their weight. Having a higher caloric budget allows for greater flexibility in the diet to

meet micronutrient needs. So, using athletes as a study group ensures a good representation of the nutritional adequacy of these dietary patterns with the increased flexibility of a higher caloric budget. This group thus serves as a benchmark for the higher end of nutritional adequacy that can be expected of these dietary patterns when consumed *ad libitum* in a healthy population without professional intervention.

Recruitment

Participants were recruited primarily through fliers at gym facilities in Colorado Springs, CO. The fliers contained a brief explanation of the study objective and the incentive for participation (Appendix D), which was receiving a nutritional analysis of their individual 7-day diet journal along with a description of any nutrients that were outside of the DRIs, and a list of foods that are good sources of those nutrients. The flier provided the email address of the principal investigator to be contacted for more information. Volunteers were provided with a brief description of the study, an informed consent form, and a screening questionnaire to determine their eligibility. The questionnaire determined sex, weight, height, average minutes per week of moderate to intense physical activity, nutritionally significant health conditions, dietary pattern, dietary supplement use, primary sources of nutrition information (e.g., magazines, internet searches, health or fitness professionals, books) and food frequency questions regarding the average servings consumed per week of dairy, fortified dairy alternatives, legumes, grains, fruits, vegetables, meat, fish, nuts, and processed snack foods. Volunteers who returned the questionnaire were contacted by email notifying them of their eligibility status and reason for exclusion when applicable.

Data Collection and Analysis

Volunteers who met study criteria had an appointment scheduled with the principal investigator to measure anthropometric data, address any questions or concerns, and to receive instructions for keeping a one-week diet journal. Each participant received a template for their diet log and an example of a well-kept recording of food/beverage intake for one day (Appendix B). Anthropometric measurements were obtained using a balance beam scale with height rod and a bioelectric impedance analysis (BIA) monitor. During a morning appointment, the principal investigator measured participants' weight to the nearest 0.1 lbs., height to the nearest cm, and body fat percentage to the nearest 0.1%. Participants were instructed to maintain an overnight fast before their measurements but to consume one liter of water before bed and another one hour before their appointment to minimize hydration influence on BIA measures. Measurements were made in light-weight clothing without shoes. The height, weight, age, and body fat percentage of participants were measured only once during the screening phase for use in the nutrition analysis. Participants were instructed to begin recording in their dietary intake journals on a day of their choosing, not to alter their dietary patterns, and to record all of their intake of food, beverages, and caloric supplements (such as protein powders or oil capsules) including any cooking oil, condiments, sweeteners, or seasonings. They were advised to measure and record quantities whenever possible and to record sizes of portions compared to standard sized objects when objective measurement was not possible (e.g., deck of cards, golf balls, baseballs). Questions regarding consumption of non-caloric supplements such as multivitamins or minerals were included on the screening questionnaire for comparison of dietary behaviors in the sample groups, but the nutritional contribution from these supplements were not included in the

nutritional analysis since the intent of the study was to assess the nutritional adequacy of diets without supplementation.

Nutritional analysis was done on each diet journal using NutriBase software. Mean daily intake of each macro- and micronutrient was calculated for each participant. The participants' mean intake for each nutrient was compared to the age-and-sex-specific DRI to determine percent intake. Recorded quantities from the food journals were used to find the total weekly intake within each food group. The nutrition analysis from the food journals and the screening questionnaires thus revealed intakes relative to the DRI and DGA recommended daily/weekly servings. The mean daily and total weekly food group intake values derived from the diet journals were also compared against the participants' estimated intakes as reported on their screening questionnaires, allowing for assessment of accuracy of the self-reported estimations of their eating habits.

Safety and Confidentiality

This research was approved by the Eastern Michigan University Human Subjects Review Committee (Appendix E). Original hard copies of the screening questionnaires and anthropometric measurements were identifiable and stored in a locking file cabinet in the principal investigator's home office when not in use. During the nutritional analysis steps, all digital entries of the data were coded without personal identifiers. Data was coded during nutritional analysis rather than anonymous so that subjects could be contacted to receive a copy of the analysis made from their diet journal, which was the incentive for participation. Digital entries of data were stored in a password-locked computer in password-locked files. Hard copies of questionnaires with personal identifiers were shredded after data entry was complete.

Chapter 4: Results and Discussion

Seven respondents volunteered, of which, six participants were recruited for the study: two followers of the Paleo diet (both female) and four followers of the HUS style (two females, two males). There were no respondents representing the vegetarian or Mediterranean style diets. One male respondent was excluded since he did not adhere to one of the specified dietary patterns. One participant (US4) consumed gluten free products for about half of her grain intake, but she was included since her consumption of gluten-free products was based on a belief that these products were healthier rather than for a medical reason. One male participant (US2) had a higher body fat percentage than the recruiting criteria (Table 5), which was explained by the participant as owing to a decrease in his regular workout activity while finishing his education. His data is included as he met all the other inclusion criteria. All participants were between 20-29 years of age and were either students, workers, or competitors in fields that require maintenance of physical fitness. All participants were non-Hispanic Caucasian except US2, who was Hispanic. See Table 6 for a summary of the anthropometric and dietary habits of all participants. Data analysis by descriptive and comparative statistics were not appropriate due to low participation. Instead, data was qualitatively and quantitatively compared between individual subjects and dietary pattern groups.

Table 6: Characteristics of Participants

	Paleo Participants		US Healthy Diet Participants			
	P1	P2	US1	US2	US3	US4
Identifier Code	P1	P2	US1	US2	US3	US4
Age	20	29	23	25	29	28
Sex	F	F	F	M	M	F
Weight (lbs)	117.7	122.7	108.9	187.1	164.7	126.0
Height (cm)	159	165	154	182	180	157
Body Fat %	17.5%	18.1%	18.2%	21.2%	11.8%	18.6%
Moderate Intensity Activity (hrs/week)	7	3	14	3.5	2	6
High Intensity Activity (hrs/week)	13	1.5	7	0	2	2
Supplements used	Protein powder Fish oil / Omega-3	Magnesium Iron	Protein powder Fish oil / Omega-3 BCAA Caffeine Probiotics	Protein powder	Protein powder	None
Sources of nutrition information	Websites Coach / Personal trainer	Websites Scientific journals	Scientific Journals Coach / Personal trainer College classes / Academic training	Websites Books / Magazines College classes / academic training	Websites	Books College classes/ academic training

Two participants (P1 and US1) had unusually high caloric intake for being young women of small stature, but they each reported routinely performing 20 hours per week of moderate-high intensity exercise, so they required extra intake to maintain energy balance. The other two female participants (P2 and US4) had caloric intakes that are more typical of maintaining energy balance for their stature with the recommended level of activity. Having female participants with both high and moderate caloric intakes for each diet group was useful for comparing nutrition adequacy at varying energy levels between the diets. See Table 7 for the mean weekly intake values derived from all participants' diet logs and Table 8 for the percent of DRI values met.

Table 7: Mean Weekly Intakes

Identifier Code	DRI Values		Paleo Participants		US Healthy Diet Participants			
	Females	Males	P1	P2	US1	US2	US3	US4
Sex			F	F	F	M	M	F
Nutrient Averages (daily average for 1 week)								
Kilocalories	2000	2400	2408	1740	2475	2257	2391	1478
Protein (g)	46	56	149	79	124	136	104	57
Carbs (g)	130	130	219	195	278	260	299	230
Fiber (g)	28	34	36	23	26	27	29	25
Fat (g)	DRI based on		108	68	100	76	88	40
Sat. Fat (g)	%kcal see Table 7		29	24	34	20	31	10
Cholesterol (mg)	No DRI		856	426	324	472	222	60
Vitamins								
Vit-A (mcg RAE)	700	900	1270	765	201	467	311	3
Vit-B1 Thiamine (mg)	1	1	1	1	1	1	1	1
Vit-B2 Riboflavin (mg)	1	1	3	2	1	2	2	0
Vit-B3 Niacin (mg)	14	16	32	16	16	37	22	7
Vit-B5 Pantothenic Acid (mg)	5	5	11	7	3	6	3	2
Vit-B6 Pyridoxine (mg)	1	1	4	2	1	2	1	1
Total Folate (mcg)	400	400	429	204	281	390	298	72
Folate, DFE (mcg DFE)	400	400	315	138	228	426	306	13
Vit-B12 Cyanobalamin (mcg)	2	2	5	4	2	4	3	2
Vit-H Biotin (mcg)	30	30	42	26	0	4	0	30
Vit-C (mg)	75	90	236	104	44	97	22	157
Vit-D (IU)	600	600	260	74	51	214	222	18
Alpha Tocopherol (mg)	15	15	7	4	7	5	1	0
Vit-E (IU)	23	23	38	17	11	16	1	25
Vit-K1 Phylloquinone (mcg)	90	120	71	40	80	148	2	17
Minerals								
Calcium (mg)	1000	1000	809	698	898	799	1091	637
Magnesium (mg)	310	400	342	221	227	329	127	129
Phosphorus (mg)	700	700	1436	769	900	1340	432	377
Potassium (mg)	4700	4700	4122	2393	2393	3147	1248	1094
Sodium Upper Limit (mg)	2300	2300	1999	1870	2537	2534	4154	2834
Chromium (mcg)	25	35	5	5	0	2	0	9
Copper (mg)	900	900	1	1	1	1	0	0
Iodine (mcg)	150	150	2	417	0	3	431	4
Iron (mg)	18	8	14	8	16	16	18	9
Manganese (mg)	2	2	2	1	2	3	2	1
Molybdenum (mcg)	45	45	5	5	0	2	0	8
Selenium (mcg)	55	55	139	69	62	123	36	16
Zinc (mg)	8	11	15	7	10	10	5	3
Note: All values are rounded to the nearest whole number.								

Table 8: Percent of DRI Met by Mean Daily Intake Over One Week

Identifier Code	DRI Values		Paleo Participants		US Healthy Diet Participants			
	Females	Males	P1	P2	US1	US2	US3	US4
Sex			F	F	F	M	M	F
Kilo Calories	2000	2400	2408	1740	2475	2257	2391	1478
Protein %kcal	10-35%		24	18	20	24	17	15
Carbohydrate %kcal	45-65%		36	44	44	46	50	62
Total Fat %kcal*	20-35%		40	35	36	30	33	24
Sat. Fat %kcal*	<10% energy		11	12	12	8	12	6
Alcohol %kcal	No DRI		1	4	1	0	1	0
Fiber (g)	28	30.8	36	23	26	27	29	25
Cholesterol (mg)	No DRI		856	426	324	472	222	60
Vitamins			% DRI met					
Vit-A (mcg RAE)	700	900	181	109	29	67	44	0
Vit-B1 Thiamine (mg)	1.1	1.2	132	72	75	104	118	46
Vit-B2 Riboflavin (mg)	1.1	1.3	229	172	97	125	116	38
Vit-B3 Niacin (mg)	14	16	230	111	117	228	138	50
Vit-B5 Pantothenic Acid (mg)	5	5	224	149	54	124	59	49
Vit-B6 Pyridoxine (mg)	1.3	1.3	292	137	105	185	100	50
Total Folate (mcg)	400	400	107	51	70	98	74	18
Folate, DFE (mcg DFE)	400	400	79	34	57	107	76	3
Vit-B12 Cyanobalamin (mcg)	2.4	2.4	225	158	100	176	142	70
Vit-H Biotin (mcg)	30	30	139	88	0	14	0	71
Vit-C (mg)	75	90	315	139	58	108	24	209
Vit-D (IU)	600	600	130	37	25	107	111	9
Alpha Tocopherol (mg)	15	15	46	24	44	34	4	3
Vit-E (IU)	15	15	167	75	47	70	7	110
Vit-K1 Phylloquinone (mcg)	90	120	79	44	89	123	2	19
Minerals								
Calcium (mg)	1000	1000	81	70	90	80	109	64
Magnesium (mg)	310	400	110	71	89	82	32	41
Phosphorus (mg)	700	700	205	110	129	191	62	54
Potassium (mg)	4700	4700	88	51	51	67	27	23
Sodium maximum (mg)*	2300	2300	133	125	169	169	277	189
Chromium (mcg)	25	35	21	19	0	5	0	34
Copper (mg)	900	900	115	98	148	100	48	48
Iodine (mcg)	150	150	6	11	0	2	0	11
Iron (mg)	18	8	75	45	89	198	226	48
Manganese (mg)	1.8	2.3	108	77	111	138	102	38
Molybdenum (mcg)	45	45	11	11	0	4	0	18
Selenium (mcg)	55	55	253	125	113	224	65	29
Zinc (mg)	8	11	186	89	125	94	43	41

Green indicates exceeding DRI, yellow indicates meeting at least 70% DRI, red indicates any value below 70% DRI. *For Sodium, Fat, and Sat. Fat green indicates within recommended range, yellow indicates within 130% of RDA and red exceeds 130%.

Some of the micronutrients' intake values were extremely low for all participants (chromium, molybdenum, biotin), which is likely a limitation of the NutriBase software and

assigned nutrient levels of the foods within the USDA's database. Iodine intake was also low for all participants, but this nutrient also may have been under-represented since sodium intake was above the adequate intake value for all participants, and it is likely that some sodium was sourced from iodized salt. Sodium intake for the Paleo participants was below the upper limit values but higher than expected considering that the available literature implies that sodium intake is low on this diet.^{3, 32, 70} However, brand selections listed on the diet journals indicated that the Paleo participants consumed poultry that was enhanced with brine during processing to preserve flavor and moisture, which was a contributing source of sodium. Additionally, both Paleo participants consumed one serving of bacon, P1 consumed several servings of cured ham and deli-style meat, and P2 had several servings of restaurant prepared beef, all of which contained added salt from curing or seasoning. The Paleo education provided in research trials typically advised participants to consume uncured, minimally processed, lean-cut meat in compliance with the Cordain^{3, 7} defined Paleo model, but data from the present study implies that Paleo followers who implement the diet without education from a dietary professional may not differentiate between enhanced/cured and unenhanced/uncured meats. As this was a younger study population than those in most of the reviewed trials, socioeconomic factors such as budget or level of cooking knowledge may have also influenced meat selection. So sodium and iodine content in the Paleo diet may be largely dependent on the dietary education received by the individual, cost and availability of uncured/unenhanced meats, and whether iodized or uniodized salt is used in commercial meat processing, but larger observational studies are needed to make this determination. Chloride and fluoride were excluded from the analysis since it is assumed that participants could meet intake requirements from tap water, but participants were not required to record their water consumption in the diet logs.

Folate intake was low for all of the female participants except for P1, which is likely because she consumed more vegetables, whole grains, and fruit than the other females. P1 was also the only participant who exceeded her RDA for fiber and came close to meeting her potassium RDA, likely for the same reason. Iron intake was also low for all of the females and well above the RDA for the males, likely because the males ate close to double the grain products often in the form of iron fortified bread and breakfast cereal. The Paleo participants both met their vitamin A requirements, though none of the HUS participants did. US4 was deficient in nearly all micronutrients, which is likely due to the combination of having the lowest energy intake and eating gluten-free grain products, which, unlike most wheat products, are not fortified/enriched or a naturally good source of B vitamins. P1 and the two male HUS participants (US2 and US3) met their vitamin D DRI, which is interesting because dairy and dairy alternative intake was close to one cup equivalent per day for all participants except US3. The adequate vitamin D intakes for US2 and US3 are partially attributable to selections within the dairy food group, as these participants consumed vitamin D-fortified cow's milk as their primarily dairy source, whereas yogurt, the primarily selection for P2, US1, and US4, is not typically fortified. Additional vitamin D was obtained from meat/poultry (all participants), eggs (P1, P2, US2), fish (US2), and fortified grains (US3). The difference between vitamin D intakes in the Paleo participants is attributable to P1 consuming twice as many eggs and four-times as much poultry as P2. US1 had high egg whites consumption, which did not contribute to her vitamin D intake, as this nutrient is contained within the egg yolks. Alpha-Tocopherol was low for all participants and total vitamin-E was inadequate for all except P1 and US4.

Percent energy from macronutrients was very similar between P2 and the HUS participants, while P1 had moderate restriction in CHO intake with a concomitant increase in

protein and fat. The two participants with the lowest percent energy from fat (US2 and US4) were the only ones who consumed below the recommended maximum of 10% energy from saturated fat.

No difference was observed between the groups on the accuracy of their intake estimates when the estimated daily and weekly servings of the food group data from the food frequency questionnaire were compared with the actual intakes gathered from the food journal. See Table 9 for the comparison of estimated food group intakes as reported on the screening questionnaire compared to actual intake from the one-week diet logs. There were some commonalities in the participants' intake estimates. For instance, all participants underestimated either their meat or poultry consumption in the questionnaire, and all except P2 and US3 underestimated both. This seems to be attributable to the participants eating portions that are larger than the recommended serving sizes, so one portion within a meal was closer to two servings of meat or poultry.

Table 9: Estimated and Actual Intake

Identifier Code	Paleo Participants				US Healthy Diet Participants							
	P1		P2		US1		US2		US3		US4	
	Estimate	Actual	Estimate	Actual	Estimate	Actual	Estimate	Actual	Estimate	Actual	Estimate	Actual
Sex	F		F		F		M		M		F	
Kilo Calories		2408		1740		2475		2257		2307		1478
Fruit servings/day	3	4.7	4	1.6	3	1	2	1.9	<1	0.1	1	1.8
Vegetable servings/day	2	1.7	2	1.2	2	0.9	4	1.5	1	0.75	1	0.9
Whole grain servings/day	1	2	1	1.3	1	0.5	3	3.6	3	5.2	2	0.3
Dairy servings/day	<1	0.4	1	1	2	1.2	<1	1.2	1	3.3	1	1
Dairy alternatives servings/day	3	0.6	<1	0	3	0	<1	0.1	<1	0	1	0.14
Tree nuts & Seeds servings/week	1	0	1	3	3	8.5	2	1	3	1	<1	2
Peanuts and PB servings/week	3	2	4	2	3	0.25	1	3	1	5	<1	1
Tofu & TVP servings/week	2	0	<1	0	3	0	<1	0	2	2	<1	0
Eggs servings/week	3	22	3	9	4	10*	4	6	<1	0	<1	0
Meat servings/week	3	7	3	7.5	3	6	3	7	4	4	2	3.2
Poultry servings/week	2	14	3	3.5	3	6	5	12	3	6	2	4.3
Fish and Shellfish servings/week	1	0	<1	1	2	0	3	4	<1	0	<1	0
Legumes servings/week	<1	1	3	1	<1	4	4	4	<1	1	<1	2.5
Refined grains servings/week	<1	2	2	0	1	27.5	3	33	>6	15	1	27
Refined sugars servings/week	<1	5	<1	5	1	16	1	6	3	6	<1	15
Deep fried foods servings/week	<1	0	<1	0	<1	1	<1	0	1	0	<1	1
Hydrogenated oil servings/week	1	0	2	0	2	2	<1	0	<1	0	<1	0
Alcohol servings/week	<1	1	1	4	1	2	<1	0	<1	2	<1	0

* 7 egg whites, 3 whole eggs

Green indicates actual intake was equal to or less than 1 serving size deviation from estimated intake. Yellow indicates actual intake was between 1.1-2 serving size deviation from estimated intake. Red indicates actual intake had >2 serving size deviation from estimated intake.

Also, there was a tendency to underestimate egg consumption except for the two participants who didn't eat any eggs while keeping their one-week diet logs. All participants underestimated

their refined sugar intake, possibly because they didn't consider added sugars in food products that are typically considered healthy and were counted in other food groups such as yogurt, granola/cereal, bakery products, and energy bars. Additionally, sugary foods were more commonly consumed between meals, so they were perhaps more impulsive food choices than the regularly scheduled meals and therefore less predictable. However, all of the participants had good estimations of their deep-fried foods and hydrogenated oil intake, which were very low for both groups. Alcohol consumption was also low, with five out of six participants accurately estimating their intake. Four participants estimated their whole grain intake correctly, which was fairly similar between the groups, but the HUS group greatly underestimated their refined grain intake and consumed at least seven times as many servings per week as the Paleo participants. The two female HUS participants consumed sugar-sweetened foods three times as often as the two female Paleo participants, though the male HUS participants' sugar-sweetened foods consumption was very similar to the Paleo participants. It is important to note that limitations in the nutrition analysis software do not allow for comparison of total grams of refined sugar consumed or percent of energy derived from refined sugar, only the total number of standard-sized servings of foods with added sugars can be compared. Consumption of refined grains seemed to be associated with refined sugar intake for the HUS females with the inclusion of sweet bakery products, but the HUS males seemed to consume more of their refined-grain foods as savory dishes such as pizza, pasta, and bagels.

Table 10 shows each participant's intake of the recommended food groups converted into USDA consensus ounce equivalents (oz.-eq). The recommended oz.-eq per day or week for each corresponding caloric level are provided for comparison. The Paleo participants were meeting recommended fruit intake but did not meet their recommended vegetable intake. Half of the HUS

Table 10:
Food Group Intake in Ounce Equivalents Compared to DGA Recommendations for Caloric Level

Identifier Code	P1		P2		US1		US2		US3		US4	
	F		F		F		M		M		F	
Sex	Guideline	Intake	Guideline	Intake	Guideline	Intake	Guideline	Intake	Guideline	Intake	Guideline	Intake
Kilo Calories	2400	2408	1800	1740	2400	2475	2200	2257	2300	2307	1400	1478
Fruit cup-eq/day	2	4.7	1.5	1.6	2	1	2	1.9	2	0.1	1.5	1.8
Vegetables (including legumes) cup-eq/day	3	2.2	2.5	1.7	3	1.1	3	3.5	3	1.25	1.5	2.14
Grains total oz-eq/day*	8	2.3	6	1.73	8	4.5	7	8.3	7.5	7.34	5	4.2
Whole grain oz-eq/day*	4	2	3	1.3	4	0.5	3.5	3.6	3.75	5.2	2.5	0.3
Refined grains oz-eq/day*	4	0.3	3	0.43	4	4	3.5	4.7	3.75	2.14	2.5	3.9
Dairy & fortified alternatives cup-eq/day	3	1	3	1	3	1.2	3	1.3	3	3.3	2.5	1.14
Nuts, peanuts, seeds & soy oz-eq/week	5	4	4	7	5	9	5	7	5	15	3	4
Meat, poultry, eggs oz-equivalents/week	31	63	23	33	31	43.7	28	63	29.5	30	19	22.5
Fish and Shellfish oz-eq/week	10	0	8	3	10	0	9	12	9.5	0	6	0

Green indicates intake that exceeds or is within a 0.5 oz-equivalent less from the DGA recommendation. Yellow indicates intake was between 0.5-1 oz-eq less than recommendation. Red indicates a deficit > 1.1 oz-equivalent less from the recommendation. *For the grain category, green indicates that whole grains comprised ≥50% of consumption, and intake was within ± 1 oz-eq of recommended. Yellow indicates that one of the green qualifiers were met. Red indicates consumption outside of recommended range with whole grains accounting for >50% of intake.

participants met their fruit and vegetable recommendations and half did not, so it does not seem that one group was superior to the other for fruit and vegetable consumption. There also did not seem to be a difference in seafood consumption, which was low in both groups. The amount of dairy/dairy alternative consumption was similarly low in both groups, but there was a difference in the types of products consumed; the Paleo participants did not use cow's milk, but did use some nut milk and goat milk products. US2 was the only participant who met the recommended fish intake and one of only two participants to meet the vegetable recommendation. His diet journal reflected some influence from traditional Latin-American eating styles, as the majority of his grain intake was from rice and corn, and he consumed more legumes and fish than the other participants. This seems to have improved the overall diet quality, as US2 met the most micronutrient DRIs out of the HUS participants and stayed below the saturated fat recommendation, and if he made just one dietary change by switching from white rice to brown rice, he would meet the DRI for fiber and be well within the recommendation that 50% of grains be whole grain. US4 ate within the recommendation for fruit, vegetables, meat, and nuts, but her grain consumption was highly refined. She would have been within the recommendation for fiber and whole grain consumption if she switched from gluten-free bread (which was mostly tapioca

and rice starch based) to whole wheat. This dietary habit is the likely reason that she was the only participant with deficient intake for all B vitamins. Gluten avoidance is not pertinent to the topic of this study, but US4's poor diet quality suggests a need to educate the public that, unless it's medically necessary, switching to gluten-free products is not nutritionally beneficial. It also suggests that people who practice gluten avoidance may not be good candidates for dietary studies as their nutritional data may be low outliers. Lastly, the Paleo group did not practice complete avoidance of grain products, but their refined grain intake was negligible and their whole grain consumption was around half of the recommended daily amount for their caloric levels. So, ultimately, the Paleo group's total grain intake was around one-fourth of that of the HUS group, and it had a much more desirable whole grain to refined grain ratio.

Chapter 5: Conclusions and Recommendations

Since the study was smaller than desired, definitive conclusions cannot be made. However, the available findings combined with the compiled information from the literature review section provide some guidance for future research and recommendations that could be incorporated by dietitians for patients following the Paleo diet. Participant P1 had the best nutrition analysis in terms of meeting most of her micronutrient requirements. However, she also had the highest energy intake of all participants, including the males, which provided more flexibility for meeting nutrient goals. At a height of 5'2" (159 cm) and 117.7 lbs. (53.5 kg) her intake of 2408 kcal per day would almost certainly cause weight gain if not for her 20 hours per week of exercise. At 5'5" (165 cm) and 122.7 lbs. (55.7 kg), P2 reported 4.5 hours of exercise per week and an average of 1740 kcal per day, and her nutritional adequacy for micronutrients was lower. This reiterates the concern that it might be difficult for people who require lower caloric intake to meet their DRIs on the Paleo diet without thorough planning. However, most of the nutrients that were low or borderline for the Paleo participants (folate, vitamin K, calcium, potassium, iron, vitamin E) could all be increased significantly without great change to their energy intake by including more dark green vegetables. It should also be noted that the HUS participants were generally deficient in the same nutrients as the Paleo group, and only half of the HUS participants consumed more vegetables than the Paleo group. Data from the *WWEIA* NHANES shows that in the 20-29 year age group, males consume an average of 1.57 cup equivalents of vegetables per day and females consume an average of 1.52 cup equivalents (when legumes are counted as a vegetable rather than protein source),⁹⁶ which does not meet the DGA recommendations for most caloric intake levels. The average daily vegetable cup equivalents for the participants in this study is only marginally better at 1.98, suggesting that

even among young athletes who maintain a healthy body composition, vegetable consumption is likely less than adequate.

Similar to the dietary composition of some of the *ad libitum* trials discussed in the literary review, P1 had over double the daily fruit intake of the HUS group, but this was not a commonality shared with P2. Likewise, egg intake for P1 was over twice as high as P2, and her poultry intake was 4 times that of P2. Macronutrient energy distribution ratios were quite different between the two Paleo participants with 26% PRO, 32% CHO, 42% Fat for P1, representing a ratio similar to that recommended by Cordain,⁷ and 19% PRO, 41% CHO, 37% for P2, which is close to the DGA recommended values.¹⁷ Also, tree nut, seed, and fish consumption were very low in the Paleo participants, though these foods are permitted on this diet. This evidence suggests that in the absence of structured food group recommendations and/or dietary coaching provided by nutrition professionals, the Paleo diet might be implemented in a variety of ways, and it is difficult to say whether it is nutritionally sufficient when there is so much variation. It also suggests that nutrient intake observed in research trials may not realistically reflect intake for people who don't have access to the same level of dietary education provided in trials. However, the self-adhering Paleo followers in this study obtained similar levels of nutritional adequacy in their diets to those of the DGA recommended diet followers. This limited data set suggests that the Paleo diet as followed by self-adherence has potential to be nutritionally adequate with some dietary education and planning.

Variation in the diet composition is not only an obstacle to establishing a baseline of the nutritional adequacy for the Paleo diet, it also complicates interpreting results from controlled trials to establish associations with health outcomes. The Paleo diet generally improved health outcomes in the trials evaluated for this literature review. However, there were enough variations

between the definitions of the Paleo diet in these studies that it is difficult to determine which characteristics are responsible for the positive outcomes. One way that future research can be improved is for the nutrition research community to establish a consensus version of the Paleo diet. Some of the existing trials have reoccurring associations that should be incorporated into the consensus guidelines. For instance, Fontes-Villalba et al.,³³ Bligh et al.,³⁸ Jönsson et al.,⁴⁰ and Lindeberg et al.⁴³ had higher fruit intake for their Paleo groups than the controls which was associated in some way with improvements for weight, waist circumference, and/or blood sugar regulation. Macro-nutrient distribution ratios were not associated with the outcomes in some studies,^{35, 38, 43} while increased protein had an association with reduced energy intake or increased satiety in others.^{32, 40} Percent of energy from carbohydrate was reduced in the Paleo groups in most studies,^{33-35, 37, 41, 43, 44} but in others it was not significantly different from the control diet or baseline values^{38, 71} and was higher in one case.³⁹ Changing the source of carbohydrates from grains to fruits and vegetables was a more significant determinant of improved outcomes than reducing the percent of energy from carbohydrates. The Paleo intervention periods nearly unanimously emphasized leaner, less processed animal protein choices and recommended daily limits for oil intake using high omega-3 types. Accordingly, the recommendations for the Paleo consensus diet should not restrict fruit intake, even for diabetics, and should have a carbohydrate intake that is only moderately lower than typical intakes for other recommended diets but supplied primarily by fruits and vegetables. Likewise, all vegetables should be allowed on the Paleo diet since all of the research had some allowance for potatoes and didn't place any restrictions on other "nightshade vegetables," which include white and yellow potatoes, tomatoes, green peppers, chili peppers, eggplants, and tomatillos. The Paleo diet as it is promoted by Loren Cordain eliminates or restricts nightshade vegetables,⁹⁷ but this

characteristic was not incorporated into the dietary interventions for the research, so it should not be included in the consensus version of the diet. Protein intake should have a moderate increase ensuring that sources are lean enough to limit saturated fat below 10% of total energy intake. The findings from the current study also suggests that special emphasis on minimum servings per day or week should be put on fish, nuts and seeds, and leafy green vegetables, which were lacking in both of the Paleo participants' diets, and would contribute greatly to improving the nutritional adequacy.

With proper consideration, a consensus Paleo diet could be in compliance with many of the latest recommendations of the DGA. The scientific report for the 9th edition of the DGA (released in July 2020) is currently under review for the creation of the new guidelines (expected to be released in December 2020).⁹⁸ It does not appear that there will be any new dietary patterns recommended, but the three patterns from the 8th edition will likely be updated based on new literature review. The committee has identified whole grain consumption to be associated with positive health outcomes with nearly the same consistency as fruit and vegetable consumption, while refined grain showed consistent association with negative health outcomes. While the 8th edition of the DGA recommended at least half of grain products be whole-grain that proportion may be increased in future editions. Low-fat dairy options continue to show positive health outcome associations, while high-fat dairy options are associated with increased risk of all-cause mortality and DMII. The protein food group will likely see an increased emphasis on legumes and fish because these foods have a consistent association with positive health outcomes, while there will likely be an emphasis on eliminating/restricting red and processed meat, as these have been consistently associated with increased risk of CVD, colorectal cancer, DMII, obesity, and all-cause mortality. Inclusion of lean meat and poultry may also be emphasized, as these have

associations with positive health outcomes. Due to its strong association with negative health outcomes, the recommendation for refined sugar will likely be reduced from < 10% of energy intake (in the 8th edition DGA) to < 6% of energy intake. Lastly, it is unlikely there will be any changes made to the AMDR. Macronutrient distribution ratios outside of the AMDR without energy restriction were assessed for associations with health outcomes, but there was not enough research for an evidence grade relating to any health outcome except CVD, which was assigned a *Limited Evidence* grade for having neither beneficial nor detrimental outcomes associated with intake outside of the AMDR. The Paleo diet already eliminates inclusion of processed meat, refined sugar, refined grains, and high-fat dairy, and an improved consensus version of the diet could easily incorporate the recommendations for increased consumption of fish, lean-meat, and poultry with reduced/eliminated consumption of red meat. The Paleo diet's main deviations from the current DGA scientific report is its elimination of whole grains, legumes, and low-fat dairy.

Once a consensus Paleo diet is formed, clinical trials should also be conducted that introduce food group variables to assess how they affect outcomes. For instance, is the complete elimination of whole grains, dairy, and legumes necessary to achieve the improvements seen in Paleo trials, or could small intakes of one or more of these food groups be even more beneficial within an otherwise-Paleo dietary pattern? Many of the trials showed much higher fruit and vegetable intake on the Paleo diet than the control diets which had correlations to desirable outcomes. This raises the question of whether the consumption of foodstuffs prohibited by the Paleo diet, including whole grains, dairy, and legumes, are problematic *per se*, or are they only problematic when/if they displace fruit and vegetable consumption? In other words, are the benefits of the Paleo diet attributable to reducing negative effects of the foods it excludes, increasing positive effects of the foods it includes, or a combination of these factors? The

positive and negative health outcome associations in the scientific report from the DGA advisory committee support the hypothesis that the Paleo diet's positive outcomes are attributable to the higher fruit and vegetable intake and lower intake of sugar, refined grain, and high-fat dairy, but not due to the elimination of legumes and low-fat dairy or alterations to macronutrient distribution ratios. In the current study, neither of the Paleo participants adhered completely to the elimination of whole grains, legumes (mostly consumed as peanuts), and dairy, but the intake of these foods was much lower than the HUS group, and their selections were less processed. It's possible that calibrating the Paleo diet to include small amounts of the best options within these food groups would be more beneficial and more nutritionally complete than excluding them entirely.

Aside from questions relating to formulating a consensus Paleo diet and health outcome associations, there are many questions that remain unanswered that require larger and longer studies in an American population. For instance, the trials in this literature review predominantly included non-Hispanic Caucasians. Considering the health disparities and higher risk of chronic diseases for minority groups in the U.S. it is essential that more controlled trials be conducted to include these groups and assess how their health outcomes for DMII and CVD are affected by the Paleo diet. Additionally, more long-term *ad libitum* controlled trials are needed to determine the true effectiveness of this diet for weight reduction and maintenance. In the only long-term trial with the Paleo diet, the weight loss in the Paleo group was not significantly greater than that of the control at 24-months.³⁷ Also, the study group was Swedish post-menopausal women, so it was not a sampling that can well-represent the diversity of the American population.

Lastly, larger observational studies with American, self-adhering Paleo participants need to be conducted to assess nutritional adequacy. At this point, there is not enough data to

conclusively determine whether certain nutrients are at risk for deficiency on this diet. A study design similar to this preliminary examination could be used, but it would be most beneficial if recruiting and data analysis capabilities were great enough to open the study to the general population rather than only including athletes, then control for compounding variables. Ideally, the Paleo diet, Healthy U.S.-style, Healthy-Mediterranean, and Healthy Vegetarian Patterns would all be represented among the participants, as this study design originally intended, so that the nutritional adequacy of the Paleo diet could be compared against all of the DGA recommended diets. Nutritional comparison against the Mediterranean diet is useful since it was used as the control diet for many of the existing trials on chronic disease outcomes. Nutritional comparison against a vegetarian diet would be particularly interesting because these diets both ideally put a heavy emphasis on fruit and vegetable consumption, but the primary protein sources of one are eliminated on the other. For the data analysis, the distribution should be assessed and outliers for each nutrient identified. Ideally, there should be enough participants that the mean percent of DRI met for each nutrient within each dietary pattern can be determined with a 95% confidence interval for comparison between the dietary patterns. Multivariate analysis of variance should be used to determine significant differences in the content of specific nutrients across dietary patterns. Conclusions can then be drawn regarding the nutritional adequacy of the Paleo diet as it compares to the Healthy U.S.-style, Healthy-Mediterranean, and Healthy Vegetarian Patterns, and recommendations can be made for altering the ratio of food group contributions to maximize nutritional adequacy. Until such research is conducted, dietitians and other health practitioners should advise patients following a Paleo diet to be mindful of their protein sources to maintain saturated fat content within the recommended limits; try to meet and possibly exceed the DGA recommended daily ounce equivalents for fruits, vegetables, fish, nuts,

and seeds for their calorie level; eat as much variety as possible; consider supplemental vitamin D and iodine; and women of child-bearing age should discuss iron and folate supplementation with their practitioners.

In spite of many uncertainties, the Paleo diet could be either a candidate for future inclusion in the DGA or could influence changes to the intake recommendations for food groups in the currently recommended DGA dietary patterns. The available research shows a good starting point with some room for improvement in the diet composition. Some of the criticisms of the diet are that it is environmentally unsustainable and expensive due to the heavy emphasis on animal foods, and it is difficult to adhere to. However, it seems that these downsides could be mitigated without reducing the beneficial effects. The formative theoretical literature on the Paleo diet largely emphasizes the importance of increased consumption of animal foods, but most of the Paleo trials only loosely incorporated those plant to animal subsistence ratios, if at all. There was poor compliance to the recommended protein increase in some studies, and carbohydrate intake usually just changed in respect to its sources rather than its percent energy contribution, but the diet still resulted in improvement from baseline measurements for many outcome variables. When the emphasis for the diet is on high intake of minimally processed fruits and vegetables with only a moderate increase in seeds, nuts, eggs, fish, meat, and poultry, its sustainability and cost should be similar to the other recommended diet patterns. Also, the diet may not be so difficult to adhere to if it were formulated with daily food group recommendations catered to American consumption trends derived from the *WWEIA* NHANES data in a manner similar to other recommended dietary patterns. Moving forward, research related to the Paleo diet should not be limited by the ideological appeal of evolution discordance nor by plant-to-animal subsistence ratios, which are not supported by genetic or anthropological data. Instead, it

should focus on evidence from well-designed controlled trials and observational studies to calibrate it to the needs of a modern population. As Österdahl et al.⁷⁰ aptly phrased it, the goal should not be “an attempt to copy stone-age eating habits in a historically correct manner, but rather to eliminate some of the harmful aspects of modern affluent diets and extract some health benefits from readily available foods, using an evolutionary paradigm as guide.”

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Glossary of Acronyms

(Listed Alphabetically)

11 β HSD1: enzyme 11 β hydroxysteroid dehydrogenase type 1

ADA: American Diabetes Association

AHA: American Heart Association

AGHE: Australian Guide to Healthy Eating

AI: Adequate Intake

AMA: American Heart Association

AMDR: acceptable macronutrient distribution range

AUC: Area under the curve

BIA: bioelectric impedance analysis

BMI: Body mass index

CHO: Carbohydrates

C_{max}: peak concentration in a serum

CVD: Cardiovascular disease

DASH: Dietary Approaches to Stop Hypertension

DGA: Dietary Guidelines for Americans

DRI: Daily Reference Intakes

DMII: Diabetes Mellitus Type II

EAR: Estimated Average Requirement

FLI: free leptin index

HbA1c: Hemoglobin A1c

HDL: High-density Lipoproteins

Glossary of Acronyms (continued)

Listed Alphabetically

HOMA: homeostatic model assessment

IOM: Institute of Medicine

LDL: Low-density Lipoproteins

MetS: Metabolic Syndrome

NNR: Nordic Nutrition Recommendations

OGTT: oral glucose tolerance test

PAL1 & PAL2: Paleo test meals

PRO: Protein

RD: registered dietitian

RDA: Recommended Dietary Allowance

RE: Retinol equivalents

REF: reference control meal

sLR: soluble leptin receptor

TC: Total cholesterol

TG: Triglycerides

USDA: United States Department of Agriculture

WHO: World Health Organization

WWEIA NHANES: What We Eat is America/National Health and Nutrition Examination Survey

APPENDICES

Appendix A: Screening Questionnaire

Name: _____ Reference Code : _____ (assigned by researcher)

The following questionnaire will be used to assess dietary trends and knowledge in athletic individuals who follow different eating patterns. The anthropometric measurements will be used in your nutrition analysis to determine your dietary reference intake standards. You may elect not to answer any questions that make you uncomfortable. If you are not sure of about the meaning of a question, feel free to ask the researcher.

-Sex: Male Female

-Age: _____

-Are you currently following a therapeutic diet or meal plan prescribed for a medical condition?

Yes No

This box to be completed with researcher:

Height: _____ Weight: _____

Body Fat %: _____

Deliver nutrition analysis:

Email Mail In person

-Which dietary pattern best describes the way you eat:

Paleo: includes meat, poultry, seafood, fruit, vegetables, eggs, seeds, tree nuts, and unrefined oils. Typically avoids cereal grains, legumes, dairy, potatoes, salt, processed foods, and refined sugars and oils.

Healthy Vegetarian: typically excludes meat, poultry, & seafood and minimizes processed/refined foods. Includes vegetables, fruits, legumes, soy products, nuts and seeds, whole grains, dairy or dairy alternatives, and eggs (optional).

Healthy U.S. Style: includes all of the USDA recommended food groups but emphasizes consuming more nutrient dense options and minimizing processed/refined foods (eating clean).

Healthy Mediterranean Style: Similar to Health-U.S. Style in that it includes nutrient dense options from all food groups but it incorporates fewer portions of dairy foods and more portions of fruit and seafood.

-Would you like to receive a copy of the finished thesis to view the study results?

Yes No

If yes, please provide your preferred receiving method:

Email: _____ Mail: _____

-How many hours/minutes per week do you perform moderate intensity activity? _____

-How many hours/minutes per week do you perform high intensity activity? _____

-Do you regularly take nutrition supplements? (Check all that apply)

Protein powders BCAAs Multivitamin/minerals Probiotics Antioxidants

Caffeine capsules/powder Creatine Fish Oil or Omega-3 capsules Other _____

-Where do you typically look for information about nutrition? (Check all that apply)

Magazines Websites Scientific journals Books Registered Dietitian

Doctor or other medical professional College classes or other academic training

Coach or Personal Trainer Other: _____

-How many servings **per day** do you typically eat of the following foods?

Fruit (serving size equals 1 medium size piece of fruit, 1 cup chopped fruit, or ½ cup dried fruit)

Fewer than 1 1 2 3 4 5 6 or more

Vegetables (serving size equals 2 cup leafy vegetables or 1 cup for all others)

Fewer than 1 1 2 3 4 5 6 or more

Whole grains (serving size equals 1/2 cup cooked pasta or rice, 1 cup cereal, or one piece of bread)

Fewer than 1 1 2 3 4 5 6 or more

Dairy (serving size equals 1 cup for low-fat milk & yogurt or 1.5 oz. of hard cheese, about the size four dice)

Fewer than 1 1 2 3 4 5 6 or more

Dairy Alternatives (soy, nut, seed, or grain milks & yogurts. Serving size equals 1 cup)

Fewer than 1 1 2 3 4 5 6 or more

-How many servings **per week** do you typically eat of the following foods?

Tree nuts & seeds (serving size equals 1 oz. or about a handful)

Fewer than 1 1 2 3 4 5 6 or more

Peanuts & peanut butter (serving size equals 1 oz. peanuts or 2 TBS peanut butter)

Fewer than 1 1 2 3 4 5 6 or more

Tofu & textured vegetable protein (serving size equals 1/2 cup)

Fewer than 1 1 2 3 4 5 6 or more

Eggs (serving size equals 1 large egg)

Fewer than 1 1 2 3 4 5 6 or more

Meat (serving size equals 3 oz. cooked, about the size of a deck of cards)

Fewer than 1 1 2 3 4 5 6 or more

Poultry (serving size equals 3 oz. cooked, about the size of a deck of cards)

Fewer than 1 1 2 3 4 5 6 or more

Fish and shellfish (serving size equals 3 oz. cooked, about the size of a deck of cards)

Fewer than 1 1 2 3 4 5 6 or more

Legumes (serving size equals 1/2 cup cooked beans)

Fewer than 1 1 2 3 4 5 6 or more

Refined grains (white flours, rice, pasta, bread, and snacks. Serving size equals 1/2 cup cooked pasta or rice, 1 cup cereal, or one piece of bread)

Fewer than 1 1 2 3 4 5 6 or more

Refined sugars (candy, beverages, or deserts with added sugar or high fructose corn syrup)

Fewer than 1 1 2 3 4 5 6 or more

Deep fried foods

Fewer than 1 1 2 3 4 5 6 or more

Hydrogenated oils (in some margarines, peanut butters, sauces, dressings, and snack foods. Serving size is 1 TBS/ 14 g)

Fewer than 1 1 2 3 4 5 6 or more

Alcohol (serving size equals 12 oz. beer, 5 oz. wine, or 1.5 oz. distilled liquor)

Fewer than 1 1 2 3 4 5 6 or more

Appendix B: Diet Journal Example and Instruction

Diet Journal Instructions

The diet journal will be most useful for the research and most useful for your nutritional analysis if it shows an accurate representation of a typical week for you. So, you should start your journal on a week when you will not have any major disruptions to your typical eating. For instance, keeping your diet journal over the week of a major holiday or when you will be attending a bachelor party and wedding would not be a very accurate representation of your typical eating and drinking habits.

Once you have selected a good starting time for keeping your journal, make sure to record all food, beverages (except water), condiments, spices, cooking oil, sweeteners, coffee creamers, and dietary supplements that contain calories (protein powders, pre-workout powders, BCAA chews, fish oil supplements etc.)

It is common for people to alter their eating habits when they are recording their intake. Please try to eat as normally as possible and do not leave out “cheat meals” from your journal. Including these foods is more valuable for the research and in providing you with an accurate nutrition analysis.

Please use measuring cups and spoons, a kitchen scale, or count out the indicated serving sizes on the nutrition fact labels whenever possible. When measuring is not possible, please compare the quantity size to standard size objects, for instance, a deck of cards, golf ball, baseball, or dice.

Recording the brand name of foods will make the nutrition analysis most accurate. If you eat out at a restaurant, please write the name of the item as it appears on the menu and the restaurant name.

If it is not convenient to carry your diet journal with you, a small note pad or note pad app on your mobile phone can be a great tool. Taking a picture of your meals with your phone is a great way to remember your intake when it is inconvenient to write it down at that time. Make every effort to record a reminder for anything you eat and drink. If you don't record something or take a picture at the time that you eat it, then you probably won't remember it later.

Below is an example diet journal for one day to use as a guide.

Please don't hesitate to contact Emily Sherwood with any questions on keeping your diet journal.

Date: 8/27/15Identification Code: V01 (<-to be assigned by researcher)

Meal	Food Item	Quantity	Brand or Restaurant (if applicable)	Cooking Method (if applicable)
Breakfast	Drip Coffee	16 oz.		
"	Unrefined coconut sugar	1.5 tsp		
"	Cashew milk, unsweetened	¼ cup	Silk	
"	Jam, blackberry	1 TBS	Smucker's Simply Fruit	
"	Bread, sprouted whole grain	1 piece	Alvarado St. Bakery	
"	Egg, brown, large	1	Organic Valley	Fried, 1 tsp canola oil
"	Sea salt and black pepper	1 dash each		
"	Strawberries, whole	1 cup		
Snack	Baby carrots	3 oz.		
"	Hummus	4 TBS	Sabra	
"	Celery	4 stalks, 6"		
"	Edamame	½ cup		
Drink	Coconut water	12 oz.	Zico	
Lunch	Baby Spring Salad Mix	1.5 cups	Simple Truth (Kroger)	
"	Red onion, sliced	1/8 cup		
"	Walnut halves, raw	1/8 cup		
"	Blackberries	½ cup		
"	Beets, cooked	2 each	Love Beets	
"	Meatless Griller Strips	85 g	Simple Truth (Kroger)	Sautéed, 1 tsp canola oil
"	Balsamic vinegar	1 TBS	Monari Federzoni	
Snack	Apple	1, baseball size		
"	peanut butter	2 TBS	Smucker's, natural creamy	
Dinner	Spaghetti, whole wheat	2 oz. uncooked	Barilla	Boiled
"	White mushrooms	1 cup		Sautéed with water
"	White onions, chopped	¼ cup		Sautéed with water

“	Meatless crumbles	¼ cup	Simple Truth (Kroger)	Sautéed with water
“	Marinara sauce	2/3 cup	Newman’s Own	
Snack	Plum, black	1, golf ball size		
Snack	Whey protein powder, frosty chocolate flavor	1 scoop, 42 g	Designer Whey	Mixed with water

Appendix C: Summary of Dietary Patterns

	Included Food Groups	Reduced or Excluded Food Groups	Nutrients of Concern for Excess*	Nutrients of Concern for Deficiency*
Healthy U.S.-style Pattern ⁴ (Used as base of comparison for other diet patterns.)	Nutrient dense options from all food groups included, at least half of all grain products whole grain.	Minimizes processed/ refined foods.	None.	Potassium~71% AI, Vitamin E~68% RDA, Vitamin D~6% RDA, Choline~82% AI
Healthy Mediterranean Pattern ^{6, 18}	Nutrient dense options from all food groups included, at least half of all grain products are whole grain. Increased inclusion of fruit and seafood.	Reduced inclusion of dairy. Minimizes processed/ refined foods.	None	Potassium~71% AI, Vitamin E~70% RDA, Vitamin D~42% RDA. Choline~81 % AI. Calcium may be insufficient for adolescents and adults older than 50 years.
Healthy Vegetarian Pattern ^{6, 19}	Vegetables, fruits, dairy or dairy alternatives, and eggs (optional). Increased inclusion of legumes, soy products, nuts and seeds, and whole grains.	Excludes meat, poultry, and seafood. Minimizes processed/ refined foods.	None.	Potassium~70% AI, Vitamin E~37 % RDA, Vitamin D~42% RDA. Choline~66% AI.
Paleo Pattern ³	Meat, poultry, seafood, fruit, vegetables, eggs, seeds, tree nuts, and unrefined oils.	Excludes cereal grains, legumes, dairy, potatoes, and salt. Minimizes processed/refined sugars, oils, and foods.	Vitamin A. ^{3, 93} Very limited data available.	Vitamin D, Calcium, and Iodine. ^{3, 84} Very limited data available. Unknown values for choline, copper, manganese, selenium, and Vitamin K

Key

-RDA: Recommended Dietary Allowance, the level at which 97-98% of healthy people will meet nutrient needs.

-AI: Adequate Intake, a level which is assumed to be nutritionally adequate, set when RDA cannot yet be established with current evidence.

*Based on nutrient needs of females aged 19-50 years on a 2000 kcal/day die

Appendix D: Recruiting Flier

Approved by the Eastern Michigan University Human Subjects Review Committee
 UHSRC Protocol Number: 784107-1
 Study Approval Dates: 10/19/15 – 10/18/16

Attention Athletes, Weight-Lifters, and Fitness Enthusiasts!

I am looking for healthy, physically fit, clean eating volunteers to participate in a dietary study.

Your participation is requested if you meet the following criteria:

- You are between 18-40 years old.
- You have a body fat percentage of 10-24% for women or 2-17% for men (this measurement will be taken as part of the research, so you do not need to know it before volunteering)
- You regularly perform at least 2.5 hours of moderate-intensity or 1.25 hours of vigorous-intensity activity per week.
- You are not following a therapeutic diet or meal plan prescribed for a medical condition and currently not pregnant.
- You regularly follow one of these eating patterns:
 - **Paleo:** includes meat, poultry, seafood, fruit, vegetables, eggs, seeds, tree nuts, and unrefined oils. Typically avoids cereal grains, legumes, dairy, potatoes, salt, processed foods, and refined sugars and oils.
 - **Healthy Vegetarian:** typically excludes meat, poultry, & seafood and minimizes processed/refined foods. Includes vegetables, fruits, legumes, soy products, nuts and seeds, whole grains, dairy or dairy alternatives, and eggs (optional).
 - **Healthy U.S. Style:** includes all of the USDA recommended food groups but emphasizes consuming more nutrient dense options and minimizing processed/refined foods (eating clean).
 - **Healthy-Mediterranean Style:** Similar to Health-U.S. Style in that it includes nutrient dense options from all food groups but it incorporates fewer portions of dairy foods and more portions of fruit and seafood.
 - **Participation involves:** filling out a survey, having some body measurements taken, and keeping a detailed diet journal for one week. Your privacy will be safeguarded and no personal identifiers will be used in the published report. **You do not need to alter your eating or exercise habits to participate.**

For participating in the study you will receive a free one week nutritional analysis. This analysis will have your weekly average consumption of all micro and macro nutrients compared against the daily recommended intake (DRI) standards for your weight, height, age, and sex. If your average consumption for any nutrients is outside of the recommendations, a list of foods that are good sources of those nutrients will be provided as well.

Please contact Emily Sherwood for more information.

Email: esherwo2@emich.edu Phone: (360) 901-9280

About the Researcher: I am in my second year of graduate school through Eastern Michigan University. This thesis study is for partial fulfillment of my Masters of Science in Dietetics.

Appendix E: EMU Human Subjects Review Committee Approval Letter

RESEARCH @ EMU**UHSRC Determination: EXPEDITED INITIAL APPROVAL****DATE: October 20, 2015****TO: Emily Sherwood, BA****Eastern Michigan University****Re: UHSRC: #****Category: Expedited category 4s****Approval Date: October 20, 2015****Expiration Date: October 18, 2016****Title: Nutritional Adequacy Comparison of Paleo, Vegetarian, and Healthy U.S. Dietary Patterns Followed by Athletic Adults**

Your research project, entitled **Nutritional Adequacy Comparison of Paleo, Vegetarian, and Healthy U.S. Dietary Patterns Followed by Athletic Adults**, has been approved in accordance with all applicable federal regulations.

This approval included the following:

1. Enrollment of 120 subjects to participate in the approved protocol.
2. Use of the following study measures: *Diet Journal; Screening Questionnaire*
3. Use of the following stamped recruitment materials: *Attention Athletes, Weight-Lifters, and Fitness Enthusiasts; Recruitment email scripts (trainer, coach, volunteer)*
4. Use of the stamped: Informed Consent Form for Participation in the Study: Nutritional Adequacy Comparison of Paleo, Vegetarian, Mediterranean, and Healthy U.S. Dietary Patterns Followed by Athletic Adults

Renewals: This approval is valid for one year and expires on October 18, 2016. If you plan to continue your study beyond October 18, 2016, you must submit a Continuing Review Form by September 18, 2016 to ensure the approval does not lapse.

Modifications: All changes must be approved prior to implementation. If you plan to make any minor changes, you must submit a **Minor Modification Form**. For any changes that alter study design or any study instruments, you must submit a **Human Subjects Approval Request Form**. These forms are available through IRBNet on the UHSRC website.

Problems: All major deviations from the reviewed protocol, unanticipated problems, adverse events, subject complaints, or other problems that may increase the risk to human subjects **or** change the category of review must be reported to the UHSRC via an **Event Report** form, available through IRBNet on the UHSRC website

Follow-up: If your Expedited research project is not completed and closed after **three years**, the UHSRC office requires a new **Human Subjects Approval Request Form** prior to approving a continuation beyond three years. Please use the UHSRC number listed above on any forms submitted that relate to this project, or on any correspondence with the UHSRC office.

Good luck in your research. If we can be of further assistance, please contact us at 734-487-3090 or via e-mail at human.subjects@emich.edu. Thank you for your cooperation.

Sincerely,

Jennifer Kellman Fritz, PhD
Chair
University Human Subjects Review Committee