Popular Diets: A Scientific Review

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EXECUTIVE SUMMARY

Introduction

Weight loss is a major concern for the US population. Surveys consistently show that most adults are trying to lose or maintain weight (1). Nevertheless, the prevalence of overweight and obesity has increased steadily over the past 30 years. Currently, 50% of all adult Americans are considered overweight or obese (2,3). These numbers have serious public health implications. Excess weight is associated with increased mortality (4) and morbidity (5). It is associated with cardiovascular disease, type 2 diabetes, hypertension, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and some types of cancer (6,7).

Most people who are trying to lose weight are not using the recommended combination of reducing caloric intake and increasing physical activity (1). Although over 70% of persons reported using each of the following strategies at least once in 4 years, increased exercise (82.2%), decreased fat intake (78.7%), reduced food amount (78.2%,) and reduced calories (73.2%), the duration of any one of these behaviors was brief. Even the most common behaviors were used only 20% of the time (8).

Obesity-related conditions are significantly improved with modest weight loss of 5% to 10%, even when many patients remain considerably overweight (6). The Institute of Medicine (9) defined successful long-term weight loss as a 5% reduction in initial body weight (IBW) that is maintained for at least 1 year. Yet data suggest that such losses are not consistent with patients' goals and expectations. Foster (10) reported that in obese women (mean body mass index [BMI] of 36.3 $\pm$ 4.3) goal weights targeted, on average, a 32% reduction in IBW, implying expectations that are unrealistic for even the best available treatments. Interestingly, the most important factors that influenced the selection of goal weights were appearance and physical comfort rather than change in medical condition or weight suggested by a doctor or health care professional. Is it any wonder that overweight individuals are willing to try any new diet that promises quick, dramatic results more in line with their desired goals and expectations than with what good science supports?

The proliferation of diet books is nothing short of phenomenal. A search of books on Amazon.com using the key words "weight loss" revealed 1214 matches. Of the top 50 best-selling diet books, 58% were published in 1999 or 2000 and 88% were published since 1997. Many of the top 20 best sellers at Amazon.com promote some form of carbohydrate (CHO) restriction (e.g., *Dr. Atkins' New Diet Revolution*, *The Carbohydrate Addict's Diet*, *Protein Power*, *Lauri's Low-Carb Cookbook*). This dietary advice is counter to that promulgated by governmental agencies (US Department of Agriculture [USDA]/Department of Health and Human Services, National Institutes of Health) and nongovernmental organizations (American Dietetic Association, American Heart Association, American Diabetes Association, American Cancer Society, and Shape Up America!).

What is really known about popular diets? Is the information scientifically sound? Are popular diets effective for weight loss and/or weight maintenance? What is the effect, if any, on composition of weight loss (fat vs. lean body mass), micronutrient (vitamin and mineral) status, metabolic parameters (e.g., blood glucose, insulin sensitivity, blood pressure, lipid levels, uric acid, and ketone bodies)? Do they affect hunger and appetite, psychological well-being, and reduction of risk for chronic disease (e.g., coronary heart disease, diabetes, and osteoporosis)? What are the effects of these diets on insulin and leptin, long-term hormonal regulators of energy intake and expenditure?

The objective of this article is to review the scientific literature on various types of popular diets based on their macronutrient composition in an attempt to answer these questions (see Appendix for diet summaries).

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Evidence-Based Guidelines

This article is limited to the effects of popular diets in overweight and obese adults; there are no good data on children and adolescents. Dietary claims are scrutinized, diets are analyzed, and information is compared with scientific data published in peer-reviewed journals. No published studies are excluded, despite inherent methodological problems (e.g., small or inadequate sample size, limited duration, lack of adequate controls and randomization, poor or minimal dietary collection and/or description of diets, and potential biases). However, the strength of the evidence supporting various conclusions made throughout the paper is based on the following grading system used by National Heart, Lung, and Blood Institute (NHLBI) (6) (Table 1).

Characterization of Diets

Diets are characterized below and in Tables 2 and 3.

- High-fat (55% to 65%), low-CHO (<100 g of CHO per day), high-protein diets (e.g., *Dr. Atkins' New Diet Revolution*, *Protein Power*, *Life Without Bread*).
- Moderate-fat (20% to 30%), balanced nutrient reduction diets, high in CHO and moderate in protein (e.g., USDA Food Guide Pyramid, DASH diet, Weight Watchers).
- Low-fat (11% to 19%), and very-low-fat (VLF) (<10%), very-high-CHO, moderate-protein diets (e.g., *Dr. Dean Ornish's Program for Reversing Heart Disease*, *Eat More, Weigh Less*, *The New Pritikin Program*).

Summary of Findings

Weight Loss

Diets that reduce caloric intake result in weight loss. In the absence of physical activity, a diet that contains ~1400 to 1500 kcal/d, regardless of macronutrient composition, results in weight loss. Individuals consuming high-fat, low-CHO diets may lose weight because the intake of protein and fat is self-limiting and overall caloric intake is decreased (11,12). Low-fat and VLF diets contain a high proportion of complex CHOs, fruits, and vegetables. They are naturally high in fiber and low in caloric density. Individuals consuming these types of diets consume fewer calories and lose weight (13–17). Balanced nutrient reduction diets contain moderate amounts of fat, CHO, and protein. When overall caloric intake is reduced, these diets result in loss of body weight and body fat (6,18). Importantly, moderate-fat, balanced nutrient reduction diets produce weight loss even when they are consumed ad libitum.

In sum, all popular diets, as well as diets recommended by governmental and nongovernmental organizations, result in weight loss. However, it is important to note that weight loss is not the same as weight maintenance.

Evidence Statement: Caloric balance is the major determinant of weight loss. Diets that reduce caloric intake result in weight loss. In the absence of physical activity, the optimal diet for weight loss contains ~1400 to 1500 kcal/d, regardless of macronutrient composition. Evidence Category A.

Evidence Statement: Free-living overweight individuals who self-select high-fat, low-CHO diets consume fewer calories and lose weight. Evidence Category C.

Table 1. Grading system and evidence categories

Evidence category	Sources of evidence	Definition
A	RCTs (rich body of data)	Evidence is from endpoints of well-designed RCTs (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendation is made.
B	RCTs (limited body of data)	Evidence is from endpoints of intervention studies that include only a limited number of RCTs, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent.
C	Nonrandomized trials observational studies	Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.

RCT, randomized controlled trial.

Table 2. Characterization of diets as percentage of calories

Type of diet	Fat (% kcals)	CHO (% kcals)	Protein (% kcals)
High-fat, low-CHO	55–65	<20% (<100 g)	25–30
Moderate-fat, balanced nutrient reduction	20–30	55–60	15–20
Low- and very-low-fat	<10–19	>65	10–20

Evidence Statement: Overweight individuals consuming high-fat, low-CHO, low-calorie diets under experimental conditions lose weight. Evidence Category C.

Evidence Statement: Overweight individuals consuming moderate-fat, balanced nutrient reduction diets lose weight because they consume fewer calories. These diets can produce weight loss when consumed ad libitum. Evidence Category A.

Evidence Statement: Overweight individuals consuming low-fat and VLF diets lose weight because they consume fewer calories. Evidence Category B.

Evidence Statement: Weight loss on VLF diets may be the result of lifestyle modification, which may include decreased fat and energy intake, increased energy expenditure, or both. Evidence Category B.

Body Composition

As body weight decreases, so does body fat and lean body mass. The optimal diet for weight loss is one that maximizes loss of body fat and minimizes loss of lean body mass. All low-calorie diets result in loss of body weight and body fat (6). Macronutrient composition does not seem to play a major role (19–22). In the short-term, however, high-fat, low-CHO ketogenic diets cause a greater loss of body water than body fat (23). When these diets end, water weight is regained (24). Eventually, however, all reduced calorie diets result in loss of body fat if sustained long term (25).

Physical activity, an important factor with respect to lean body mass, should be promoted to enhance the effects of diet on body composition.

Evidence Statement: All low-calorie diets result in loss of body weight and body fat. Macronutrient composition does not seem to play a major role. Evidence Category A

Evidence Statement: In the short term, low-CHO ketogenic diets cause a greater loss of body water than body fat. Water weight is regained when the diet ends. If the diet is maintained long term, it results in loss of body fat. Evidence Category C.

Nutritional Adequacy

Proper food choices are always important when considering the nutritional quality of a diet. When individuals consume foods from all food groups, it is more likely that their diet will be nutritionally adequate. The moderate-fat, balanced nutrient reduction diet is optimal for ensuring adequate nutritional intake. However, poor food choices may result in inadequate levels of nutrients (e.g., calcium, iron, zinc), regardless of overall macronutrient composition. High-fat, low-CHO diets are nutritionally inadequate. They are low in vitamins E, A, thiamin, B_6, folate, calcium, magnesium, iron, potassium, and dietary fiber, and require supplementation. These diets are high in saturated fat and cholesterol. VLF diets are low in vitamins E, B_{12}, and zinc because meat and fat intake is low.

Evidence Statement: With proper food choices, the moderate-fat, balanced nutrient reduction diet is nutritionally adequate. Evidence Category B.

Table 3. Characterization of diets in absolute amount (grams)

Type of diet	Total kcals	Fat g (%)	CHO g (%)	Protein g (%)
Typical American	2200	85 (35)	275 (50)	82.5 (15)
High-fat, low-CHO	1414*	94 (60)	35 (10)	105 (30)
Moderate-fat, balanced nutrient reduction	1450	40 (25)	218 (60)	54 (15)
Low- and very-low-fat	1450	16–24 (10–15)	235–271 (65–75)	54–72 (15–20)

* Based on average intake of subjects who self-selected low-CHO diets (see Table 4).

Evidence Statement: High-fat, low-CHO diets are nutritionally inadequate, and require supplementation. Evidence Category C.

Evidence Statement: VLF diets are low in vitamins E, B_{12}, and zinc. Evidence Category B.

Metabolic Parameters

Low-CHO diets result in ketosis, and may cause a significant increase in blood uric acid concentrations.

Blood lipid levels (e.g., total cholesterol [TC], low-density lipoprotein [LDL], high-density lipoprotein [HDL] and triglycerides [TGs]) decrease as body weight decreases (6,26,27). However, the macronutrient and fatty acid composition of energy-restricted diets can exert substantial effects on blood lipids. There are significantly greater decreases in LDL cholesterol during active weight loss when diets are low in saturated fatty acids. Changes in HDL cholesterol depend on dietary fat content and duration of energy restriction (28). Moderate-fat, balanced nutrient reduction diets reduce LDL-cholesterol and normalize the ratio of HDL/TC.

Plasma TG levels also decrease with weight loss (6). Although they increase in response to short-term consumption of a VLF, high-CHO diet (29), the type of CHO consumed must be considered. High-fiber foods, including vegetables and legumes, do not lead to hypertriglyceridemia (30), and may easily be incorporated into moderate-fat, balanced nutrient reduction diets to help normalize plasma TG levels.

Energy restriction, independent of diet composition, improves glycemic control (21,22,31–33). As body weight decreases, so does blood insulin and plasma leptin levels (21,34).

Blood pressure decreases with weight loss, independent of diet composition (6,22,26). However, the DASH diet, high in fruits, vegetables, and low-fat dairy products effectively lowers blood pressure (35).

Evidence Statement: High-fat, low-CHO diets result in ketosis. Evidence Category B.

Evidence Statement: Metabolic profiles are improved with energy restriction and weight loss. Evidence Category A.

Evidence Statement: Low-CHO diets that result in weight loss may also result in decreased blood lipid levels, decreased blood glucose and insulin levels, and decreased blood pressure. Evidence Category C.

Evidence Statement: Low-fat and very low-fat diets reduce LDL-cholesterol, and may also decrease plasma TG levels, depending on diet composition. Evidence Category B.

Evidence Statement: Moderate-fat, balanced nutrient reduction diets reduce LDL-cholesterol, normalize the ratio of HDL/TC, and normalize plasma TGs. Evidence Category A.

Hunger and Compliance

Many factors influence hunger, appetite, and subsequent food intake. Macronutrient content of the diet is one, and it may not be the most important. Neurochemical factors (e.g., serotonin, endorphins, dopamine, hypothalamic neuropeptide transmitters), gastric signals (e.g., peptides, stomach distention), hedonistic qualities of food (e.g., taste, texture, smell), genetic, environmental (e.g., food availability, cost, cultural norms) and emotional factors (e.g., eating when bored, depressed, stressed, happy) must be considered. These parameters influence appetite primarily on a meal-to-meal basis. However, long-term body weight regulation seems to be controlled by hormonal signals from the endocrine pancreas and adipose tissue, i.e., insulin and leptin. Because insulin secretion and leptin production are influenced by the macronutrient content of the diet (36,37), effects of different diets on these long-term regulators of energy balance also need to be considered when investigating hunger and appetite.

All fat-restricted diets provide a high degree of satiety. Subjects who consume fat-restricted diets do not complain of hunger, but of having "too much food" (38,39). These diets, high in fiber and water content are low in caloric density. Subjects who consume these diets develop a distaste for fat (40), which may be useful in long-term adherence to reduced fat, low-calorie diets. However, it is not clear that restricting fat provides any advantage over restricting CHOs. Ogden (41) reports weight loss maintainers used healthy eating habits and adhered to calorie-controlled diets.

Long-term compliance to any diet means that short-term weight-loss has a chance to become long-term weight maintenance (42–44). Dietary compliance is likely a function of psychological issues (e.g., frequency of dietary counseling, coping with emotional eating, group support) rather than macronutrient composition, per se (42,45). Being conscious of one's behaviors, using social support, confronting problems directly, and using personally developed strategies may enhance long-term success (46). Ogden (41) notes that successful weight loss and maintenance may be predicted by an individuals' belief system (e.g., that obesity is perceived as a problem that can be modified and if modifications bring changes in the short-term that are valued by the individual concerned).

Evidence Statement: Many factors influence hunger, appetite, and subsequent food intake. There does not seem to be an optimal diet for reducing hunger. Evidence Category B.

Evidence Statement: Long-term compliance is likely a function of psychological issues rather than macronutrient composition. Evidence Category B.

Summary and Recommendations

Caloric balance (calories in vs. calories out), rather than macronutrient composition is the major determinant of weight loss. However, what is not clear is the effect of macronutrient content on long-term weight maintenance and adherence. Furthermore, it is not known whether maintenance of weight loss and dietary adherence is related to psychological issues (and brain neurochemistry), physiological parameters (e.g., hormones involved in body weight regulation such as insulin and leptin), physical activity, energy density, or some other factor(s).

Controlled clinical trials of high-fat, low-CHO, and low-fat and VLF diets are needed to answer questions regarding long-term effectiveness (e.g., weight maintenance rather than weight loss) and potential long-term health benefits and/or detriments.

Prevention of weight gain and weight maintenance are important goals. Scientifically validated, yet understandable information is clearly needed by millions of overweight and obese Americans who often find weight loss attainable, but maintaining weight loss nearly impossible.

I. High-Fat, Low-Carbohydrate Diets (55% to 65% fat, <100 g of CHO per day)

Despite controversy surrounding their use, high-fat, low-CHO diets are among the most popular types of diets today. The most famous is *Dr. Atkins' Diet Revolution* (47) first published in 1972, and updated 20 years later as *Dr. Atkins' New Diet Revolution* (48). Promoting a "lifetime nutritional philosophy," Atkins claims that his diet has been embraced by an estimated 20-plus million people worldwide since the release of his first book (www.atkinscenter.com). His program was one of the first to popularize low-CHO, high-protein, ketogenic diets that individuals could use on their own, rather than in a medical setting (e.g., a protein-sparing modified fast). Other low-CHO diets with similar themes include *Protein Power* (49), *The Carbohydrate Addict's Diet* (50), *Dr. Bernstein's Diabetes Solution* (51), and *Life Without Bread* (52).

A. Underlying Philosophy, Claims, and Proposed Solutions

Proponents of high-fat, low-CHO diets dismiss the notion that caloric intake is important to either weight gain or weight loss. They claim that "most overweight individuals do not overeat" (48, p. 7; 50, p. 21), even as they suggest that high-CHO meals leave individuals less satisfied than meals that contain adequate fat, resulting in increased hunger and increased food intake (48, p. 55; 50, p. 43). They suggest that those who do overeat do so "because of a metabolic component driving them on, most often a truly addictive craving for CHOs" (48, p. 7; 52, p. 142). Because "carbohydrates are addictive," the carbohydrate "addict" continues to eat carbohydrates, producing more and more insulin, which inhibits brain serotonin release. Reductions in this "satiety" neurotransmitter result in a decreased sense of satisfaction (50, pp. 26, 43; 51, p. 41). With respect to weight loss, Atkins (48) claims that on a low-CHO diet there are "metabolic advantages that will allow overweight individuals to eat as many or more calories as they were eating before starting the diet yet still lose pounds and inches" (p. 10).

Furthermore, proponents contend overproduction of insulin, driven by high CHO intake, is the cause of the metabolic imbalance that underlies obesity (48,50,53). Eating too much CHO results in increased blood glucose, increased blood insulin, and increased TGs (48, pp. 50–51). An already overweight person who continues to overeat CHOs develops hyperinsulinemia and insulin resistance, "resulting in insulin's lack of effectiveness in converting glucose into energy, but enabling glucose (e.g., dietary CHO) to be stored as fat" (48, p. 52).

Advocates of low-CHO diets propose a simple solution to this "vicious cycle" of CHO addiction, CHO overeating, hyperinsulinemia, decreased glucose use and increased fat storage. It involves restricting CHOs severely enough to produce ketosis. The ketosis is a reliable indicator of fat mobilization. In this condition, the key benefit is that blood glucose and blood insulin levels are reduced, and appetite is suppressed. In short, authors contend that a high-fat, low-CHO, high-protein, ketogenic diet results in weight loss, body fat loss, preservation of lean body mass, and correction of serious medical complications of diabetes (51), heart disease, and high blood pressure (48, pp. 6, 63). The contention is that the high-fat, low-CHO diet supports long-term health, controls weight without hunger, and should be followed for the rest of one's life (48, p. 27).

B. Scientific Evaluation of Claims

1. Caloric Intake, Body Weight, and Body Composition

- Is caloric intake relevant when looking at weight gain and weight loss?
- What is the effect of diet composition on weight loss, e.g., will consuming a high-fat, low-CHO diet, regardless of caloric intake, result in weight loss, body fat loss, and preservation of lean body mass?

Table 4. Diet composition of subjects who self-selected low-CHO diets

Study	Total kcals	CHO g	CHO %	Fat g	Fat %	Protein g	Protein %
Evans (11)	1490	86	24	94	56	75	20
Yudkin (12)	1383	43	12	96	62	80	23
Rickman (56)	1325	7	1	73	50	160	48
Larosa (57)	1461	6	1.6	108	66	107	29

Energy intake and energy expenditure are relevant when looking at weight gain and weight loss. Overweight and obesity results from an energy imbalance (e.g., excess caloric intake, decreased energy expenditure, or both) (54). Reduction of body weight and body fat can be achieved by creating an energy deficit (e.g., restricting energy intake, increasing energy expenditure, or a combination of the two) (6,18,54). Atkins (48) calls these basic thermodynamic principles "a millstone around the neck of dieters and a miserable and malign influence on their efforts to lose" (p. 6). Do followers of high-fat, low-CHO diets have a metabolic advantage that enables them to eat a greater number of calories, and still lose body weight and body fat?

No scientific evidence exists to suggest that low-CHO ketogenic diets have a metabolic advantage over more conventional diets for weight reduction (55). Studies consistently show that under conditions of negative energy balance, weight loss is a function of caloric intake, not diet composition (54). Table 4 indicates diet composition of individuals who self-select high-fat, low-CHO diets, and Tables 5a and 5b show weight change in obese individuals consuming high-fat, low-CHO diets. In all cases, individuals on high-fat, low-CHO diets lose weight because they consume fewer calories.

Evidence Statement: Free-living overweight individuals who self-select high-fat, low-CHO diets consume fewer calories and lose weight. Evidence Category C.

Evidence Statement: Overweight individuals consuming high-fat, low-CHO, low-calorie diets under experimental conditions lose weight. Evidence Category C.

Caloric Intake and Weight Change

Studies cited by Atkins (pp. 67–74) to support his contentions were of limited duration, conducted on a small number of people, lacked adequate controls, and used ill-defined diets (24,58,61,63–65,67,68,71). Some of these, as well as other studies, actually refute the contention that low-CHO diets, in the absence of energy restriction, provide a metabolic advantage (11,12,21,22,45,56,57,59,60–64,66–68, 70,72). These studies are reviewed below.

Early Studies (Pre-1960)

Early studies on a limited number of obese men and women indicate individuals consuming low-CHO diets

Table 5a. Effect of low-carbohydrate intake on body weight in obese subjects in studies without a control group(s)

Study	*n*	Duration	CHO (g)	kcal/day	Weight change (kg)	Weight change (g/day)
Kekwick (24)	14	5–9 days	10	1000	N/A	N/A
Rickman (56)	12	7 days	7	1325	−3.1	−442
Benoit (58)	7	10 days	10	1000	−6.6	−660
Yudkin (12)	6	14 days	43	1383	≃2.8	−200
Fletcher (59)	6	14 days	36	800	≃3.125	−223
Lewis (60)	10	14 days	27	1115	−5.2	−371
Kasper (61)	16	16 days	56	1707	−4.8	−300
Bortz (62)	9	21 days	0	800	N/A	N/A
Krehl (63)	2	30 days	12	1200	N/A	N/A
Evans (11)	8	6 wk	80	1490	−3.2 to −5.0	−76 to −119
Golay (22)	22	6 wk	37.5	1000	−8.0	−111
Young (64)	3	6 wk	30	1800	−16.18	−385
Larosa (57)	24	12 wk	6	1461	−6.8 ± 0.91	−81
Golay (21)	31	12 wk	75	1200	−10.2 ± 0.7	−121
Cedarquist (65)	7	16 wk	85	1500	−8.8 to −16.8	−78 to −150

Table 5b. Effect of low-CHO intake on body weight in obese subjects in studies with a control group(s)

Study	*n*	Duration	CHO (g)	kcal/day	Weight change (kg)	Weight change (g/day)
Worthington (66)	20	21 days	17	1182	−12.0 ± 3.7	−571
Rabast (67)	13	25 days	48	1871	−8.76 ± 0.74	−350
Rabast (68)	25	30 days	25	1000	−11.77 ± 0.77	−392
Wing (69)	11	4 wk	10	800	−8.1	−270
Alford (45)	11	10 wk	75	1200	−6.4 ± 7.59	−91
Baron (70)	66	3 months	50	1000	−5.0	−55

reduce overall caloric intake and lose weight (12,65,72,73). Pennington's (73) was one of the earliest low-CHO diets, and contained less than 60 g CHO per day, an amount "calculated to not interfere with ketogenesis." The diet allows 24 ounces of meat with fat daily, and one ordinary portion of any of the following: white potatoes, sweet potatoes, boiled rice, half of a grapefruit, grapes, melon, banana, pear, raspberries, or blueberries; it allows no bread, flour, salt, sugar, or alcohol. The Pennington diet resulted in an unspecified amount of weight loss but critics were suspicious that the unpalatability, or high satiety value of the diet, resulted in food intake well below the minimum recommended 2870 kcal/d. However, Pennington concluded, "there is nothing remarkable in the observation that some obese must, of necessity, lose weight on an intake of 3000 kcal or more per day," considering their normal intake to be up to 4500 kcal/d (72,73).

To substantiate weight loss could occur on 2870 kcal/d, regardless of diet composition, Werner (72) studied 6 obese subjects confined to a metabolic ward for 35 to 49 days. He fed them Pennington's low-CHO, high-fat diet (2874 kcal, 52 g CHO, 242 g fat) or an isocaloric, high-CHO, lower-fat diet (2878 kcal, 287 g CHO, 146 g fat). Apart from transient changes in water balance, the rate of weight loss in obese subjects was the same on both diets, showing diet composition did not matter. Atkins (48) called Pennington's study "exciting" (p. 67) yet he dismisses Werner's study as too high in CHOs to promote ketosis (p. 70), despite the fact that Werner received the diet from Dr. Pennington.

To support the concept of total caloric intake over diet composition, Yudkin and Carey (12), studied six adult overweight subjects and found that when they followed a low-CHO diet (<30 to 55 g/d) for 2 weeks, caloric intake was reduced 13% to 55% (180 to 1920 fewer daily calories). Caloric intake averaged 1383 per day. Although all subjects were allowed to consume an "unlimited" amount of fat, none consumed significantly more fat than before, and three showed a significant reduction of fat intake. Only one showed a slight increase in protein intake.

Studies by Kekwick and Pawan (24,71) are cited by Atkins to support his contention that diet composition, rather than caloric intake, is the key variable for weight loss. Yet, despite this contention, these studies support the notion that calories do count. Obese individuals confined to a metabolic ward were given diets with the same ratio of fat, protein and CHO, but different caloric values. Individuals lost more weight when they consumed lower calorie diets (e.g., 500 and 1000 kcal/d) compared with when they consumed higher calorie diets (e.g., 1500 and 2000 kcal/d). In another study, 14 obese patients were fed 1000-kcal diets containing either 90% protein (5 g of CHO), 90% fat (10 g of CHO), or 90% CHO (225 g of CHO). Food available in each of the diets was unspecified. Each subject consumed the high-fat, high-protein, or high-CHO diet for 5 to 9 days before being switched to another diet. Twenty-one days later, all patients had lost weight, regardless of the order they had consumed the different diets. However, patients consuming 90% fat lost the most weight over 5 to 9 days, whereas those eating 90% CHO lost little or none; some even gained back some weight lost earlier on the 90% fat or 90% protein diets. These results led Kekwick and Pawan to suggest, "obese patients must alter their metabolism in response to the contents of the diet." In another study, they fed five obese individuals 2000 kcal balanced diets for 7 days, followed by a low-CHO, high-fat, high-protein diet providing 2600 kcal/d for 4 to 14 days. Although patients could maintain or gain weight on 2000 kcal/d, all, except one, lost weight on 2600 kcal/d. Weight loss was reported to be partly from body water (30% to 50%) and partly from body fat (50% to 70%). Unfortunately, none of these studies reported actual food intake, despite the author's remarks, "the main hazard was that many of these patients had inadequate personalities. At worst they would cheat and lie, obtaining food from visitors, from trolleys touring the wards, and from neighboring patients."

Convinced that fluid balance, not diet composition, was the cause of the weight loss reported by Kekwick and Pawan, Pilkington et al. (74) repeated their studies for longer periods of time (18 or 24 days). His results were

comparable with Kekwick and Pawan's during the first few days on each of the diets. However, there was a steady rate of weight loss with each of the 1000-kcal diets thereafter, regardless of whether the calories came from fat, protein, or CHO. Although he did not measure fluid balance, Pilkington (74) concluded that temporary differences in weight loss were due to such changes. He stated "if the periods of study are long enough to achieve a 'steady state' the rate of weight loss on a diet consisting mainly of fat does not differ significantly from the rate of weight loss on an isocaloric diet consisting mainly of CHO." Oleson and Quaade's (75) experiment, which lasted for 3 weeks, had a similar conclusion.

Studies from 1961 to 1979

Fletcher et al. (59) gave six obese women who were confined to a metabolic ward 800 kcal/d diets containing mostly CHO, protein, or fat. They received each diet for 14 days. The high-fat and high-protein diets each contained 36 g of CHO. Statistical analysis showed no significant difference in the rate of weight loss on the different diets. Kinsell et al. (19) maintained obese subjects on a fixed caloric intake and varied the macronutrient composition of the diet (e.g., fat intake varied from 12% to 80%, protein from 14% to 26%, and CHO from 3% to 61%). In any given subject, the rate of weight loss after the initial depletion of fluid was essentially constant throughout the entire study, irrespective of diet composition. Bortz (62) fed an 800-kcal liquid formula diet containing 80 g of protein, and either 54 g of fat (no CHO), or 120 g of CHO (no fat) to nine obese subjects who were confined to a metabolic ward. Each diet was given for 24 days, before switching to the other. No difference in rate of weight loss was noted, apart from that attributable to alterations in sodium and fluid balance. Krehl et al. (63) studied four healthy, normal weight male prison volunteers, and seven obese females (five were from 15 to 21 years old, and two were 36 and 53 years old) on a metabolic ward. The obese females were given 1200-kcal, 12-g CHO diets, comprised of fat and protein in different ratios (50/50; 60/40; 40/60; 70/30; 30/70). They received each diet for 1 month. They also had three ~1-hour periods of supervised physical activity daily. Although it is difficult to draw any conclusions from this small study, Krehl et al. (63) reported that all patients lost weight at a rate commensurate with caloric restriction and physical activity, regardless of diet composition.

In another short-term study, Worthington and Taylor (66) fed isocaloric diets (1182 kcal/d) for 2 weeks to 20 obese women who were confined to a state correctional institution. One diet was a low-CHO, ketogenic diet (17 g/d) with a 6:48:44 ratio of CHO to protein to fat calories. The other was a "balanced low-calorie diet" and contained 96 g of CHO and a 32:20:47 ratio of CHO to protein to fat. Although this diet was not meant to be ketogenic, two subjects tested positive for urinary ketones on Day 7 and four tested positive on Day 14. The 10 women on the low-CHO diet lost significantly more weight at the end of 14 days compared with the 10 women on the balanced diet (12.0 $\pm$ 3.7 vs. 8.7 $\pm$ 3.5, low-CHO vs. balanced). The difference in total weight loss was established primarily during the first week, when the average weight loss in the low-CHO group was 8.2 pounds, and that of the control group was 6 pounds. During the second week, weight loss was similar for the two groups.

In 1971, Young et al. (64), at Cornell University, looked at the effect of diet composition on weight loss and body composition. Eight moderately obese young male college students were fed isocaloric diets for 9 weeks (interrupted after 3 weeks for 1 week of spring vacation). Each diet contained 1800 kcal and 112 g of protein, but different amounts of CHO: either 104, 60, or 30 g/d. Physical activity was not controlled. Only those in the 30 g/d group tested positive for ketones throughout the 9-week study. As CHO in the diet decreased, weight and fat loss slightly, but not significantly, increased. Using underwater weighing to determine body composition, Young et al. reported that the weight lost by the lowest CHO group (30 g/d) was close to 100% fat. However, no difference between the groups with respect to nitrogen, sodium, or potassium balances was reported. Young et al. (64) concluded, "it would seem that of the low CHO diets used, the one at the 104-g level would be most suitable for long-term use." Although their study lasted 9 weeks, Atkins extrapolated data to 30 weeks, implying even greater benefit (p. 73).

Rickman (56) monitored weight changes in 12 healthy volunteers (hospital employees) who were no more than 10% above ideal body weight (based on Metropolitan Life Insurance tables). Subjects were instructed to follow the Stillman diet, which allowed unlimited quantities of protein and fat, but no CHO. Average caloric intake was 1325 per day, with 50% of calories from fat (73 g), 48% from protein (160 g), and less than 1% from CHO (7 g). Subjects followed the diet for 3 to 17 days (average 7.6 days). During the first 3 to 5 days, each subject lost 1.3 to 2.2 kg. At the end, mean weight loss was 3.1 kg. In 8 of 10 subjects for whom there was follow-up within 7 days of the diet, average weight regain was 2 kg (range, 1 to 4.5 kg).

Studies using low-CHO, liquid formula diets conducted in Germany had small sample sizes, short duration (1 month), and poor design (61,67,68). Kasper et al. (61) compared the weight loss of 16 obese subjects on low-CHO diets (56g/d) with 4 obese subjects on isocaloric (1707 kcal), high-CHO diets (156 g/d). The average duration on the low-CHO diet was 16 days (range, 6 to 30 days); mean weight loss was 0.3 kg/d. The average duration on the high-CHO diet was 10 days (range, 6 to 14 days); mean weight loss was 0.05 kg/d. The small sample size, difference in study duration, and fact that 3 of the 4 subjects on the

high-CHO diet also received the low-CHO diet (before or after?) prevents adequate interpretation. Seventeen subjects (some of whom had received other diets) were fed a high-fat formula diet containing 2150 kcal and 112 g of CHO per day. The average length of time on this diet was 18 days (range, 6 to 40 days) and the mean weight loss was 0.32 kg/d, an amount comparable with the low-CHO, lower calorie (1707) diet. Body composition was not measured during any of these studies.

A similar, but better controlled study was conducted by Lewis et al. (60). They compared the responses to two cholesterol-free, isocaloric (10 kcal/kg per day; ~1115 kcal), liquid formula diets of differing composition (70% CHO, 20% protein, 10% fat vs. 70% fat, 20% protein, 10% CHO) in 10 obese men who were confined to a metabolic ward. Diets were administered for 14 days in random order and each diet was preceded by a 7-day control, weight-maintenance diet (30 kcal/kg per day, 40% CHO, 20% protein, 40% fat). Although the low-CHO diet was clearly ketogenic, Lewis et al. (60) concluded that both low-calorie diets effected similar losses of nonaqueous body weight. Their conclusions regarding body composition changes were not based on actual body composition measurements. Instead, they were based on the significant rebound in body weight and the significant urinary sodium retention observed when the weight maintenance diet followed the ketogenic diet, along with the significant increase in serum albumin concentration noted during the period in which the low-CHO diet was ingested. These changes were not seen when the maintenance diet followed the high-CHO diet.

However, to support that low-CHO diets result in loss of body fat, Atkins cites Benoit et al. (58), who compared the effects of 10 days of fasting with a 1000-calorie, 10 g of CHO ketogenic diet in seven active-duty Naval personnel (mean weight, 115.6 kg). Over the 10-day period, the mean weight loss for the fasting and ketogenic groups were 9.6 kg and 6.6 kg, respectively. The ketogenic diet resembled fasting in terms of ketosis, acidosis, and mild anorexia (which the authors speculated may influence caloric restriction by the patient). However, the ketogenic diet resulted in greater fat loss (97% vs. 35%) and decreased loss of lean body mass (3% vs. 65%) relative to fasting. Although all patients on both diets were in negative N balance, potassium balance seemed unaffected by the ketogenic diet, an impossibility according to Grande (76), who seriously questioned the scientific validity of Benoit's entire study.

Atkins cites Rabast et al. (67,68) to support his contention that low-CHO diets result in greater weight loss than high-CHO diets. Rabast et al. (66,68) fed 45 obese German men and women 1000-calorie, isonitrogenous, low-CHO (25 g/d) or high-CHO (170 g/d) formula diets. The duration of the treatment period differed between the two groups. On the low-CHO diet, it averaged 38 ± 19 days (range, 15 to 78 days). On the high-CHO diet, it averaged 32 ± 13 days (range, 18 to 59 days). Due to significant drop out in both groups, data were analyzed only up to Day 30. Results indicate by Day 15, the 25 subjects following the low-CHO diet lost significantly more weight than the 20 subjects following the high-CHO diet (6.81 ± 0.30 kg vs. 5.49 ± 0.37 kg). There was no significant difference in weight loss between the groups at Day 20 or 25. By Day 30, the weight loss between the two groups again reached statistical significance (11.77 ± 0.77 kg vs. 9.81 ± 0.43 kg, low-CHO vs. high-CHO, respectively), even though by day 30, almost 40% of subjects in each group had dropped out (no reasons given). Body composition data were not presented, and the authors did not report any increased water or electrolyte excretions during either of the diets. In another article, Rabast et al. (67) presented the exact same data found in the article just described (68). In addition, it included new data from 28 additional subjects who received low-CHO (48 g/d, $n = 13$) or high-CHO (355 g/d, $n = 15$) liquid formula diets containing 1900 kcal/d for 25 days. In this study, all subjects lost weight, regardless of caloric intake or diet composition.

The Rabast study that Atkins cites (p. 74) in support of his position actually refutes it. This study confirms weight loss on low-calorie diets, independent of CHO content after Day 10 on 1900 kcal, and after Day 15 on 1000 kcal. Atkins cites the difference of 4.2 kg (9.24 pounds) in total weight loss between the 1000-calorie low-CHO and 1000-calorie high-CHO groups as proof that the low-CHO diet works better. The problem with this is that these data (e.g., the 4.2-kg weight difference) represent the final weight loss between the two groups at the end of the study (59 to 78 days). However, we have no idea how many subjects actually completed the study. We do know that of 45 persons who started the study, only 28 remained by Day 30.

Studies after 1980

Larosa (57) studied 24 obese free-living men and women for 12 weeks. For the first 2 weeks, they followed their current diet. For the next 4 weeks, they were instructed to follow Stage I of the study diet, taken from the book, *Dr. Atkins' Diet Revolution* (47). Stage I is devoid of CHOs but places no caloric limits on protein or fat. Based on urinary ketone measurement all but 3 were confirmed as restricting CHOs. After 4 weeks on Stage I, patients advanced to Stage II, which allows 5 to 8 g of CHO per day for an additional 4 weeks, bringing the total time on the low-CHO diet to 8 weeks. The final 2 weeks (off the diet) allowed ad libitum intake. No prescription for changes in exercise was given and subjects were asked not to alter their exercise habits from prestudy levels.

Results indicated that all but 2 of 24 subjects lost weight the first 2 weeks of the study while eating ad libitum. After 8 weeks on the low-CHO diet, all subjects (except for 1 male) lost weight. Mean weight loss was 4.1 ± 0.64 kg from the ad libitum period, and 7.7 ± 0.73 kg from the pre-diet period (10 weeks before). Almost half of the total weight loss occurred in the first 2 weeks on the low-CHO diet. When subjects resumed ad libitum food intake at the end of the 8-week diet period, some weight was gained back (+1.5 ± 0.45 kg). However, data from 21 subjects showed an overall significant loss of body weight (6.8 ± 0.91 kg) over the course of the 12-week study. One year later, weight data were available from 62% of subjects. Although almost all had gained back some of the weight they had previously lost while on the low-CHO diet, only 2 subjects weighed more than they had at the start of the study, whereas 13 weighed less (mean weight loss 5.9 ± 1.7 kg). Body composition was not determined.

Results of this uncontrolled study support that low-CHO diets lead to weight loss. Closer examination reveals weight loss results from caloric restriction. Diet analysis (assessed using food intake records) revealed a 500-kcal decrease in total caloric intake from the start of the study to the end of Stage II, 8 weeks later, when the average intake was 1461 kcal/d. Just as Yudkin and Carey (12) reported 20 years earlier, when protein and fat were permitted in unlimited quantities, subjects did not greatly increase their intake of these nutrients. In fact, fat intake decreased (5 g) and protein intake only slightly increased (11 g). The greatest caloric effect was the near total elimination of CHO (165 g).

Alford et al. (45) manipulated CHO content of low-calorie diets (1200 kcal/d) to determine possible effects on body weight and body fat reduction over 10 weeks. At least 11 women in each diet group consumed either a low-, medium-, or high-CHO diet. The low-CHO diet was 15% to 25% CHO (75 g/d) (30% protein, 45% fat), the moderate-CHO diet was 45% CHO (10% protein, 35% fat), and the high-CHO diet was 75% CHO (15% protein, 10% fat). The women were free-living, but attended weekly classes on nutrition and behavior modification. All were sedentary and agreed to remain so for the duration of the study. Weight loss occurred in all groups, but there was no significant difference in weight loss among the groups. Percent body fat loss, based on underwater weighing was similar among the groups. Alford et al. (45) concluded, "there is no statistically significant effect derived in an overweight adult female population from manipulation of percentage of CHO in a 1200-kcal diet. Weight loss is the result of reduction in caloric intake in proportion to caloric requirements."

Baron et al. (70) conducted a three-month randomized controlled trial to determine acceptability of different sets of dietary advice (e.g., low-CHO vs. low-fat) among free-living subjects. Participants included 135 men and women ranging from barely overweight to frankly obese, recruited with the help of six diet clubs in Oxford, England. Within each participating diet club, subjects were randomly given a low-CHO diet (<50 g/d) or a low-fat/high-fiber diet (<30 g fat/d). All diets contained 1000 kcal/d. Each subject planned his/her own menus, with the assistance of group leaders and study investigators, and received appropriate dietary instruction. Moderate weight loss occurred in both groups during the 3-month period, although at 1 year, much of this was regained. Body weight changes at 3 months indicated that those following the low-CHO diet, especially women, lost more weight than those following the low-fat/high-CHO diet (5.0 vs. 3.7 kg, low-CHO vs. high-CHO). However, further analysis consistently showed club membership (e.g., nature of participants in each club, or effectiveness of leaders) to be a better predictor of weight loss than composition of diet.

Golay et al. (21,22) studied the effect of varying levels of CHO intake (15%, 25%, and 45%) on weight loss in obese subjects. In one study, 68 outpatients followed for 12 weeks received a low-calorie (1200 kcal), 25% CHO (75 g), or 45% CHO diet (21). Protein content of the diets was comparable (~30%); fat made up the difference. After 12 weeks, the mean weight loss was similar between the two groups (10.2 ± 0.7 kg vs. 8.6 ± 0.8 kg; 25% vs. 45% CHO, respectively). Loss of adipose tissue was similar. Despite a high protein intake (1.4 g/kg IBW) there was a loss of lean body mass in both groups. The waist-to-hip ratio diminished significantly and identically in both groups. In another study (22), 43 obese inpatients followed for 6 weeks received a low-calorie diet (1000 kcal), and participated in a structured, multidisciplinary program that included physical activity (2 h/d), nutritional education, and behavioral modification. The natural food diet contained either 15% CHO (37.5 g), or 45% CHO. Protein content of the diets was comparable (~30%); fat made up the difference. After 6 weeks, there was no significant difference in weight loss in response to either diet (8.9 ± 0.6 kg vs. 7.5 ± 0.5 kg; 15% vs. 45% CHO, respectively). Significant and comparable decreases in total body fat and waist-to-hip ratios were seen in both groups. Both studies show that energy intake, not diet composition determines weight loss and fat loss in response to low-energy diets over a short time period.

Wing et al. (69) confined 21 severely obese women to a metabolic ward for 31 days. They were randomly assigned to ketogenic (10 g of CHO) or nonketogenic liquid formula diets containing ~600 kcal/d for 28 days. Weight losses were comparable between the two diets (mean, 8.1 kg). Because the objective was to determine whether ketogenic weight reducing diets have adverse effects on cognitive performance, no data on body composition were obtained.

Table 6. Dr. Atkins' New Diet Revolution: diet analysis compared with the USDA Food Guide Pyramid

Nutrient	Atkins' induction	Atkins' ongoing	Atkins' maintenance	Food guide pyramid	RDAs, DRVs, DRIs*
Total energy (calories)	1152	1627	1990	1972	2000–2200
Moisture (H_2O), g	682	736	1132	1879	none
Total fat, g (% total kcal)	**75 (59)**	**105 (58)**	**114 (52)**	54 (24)	65 (30)
Saturated fat, g	**29**	**49**	**44**	17	20
Monounsaturated fat, g	**31**	**36**	**41**	19	20
Polyunsaturated fat, g	6	11	19	15	20
Cholesterol (mg)	**753**	**1115**	**955**	154	300
Total protein, g (% total kcal)	102 (35)	134 (33)	125 (25)	90 (18)	75 (15)
Total CHO, g (% total kcal)	**13 (5)**	**35 (8.6)**	**95 (19)**	292 (59)	55%–60%
Alcohol, g	0	0	14	0	moderation
Dietary fiber (g)	**3**	**8**	**13**	22	20–35
Vitamin E (mg)	**3**	**7**	**10**	40	15
Vitamin A (RE)	**669**	2183	2231	4140	700
Thiamin (mg)	**.5**	1.4	**.7**	3.8	1.1
Riboflavin (mg)	1.3	2.5	2.0	4.3	1.1
Niacin (mg)	18	20	25	51	14
Vitamin B_6 (mg)	**1.2**	1.8	2.2	5.5	1.3
Folate (μg)	**135**	**391**	**282**	1010	400
Vitamin B_{12} (μg)	8	8	4.3	17	2.4
Vitamin C (mg)	**67**	95	226	288	75
Calcium (mg)	**294**	1701	**889**	1749	1000
Phosphorus (mg)	1096	1993	1418	1800	700
Magnesium (mg)	**126**	**294**	**233**	425	320
Iron (mg)	**10.4**	**12.6**	**8.7**	39	18
Zinc (mg)	15	14	11.7	31	8
Sodium (mg)	2934	4046	3604	2757	2400
Potassium (mg)	**1734**	**2562**	3339	4718	3500

RDAs, Recommended Dietary Allowances; *DRVs*, Dietary Reference Values; *DRIs*, Dietary Reference Intakes.
Note: Items in bold indicate values different from RDAs, DRVs, and DRIs.
* RDAs and DRIs used are those of a female, 31–50 years old. Calculated values (DRV) are based on a 2000-kcal diet: 30% total calories from fat, 10% of total calories from saturated, monounsaturated, and polyunsaturated fat, and 15% total calories from protein.

One might argue that because low-CHO diets result in decreased caloric intake, these diets offer an advantage. If subjects lose weight on these diets, or even gain some weight back when the diet ends (57), these diets might still be of long-term benefit. Astrup and Rössner (77) concludes that a greater initial weight loss improves long-term maintenance, so long as the weight loss is followed by 1 to 2 years of an integrated weight maintenance program consisting of dietary change, behavior modification, and increased physical activity.

Body Composition Changes

During the early days of a ketogenic diet, weight loss is partly due to water loss (25,55,78). In contrast, during the early days on a mixed diet, weight loss is primarily due to loss of body fat (23). After several weeks, subjects who stay on a ketogenic diet regain water equilibrium (25). Because they restrict calories, low-CHO diets result in loss of body fat if the diets are maintained for a longer period of time. A 4.5% reduction in body fat was reported in individuals consuming low-CHO diets for 10 weeks (45). Golay et al. (21,22) reported significant body fat reduction (16.8% to 21.6%) in obese subjects consuming 15%, 25%, or 45% CHO isocaloric diets for 6 and 12 weeks. Losses of protein and fat are about the same during a ketogenic diet as during an isocaloric, nonketogenic diet (21,22,25).

Table 7. Nutrition analysis of various diets: Carbohydrate Addict's, Sugar Busters!, Weight-Watchers, and Ornish Diets

Nutrient	Carbohydrate Addict's diet	Sugar Busters!	Weight Watchers diet	Ornish diet	RDAs, DRVs, DRIs*
Total calories	**1476**	**1521**	1462	**1273**	2000–2200
Moisture (H_2O), g	**746**	1696	1200	1993	none
Total fat, g (% total kcal)	**89 (54)**	44 (26)	42 (25)	13 (9)	65 (30)
Saturated fat, g	**35**	11	9	2	20
Monounsaturated fat, g	**31**	20	18	3	20
Polyunsaturated fat, g	15	9	9	5	20
Cholesterol (mg)	**853**	128	116	4	300
Total protein, g (% total kcal)	84 (23)	89 (23)	73 (20)	48 (15)	75 (15)
Total CHO, g (% total kcal)	**87 (24)**	176 (46)	207 (56)	258 (81)	55–60%
Alcohol, g	0	14	0	2	moderation
Dietary fiber (g)	**8**	25	26	38	20–35
Vitamin E (mg)	**7**	**7**	29	**7**	15
Vitamin A (RE)	3039	948	5638	2318	700
Thiamin (mg)	**.8**	2.4	3.0	1.8	1.1
Riboflavin (mg)	1.8	1.7	3.6	1.5	1.1
Niacin (mg)	16.4	32	37	17	14
Vitamin B_6 (mg)	1.8	2.6	4.0	2.5	1.3
Folate (μg)	**176**	**377**	636	615	400
Vitamin B_{12} (μg)	6.5	3.4	11.6	**1.0**	2.4
Vitamin C (mg)	**53**	109	207	380	75
Calcium (mg)	**640**	**712**	1147	1053	1000
Phosphorus (mg)	1150	1510	1432	1181	700
Magnesium (mg)	**173**	400	325	477	320
Iron (mg)	**8.2**	20	28	24	18
Zinc (mg)	11	11	23	8	8
Sodium (mg)	3192	4012	2243	3358	2400
Potassium (mg)	**2479**	**3020**	3773	4026	3500

RDAs, Recommended Dietary Allowances; *DRVs*, Dietary Reference Values; *DRIs*, Dietary Reference Intakes.
Note: Items in bold indicate values different from RDAs, DRVs, and DRIs.
* RDAs and DRIs used are those of a female, 31–50 years old. Calculated values (DRV) are based on a 2000 kcal diet based on 30% total calories from fat, 10% of total calories from saturated, monounsaturated, and polyunsaturated fat, and 15% total calories from protein.

Evidence Statement: In the short-term, low-CHO ketogenic diets cause a greater loss of body water than body fat. Water weight is regained when the diet ends. If the diet is maintained long-term, it results in loss of body fat. Evidence Category C.

In conclusion, calories count, and low-CHO diets fail to confer a metabolic advantage with respect to body weight or body composition.

2. Nutritional Analysis

- What is the nutritional profile of high-fat, low-CHO diets?
- Do these diets provide adequate levels of nutrients, based on current dietary recommendations?

Tables 6 and 7 are nutritional analyses of 1-day menus of popular diets (presented in Tables 8 and 9), and a diet based on the USDA Food Guide Pyramid. Menus came from books (48, pp. 338–340; 49, pp. 147–164; 50, pp. 209–217) and a representative diet based on the Food Guide Pyramid.

Table 8. Dr. Atkins' New Diet Revolution: menu items compared to the USDA Food Guide Pyramid

Meal	Atkins' induction	Atkins' ongoing	Atkins' maintenance	Food Guide Pyramid
Breakfast	• 2 scrambled eggs • 2 strips bacon • Decaffeinated coffee	• 3 egg Western omelet (with milk, butter, peppers, onions, ham) • 3 oz. tomato juice • 2 CHO g bran crisp bread	• 2 egg spinach & cheese omelet • 2 CHO g bran crisp bread, 1 T butter • 1/2 cantaloupe	• 1 C orange juice • 1 C Total cereal with 3/4 C skim milk • Coffee with 1 oz. 1% milk
Snack				• 6 oz. apple juice
Lunch	• Bacon (1 slice) cheeseburger (4 oz; 1 oz cheese) • Small salad (no dressing) • Seltzer water	• Chef's salad with 1 hard-boiled egg, 2 oz. ham, 1 oz. cheese, 2 oz. chicken • Iced tea	• 4 oz. roast chicken • 2/3 C broccoli • Green salad with creamy Italian dressing	• Turkey sandwich (3 oz. meat, 1 T mayonnaise, tomato) • 10 baby carrots • 1 C milk (1%)
Snack			• 1 C deep-fried pork rinds	• 10 saltine crackers (low-salt) • 6 oz. V-8 (no-salt added)
Dinner	• Clear consommé • 1.5 C shrimp salad • Steak (4 oz) • Salad with dressing • 1 C Sugarless Jell-O with 1 T whipped sugar-free cream	• 3 oz. poached salmon • 3/4 C spinach • 1/2 C strawberries with 1 T heavy whipping cream	• Salad w/tomatoes, onions, carrots • 1 C green beans • 1/2 small baked potato w/sour cream, chives • 5 oz. loin of veal • 1 C fresh fruit salad • 5 oz. white wine	• 3 oz. Atlantic salmon • 1/2 C rice • 1/2 C zucchini w/parmesan cheese • 1 slice whole wheat bread with 1 T canola margarine
Snack		• 4 oz. Swiss cheese, 3 slices of bacon, fried		• 6 gingersnaps, 1 banana • 1/2 C chocolate ice cream

Diets are compared with current Recommended Dietary Allowances (RDAs) and Dietary Reference Intakes (DRIs). All food records were analyzed using the USDA 1994 to 1998 Continuing Survey Nutrient Database.

Analyses reveal high-fat, low-CHO diets are also low in calories (e.g., 1152 to 1627 kcal/d). The Atkins' Maintenance Diet, to be followed after weight loss, provides 1990 kcal/d.

Low-CHO diets are high in fat, especially saturated fat, and cholesterol. They are also high in protein (mainly animal), and provide lower than recommended intakes of vitamin E, vitamin A, thiamin, vitamin B_6, folate, calcium, magnesium, iron, potassium and dietary fiber.

Evidence Statement: High-fat, low-CHO diets are nutritionally inadequate, and require supplementation. Evidence Category C.

Low-CHO diets are often referred to as high-protein or high-fat diets because of the high percentage of calories from protein (25% to 30%) and fat (55% to 60%). Because overall caloric intake decreases on low-CHO diets, and consumption of protein and fat is self-limiting (11), the absolute amount of protein and fat is not as high as these percentages imply. However, the absolute amount of these nutrients are higher in low-CHO as compared with the typical American diet (105 g vs. 82.5 g of protein and 94 g vs. 85 g of fat, low-CHO vs. American diet, respectively) (Table 3). When low-CHO diets are compared with moderate-fat, balanced nutrient reduction diets, they provide twice as much protein and 2.4 times more fat at the same caloric level.

3. Metabolic and Adverse Effects

- What are the metabolic effects of high-fat, low-CHO diets?
- Will these diets correct the complications of diabetes, heart disease, and high blood pressure?
- What effects, if any, do these diets have on bone health, cancer risk, and renal function?
- Are there any adverse effects when consuming these diets?

A number of different metabolic effects have been reported for high-fat, low-CHO diets. The most common is ketosis, as measured by increased urinary ketones (24,57,58,60,63,69,79). Ketogenic diets usually have less than 20% calories from CHOs (80). Because many of these are also low calorie, average CHO intake is 50 to 100 g/d. All popular low-CHO diets recommend <100 g of CHO per day. Ketogenic diets may cause a significant increase in blood uric acid concentration (57,60,63,67,78).

Other metabolic effects range from decreased blood glucose and insulin levels, to altered blood lipid levels (Table 10). Many of these effects (e.g., decreased LDL and HDL cholesterol) may be the consequence of weight loss, rather than diet composition, especially considering that the absolute amount of fat consumed on the low-CHO diet may be similar to that consumed before the diet (Table 3).

Evidence Statement: High-fat, low-CHO diets result in ketosis. Evidence Category B.

Evidence Statement: Low-CHO diets that result in weight loss may also result in decreased blood lipid levels, decreased blood glucose and insulin levels, and decreased blood pressure. Evidence Category C.

Possible effects of such high saturated fat diets on endothelial dysfunction need to be assessed. It has been proposed that a single high-fat meal transiently impairs conduit vessel endothelial function (81). However, this hypothesis has been recently challenged (82).

If excess weight causes complications of diabetes, heart disease, and high blood pressure, then individuals who lose weight on low-CHO diets, and maintain weight loss, may see health benefits. However, no data support long-term adherence to such diets, and high-fat, low-CHO diets contradict all governmental and nongovernmental dietary recommendations with respect to reducing risk, or treating such conditions.

Bone Health, Cancer Risk, and Renal Function

The potential effect of low-CHO diets on bone health is an important consideration. In a study of diet and osteoporosis, Wachman and Bernstein (83) hypothesized the role of the skeleton in acid-base homeostasis in adults, observing a reservoir of alkaline salts of calcium as key to the regulation of pH and plasma bicarbonate concentrations (see also 84–86). New (87), after reviewing other studies showing that acidification increases the activity of osteoclasts and inhibits that of osteoblasts, concluded that a diet high in meat but low in fruits and vegetables could lead to bone loss. Barzel and Massey (88) concluded that excessive dietary protein from foods with high potential renal acid load leads to calciuria, which adversely affects bone, unless buffered by the consumption of alkali-rich foods (e.g., fruits and vegetables). Recently, New et al. (89) found that potassium, magnesium, fiber, β-carotene and vitamin C, and a high intake of fruit was important to bone health. Low-CHO diets, often providing inadequate amounts of these nutrients (and foods) may pose long-term risks to the skeleton.

The effect of high protein intake on renal function during weight loss induced by high- (25%) vs. low-protein (12%), moderate-fat (30%) diets in overweight subjects over 6 months was assessed by Skov et al. (90). Protein intake in the low-protein group decreased from 91 to 70 g/d, and increased from 91 to 108 g/d in the high protein group. Results indicate moderate changes in dietary protein intake caused adaptive alterations in renal size and function without indications of adverse effects. However, CHO content of diet was not restricted (e.g., 45% or 58%) so this study did not directly speak to the issue of a high-protein, high-fat, and low-CHO diet. For further information on metabolic consequences of high-protein intake see Metges and Barth (91).

Finally, low-CHO diets are often low in fruits, vegetables, and dietary fiber. This raises the specter of increased cancer risk if such diets are consumed long-term (92–95). However, because no long-term consumption data exist, it is currently impossible to assess cancer risk in individuals consuming low-CHO diets.

Adverse Effects

Few clinically significant adverse effects have been reported in subjects consuming high-fat, low-CHO diets. Some reported side effects include bad taste in mouth (57), constipation (70), diarrhea (49,56,72), dizziness (66), halitosis (57), headache (66), insomnia (49), nausea (56,66,74), thirst (57), and tiredness, weakness, or fatigue (49,56,57,64,74).

Only one study assessed cognitive effects of low-CHO diets (69). Performance on attention tasks did not differ as a function of diet. Performance on the trail making task, a neuropsychological test that requires higher order mental processing and flexibility, was adversely affected by the ketogenic diet. Worsening of performance was observed primarily between baseline and Week 1 of the diet.

4. Hunger and Appetite: *Compliance, CHO Cravings, and Addiction*

- Do low-CHO ketogenic diets decrease hunger?
- What data support compliance to a low-CHO diet?
- Are CHOs addictive?

Dietary adherence is one of the most difficult challenges faced by obese dieters (54). The stronger the feeling of hunger, the greater the urge to break the diet. If diet com-

Table 9. Menu items of various diets: Carbohydrate Addict's Diet, Sugar Busters!, Weight Watchers, and Ornish Diets

Meal	Carbohydrate Addict's	Sugar Busters!	Weight Watchers diet	Ornish diet
Breakfast	• 3 egg onion-cheese (1 oz. cheese) omelet (made with whole milk and margarine) • 2 sausage links • Coffee or tea	• 3/4 C grapefruit juice • 1 pkg instant oatmeal, 2/3 C skim milk • Coffee	• 1 oz. Total Corn flakes, 1/2 C non-fat milk • 1 slice whole wheat bread, 1 pat margarine • orange	• 1/2 grapefruit • 1 package oatmeal, 1 oz. raisins • 1 C skim milk • Brewed tea
Snack	• None allowed	• 3 rye crispbread with 1 T peanut butter	• 1 apple	• apple
Lunch	• 1/2 C water-packed tuna salad (mayonnaise, scallion and eggs) • 1 C salad	• Turkey (3 oz.) sandwich on whole wheat bread with mustard, lettuce, tomato • Diet cola	• 2 oz. roast beef on rye bread • 2 raw carrots • tossed green salad, low-calorie French dressing • 1 cup non-fat milk • 10 grapes	• 1 corn tortilla, 2 T salsa, 1/2 C black beans, 1/2 C canned tomatoes, onions, 1/4 C green peas • 1 C salad, 1/4 cantaloupe
Snack	• None allowed	• Apple	• 1 ounce almonds • 1 fig bar	
Dinner	• 3 oz. steak • Baked potato with sour cream and chives • 1.5 C salad with 1 T buttermilk dressing, 1 raw carrot • 1/2 butter pecan ice cream	• 4 oz. pork tenderloin broiled with chopped onion • 1/2 C brown rice made with fat-free chicken broth • 1/2 C green beans • 1 C salad • 5 oz. red wine	• 1 C beef bouillon soup; 2 saltines • 2.5 oz. salmon, broiled • 3/4 C zucchini • 1/2 baked potato	• 1 C brown rice with 1/4 C tofu, stir-fry vegetables (1/2 C broccoli, 1/8 C cabbage, 3 scallions, 1/8 C bean sprouts, 1/8 C peppers, 1/4 C snow peas, 1/8 C carrots); teriyaki sauce, 2 oz. cooking wine, 1/4 t sesame seeds, 1/4 C pineapple • 1 C salad with no-oil salad dressing • 1 orange
Snack	• None allowed	• 12 nuts (mixed)	• 1/2 C chocolate ice cream • 1/2 C non-fat milk	• 1/2 C strawberries

position affects feelings of hunger, it may influence the ability of patients to adhere to the weight-loss regimen. Atkins claims the low-CHO diet is a revolution because no hunger is experienced (48, pp. 112–113). Individuals are allowed to eat as much protein and fat as they desire as long as they avoid CHOs. Atkins believes this combination of nutrients has a high satiety value and results in individuals eating less (and losing weight). In studies lasting up to 16 weeks, data indicate subjects consuming low-CHO diets decrease food intake and lose weight (Tables 5a,b). Young et al. (64) found each of the low-CHO levels (30 g to 104 g/d) effective in controlling hunger, and that hunger was not a problem after the first week. Cedarquist et al. (65) wrote "subjects had a feeling of well-being and satisfaction. Hunger between meals was not a problem." Krehl et al. (63) reported the highest level of satiation on a 12-g CHO diet with a 70:30 ratio of fat to protein compared with diets having 60:40, 50:50; 40:60; or 30:70 ratios. (Note: this 70:30 ratio is close to the Atkins' ongoing weight loss phase, which has a ratio of fat to protein of 60:30.).

Not all studies support these findings. Baron et al. (70) found that low-CHO dieters complained of hunger with the

Table 10. Reported metabolic effects of low-CHO, ketogenic diets

Clinical measure	Increased	Decreased	No change
Blood uric acid	57,60,63,67		11
Blood glucose		21,22,60,67	24
Blood insulin		21,22,60	
Blood glucagon		60	
Glucose tolerance			60,79
SGOT	67		
SGPT	67		
Serum albumin	60		
Blood urea nitrogen	45		79
Sodium balance		62	63,64
Potassium balance		64	63
Blood cholesterol	56		11,57
HDL cholesterol		21,57 [women only], 60	22,57 [women only], 60
LDL cholesterol	57 [women only]		60
Blood TG		21,45,57 [men only], 60,61,63,67	11,56
Blood pressure		22,67	

Blank cells indicate no published data; numbers refer to studies cited.

same frequency as low-fat dieters. Worthington (66) reported no difference in acceptability, appetite, or satiety after 2 weeks on either low-CHO or balanced diets, and ketosis did not suppress appetite. Rosen et al. (96,97) found no support for the idea that a minimal-CHO, protein-supplemented fast (800 kcal; 58% protein, and 42% fat) decreases appetite and elevates mood in comparison with an isocaloric CHO-containing diet that minimized ketosis. Thus, the effect of low-CHO diets on hunger and satiety remains controversial.

Compliance

Although compliance was not directly assessed, some data indirectly apply to this issue. Kekwick and Pawan (24) fed patients low-calorie diets containing either 90% calories from fat, protein, or CHOs. They noted, "Many of these patients had inadequate personalities. At worst they would cheat and lie, obtaining food from visitors, from trolleys touring the wards, and from neighboring patients. (Some required almost complete isolation). A few found the diet so trying they could not eat the whole of their meals. When this happened, the rejected part was weighed, and the equivalent calories and foodstuffs were added to a meal later in the day. A considerable number of failures in discipline were discarded." Rabast et al. (67,68), who studied subjects on a metabolic ward receiving low-calorie, low-CHO liquid formula diets, reported that after 30 days, "conditions for comparative investigations were no longer met because the two groups were declining rapidly." No explanation for dropouts was given.

Most studies on low-CHO diets (or of subjects receiving advice to consume low-CHO diets) were of short duration and had small sample sizes (Tables 5a,b). Of studies published over the last 44 years, those that lasted 9 weeks or longer included a total of 76 subjects (21,45,57,64,65).

Are CHOs Addictive?

Some authors state that "CHOs are addictive" (50,51). Furthermore, they speculate that hyperinsulinemia prevents a rise in brain serotonin, leading the CHO craver to feel hungry and eat more CHOs. This vicious cycle of hunger, CHO craving, CHO consumption, and hyperinsulinemia is proposed to be the underlying cause of obesity (50,51). Some confuse the matter further by stating, "certain people have a natural, overwhelming desire for CHO that doesn't correlate to hunger. These people in all likelihood have a genetic predisposition toward CHO craving . . . which can be reduced for some by embarking on a low-CHO diet" (51, p. 118). The latter suggests that a change in dietary composition will override a purported genetic defect. Research has not substantiated any of these contentions.

Wurtman (98) characterized self-selected, obese, "CHO cravers" by their powerful and frequent cravings for and consumption of foods rich in CHO over those high in protein, especially during the afternoon snacking period. This snacking among obese CHO-cravers represents a variable that contributes to excess caloric intake (and weight), and became the basis for *The Carbohydrate Addict's Diet* (50). This diet limits daily food intake to two "Complementary" high-fiber, low-fat, low-CHO meals (how is that pos-

sible?) and one "Reward Meal" of unlimited quantity or quality, consumed within 60 consecutive minutes. No snacks are allowed. The authors claim that eating "Complementary Meals" fools the body into producing less insulin, relative to what it would have produced if CHOs were consumed at each meal. The claim that insulin output will be low no matter what is consumed at the "Reward Meal" so long as it is limited to 1 hour (50, p. 96) is unsubstantiated (and if true, potentially dangerous). This diet works simply because eliminating snacks and after-dinner eating results in decreased caloric intake.

If CHO cravings were due to decreased serotonin, then drugs that increase serotonergic output should alleviate cravings and result in decreased food intake. Early studies with the serotonergic drug fenfluramine showed effectiveness in decreasing CHO intake (99). However, the effect was not limited to CHO; it resulted in decreased intake of protein as well (100). Toornlivet et al. (101,102) demonstrated that obese CHO cravers and non-CHO cravers responded similarly to treatment with fenfluramine with respect to eating behavior and weight loss. Although the evidence may be interpreted to provide support for the existence of a self-medication effect among a large segment of obese individuals, the mechanism by which CHO mediates this effect has not yet been identified. Furthermore, a more likely interpretation is that some people simply have an unusually large appetite (i.e., they are cravers). Drewnowski (103) has pointed out that the so-called "sweet-tooth" characterizing CHO cravers is just as much a "fat-tooth" because the foods typically selected are high in both CHO (often sugar) and fat. Thus, the effect of low-CHO diets on hunger, appetite, and satiety need further study.

4a. Role of Insulin in Obesity

- Is overproduction of insulin, driven by high CHO intake, the cause of the metabolic imbalance that underlies obesity?
- If so, can obese, hyperinsulinemic individuals lose more weight on low-CHO diets as compared with high-CHO diets?
- Does leptin interact with insulin in regulation of appetite and body weight?

Dietary CHO, as well as dietary protein, increases insulin secretion. The hyperinsulinemia of obesity may be the result of dietary factors, genetic factors (e.g., "thrifty genotype") or secondary adaptation to insulin resistance (31). Increased appetite and consequent overconsumption may drive increased insulin, but as body weight increases, and insulin resistance develops, this too will drive increased insulin secretion.

The relationship between insulin resistance and weight gain yield conflicting results (104). Swinburn et al. (105) and Schwartz et al. (106) indicated that insulin resistance and hyperinsulinemia predicted decreased weight gain over 3 years in glucose-tolerant adult Pima Indians. In contrast, Sigal et al. (107) reported hyperinsulinemia predicts increased weight gain. However, this study was questioned on the basis of subject sampling and methodology (33). Even if hyperinsulinemia is the cause of the metabolic imbalance, is there evidence to show that low-CHO diets are better for weight loss than high-CHO diets?

Energy restriction, independent of diet composition (e.g., 15% to 73% CHO) improves glycemic control (21,31–33). The ability to lose weight on a calorically restricted diet over a short-time period does not vary in obese healthy women as a function of insulin resistance or hyperinsulinemia (104). Although diet composition may play a role in absolute reduction in blood insulin levels, weight loss seems to be independent of such changes. For example, Golay et al. (21) reported subjects consuming isocaloric diets (1000 kcal) containing 15% CHO had significantly lower insulin levels as compared with those consuming 45% CHO, yet there was no difference in weight loss between the two groups. In another study, isocaloric diets (1200 kcal) containing 25% and 45% CHO resulted in similar reductions in blood insulin levels as well as similar average weight losses (22).

Grey and Kipnis (31) studied 10 obese patients who were fed hypocaloric (1500 kcal/d) liquid-formula diets containing either 72% or 0% CHO for 4 weeks before switching to the other diet. A significant reduction in basal plasma insulin levels was noted when subjects ingested the hypocaloric formula devoid of CHO. Refeeding the hypocaloric, high-CHO formula resulted in a marked increase in the basal plasma insulin. However, patients lost 0.75 to 2.0 kg/wk irrespective of caloric distribution.

The effect of protein vs. CHO on blood insulin levels and subsequent weight loss was assessed by Baba et al. (32), who studied 13 male obese hyperinsulinemic subjects for 4 weeks. They were fed a hypoenergetic diet (comprised of 80% of the person's resting energy expenditure) containing either 25% CHO and 45% protein, or 58% CHO, and 12% protein. Both diets contained 30% calories from fat. Despite the significant, but not different degrees of reductions in blood insulin levels that occurred on both diets, the insulin levels were reduced to within the normal range only in the high-protein group. Although individuals in both groups lost weight, the mean weight loss was significantly higher on the high-protein as compared with the high-CHO diet, a consequence, perhaps, of the higher protein, lower CHO content of the diet.

The optimal macronutrient composition of a weight-reducing regimen in obese hyperinsulinemic patients is the subject of research, but beyond the scope of this article (for more information see Reaven et al. (108)).

Insulin and Leptin in the Endocrine Regulation of Appetite and Body Weight

Insulin and leptin are hormones that act as medium- to long-term regulators of body weight through their actions to decrease food intake and increase energy expenditure (metabolic rate), ensuring that energy intake and energy expenditure is closely matched (109–111).

People who do not produce leptin due to a genetic deficiency, or who have defects in the leptin receptor, have dramatically increased appetites and overeat to the point of becoming massively obese (112,113). The effects of leptin deficiency are ameliorated by the administration of recombinant leptin (114).

Insulin, in addition to its effects in the central nervous system to inhibit food intake, acts in the periphery to ensure the efficient storage of incoming nutrients. The role for insulin in the synthesis and storage of fat has obscured its important effects in the central nervous system, where it acts to prevent weight gain, and has led to the misconception that insulin causes obesity (115). It has recently been shown that selective genetic disruption of insulin signaling in the brain leads to increased food intake and obesity in animals (116) demonstrating that intact insulin signaling in the central nervous system is required for normal body weight regulation.

Insulin also has an indirect role in body weight regulation through the stimulation of leptin (117). Both insulin and leptin are transported into the central nervous system, where they may interact with a number of hypothalamic neuropeptides known to affect food intake and body weight (118).

Insulin and leptin are released and circulate in the bloodstream at levels that are proportionate to body fat content. Secretion and circulating levels are also influenced by amount and type of foods eaten, with decreased concentrations noted during fasting or energy-restricted diets (119,120). The decrease of leptin during a prolonged energy-restricted diet has been shown to be related to increased sensations of hunger (120) suggesting a role for low leptin levels to increase appetite during dieting in humans, and therefore to the predisposition for weight regain after initially successful dieting.

Circulating concentrations of both insulin and leptin, measured over a 24-hour period, are reduced in women consuming high-fat meals (60% fat, 20% CHO) compared with when equicaloric meals high in CHO and low in fat (60% CHO, 20% fat) are consumed (36,37). Increased insulin secretion has been suggested to protect against weight gain in humans (106). Because insulin also stimulates leptin production, which acts centrally to reduce energy intake and increase energy expenditure, decreased insulin and leptin production during the consumption of high-fat diets could help contribute to the obesity promoting effects of dietary fat (42,44,121).

Recent studies show consuming a high-fat diet induces resistance to the actions of leptin to decrease food intake (122,123), and that increased energy intake and weight gain is related to an impairment of insulin transport into the brain (124). Therefore, dietary macronutrient composition affects not only production of insulin and leptin but also may influence their ability to gain access to the brain to signal target neurons. In studies investigating the efficacy and long-term consequences of weight loss diets, it is important to consider the effects of dietary macronutrient content and composition on the production of insulin and leptin, and their actions to regulate energy intake and expenditure.

5. Performance and Physical Activity

- Does the low-CHO diet affect physical performance?

Although reference is made to physical activity and exercise by proponents of low-CHO diets (48, pp. 260–267; 49, pp. 187–206; 50, pp.143–144), only one study examined the capacity for moderate exercise in obese subjects after adaptation to a hypocaloric, ketogenic diet. This study was conducted in six slightly to moderately overweight, untrained subjects on a protein-supplemented fast for 6 weeks (e.g., 500 to 750 kcal/d, $<$10 g CHO, weight loss, 10.6 kg). Results indicate that subjects adapt to prolonged ketosis and use lipid, rather than CHO, as the major metabolic fuel during prolonged exercise at 60% of maximum oxygen concentration. This shift was confirmed by an respiratory quotient of 0.66 during exercise (125).

Other studies were conducted in physically untrained, but normal weight males who were fed eucaloric low-CHO ($<$20 g/d), high-fat (80%) ketogenic diets, or non-ketogenic, low-, medium-, or high-fat diets (15%, 30%, or 55% fat) (126,127). They report diet manipulation, per se, did not effect maximal or submaximal aerobic performance in untrained individuals. However, one cannot extrapolate results from these studies to typically untrained, sedentary, overweight individual consuming low-calorie, low-CHO diets.

II. Moderate-Fat, Balanced Nutrient Reduction Diets

Moderate-fat, balanced nutrient reduction diets contain 20% to 30% fat, 15% to 20% protein, and 55% to 60% CHO. Popular diets in this category include those promoted by commercial weight loss centers (e.g., Weight Watchers, Jenny Craig, Nutri-Systems). These diets have a long history of use, millions of followers worldwide, and are typically based on sound, scientific principles. The DASH diet, diets based on the USDA Food Guide Pyramid, and the National Cholesterol Education Program Step I and Step II Diets also fit into this category if calories are reduced (128).

Table 11. Relation between dietary fat intake (20% to 30% kcal) and weight change in overweight subjects

Study	*n*	BMI	Duration (weeks)	Fat g (%)	Energy start (kcal)	Energy end (kcal)	Energy change (kcal)	Weight change (kg)	Weight change (g/day)
Buzzard (132)	17	28.6	13	35 (23)	1840	1365	475	−2.8	−31
Carmichael (133)	39	35	0–17	40 (22)	2177	1608	(569)	−3.0	−25
			17–26	46 (25)	2177	1658	(519)	−2.6	−21
Golay (22)	21	38	6	30 (26)	N/A	1027	N/A	−7.0	−167
Golay (21)	37	33	12	34 (26)	N/A	1178	N/A	−9.0	−100
Hammer (134)	4	37	16	37 (23)	1934	1450	(484)	−5.8	−52
Harvey-Berino (40)	29	30	24	45 (27)	2171	1477	(694)	−11.8	−70
	28		24	38 (21)	1929	1650	(279)	−5.2	−31
Insull (135)	184	68.8	26	31 (21)	1734	1316	(418)	−3.16	−17
	173		52	31 (22)	1734	1299	(435)	−2.93	−8
Henderson (136)	163		104	34 (23)	1734	1355	(379)	−1.91	−3
Jeffery (137)	39	31	26	36 (23)	1506	1125	(391)	−4.6	−25
			52	40 (26)	1506	1112	(394)	−2.1	−6
			78	40 (26)	1506	1199	(307)	0.4	1
Knopp (131)	57	28	52	63 (28)	2395	2019	(356)	−2	−5
	55	27	52	58 (26)	2294	1995	(299)	−2	−5
	62	28	52	52 (25)	2281	1917	(364)	−6	−16
Pascale (138)	15	N/A	16	30 (22)	1658	1201	(457)	−7.7	−69
	16		16	31 (22)	2024	1246	(778)	−7.5	−67
Powell (20)	8	20%	12	26 (20)	1642	1163	(479)	−5.0	−60
	9	above IBW	12	37 (28)	2081	1190	(891)	−4.6	−55
Prewitt (139)	6	38	1–4	70 (37)	1894	2047	153	−1.5	−53
			5–20	58 (21)	2047	2428	381	−0.6	−5
Puska (140)	35	28% body fat	6	51 (23)	2490	2001	(489)	−0.7	−17
Rumpler (141)	4	28% body fat	4	34 (20)	3095	1542	(1553)	−5.0	−178
Shah (142)	47	31	26	37 (21)	1893	1580	(313)	−4.4	−24
Skov (143)	23	30	0–13	80 (29)	N/A	2533	N/A	−5	−54
			13–26	86 (29)	2533	2676	143*	−5	−27
Swinburn (144)	49	30	52	52 (26)	2195	1832	(369)	−3.1	−8

N/A, Not available.

Adapted from Bray G and Popkin BM (42).

* Weight loss occurred from 0–13 weeks, and no further weight was lost from 13–26 weeks. Caloric intake was not significantly different during the two time periods. Actual caloric intake is suspect based on methodology.

However, most consumers (and governmental agencies) do not perceive the latter as "popular diets," probably because they are typically promoted for reasons other than weight loss and because they are not promoted as commercial diets. For example, the DASH diet (35) has been shown to reduce hypertension, and the Food Guide Pyramid, in conjunction with the Dietary Guidelines, provides recommendations for healthful eating. Although the main focus of the National Cholesterol Education Program Step I and Step II diets is the reduction of saturated fat and cholesterol, these diets also promote weight control because obesity contributes to high blood cholesterol in many patients (128).

Balanced nutrient reduction diets (moderate-fat, high-CHO) used for weight loss have been studied extensively (6,18,42).

Table 12. Change in body weight, overall caloric intake, and diet composition in studies that evaluated the efficacy of low-fat, ad libitum diets (LFAL) vs. low-energy (LE) diets for weight loss*

Shah (142)	Δ BW (kg)	Calories	Fat g (%)	CHO g (%)	Protein g (%)
LFAL	4.4	1580	37 (21)	245 (62)	60 (16)
LE	3.8	1550	34 (30)	206 (54)	60 (16)
Jeffery (137)	Δ BW (kg)	Calories	Fat g (%)	CHO g (%)	Protein g (%)
LFAL	1.9	1350	40 (26)	N/A	N/A
LE	.5	1414	50 (32)	N/A	N/A
Schlundt (145)	Δ BW (kg)	Calories	Fat g (%)	CHO g (%)	Protein g (%)
LFAL	4.6	1425	30 (19)	210 (58)	64 (18)
LE	8.3	1265	28 (19)	179 (58)	61 (18)
Harvey-Berino (40)	Δ BW (kg)	Calories	Fat g (%)	CHO g (%)	Protein g (%)
LFAL	5.2	1650	38 (20)	251 (61)	69 (16)
LE	11.8	1477	45 (27)	200 (54)	60 (16)

N/A, Not available.
* Bold indicates the type of diet (in each study) that was more effective for weight loss. No difference between diets in the Shah paper.

A. Underlying Philosophy, Claims, and Proposed Solutions

The underlying philosophy of moderate-fat, balanced nutrient reduction diets is that weight loss occurs when the body is in negative energy balance. Diets are calculated to provide a deficit of between 500 to 1000 kcal/d, but a minimum number of daily calories (e.g., 1000 to 1200 for women, 1200 to 1400 for men) are recommended. Increased energy expenditure (e.g., physical activity) is promoted as well.

The goal of moderate-fat, balanced nutrient reduction diets is to provide the greatest range of food choices to the consumer, to allow for nutritional adequacy and compliance, while still resulting in a slow but steady rate of weight loss (e.g., 1 to 2 lbs/wk). Programs are usually based on up-to-date, scientific information. For example, recently Weight Watchers started a new program called the 10% difference, based on scientific findings that a 10% reduction of body weight improves health (e.g., decreases blood pressure, improves lipid profile, etc). A similar program is the Shape Up and Drop 10! program of Shape Up America! (129).

B. Scientific Evaluation of Claims

1. Caloric Intake, Body Weight, and Body Composition

- What is the effect of balanced nutrient reduction diets on body weight and composition?
- Which is better for weight loss: reducing calories or reducing fat?

The NHLBI evidence report *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* reviewed the effects of dietary therapy on weight loss (6). Key evidence statements from that report follow.

> **Evidence Statement:** Low-calorie diets* can reduce total body weight by an average of 8% over 3 to 12 months. Evidence Category A.
>
> **Evidence Statement:** Although lower-fat diets without targeted caloric reduction help promote weight loss by producing a reduced calorie intake, lowerfat diets coupled with total caloric reduction produce greater weight loss than lower-fat diets alone. Evidence Category A.

The NHLBI concludes, "there is little evidence that lower-fat diets cause weight loss independent of caloric restriction." This is supported by Powell et al. (20), who studied obese subjects consuming isocaloric reduced calorie diets (1200 kcal/d) containing either 15%, 20%, 28%, or 34% calories from fat for 12 weeks. All subjects lost body weight and body fat. However, there were no significant differences in the rate or amount of body weight or percent body fat lost across the four groups during the intervention.

Bray and Popkin (42) and Astrup et al. (43,121) reviewed the relationship between dietary fat intake and weight change extensively. Based on a meta-analysis of normal weight and overweight subjects, Bray and Popkin concluded a 10% reduction in the percentage of energy from fat would reduce body weight by 16 g/d†. Table 11 summarizes

* Low-calorie diets contain 1000 to 1200 kcal/d.

† The meta-analyses by both Bray and Astrup included normal weight and overweight individuals.

Table 13. Effect of low-fat ad libitum diets (LFAL) vs. low-energy diets (LE) on caloric intake, diet composition and change in body weight

	Δ BW	Calories			Fat		CHO		Protein	
Diet	**(kg)**	**Start**	**End**	**Δ**	**Δ g**	**Δ %**	**Δ g**	**Δ %**	**Δ g**	**Δ %**
Shah (142): Data from 6 months.										
Conclusion: No difference between groups at 6 months.										
LFAL	4.4	1893	1580	313	−39	−13	−1	+11	−13	+0.7
LE	3.8	2119	1550	569	−24	−4	−49	+3.5	−15	+0.6
	Δ BW	**Calories**			**Fat**		**CHO**		**Protein**	
Diet	**(kg)**	**Start**	**End**	**Δ**	**Δ g**	**Δ %**	**Δ g**	**Δ %**	**Δ g**	**Δ %**
Jeffery* (137): Data from 12 months.										
Conclusion: Low-fat better at 12 months; no difference at 18 months.										
LFAL	2.1	1735	1350	385	−31	−11	N/A	N/A	N/A	N/A
LE	.5	1774	1414	360	−20	−4	N/A	N/A	N/A	N/A
	Δ BW	**Calories**			**Fat**		**CHO**		**Protein**	
Diet	**(kg)**	**Start**	**End**	**Δ**	**Δ g**	**Δ %**	**Δ g**	**Δ %**	**Δ g**	**Δ %**
Schlundt (145): Data from 16–20 weeks.										
Conclusion: Low-energy better at 16–20 weeks, no difference at 9–12 months										
LFAL	4.6	2200	1425	775	−64	−19	−19	+17	−20	+3
LE	8.3	2000	1265	735	−59	−20	−12	+19	−38	+2
	Δ BW	**Calories**			**Fat**		**CHO**		**Protein**	
Diet	**(kg)**	**Start**	**End**	**Δ**	**Δ g**	**Δ %**	**Δ g**	**Δ %**	**Δ g**	**Δ %**
Harvey-Berino (40): Data from 24 weeks.										
Conclusion: Low-energy better at 24 weeks. No long term follow-up available.										
LFAL	5.2	1929	1650	279	−26	−9.2	−3	+8.3	−9	+4.2
LE	11.8	2170	1477	693	−33	−5.1	−75	+3.6	−23	+1.1

N/A, Not available.

* Data was taken as the average of intakes reported by food frequency and food recalls.

the relationship between dietary fat intake and weight change in overweight subjects consuming 20% to 30% fat diets. Clearly, subjects who reduce fat intake reduce overall caloric intake, and lose weight. Despite these data, Willett (130) argues that the relationship between dietary fat and obesity is unconvincing. In support, Knopp et al. (131) is cited. In this study, moderately overweight hypercholesterolemic men were randomly assigned to one of four levels of dietary fat for 1 year. Despite differences in actual fat intake in the seven diet groups (ranging from 22% to 28% fat), all groups lost an equivalent amount of body weight (2 to 3 kg). Willett (130) argues that if fat matters, then those consuming 22% fat should lose more weight than those consuming 28% fat.

The retort may be "reduction in fat alone is not enough, calories matter too!" (see Calories vs. Fat below). Second, the reduction of fat to 27% may have accounted for the majority of weight loss effects and that further reductions provide minimal additional benefit (e.g., there may exist a threshold of dietary fat below which changes in body weight are minimal) (44). In reality, the study by Knopp et al. (131) supports the relationship between fat intake and body weight. When fat decreases from 34% to 36% to less than 30%, caloric intake significantly decreases and results in significant body weight reduction. This occurs in all groups, but is most pronounced in overweight subjects (BMI, 27) who decreased fat intake from 34% to 25%, and who lost 6 kg over the course of a year (16 g/d), as Bray and Popkin

Table 14. Effect of moderate-fat diets on changes in body composition

Study	Duration	Body fat (% change)	LBM (kg)	Waist circumference	Hip circumference
Golay (22)	6 weeks	↓ 17	N/A	↓	↓
Golay (21)	12 weeks	↓ 5	N/A	↓	↓
Siggaard (39)	12 weeks	↓ 4.2	+.25	N/A	N/A
Prewitt (139)	20 weeks	↓ 2.3	+8	N/A	N/A
Carmichael (133)	6 months	N/A	N/A	↓	↓
Shah (142)	6 months	↓ 2.2	−1.2	N/A	N/A
Skov (143)	6 months	Yes (4 kg)*	N/A	Yes	N/A

N/A, Not available.
* % change not available.

(42) predicted. That there was not a significant difference in total caloric intake and weight loss at levels of fat between 22% to 28% does not mean that reducing fat below 30% kcal does not make a difference in body weight; it does.

Calories vs. Fat

Which diet is better for weight loss: a low-fat ad libitum (LFAL) or a low-energy (LE) diet? At present, data are insufficient to say that one is better: weight loss occurs on both.

Tables 12 and 13 are from studies in which subjects consumed either LFAL or LE diets containing 19% to 30% calories from fat (40,137,142,145). Both diets result in reduction of total caloric intake from fat, CHO and protein, and both result in weight loss independent of diet composition. Studies reveal percent fat does not always correlate with calories, so that fat content of a diet, in and of itself, may not determine weight loss (131). Just because a diet is lower in fat does not mean it is lower in calories (40), and two diets may be the same percent fat, but differ in caloric content, resulting in differences in weight loss (145). Finally, studies show that what predicts short-term weight loss may be different from what predicts long-term weight maintenance.

Body Composition

The NHLBI concludes that low-calorie diets resulting in weight loss decrease body fat. Subjects who consume moderate-fat, balanced nutrient reduction diets lose body fat, and decrease waist and hip circumferences. The change in lean body mass is inconsistent (Table 14).

2. Nutritional Analysis

- What is the nutritional profile of balanced-nutrient reduction diets?
- Do diets provide adequate levels of nutrients, based on current dietary recommendations?

The nutritional profile of a balanced-nutrient reduction diet (e.g., "Weight Watchers") is presented in Table 7. When proper food choices are made, these diets are nutritionally adequate (128, 146).

> **Evidence Statement:** With proper food choices based on the USDA Food Guide Pyramid the moderate-fat, balanced nutrient reduction diet is nutritionally adequate. Evidence Category B.

However, if appropriate food choices are not made, diets may fall short with respect to calcium, zinc, magnesium, iron, vitamin B_{12} and dietary fiber (132,135,144). Swinburn et al. (144) studied the effect of reduced fat ad libitum diets over a 1-year period in 110 New Zealand adults. Nutrient intakes were derived from 3-day food diaries at the beginning and end of the study. Blood levels of retinol, α-tocopherol, and β-carotene were determined at the end of the study. Results show that reduced fat intake (from 35% to 25% of energy) led to reduced calorie intake and weight loss compared with a usual diet (33% fat). There were no differences between the diets in changes in micronutrient intakes, except for an energy-adjusted increase in β-carotene intake in the reduced-fat group. Fiber intake remained at 20 g/d. However, the calcium intake in both groups was low ($\sim$600 mg/d).

Buzzard et al. (132) indicated that intake of zinc and magnesium was significantly reduced in women with stage II breast cancer consuming reduced fat (22%) diets. Calcium intake (628 mg/d) was similar to that reported by Swinburn et al. (144), but this amount is less than two-thirds the recommended intake. Fiber intake (15 g/d) was also low. Insull et al. (135) assessed dietary intake among women consuming low-fat vs. control diets (22% vs. 37% fat, respectively). Despite similarities in dietary intakes between

groups, calcium, iron, and vitamin B_{12} intake was slightly below daily requirements, necessitating the use of dietary supplements.

3. Metabolic and Adverse Effects

- What are the metabolic effects of moderate-fat, balanced nutrient reduction diets?

Studies allowing ad libitum intake of reduced-fat, high-CHO diets show the changes in blood lipids are dominated by the slight weight loss induced by such diets (43). This is confirmed by the systematic review of effects of the National Cholesterol Education Step I and II dietary intervention programs on cardiovascular disease risk factors. Meta-analysis reveals these diets reduce LDL-cholesterol, normalize plasma TGs, and normalize the ratio of HDL/TC (27).

In studies reviewed here, Golay et al. (21,22) reported diets containing 26% fat (and either 1000 or 1200 kcal) resulted in reduced TC, HDL cholesterol, and TGs. Skov et al. (143) reported diets containing 29% fat (but 2600 kcal) reduced TC and HDL but increased TGs. Theusen et al. (147) reported subjects consuming 21% fat diets containing 1835 to 2026 kcal for 1 year had decreased levels of total and LDL cholesterol, no change in HDL cholesterol, and decreased TGs. Henderson et al. (136) measured changes in plasma TC among intervention group women at 12 and 24 months, and reported TC decreased in the group consuming low-fat diets (22% fat) but not in those consuming control higher-fat diets (37% fat).

Moderate-fat, balanced nutrient reduction diets reduce blood pressure (6,21,22,35).

Only Golay et al. (21,22) measured fasting insulin levels, which were significantly reduced in subjects who lost weight on balanced nutrient reduction diets. When moderate-fat (20%) meals are consumed, postprandial insulin secretion is enhanced and circulating leptin levels are increased over a 9-hour (37) or 24-hour (36) period. These changes of insulin secretion and leptin production could contribute to the effects of balanced nutrient reduction diets on energy intake, hunger and appetite, and energy expenditure.

Evidence Statement: Moderate-fat, balanced nutrient reduction diets reduce LDL-cholesterol, normalize plasma TGs, and normalize the ratio of HDL/TC. Evidence Category A.

Evidence Statement: Moderate-fat, balanced nutrient reduction diets reduce blood pressure. Evidence Category A.

4. Hunger and Appetite: *Compliance*

- What is the effect of moderate-fat, balanced nutrient reduction diets on hunger and appetite?
- What data support compliance to these diets?

A number of studies in which subjects consumed LFAL diets report that individuals do not complain of hunger, but rather, that there is too much food. Siggaard et al. (39) reported a high degree of satisfaction with the changes in food intake in Danish workers consuming a LFAL diet for 12 weeks. Subjects stated, "I have never been eating as much as I do now" and "I have not felt hungry at any time." Shah et al. (142) reported subjects consuming LFAL diets rated these higher than LE diets in palatability, satiety, and quality of life measures. Jeffery et al. (137) found that subjects asked to reduce fat were more compliant with treatment instructions, reported greater success in reaching their dietary goals, and rated their diet as higher in palatability. They had greater decreases in binge eating scores than those in the LE group.

In support of LE diets (over LFAL diets), Harvey-Berino (40) found that subjects consuming LE diets had more positive changes in eating behaviors, and greater improvements in feelings of physical wellness that were not correlated to weight loss. However, these diets were rated more inconvenient than LFAL diets.

Subjects consuming both LE and LFAL diets reported an increased distaste of fat. Subjects in both groups reported increased feelings of deprivation, but the changes in the group were not significant (40). Bray and Popkin (42) conclude adherence to an LFAL diet is a function of the frequency of dietary counseling. This may be the case for any reduced-calorie diet, regardless of macronutrient composition. Alford et al. (45) remarked, "For the women in our group, the interaction and support were the most important aspects. I think that is true for most women. We tried to make the nutrition classes personal, so the women wouldn't tune them out." Perhaps psychological issues are more important than dietary factors in the discussion on compliance.

Finally, The Women's Health Trial Vanguard Study (135,136) examined the feasibility of a nationwide, randomized multicenter intervention trial to test the hypothesis that a low-fat diet followed for 10 years reduces breast cancer risk. Feasibility studies of women at increased risk show dietary intervention targeted to lower dietary fat below 25% can be implemented and maintained successfully over a 2-year period. However, because women in these studies were highly selected and motivated, caution is urged in extrapolating compliance data to the "dieting" public, whose motivation for reducing fat may be very different from those in this study group.

Table 15. Relation between dietary fat intake (<10–19% kcal) and weight change in overweight subjects

Study	*n*	BMI	Duration	Fat g (%)	Energy (kcal)	Weight change (kg)	Weight change (g/day)
Agus (152)	10	30.6	9 days	30 (18)	1493	−3.23	−358
Alford (45)	12	28	12 wk	13 (10)	1200	−4.8	−57
Barnard (155)	2643	>30	3 wk	13 (10)	1200	−5.1	−242
	1897	>30	3 wk	13 (10)	1200	−3.3	−157
Djuric (150)	113	27.8	12 wk	35 (17)	1843	−.9	−10
				57 (32)	1559	−2.3	−27
				28 (18)	1392	−3.6	−42
Havel (34)	17	35.1	6 mo	N/A (12)	N/A	−4.0	−21
			8 mo	N/A (11)	N/A	−5.0	−21
Heilbronn (33)	35	N/A	12 wk	18 (10)	1600	−6.6	−78
Kasim-Karakas (151)	54	27.6	6 mo	20 (12)	1449	−2.5	−13
			8 mo	19 (11)	1503	−3.1	−13
			10 mo	19 (12)	1420	−3.3	−11
			12 mo	19 (12)	1474	−4.6	−13
Lissner (149)	12	>101% MLI standards*	2 wk	40 (18)	2087	−.4	−28
Noakes (28)	22	31	12 wk	17 (10)	1553	−7.9	−94
Ornish (156,14)	25	28.4	52 wk	13 (6)	1821	−10.7	−29
	20	28.4	260 wk	17 (8)	1846	−5.8	−8
Powell (20)	8	20% above IBW	12 wk	19 (15)	1113	−4.5	−53
Schaefer (38)	27 (LFAL)	26.3	10–12 wk	N/A (15)	N/A	−3.63	−43
Schlundt (145)	27 (LFAL)	31	16–20 wk	30 (19)	1425	−4.6	−32
	29 (LE)	35	16–20 wk	28 (19)	1264	−8.3	−59
Surwit (153)	20	36	6 wk	13 (11)	1087	−7	−166
	22	35	6 wk	14 (11)	1156	−7.4	−176

N/A, Not available.
* MLI is Metropolitan Life Insurance Tables.

III. Low-Fat and VLF Diets (<10% to 19% Fat)

VLF diets are defined as containing <10% fat, and low-fat diets contain between 11% and 19% fat. Both are very high in CHO, and moderate in protein. Representative VLF diets are those promoted by Dr. Dean Ornish, and Nathan and Robert Pritikin. There are no commercial diets that fit in the category of low-fat diets, although there is research on these diets meriting their inclusion in this paper.

The American consumer has traditionally ignored the VLF diet for weight loss. It seems they would rather restrict CHO intake to less than 10% of calories than to restrict intake of their favorite fat (or sweet-fat combination) to the same degree. In addition, these diets were not historically promoted as weight loss diets, but rather, diets to prevent or reverse heart disease. VLF diets recommended reduction of dietary fat and cholesterol based on the (now) well-known association between saturated fat consumption and cardiovascular disease.

However, as Americans became fatter, and their hunger for diet books remained unsatiated, proponents of VLF diets (e.g., Ornish and Pritikin) capitalized on their program's apparent effect on body weight. They changed the focus (and title) of their books from heart disease to weight loss‡. Neither trial (e.g., The Lifestyle Heart Trial or The Pritikin Program was originally designed to assess the effect of diet

‡ This theory is supported by changing book titles over the past 20 years. Ornish's book titles include *Stress, Diet and Your Heart* (1982), *Dr. Dean Ornish's Program for Reversing Heart Disease* (1990), and *Eat More, Weigh Less* (1993). The Pritikin plan was originally popularized by Nathan Pritikin, whose books included *The Pritikin Program for Diet and Exercise* (1979) and *The Pritikin Promise* (1983). His son, Robert, head of the Pritikin Longevity Center wrote *The New Pritikin Program* (1990), *The Pritikin Weight Loss Breakthrough* (1998), and *The Pritikin Principle* (2000).

Table 16. Energy intake from 0–5 years (The Lifestyle Heart Trial)

	Experimental			Control			*p**	
	Baseline (B)	1 year	5 years	Baseline	1 year	5 years	B–1 year	B–5 years
Energy intake	1950	1821	1846	1711	1673	1572	0.64	0.86
Energy change		−129	−104		−38	−139		
Body weight (kg)	91.4	80.64	85.64	75.74	77.18	77.09	0.001	0.001

* All *p* values are two-tailed and each is the result of a test of the null hypothesis that the change between two particular visits (e.g. baseline and 1 year) does not differ between the experimental and control groups (14). Adapted from Ornish (14,156).

on weight loss. Thus, the scientific information on the effect of these diets on body weight and body composition is limited. In addition, caution in the interpretation of results is necessary because diet is but one component of these total lifestyle-modification plans.

A. Underlying Philosophy, Claims, and Proposed Solutions

Proponents of VLF diets support reducing caloric intake and increasing energy expenditure to achieve weight loss. Rather than counting calories, per se, dietary recommendations focus on "type of calories" (13, p. 31) and "caloric density" (17, p. 5). "Eat more, weigh less" (13) does not mean, "eat more calories." It means, "consume more high complex CHO, and high-fiber foods whenever you feel hungry and until you feel full, but not stuffed" to lose weight (13, p. 32). The "calorie density solution" enables individuals to eat as much as they want—six to seven times daily—and lose weight safely, gradually, and without hunger (17, p. 17). These VLF diets are based primarily on vegetables, fruits, whole grains, and beans, with moderate quantities of egg whites, nonfat dairy or soy products, and small amounts of sugar and white flour. Ornish's diet is vegetarian; Pritikin allows a limited amount of low-fat animal protein daily (no more than 3.5 ounces of lean beef, fowl or fish).

Dr. Dean Ornish's Program for Reversing Heart Disease (148) and *The Pritikin Program* (15,16) promotes lifelong changes in diet, exercise, and lifestyle. Each plan includes a nutrition and exercise component; Ornish's plan includes stress reduction and emotional support as well. Current claims range from weight loss, to overcoming or reversing heart disease, reducing symptoms of type 2 diabetes, high blood pressure, cancer, arthritis, stress, and smoking, in addition to general wellness, sometimes in as little as 2 weeks (13,15,16,148). Pritikin also claims medications for heart disease, diabetes, and high blood pressure may be reduced or completely eliminated by following these plans.

B. Scientific Evaluation of Claims

1. Caloric Intake, Body Weight, and Body Composition

- Do low-fat and VLF diets result in decreased caloric intake?
- What is the effect of these diets on body weight and body composition?

Overweight subjects who consume low-fat, and VLF, high-CHO diets eat fewer calories and lose weight (20,34,38,145,149,150–152) (Table 15). Again, total caloric intake is more important than diet composition, in this case fat, for weight loss (28,33,45,154). In the context of reduced caloric intake (1200 kcal/d) percent calories derived from fat (15% to 35%) does not influence weight loss (20). Havel et al. (34) reports a family history of diabetes is predictive of weight loss (and fat loss) in women consuming LFAL diets for 6 months.

Subjects who lose weight on low-fat diets lose body fat (120,34,45,151) and lean body mass (145). However, in the context of a reduced calorie diet, the amount of dietary fat (10% to 40%) does not affect losses of body fat or lean body mass over 12 weeks (20).

Evidence Statement: Overweight subjects consuming low-fat, high-CHO diets eat fewer calories, lose weight, and lose body fat. Evidence Category A.

Alford et al. (45) fed adult, sedentary, overweight women reduced calorie diets (1,200 kcal/d) containing 10%, 35%, or 45% calories from fat for 12 weeks. The 10% fat diet was 70% to 80% CHO. Weight loss was the same on each diet. Noakes and Clifton (28) fed 62 overweight subjects (mean BMI ~31) one of three test diets for 12 weeks. One was VLF (10% fat), high-CHO (71.6%), whereas the other two were moderate-fat (31.8%), and moderate-CHO (~50%). Caloric intake on all diets was limited to 1533 kcal/d. Overall weight loss was 8.6 ± 0.4 kg (9.7%) with a reduc-

Table 17. Energy expenditure from 0–5 years (The Lifestyle Heart Trial)

	Experimental			Control			*p**	
	Baseline (B)	1 year	5 years	Baseline	1 year	5 years	B–1 year	B–5 years
Times/week (F)	2.66	4.97†	4.34	2.38	2.87	3.57	0.06	0.64
Hours per week (D)	2.26	5.02‡	3.56	2.42	2.52	2.90	0.12	0.50
Minutes/bout	51	60	30	61	53	49		
F × D (minutes/week)	135	298	130	145	152	174		

* All *p* values are two-tailed and each is the result of a test of the null hypothesis that the change between two particular visits (e.g. baseline and 1 year) does not differ between the experimental and control groups (14). Adapted from Ornish et al. (14,156).
† $p = 0.0008$ for frequency, baseline to year one in the experimental group (156).
‡ $p = 0.0004$ for duration, baseline to year one in the experimental group (156).

tion in waist circumference of 8%. There were no significant differences in weight loss between diet groups, although weight loss was least on the VLF as compared with the moderate-fat diet.

Surwit et al. (153) conducted a 6-week weight-loss trial that compared the efficacy of two hypoenergetic (1100 kcal/d), VLF (<11%), high-CHO diets (71%) varying in sucrose content. The high-sucrose diet contained 43% total energy from sucrose; the low-sucrose diet only 4%. Subjects in both groups lost comparable amounts of body weight and body fat. CHO source had no effect on weight loss as long as energy was restricted. These data clearly show that high sucrose or complex CHO consumption does not cause obesity, hyperglycemia or insulin resistance in the absence of dietary fat. Although it is quite possible that sucrose or complex CHOs may produce different effects when total energy intake is greater, the use of sucrose or other CHOs in a low-fat, weight-reduction program seems both safe and effective (providing a good refutation to proponents of low-CHO diets).

Heilbronn et al. (33) studied 35 obese patients with type 2 diabetes assigned to one of three 1600 kcal/d diets for 12 weeks. The diets were VLF (10%), high CHO (72%), or high-monosaturated or high-saturated fat (32%), lower CHO (50%). Diet composition did not affect the magnitude of weight loss, with subjects losing an average of 6.6 ± 0.9 kg.

VLF diets

Do VLF diets, when consumed ad libitum, decrease caloric intake? The answer is a qualified yes because most studies of individuals consuming these types of diets were not designed to assess the effect of diet on weight loss, but rather the effects of lifestyle change (e.g., low-fat diet, exercise, stress reduction) on disease risk or reversal. One exception is the study of Shintani et al. (157) who fed 20 obese native Hawaiians a pre-Western contact traditional Hawaiian diet low in fat (7%), high in complex CHOs (78%), and moderate in protein (15%) for 21 days. Participants were encouraged to eat to satiety. Average energy intake decreased from 2594 to 1569 kcal/d and average weight loss was 7.8 kg. Although interesting, this study is not relevant outside Hawaii.

Other studies allowing ad libitum intake of VLF diets were published by Barnard (using the Pritikin diet) and Ornish. In the Barnard articles (155,158–166), the subjects were 3-week residents of the Pritikin Longevity Center who engaged in medically supervised daily aerobic exercise, primarily walking on a treadmill, and consumed the Pritikin high-complex CHO, high-fiber, low-fat, low-cholesterol, and low-salt diet. All meals and food were provided onsite. Barnard (155) reports 2643 males and 1897 females consuming VLF, high-fiber diets for 3 weeks lost 5.1 and 3.3 kg, respectively, representing a 5.5% and 4.4% decrease in body weight (men and women, respectively.) Although BMI of patients is not provided, average weights of 91.9 kg and 74.8 kg (men and women) indicate program participants were overweight.

Another 3-week study (162) assessed the role of diet and exercise in management of hyperinsulinemia. Seventy-two patients were divided into three groups based on fasting serum glucose and insulin measurements. Thirteen type 2 diabetic and 29 insulin-resistant subjects had a BMI >30. Normal subjects ($n = 30$) had a BMI ~27. (Data collected before BMI levels were lowered for overweight.) An overall body weight reduction of 4% was reported for all three groups.

One drawback to the Barnard studies is the omission of information regarding actual caloric intake (or energy expenditure). It can be assumed that participants ate low-calorie diets because these diets are very high in dietary fiber (35 to 40 g per 1000 kcal), and The New Pritikin Program (15) recommends a daily caloric intake of 1000 to 1200 kcal/d. An analysis of 7 days of menus from *The*

Pritikin Principle (17)§ indicates an average intake of 1467 kcal/d. Amazingly, this is nearly identical to intakes reported by Larosa et al. (57; 1461 kcal/d) for subjects consuming high-fat, low-CHO diets.

Ornish et al. (156) collected data on 28 patients who followed The Lifestyle Heart Trial for 1 year (experimental group), and 20 patients who made more moderate changes (control group). At 5 years (14), data were available from 20 experimental and 15 control patients (starting BMI 28.4 and 25.4, experimental vs. control, respectively). All completed a 3-day diet diary at baseline, and after 1 and 5 years. Although energy intake at baseline was slightly higher than 5 years later, these changes were not significantly different between groups, or over time (Table 16). Intake of fat, both as percent calories, and absolute amount (g/d) significantly decreased in the experimental group from the baseline high of 29.7% (63.7 g/d) to 6.22% (12.7 g/d) at 1 year, and 8.5% (17.3 g/d) at 5 years. The control group also decreased fat intake over time, from 30.5% (57.4 g/d) at baseline, to 28.8% (52.4 g) at 1 year, and 25% (44.1 g/d) at 5 years. Fat intake was significantly different between the two groups at 1 and 5 years. Patients in the experimental group lost 10.9 kg (23.9 lb.) at 1 year, and sustained a weight loss of 5.8 kg (12.8 lb.) at 5 years. Weight loss was significantly different from the control group, whose body weight changed little from baseline. The Ornish Multicenter Lifestyle Demonstration Project (167) was conducted in 333 patients (194 experimental, 139 control) at eight sites throughout the United States. Data from this project show that mean weight significantly decreased in the experimental group from baseline to 3 months (4.2 kg), 1 year (4.7 kg), 2 years (4.9 kg), and 3 years (3.3 kg). However, dietary intake data and BMI was not provided.

That weight loss resulted from decreased fat intake is not controversial (42,43,121). One would expect that a 46.33 to 51 g/d (417 to 459 kcal) fat decrease would result in weight loss. What is curious is that the significant reduction in fat intake did not apparently result in a significant reduction in total caloric intake, and yet subjects still lost weight. Can subjects consume less fat, the same number of calories, and still lose weight? If so, these data would disagree with all studies (but two) which show that as dietary fat decreases so does caloric intake in both normal weight (168–173) and overweight subjects (20,39,40,134,137,138,140–142,145,157 [see references 27,42,43,117 for reviews of the effect of dietary fat intake and weight change]).

Two studies show that consumption of a low-fat (but not a VLF) diet results in increased caloric intake but decreased body weight (174,139). Raben et al. (174) reports that over a 12-week period, normal weight individuals consuming LFAL diets (25.6% fat) lost weight (1.3 kg) despite decreased fat intake (37.4% to 25.6%) but increased total caloric intake (3,059 to 3,203 kcal). Dietary fiber was significantly increased as well. The authors were puzzled by these results, noting subjects did not change physical activity levels while under study. They attribute the "paradoxical" finding to an underestimation of daily intake (based on 7-day food records) before the study (by 11%) and an overestimation of energy content of the experimental diet¶.

The study by Prewitt et al. (139) was not designed to study weight loss but rather weight maintenance. Eighteen subjects (12 with BMI 22.9 and 6 with BMI 38.4) were studied in an outpatient metabolic setting for 24 weeks to determine the effects of diets with different compositions as part of a weight-maintenance regimen. All subjects were fed a 37% (high-fat) control diet for 4 weeks, the caloric intake estimated by energy requirements (basal energy expenditure $\times$ 1.4). For the next 20 weeks, they received a low-fat (20%), low-fiber diet (3g/d) containing $\sim$1800 kcal. All meals were provided onsite. Throughout the study, energy adjustments were made as needed in an attempt to maintain body weight of subjects within $\pm$1 kg of initial weight at study entry. If a subject's weight varied beyond $\pm$1 kg over 3 days, she was switched to a higher calorie level until weight returned within 1 kg of initial weight. Over the course of the 20-week low-fat diet, despite adjustments in energy to maintain body weight, subjects lost body weight (2.8%) and body fat (11.3%)‖. Prewitt concludes, "a higher energy intake was needed to maintain body weight on a low-fat than a high-fat diet," especially in subjects with a BMI of $>$30.

How can these disparate results be explained? In examining possible reasons for weight loss in the face of increased energy (and decreased fat) intake, changes in physical activity, metabolic rate, and thermic effect of food are considered. Prewitt et al. (139) examined each of these factors and concluded that because physical activity had not changed, most, but not all, of the observed energy intake

§ It is interesting to note that *The Pritikin Principle* is based on caloric density, not reduction of fat. However, when one regularly consumes foods low in caloric density, a low-fat, low-calorie diet results.

¶ An 11% increase in caloric intake at the beginning of the study would mean subjects consumed 3395 kcal before and 3203 after reduction in fat. These data would then make sense, and support the contention that ad libitum intake of a low-fat, high-fiber diet results in decreased caloric intake.

‖ The largest single increases in caloric intake occurred when subjects went from consuming the high-fat diet to the low-fat diet (7% increase, 132 kcal) and during the last 4 weeks of the study. By the end of the 20-week low-fat diet period, individuals with a BMI $>$30 consumed 28% more energy (534 kcal), and those with BMI $<$30 consumed 14% more energy (259 kcal) as compared with their consumption during the 4-week high-fat diet period.

was accounted for by increased metabolic rate and increased thermogenesis. Dietary adherence may have also been a problem.

In The Lifestyle Heart Trial (14,156), weight loss from baseline to 1 year could be due to changes in physical activity. Data indicate that frequency (F) (times per week) and duration (D) (h/wk) doubled in the experimental group (from 135 min/wk to 298 min/wk) from baseline to year 1 (Table 17). Intensity was not reported in this study. The increase in frequency and duration, however, could account for almost all the first-year weight loss**. Interestingly, from 1 to 5 years, exercise duration and frequency decreased in the experimental group (although there was no significant difference between groups, or over time). Even with a possible (and probable††) increase in exercise intensity, the decrease in duration and frequency, coupled with the same energy intake is not enough to prevent some weight regain, which is exactly what happened between years one and five‡‡. It is unclear from the data if weight gain from year 1 to 5 was significant in the experimental group because analysis was conducted to determine differences between groups over time. Furthermore, that the experimental group was overweight, and the control group normal weight may confound the analysis. The data show that the normal weight controls maintained a consistent level of physical activity (1 hour, 3 times per week, e.g., 20 min/d), and energy intake (1652 kcal/d) over the 5 years, resulting in maintenance of a stable weight. This occurred in the context of a diet that contained <30% fat.

In addition to physical activity, other factors to consider include changes in metabolic rate, the thermic effect of a high-CHO diet (although this could not account for a significant portion of the weight loss) (54), and possible inaccuracies of the diet diaries. Food intake was assessed using 3-day diaries, collected at baseline, year 1 and year 5. It is likely that subjects consumed fewer than the reported 1800 kcal/d from baseline to year 1, and greater than 1800 kcal/d from years 1 to 5§§. Finally, the sample size at 5 years (experimental $n = 20$; control $n = 15$) may not have been large enough to detect differences (175).

Evidence Statement: Weight loss on VLF diets may be the result of lifestyle modification, which may include decreased fat and energy intake, increased energy expenditure, or both. Evidence Category B.

Body Composition

The Ornish Multicenter Lifestyle Demonstration Project (167) reported a significant decrease in body fat from 25.7% at baseline to 21.3% at 1 year and 22.4% after 2 years. Body fat of 23.4% at 3 years was not significantly different from baseline.

2. Nutritional Analysis

- What is the nutritional profile of low-fat and VLF diets?
- Do diets provide adequate levels of nutrients, based on current dietary recommendations?

Nutritional analysis of a VLF diet (13, pp. 107–111) indicates that VLF diets provide adequate levels of all nutrients except vitamin E, $B_{12,}$ and zinc (Table 9). This 1-day analysis seems slightly high in sodium, probably the result of added seasoning (teriyaki sauce). Ornish et al. (156) report the diet to be nutritionally adequate for all nutrients except vitamin B_{12}, as expected, which was supplemented. Scherwitz and Kesten (176) conducted the German Lifestyle Change Pilot Program (GLCPP) to gain experience applying the program to a culture other than the United States. Nutritional analysis of lifestyle and control groups show the nutritional content of the low-fat vegetarian diet was very nutrient dense, containing more vitamin and mineral content for the same caloric value than the control group's more typical German diet. However, the treatment group's intake of vitamins E, B_{12}, D and zinc fell below the Recommended Daily Allowance because of the omission of animal food products. Addition of animal protein (e.g., Pritikin) and education to consume more diverse foods that are high in these nutrients would be beneficial and eliminate the need for supplementation¶¶. Computer analyses of menus used at the Pritikin Longevity Center show that the therapeutic plan is nutritionally adequate (161).

Evidence Statement: VLF diets are low in vitamins E, B_{12}, and zinc. Evidence Category B.

VLF, very high-CHO diets, high in fruits, vegetables, grains, beans, and soy contain thousands of protective phytochemicals, e.g., isoflavones, carotenoids, bioflavonoids, retinols, ly-

** For example, Joe Hartman is 5 feet, 8 inches tall and weighs 184 pounds (BMI 28). Walking 2.3 mph (26 min/mile), 298 min/wk burns 4.3 kcal/min or 1281 kcal/wk, translating into a potential weight loss of 19 pounds per year (1281 kcal × 52 weeks/3500 kcal).

†† Exercise capacity significantly increased from 9.59 METS at baseline to 11.15 after 3 months, 11.66 after 1 year, to 10.88 after 2 years, and to 11.03 after 3 years in the Multicenter Trial (167).

‡‡ After 1 year, and an ~19-pound weight loss, Joe increases exercise intensity to 3.2 mph (18:45 min/mile), and burns 5.2 kcal/min. However, because F × D has decreased to 130 min/wk, total weekly energy expenditure is now only 676 kcal/wk, half as much as before and weight is regained.

§§ This is supported by a) nutritional analysis of diets presented in *Eat More, Weight Less*, and *Dr. Ornish's Program for Reversing Heart Disease*, which indicate average 3-day caloric intake of 1315 kcal/d, not 1800, b) Ornish (148), which indicates an intake of 1400 kcal/d, and c) the question of compliance to an 1800-kcal diet containing 50 to 60 g of fiber per day.

¶¶ See Appendix for Ornish's recommendations regarding supplements (www.web.md).

copene, and genistein that have anti-aging, anti-cancer, and anti-heart disease properties. However, some VLF diets, based on poor food choices, may mean lower than recommended levels of certain nutrients such as iron, phosphorus, calcium, and zinc. Fiber intake may also be low (154). This means that specific food choices within the context of a VLF diet are critical. Data on the impact of a relatively high proportion of low-fat and fat-free alternatives to traditional foods in a free-living population in the absence of intensive dietary counseling are not yet available (29).

Nutritional questions on the use of VLF diets include uncertainty about compromised absorption of fat-soluble vitamins, and the impact of increased dietary fiber on the absorption of minerals. Twenty patients who had complied with the Pritikin diet longer than 4 years showed no signs of nutritional inadequacy in more than 50 blood tests, including those for iron status, trace minerals, and vitamins (161).

3. Metabolic and Adverse Effects

- Do very low-fat diets affect blood lipids, blood pressure, and blood insulin levels?
- Are adverse effects associated with these diets, or are there subgroups that should not use them?

Blood Lipids

Diets that lower serum TC, specifically LDL-cholesterol levels, are believed to lower the risk of coronary heart disease. In studies that lasted from 21 days to 1 year, reducing fat content to <10% of energy reduces total and LDL cholesterol levels in both men and women (14,28,33,154–156,158,162–165,180). Some changes were sustained for 2 to 3 years (14,159), and up to 5 years (158). Intensive diet and lifestyle modification provided additive benefit to that of cholesterol-lowering medication (165).

The Ornish Multicenter Project (167) reported significant changes in total and LDL cholesterol were sustained for 3 years (despite the program lasting for 1 year). Total cholesterol decreased from 202 mg/dL to 183.7 mg/dL, and LDL decreased from 122.9 mg/dL to 101.7 mg/dL (baseline to year 3). It is not known what affect, if any, the intervention had on use of lipid-lowering drugs, which were used by 54% of experimental group patients. In the Lifestyle Heart Trial, data collected from subjects 4 years post-treatment indicate total and LDL cholesterol were higher than at 1 year but lower than at baseline. These changes were relative to the reduction in fat intake (greatest at 1 year vs. 5 years). In this study, no significant difference between groups, or over time, was reported for total and LDL cholesterol at five years (167).

Men and women (premenopausal and postmenopausal) who participate in the 3-week Pritikin Longevity Center residential program consistently show decreased total and LDL cholesterol levels (166). When an aggressive diet and exercise program is added to cholesterol-lowering drugs, a dramatic reduction in total and LDL cholesterol is noted. For example, use of drug alone reduces cholesterol by 20%; addition of lifestyle intervention achieves an additional 19% reduction (165). In one study, patients were contacted 2 to 3 years after leaving the center. Blood samples obtained from 52 (75%) patients revealed significant increases in cholesterol. However, the follow-up values were significantly lower than the entry values (159). Similar results were reported at 5-year follow-up (158).

In addition, qualitative changes in LDL show that particle size was increased, and LDL oxidation was decreased implying a reduction in risk for atherosclerosis and its clinical sequelae (177).

Schaefer et al. (38) reported consumption of a low-fat diet under weight maintenance conditions significantly lowered plasma TC, LDL and HDL-cholesterol (mean change, −12.5%, −17.1%, and −22.8%, respectively), but that this diet significantly increased plasma TG levels (47.3%) and the TC/HDL ratio (14.6%). In contrast, consumption of an LFAL diet accompanied by significant weight loss (−3.63 kg) resulted in a mean decrease in LDL cholesterol (−24.3%), and mean TG levels and TC/HDL ratios not significantly different from values obtained at baseline. They concluded that an LFAL diet when combined with weight loss is better than a low-fat diet without weight loss with respect to blood lipid levels.

In the study by Kasim-Karakas et al. (151), subjects received a controlled euenergetic diet in which dietary fat was reduced stepwise from 35% to 25% to 15% over 4 months. Thereafter, they followed an ad libitum 15% fat diet for 8 months. Two months after subjects switched to the LFAL diets, TG levels decreased. Levels remained stable for the rest of the 12 months and were not different from baseline values. During the ad libitum period, TC levels remained low. An unexpected finding was the increase in LDL cholesterol to baseline levels within 2 months of switching to the ad libitum diet (levels had previously decreased in response to decreased fat intake), although LDL levels remained stable for the rest of the study. HDL levels decreased as dietary fat decreased, and remained the same during the LFAL condition.

Blood lipid changes occurring in individuals following VLF diets may be attributed to weight loss (6), decreased intake of fat and saturated fat, and/or high fiber intake, rather than increased CHO content, per se (28,29).

However, low-fat, high-CHO diets often lower not only LDL cholesterol but also HDL cholesterol (28,33,153–155,162,164,165). Although lower HDL levels usually increase risk of coronary heart disease (178) there are no data showing that physiological reduction of HDL cholesterol levels with a low-fat diet is detrimental. In countries where VLF diets are the norm, and TC and HDL cholesterol are both very low, the incidence of heart disease is much lower than in the United States (179). In the Lifestyle Heart Trial, however, no change in HDL was reported at 1 or 5 years

(14). In the Multicenter Project, HDL initially decreased from baseline to 3 months, but then showed a significant increase by 2 and 3 years (e.g., 36.7 mg/dL vs. 42.2 mg/dL, baseline vs. 3 years) (167).

Although TG levels are reported to increase in response to short-term consumption of VLF diets (20), the type of CHO consumed may play a role in determining the metabolic response. For example, diets containing 70% CHO do not lead to hypertriglyceridemia as long as leguminous, high-fiber foods are consumed (30). In addition, TG levels may be reduced by weight loss (6). These factors may be the reason why TG levels decreased (28,154,155,158,162), or did not change (180,156). Some attribute adverse metabolic effects of high-CHO diets to their sucrose content (181). However, Surwit (154) reported reduction in TG levels even after overweight women were fed a high-sucrose but reduced calorie diet (1553 kcal/d) for 12 weeks, indicating that high-sucrose is not a problem in the presence of a low-fat, low-calorie diet.

Evidence Statement: Low-fat and very-fat diets reduce LDL-cholesterol, and may also decrease plasma TG levels, depending on diet composition. Evidence Category B.

Blood Pressure

Blood pressure decreased in most subjects consuming VLF diets (28,154,160,162–164). These diets alone, or in combination with exercise, resulted in reduction or elimination of antihypertensive medication in some patients (160). Benefits may be attributed to dietary changes, physical activity, or weight loss (6).

Blood pressure did not change in individuals following The Lifestyle Heart Trial, because individuals already were being treated appropriately. Effect of lifestyle change on medication use was not addressed.

Blood Glucose, Insulin, and Leptin Levels

The very high-CHO content of VLF diets has led to concern about possible effects on blood glucose and insulin levels. Unfortunately, no study of VLF diets in the absence of caloric restriction exists, so that any effect on blood glucose and insulin could be attributed to energy restriction and weight loss rather than diet composition (33).

Nevertheless, very low-fat, high complex CHO, high-fiber, energy-restricted diets usually result in decreased blood glucose and insulin levels (28,33,154,158,162–164). In some patients with type 2 diabetes these types of diets combined with daily exercise and weight control may result in discontinuation of insulin usage (160). However, Grey and Kipnis (31) reported basal plasma insulin levels on a hypocaloric, high-CHO formula diet did not differ significantly from those observed during an ad libitum diet period, although rate of weight loss was unaffected by insulin levels.

Surwit et al. (153) reports that high sucrose or complex CHO intake does not cause hyperglycemia or insulin resistance in the absence of dietary fat, and when calories are restricted. The confusion in this area is probably due to the fact that hyperinsulinemia results from a high sucrose intake in the presence of high fat (e.g., typical American diet). VLF diets that are also high in fiber decrease blood insulin levels and improve insulin sensitivity (182) as does physical activity. Thus, the decreased blood glucose and/or insulin levels reported for VLF diets may be a consequence of caloric restriction, weight loss, dietary fiber, and/or physical activity, rather than diet composition. In the context of a low-calorie diet, consuming a very-low CHO (e.g., Atkins) or VLF diet (e.g., Pritikin) results in decreased fasting insulin levels.

Kasim-Karakas et al. (151) reported lower plasma glucose concentrations during the 10th and 12th months of the LFAL diet compared with other times. Insulin and hemoglobin A_{1c} concentrations did not change significantly during the study. Plasma free fatty acid concentrations decreased significantly at only one time point, during the 25% fat phase of the controlled euenergetic diet.

Agus et al. (152) compared the effect of high-glycemic index (67% CHO, 15% protein, 18% fat) with the effect of low-glycemic index (43% CHO, 27% protein, 30% fat) energy-restricted diets. Although weight loss was similar between the two groups, plasma insulin and serum leptin levels decreased to a greater extent with the low-glycemic index diet.

Havel (34) reported that during weight maintenance, reducing fat content from ~30% to ~15% of the energy content of the diet did not affect fasting plasma leptin or insulin concentrations; however, only fasting insulin and leptin concentrations were examined in this study. After the weight maintenance phase of the study, the subjects were followed during a 6-month period during which they consumed a 15% fat ad libitum high-CHO diet. In women who lost less than 7% of body mass, fasting plasma leptin and insulin levels were unchanged, despite a modest but significant average weight loss and more than 10 months on a VLF diet. However, women with a weight loss greater than 7% had larger reductions of percent body fat, and both fasting plasma leptin and insulin levels decreased by ~35%. The decreases of fasting insulin are likely to represent an improvement of insulin sensitivity due to weight loss and the decreases of leptin are mostly due to decreases of body fat. However, they are also likely to be partially due to the decreases of insulin during the fasting period because the decreases of insulin and leptin were shown to be correlated independently of the changes of body fat (34)‖‖.

‖‖ Because insulin is secreted rapidly during and in the period immediately after the consumption of meals, and because circulating leptin exhibits a diurnal pattern that is dependent and proportional to insulin responses to meals, relying on fasting levels of insulin

Adverse Effects

Few adverse effects of low-fat and VLF diets have been reported. Barnard et al. (162) noted an initial increase in flatus, which generally subsides. No other adverse metabolic or behavioral effects were reported.

Results of studies seem impressive but questions about long-term efficacy and risk reduction remain. Extrapolation to the general population from motivated individuals (e.g., those with coronary heart disease) is questionable. The independent effects of weight loss, physical activity and accompanying lifestyle interventions complicate interpretation (29). The American Heart Association's Science Advisory recommends persons with insulin-dependent diabetes mellitus, elevated TG levels, and CHO malabsorption illnesses avoid VLF diets (29).

4. Hunger and Appetite: *Compliance*

- What is the effect of low-fat and VLF diet on hunger and appetite?
- What data supports compliance to low-fat and VLF diets?

Low-Fat Diets

The issue of satiety following ingestion of various macronutrients (e.g., CHO, fat, and protein) has been the subject of much research and is briefly reviewed here (see also references 183–187).

Studies of early satiety (occurring within 30 minutes after a preload) found protein having the greatest effect, followed by CHO, and then fat (186,187). However, these studies did not adequately control for the differences in palatability or energy density of test foods (187). Short-term studies (2 and 12 weeks) investigating the effect of covert manipulation of the fat content of foods on total energy intake were conducted in normal weight women. Those consuming lower fat diets (15% to 20%, or 20% to 25% fat) vs. higher fat diets (30% to 35%, or 35% to 40% fat) consumed fewer calories and lost more weight (149,188). Stubbs et al. (184) provided normal weight male subjects ad libitum access to one of three covertly manipulated diets: low-fat (20% energy as fat, 67% as CHO), medium-fat (40% energy as fat, 47% as CHO) or high-fat (60% energy as fat, 27% as CHO). They reported that energy intake increased with percent fat, and that lower fat, lower-energy diets were more satiating than higher fat, higher energy diets.

When dietary fat content is drastically reduced, the weight of the food consumed is maintained or slightly increased (38,188). Thus, exposure to high-CHO foods can give rise to a marked restraining effect on the expression of appetite, the potency and time course varying with the amount consumed and chemical structure (e.g., simple vs. complex CHO) (183).

Low-fat diets (15% to 20% fat) received higher hedonic ratings compared with higher-fat diets (30% to 35% or 45% to 50% fat (150). Hunger was not a problem in subjects consuming low-fat diets. In fact, Schaefer et al. (38) reported that during the low-fat, weight maintenance phase, subjects frequently complained about the quantity of food and of abdominal fullness, making it difficult for them to consume all the food provided. The authors speculate that complaints occurred because the low-fat diet weighed more than the baseline diet. When subjects were allowed to choose their own foods during the LFAL phase, they ate less than what was provided during the low-fat weight-maintenance phase and lost weight. Decreases of leptin are related to increases of hunger in women during a prolonged, moderately energy restricted diet (120). It is therefore possible that maintaining the diurnal pattern of leptin production (induced by the insulin responses to dietary CHO) may contribute to effects of ad libitum, moderately low-fat, high-CHO diets to lower energy intake by preventing hunger from increasing during weight loss.

Schlundt et al. (145) reported that compliance to dietary advice to reduce fat or calories was best during the first 6 weeks of a 15-week study. A follow-up of 71% of subjects who completed the study, obtained 9 to 12 months later, showed average total weight losses of 2.6 kg in the low-fat group, and 5.5 kg in the low-calorie group. Of these subjects, 14% showed no weight regain from the end of the treatment to follow-up, 20% regained 1 kg or less, and 40% regained less than 3 kg. Results did not differ as a function of the treatment group. Both groups experienced compliance problems related to eating at social events, eating in the car, and emotional eating (both negative and positive emotions). Despite three treatment sessions devoted to handling social situations and three devoted to overcoming emotional eating, problems with these issues persisted. It is likely that high-risk situations that precipitate relapse are independent of diet composition.

Djuric et al. (150) designed an intervention trial to selectively decrease fat and/or energy intake in free-

and leptin to assess overall central nervous system exposure to changes of insulin and leptin is inadequate. Consumption of moderately fat restricted (~20%) meals results in increased postprandial insulin secretion and higher leptin levels over a 24-hour period compared with a day during which the same subjects consumed relatively high-fat (60%), low-carbohydrate (20%) meals (36). Therefore, it is necessary to examine the time-course of insulin responses to meals and leptin concentrations over a prolonged period of time to assess the impact of dietary macronutrient content and composition on insulin secretion and leptin production adequately.

Increased insulin secretion and leptin production may contribute to the effects of these diets because both insulin and leptin act as long-term signals back to the brain to regulate appetite, energy intake and energy expenditure. Regarding energy expenditure, during the weight maintenance phase of the study discussed above, subjects needed to be fed 7% more calories (+120 ± 30 kcal/d) to maintain a stable body weight when they consumed 15% energy from fat compared with when they consumed 30% energy from fat. This suggests that lowering dietary fat content also lowers regulated level of body adiposity, independent of energy intake. This change of the regulated level of body fat independent of energy intake would have to be due to an increase of energy expenditure, an effect that could potentially be mediated by increases of carbohydrate-induced postprandial insulin responses and 24-hour leptin production (36).

Table 18. Dietary intakes of National Weight Control Registry enrollees by method of weight loss

	Women (number)		Men (number)	
Nutrient	On own (128)	With assistance (227)	On own (46)	With assistance (37)
Calories	1336 ± 494	1289 ± 443	1809 ± 733	1531 ± 478
Protein (%)	18.1 ± 3.3	19.9 ± 3.8	17.5 ± 4.3	19.1 ± 3.4
CHO (%)	55.9 ± 10.7	55.2 ± 8.4	55.5 ± 8.8	57.1 ± 8.1
Fat (%)	24.8 ± 9.6	24.0 ± 7.2	24.1 ± 8.5	22.8 ± 6.8

Adapted from Shick et al. (195).

Table 19. Characterization of diets used for weight loss and weight maintenance

Type of diet	Total kcals	Fat g (%)	CHO g (%)	Protein g (%)
High-fat, low-CHO*	1450	97 (60)	36 (10)	108 (30)
Moderate-fat, balanced nutrient reduction	1450	40 (25)	218 (60)	54 (15)
Low- and very-low-fat	1450	16–24 (10–15)	235–271 (65–75)	54–72 (15–20)
Weight maintenance†	1491	40 (23.9)	208 (55.9)	72 (19.2)

* Based on average intake of subjects who self-selected low-CHO diets; studies lasting more than one week.
† Numbers determined by averaging data in Table 18.

living, premenopausal somewhat overweight women, to examine the relative importance of these dietary factors on markers of cancer risk. Diets were nonintervention, low-fat (15%) maintenance of energy intake, low-energy (25% reduction), or a combination of the two (low-fat and low-energy). Meetings with a registered dietitian occurred at 2-week intervals for all diet groups. Daily records served as self-monitoring of intake and as a tool for the dietitian to verify food intake. A total of 88 women completed the 12-week program. The 25 women who dropped out did so within 6 weeks of their randomization date, with similar dropout rates in all intervention groups. Reasons for withdrawal included being too busy ($n = 12$), diet too hard to follow ($n = 5$), unhappy with diet assigned ($n = 1$), too stressed due to illness ($n = 2$), changed eligibility status ($n = 2$), and no longer interested/unable to contact ($n = 3$).

VLF Diets

Studies of ad libitum VLF diets were generally short, ranging from 3 to 12 weeks (28,153,155,157). The Lifestyle Heart Trial, originally a 1-year study (156), was extended to 5 years (14). Limited data from short- and long-term interventions indicate hunger was not a problem for subjects following these diets. Using a seven-point analog scale that ranked hunger vs. satiety, Noakes and Clifton (28) reported subjects perceived hunger more before dinner, although caloric intake at this meal was not assessed. Using a five-point analog scale, Surwit et al. (153) reported hunger decreased as diet duration increased (to 6 weeks), with all subjects reporting lower hunger levels at the end, rather than the beginning, of the study.

Because energy density has been demonstrated to have a robust and significant effect on both satiety and satiation independently of palatability and macronutrient content (187), the energy density of VLF diets must be considered when determining their effects on hunger and appetite. In addition to dietary fiber, water content of the diet must be considered, as both fiber and water decrease the caloric density of individual foods, and the overall diet.

VLF diets are often high in fiber, providing 35 to 40 g dietary fiber per 1000 kcal (13,15–17). Burton-Freeman (189) reports that women may be more sensitive to dietary manipulation with fiber than men, and obese individuals, as compared with lean, may be more likely to reduce food

intake with dietary fiber inclusion. Dietary fiber promotes satiation and prolongs satiety, aids in long-term compliance to low-energy diets, and encourages healthy food choices and eating habits. Thus, the amount of fiber in the particular VLF diet is an important consideration when assessing compliance.

At present there are no long-term clinical studies of the effects of energy density independent of variations in fat content.

Compliance

Although short-term effects of these diets on hunger are promising, long-term effects are more important. Do subjects continue to consume VLF diets long-term? Ornish et al. (14) reported excellent adherence to all aspects of the program during the first year, and good adherence after 5 years, as measured by percent diameter stenosis. Percentage of daily energy intake from fat was maintained at less than 10%. The average person lost 24 pounds in the first year and kept off more than half that weight 5 years later, even though they were eating more food, and more frequently, than before without hunger or deprivation. It is important to note, however, that the motivation of cardiac patients to reverse heart disease by following a lifestyle intervention plan (which includes significantly reducing fat intake) may differ from that of obese patients whose motivation to lose weight may be for reasons other than health. Thus, long-term compliance seen in the Ornish study does not necessarily translate to obese individuals.

Theusen et al. (147) studied Danish heart disease patients to assess how much dietary fat can be reduced for long-term treatment to obtain an effective cholesterol-lowering effect. For 3 months, 14 patients with severe coronary heart disease were treated with a diet containing 10% of total energy from fat. Patients (and their wives) were instructed to eliminate intake of visible fats and cholesterol-rich foodstuffs (e.g., egg yolk, liver, shellfish), limit meat to 50 mg/d, and keep sugar intake low. The consumption of rice, potatoes, vegetables and legumes was encouraged and up to five alcoholic drinks per day were allowed. After 3 months, patients were asked to maintain a diet as low in fat as possible for long-term treatment. Very few patients managed this diet for longer than 3 months; only two had a fat intake of ~10% after 1 year. However, half had a fat intake below 20%, and a 4-day diet recall showed a mean fat intake at the end of 12 months of 21.4% (range, 7.3% to 37.8%). No explanations for increased fat (and energy intake) were provided. It is also important to note that the motivation and adherence of a patient with existing heart disease may be different from that of a patient who is overweight, but has not yet been diagnosed with a chronic disease.

Trials allowing ad libitum consumption of very low-fat (or even low-CHO diets) are equivocal in terms of efficacy due, in part, to differences in adherence to the targeted macronutrient composition. The validity of dietary information given by trial participants is not always valid (190–192). Obese subjects typically under-report energy intake, especially fat intake (190) and overestimate physical activity (191).

Lyon et al. (192) assessed compliance to dietary advice to decrease fat and increase CHO intake in eight moderately overweight Swiss women during a 2-month period. At supper, they were requested to eat a meal containing ^{13}C-glucose, and measure ^{13}C by self-collection of expired air. Subjects were asked not to intentionally restrain their total energy intake, but have their appetite drive their food consumption. At the end of the study, intake of fat (g), protein (g), and total calories were significantly reduced (fat: 92.5 to 52 g; protein 71 to 64 g; and calories: 1893 to 1518). Intake of CHO remained the same (182 g). When expressed as percent calories, fat intake significantly decreased (from 44% to 31%), and both CHOs and protein significantly increased (CHO: from 38% to 50% and protein from 15% to 17%). With this method, 54% of the variation in achieved weight loss was explained by differences in diet compliance (which ranged from 20% to 93%; mean 60 ± 8%)***. Patients with the greatest adherence lost the most weight. Those who fail to lose weight on any diet are likely to be those who do not adhere to the dietary composition no matter what it is (186).

5. Performance and Physical Activity

- What is the effect of VLF diets on physical performance?

Physical activity and exercise is strongly recommended as part of the overall lifestyle plans recommended by both Pritikin and Ornish. Data support the use of CHO as fuel for exercising muscle (193). VLF diets have plenty of CHO (70% to 80%), supporting physical activity. No adverse affects on performance have been reported in individuals consuming VLF diets. Ornish et al. (14) report no significant difference in exercise duration or frequency in individuals following these diets for 5 years, however they do report a significant increase in exercise intensity.

Weight Maintenance

Is There an Optimal Diet for Weight Maintenance?

In light of the current obesity crisis, prevention of weight gain and weight maintenance is critical. Is there an optimal diet for accomplishing these goals?

*** It is interesting to note the range of compliance to the advice to decrease fat intake, in this case, from 44% of total calories to 31%, an amount that is considered moderate, but not low-fat.

Data support the contention that those consuming low-fat, low-calorie diets are most successful in maintaining weight loss (194–196) (Table 18). Insulin and leptin responses to dietary CHO may play a role in the effects of these diets to sustain weight loss through long-term signals promoting decreased energy intake, increased energy expenditure, or both. Increased physical activity and decreased consumption of (high-fat) fast food meals are also key variables (46,195,197). Palatability and dietary variety within food groups may predict body fatness. McCrory et al. (198) report that the direction of the association depends on which foods provide the variety (e.g., the variety of sweets, snacks, condiments, entrees, and carbohydrates consumed was positively associated with body fat, whereas the variety of vegetables was negatively associated).

Table 19 summarizes the macronutrient composition of diets reviewed in this article. The last line represents the diet consumed by individuals enrolled in the National Weight Control Registry, who have maintained a 13.6 kg (30 pound) weight loss for at least 1 year but who, on average, have lost 30 kg and have maintained the loss for 5.1 years. Data from the Registry indicate that successful weight maintainers comsume a low-calorie diet containing ~40 g of fat (24% of energy), 200 g of CHO (56% of energy), and 70 g of protein (19% of energy) (195–197). This diet most closely resembles the moderate-fat, balanced nutrient reduction diet promoted by every health organization in the United States. The high vitamin and calcium intakes of successful weight loss maintainers suggest they eat a diet high in fruits, vegetables, and calcium-rich foods (dairy). The low iron intake suggests a low intake of animal products.

The American public needs to be told (and believe) that diets are not followed for 8 days, 8 weeks, or 8 months, but rather form the basis of everyday food choices throughout their life. A diet high in vegetables, fruits, complex CHOs (whole grains and legumes), and low-fat dairy is a moderate-fat, low-calorie diet that prevents weight gain, results in weight loss and weight maintenance. It is associated with fullness and satiety. It reduces risk of chronic disease. It is fast, convenient, and inexpensive. How can we convince people it works, and to try it?

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Appendix I: Descriptions of Popular Diets

1.* Dr. Atkins' New Diet Revolution *by R. C. Atkins. New York: Avon Books, Inc., 1992.

- Diet Summary: The four stages include 1) the Fortnight Induction Diet; 2) the Ongoing Weight Loss Diet, 3) Premaintenance, and 4) Maintenance. The Induction Diet limits carbohydrate to 20 g/d (1 cup permitted vegetables and 1 cup salad vegetables). Unlimited amounts of beef, turkey, fish, chicken, and eggs as well as fats are allowed. This phase of the diet allows no fruit, bread, grains, starchy vegetables, or dairy products other than cheese, cream, or butter. Carbohydrate restriction is lessened during the other stages until individuals determine the level of carbohydrate they can consume while maintaining their weight loss. For some, this could be as low as 25 g/d and for others it could be as high as 90 g/d.
- Concerns: Calories not specified; diet nutritionally inadequate, providing lower than recommended intakes of vitamin E, vitamin A, thiamin, vitamin B_6, folate, calcium, magnesium, iron, zinc, potassium and dietary fiber. No calcium or potassium supplements, yet multiple other supplements. Diet is high in saturated fat, cholesterol, and animal protein.
- Most Outrageous Statement: "Most obese people gain weight on fewer calories than nonobese."

2.* Protein Power! *by M. R. Eades and M. D. Eades. New York: Bantam Books, 1996.

- Diet Summary: Diet provides 0.75 g of protein per kilogram IBW. Less than 30 g of carbohydrate per day allowed during the induction phase, up to 55 g/d thereafter. Calories based on protein requirements.
- Concerns: Low protein, low calcium intake.
- Most Outrageous Statement: "Not a single adverse reaction."

3.* Carbohydrate Addict's Diet *by R. F. Heller and R. F. Heller. New York: Penguin Books, 1991.

- Diet Summary: Diet comprises two Complementary Meals (breakfast and lunch) and one Reward Meal (dinner). Complementary meals contain 3 to 4 ounces of meat, 2 cups of vegetables. Reward Meals start with salad, then 1/3 protein, 1/3 low-carbohydrate vegetables, and 1/3 high carbohydrate, all consumed within 1 hour. No snacking allowed.
- Concerns: Low in calcium, iron, potassium and fiber; high in fat and cholesterol.
- Most Outrageous Statements: "When unlimited food is consumed at the Reward Meal, the body doesn't produce as much insulin as normal because it was 'fooled' by the complementary meals into producing less insulin." "Carbohydrate addiction."

4.* Sugar Busters! *by H. L. Steward, M. C. Bethea, S. S. Andrews, and L. A. Balart. New York: Ballantine Books, 1995.

- Diet Summary: Refined sugar and high-glycemic foods (e.g., potatoes, corn, white rice, white bread, carrots, and beer) are eliminated, resulting in weight loss, regardless of whatever else you eat. Rationale: these foods cause a sugar spike and make you crave more high-glycemic foods, leading to insulin resistance, which then makes you overweight.
- Concerns: Protein intake and portion sizes not presented. Normal protein requirement miscalculated. Intake of calcium, iron, and vitamin E is low.
- Most Outrageous Statement: "Sugar is toxic!"

5.* Eat More, Weigh Less *by D. Ornish. New York: Harper Paperbacks, 1993.

- Program Summary: Dr. Ornish's multifaceted approach focuses on reversal of heart disease but is also recommended for weight loss. His program incorporates aspects of nutrition, exercise, stress management, and love and intimacy. Moderate exercise (e.g., walking) is recommended. Stress management techniques include 1 hour per day of stretching, breathing, meditation or prayer, progressive relaxation, and group support. Love and intimacy is accomplished through group support (one or two times a week) designed to create a community in which participants enhance intimate, nurturing relationships that further facilitate their adherence to the program.
- Diet: VLF (10% fat) plant-based diet based on ad libitum intake of fruits, vegetables, whole grains, beans, and soy products. It incorporates moderate quantities of egg whites, and nonfat dairy or soy products and small amounts of sugar and white flour.
- The following daily supplements are recommended:
  - Vitamin C: 2 to 3 g.
  - Vitamin E: 100 to 400 IU.
  - Folate: 400 to 2000 μg.
  - Women: flax seed oil: 2 g and fish oil: 2 g.
  - Men: fish oil: 2 g.
  - Selenium: 100 to 200 μg.
  - Multivitamin: without iron for men and postmenopausal women. Premenopausal women may benefit from a multivitamin with iron.
  - Concerns: Diet low in vitamins E, B_{12}, and zinc. Adherence and palatability.