

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Shai I, Schwarzfuchs D, Henkin Y, et al. Weight loss with a low-carbohydrate, Mediterranean, or low-fat diet. *N Engl J Med* 2008;359:229-41.

(PDF updated October 24, 2008.)

Appendix 1. Topics and content of dietary education sessions — the DIRECT Study

Background

Each dietary education session started with weighing and attaching stickers on shirts with the current weight as well as the weight change since the previous meeting. The dietician solicited feedback and led a problem-solving discussion, provided more examples of daily menus, and specific targets according to weight loss phase and upcoming events (holidays, etc). The second part of each dietary session was dedicated to a specific topic, as described in detail below. Most sessions concluded by discussing the "Myth of the Day" (a common misconception or unproven notion about food, diet and health). Dietitians met with their groups in the workplace during weeks 1,3,5,7, and then at 6 week intervals, for a total of 18 90-minute sessions. The exact same workshop format and Power Point slides were used by each of the dietitians coordinating the 3 intervention arms, apart from the instructions that were specific to each diet strategy. These workshops were periodically monitored by the primary investigator to ensure equal intensity of intervention. Additional diet recipes, notes (prior to holidays) and notifications about upcoming measurements / electronic questionnaires and reminders for the monthly visit date in the nurse clinic were delivered via the workplace's intranet system. Six times during the two-year intervention, a different dietitian than the one in charge of the intervention arm conducted 10-15 minute motivational telephone calls, and provided a written summary.

At the end of the study after data analysis, each participant was provided, as guaranteed, all of their individual data and figures of trends and normal range values of the nutritional and health parameters assessed during the 2-year intervention, accompanied by comments from a physician.

1. Introduction, basic concepts of each diet

Participants were introduced to the aims of the study: weight loss and improvement in health parameters in a long-term project. Furthermore, participants were introduced to their assigned diet strategy (detailed below), and its apparent advantages. Each group was given initial examples of menus. In all diets, the participants were encouraged to avoid *trans* fat.

Low Fat Diet– Participants were counseled to consume low-fat grains, vegetables, fruits, and legumes and to limit added fats, sweets, and high-fat snacks. For the low-fat, restricted-calorie diet we aimed at up to 30% of calories from fat, 10% from saturated fat and up to 300mg cholesterol/day, with 1500kcal for women and 1800kcal/day for men.

Mediterranean Diet– The moderate-fat, calorie-restricted diet is rich in vegetables and low in meat, with poultry and fish replacing beef and lamb. We aimed to have 35% of calories from fat; the main sources of added fat were from 30-45 grams of olive oil and a handful of nuts (5-7, less than 20 grams) per day. We restricted energy to 1500kcal for women and 1800kcal/day for men.

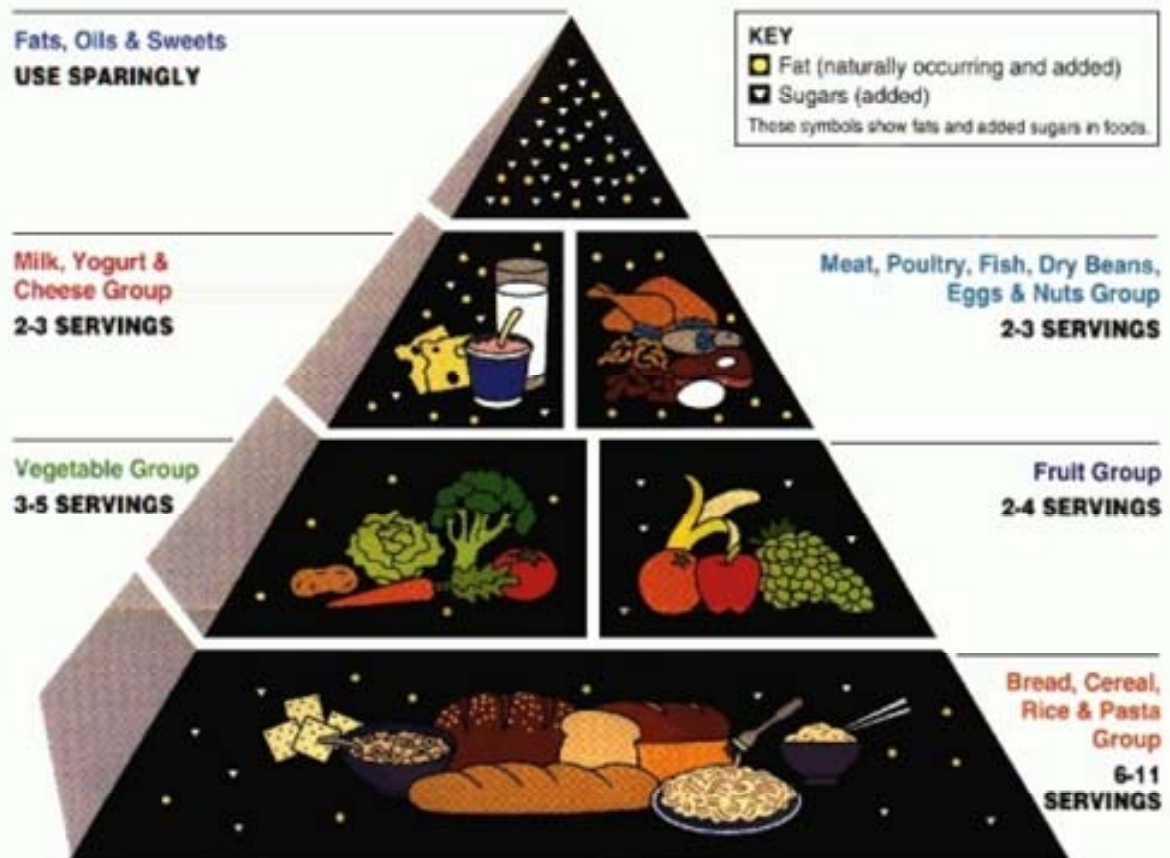
Low Carbohydrate Diet- This low-carb, non-calorie restricted diet aimed to provide 20g/day of carbohydrates during the induction phase (first 2 months), and returned to this level of severe carb restriction after each religious holiday. At other times participants were instructed to increase carbs gradually up to maximum of 120g/day to maintain the weight loss. Total calories, protein and fat intake from any source (except industrial- *trans* fats) were not limited.

2. The Food Pyramid for each diet

Participants learned more about their diet strategy through specific diet food pyramids, the history of the specific dietary approach, and the food sources of each food group. They further learned how to choose their food items in the cafeteria by following their specific color food labels.

Myth of the day: “Mixing vegetables and fruits with water cause stomach ache.”

Principles of low-fat diet strategy



Source : USDA, public domain

Principles of Mediterranean diet strategy



Adapted from The Healthy Eating Pyramid, Department of Nutrition, Harvard School of Public Health.
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 and *Eat, Drink, and Be Healthy*, by Walter C. Willett, M.D. and Patrick J. Skerrett (2005), Free Press/Simon & Schuster.

Principles of low-carbohydrate diet strategy

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EXAMPLES OF EACH DIET ARE PRESENTED HERE

Low fat diet, day 1

	Ingredient	Quantity
Breakfast	Light whole-wheat bread	2 slices
	Cottage Cheese (5% fat)	75 g
	tomato	1 medium (160 g)
	Peach	1 medium (160 g)
Lunch	Roast chicken breast	150 g
	Roast potatoes	2 medium (240g)
	Cabbage salad	100 g
4 pm	Low fat yogurt (1.5% fat)	150 g
	Energy bar	1 bar (43 g)
Dinner	Whole-wheat bread	2 slices
	Hard cheese (9% fat)	1 slice (20g)
	Carrot salad, low-fat dressing	200 g
	Watermelon	250 g

Low fat diet, day 2

	Ingredient	Quantity
Breakfast	Low fat yogurt (0% fat)	150g
	Grapes	6 medium (42 g)
	Plum	1 medium (70 g)
	Granola	2 spoons (30 g)
lunch	Chicken legs, baked, w/o skin	2 units
	Spaghetti in tomato sauce	1 cup (200 g)
	Mixed vegetable salad , low-fat dressing	1 cup (150 g)
4 pm	Whole-wheat cracker	2 crackers
	Strawberry jam	2 teaspoon (12 g)
Dinner	Whole-wheat bread	2 slices
	Low fat cream-cheese	35 g
	Smoked salmon	50 g
	Tomato	1 medium (90 g)
	Low fat yogurt (0% fat)	150g
	Banana	1 medium (100 g)

Mediterranean diet, day 1

	Ingredient	Quantity
Breakfast	Coffee with 1% fat milk	
	Light whole wheat bread	2 slices
	With low fat white cheese	2 TB
	Cucumber and tomato	few slices each
	Fruit , anything	1 unit
lunch	Grilled fish	1 portion , 150 gr
	Cooked chickpeas	1 cup
	Fresh and cooked vegetable salad + olive oil	1 cup
		1.5 TB
4 pm	Low-fat yogurt	1, 150cc
	fruit+	1 unit
	Fresh vegetables	few slices
Dinner	Light whole wheat bread	2 slices
	Low fat white cheese	3 TB
	Fresh vegetable salad + olive oil	1 cup 1TB
	+ walnuts	5 units
	Fruit	1 unit
	Fresh vegetables	few slices

Mediterranean diet, day 2

	Ingredient	Quantity
Breakfast	Coffee with 1% fat milk	
	Low-fat yogurt	150cc
	Fruits	2 units
lunch	Greek salad with low-fat feta cheese + olive oil	big bowl 1.5 TB
	Cooked peas	1/2 cup
	Whole wheat rice	1/2 cup
4 pm	Light whole wheat bread + low-fat white cheese	1 slice 2 TB
	Fruit	1 unit
	Fresh vegetables	few slices
Dinner	Light whole wheat bread + low fat white cheese	1 slice 3 TB
	Fresh vegetable salad + olive oil + walnuts	big bowl 1TB 5 units
	Hard boiled egg	1 unit
	Chickpeas, cooked	1/2 cup
	fruit	1 unit
	fresh vegetables	few slices

Low-carb, initiation phase

	Ingredient	Quantity
Breakfast	walnut	1 (6 g)
	High fat cream cheese	100 g
Lunch	Fried chicken breast	Liberal
	cucumber	1 small (82 g)
	tomato	1 small (80 g)
	Tachini (sesame based spread)	2T (7 g)
4 pm	Turkey pastrami	2 slice (64 g)
Dinner	Tuna fish preserved in oil	Liberal
	Fried Eggs	Liberal
	Avocado	Liberal
	cucumber	2 medium (160 g)
	lettuce	1 cup (55 g)

Low-carb, maintenance phase

	Ingredient	Quantity	
Breakfast	Sour cream 15% fat	Liberal	
Lunch	Fish or chicken/or beef, fried or roasted /not bread coated	Liberal	
	Stir fried zucchini with herbs	1/2 cup	
	Roasted eggplants	1/2 cup	
	Fresh vegetable salad with 2 tablespoons (17 g) of Tachini (sesame based spread)	2 cup	
4 pm	Almond cookies (based on eggs, almonds and sugar substitute)	2 small (12 g)	
Dinner	Cream cheese	250g	
	Broccoli and mushrooms coated with eggs, no flour	1/2 cup	
	Tuna	Liberal	
	Olives		
night	Fruit flavor diet yogurt	150 g	
	Walnuts	5 (28 g)	1 small (100 g)
	Apple		

3. Lipids and Fats

Participants learned about the chemical structure of dietary saturated, unsaturated and trans fats and omega 3, about their distribution in food sources and their effects on HDL, LDL and TG. They further learned about cooking with fats and oils.

Myth of the day: "One central huge meal a day is better than smaller spread meals for weight loss."

4. Energy Balance

Participants learned about overweight, the meaning of calories, basal metabolic rate and energy expenditure, and examples of food items and their caloric values.

Myth of the day: "Consuming dietetic foods prevents you from gaining weight."

5. Physical activity

Participants learned about the role of physical activity in energy balance, its benefits for general health and weight loss maintenance, the guidelines for a moderate activity and the difference between fat and muscle tissue.

Myth of the day: "I am busy, so I don't have time for physical activity."

6. Dining out

Participants were introduced to the principles of dining out: planning, assertiveness, controlling and choosing. The dietitians suggested examples of appropriate restaurant food dishes, according to the specific diet intervention arms, and discussed the risks when eating in restaurants and further issues of eating in social meetings and during travels.

Myth of the day: "You can only gain weight when dining out."

7. Environmental distraction and extra eating

Participants were provided examples of environmental distractions (e.g., watching TV, eating with kids, shopping near a bakery, traveling, getting back home very hungry, etc) and possible ways of overcoming the potential for extra eating due to distraction.

Myth of the day: "It is not me, blame him."

8. Scientific background – dietary arm specific

In this session, each diet group was provided scientific background and historical perspective about what was published in the literature regarding their designated type of diet.

9. Subcutaneous vs. visceral fat

Participants learned about abdominal fat, waist circumference, fat distribution, and what is known about differences between subcutaneous and visceral fat.

10. Weight maintenance

Participants learned about adaptation of basal metabolic rate to changes in energy intake, and further metabolic and behavioral explanations for weight regain. They learned about successful strategies that were found for weight maintenance and were exposed to personal successful stories, including pictures before and few years after weight loss.

Myth of the day: "You need to be highly disciplined in order to maintain your body weight, and I have such a weak character..."

11. Atherosclerosis

The participants learned about the development of arterial plaques, their pathogenesis and stages, and risks for development of coronary heart disease and stroke.

Myth of the day: "My cholesterol level is OK- I am safe."

12. Physical activity

Participants were encouraged to be physically active, 30 minutes, at least 3 times per week. They learned about the role of exercising in the weight loss process, types of aerobic and anaerobic activities, and how to cope with excuses for "not exercising." The subjects were advised to use a pedometer.

Myth of the day: "We can loose weight and maintain weight loss without exercising."

13. Glycemic index

In this session the subjects learned about the glycemic response and about the role of insulin. They learned about the glycemic index and glycemic load and what is known about its association with health parameters. They learned about further factors modifying the glycemic index (e.g., degree of fruit maturity, cooking method, mixture with other ingredients) and the limitations of this approach. Finally, they were provided a food list with their glycemic index values.

14. More perspectives on lipids and proteins

Participants learned about the biochemistry of lipid particles (chylomicrons, VLDL, LDL, HDL, TG) in the body and target levels according to the NCEP-ATP guidelines.

Myth of the day: "If you already lost enough weight you can stop dieting."

15. Sugar substitutes

Participants were taught about natural and artificial sweeteners and sugar substitutes, and about the controversies related to their impact on health. They were specifically provided information regarding aspartame (avoid cooking/boiling), sucralose, and cyclamate.

16. Childhood obesity

In this session we discussed the family perspective on dieting, and the standard obesity definitions, and focused on childhood obesity. We described the epidemic, discussed possible explanations for it, the associated risks, and the cycle of gaining weight. We concluded with the role of parents in their children's obesity and the importance of providing good role models, taking the DIRECT study as a platform.

Myth of the day: "A child is a child. Don't worry about his weight when he is young – he will grow out of it."

17. Food labels

Participants learned about the rules and laws related to food labels, their components, and how to read them and were encouraged to look carefully at food labels, as well as the ingredients list. They learned about the meaning of "health food declarations" (for example, in Israel, declaration of "light" means up to 2/3 of nutrient component compared with the original food item; "low-sodium" means up to 100mg sodium/100grams, etc.).

Myth of the day: "What I don't know can't harm me."

18. Long-term weight maintenance

At the final dietary session of the DIRECT, we summarized some take-home messages for life. We started by reviewing the DIRECT objectives, and emphasized that weight loss is just part of the overall health benefit of switching to healthy regimens. We summarized the group achievements, warned about risks of weight regain and the future use of "magic diets", and highly recommended that participants continue to follow their diet strategies, keep weighing themselves, eat breakfast, keep exercising, and keep following their health parameters. We thanked the DIRECT participants for their active involvement.

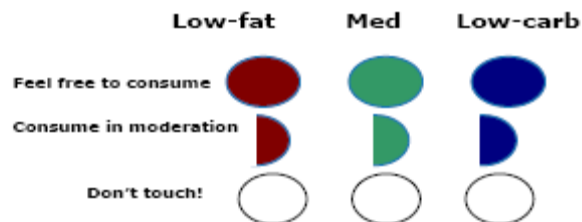
Myth of the day: "If the DIRECT is over, there is no chance I could keep my achievements."

Appendix 2. Dietary intervention

2a. diet protocols

	Low Fat	Mediterranean	Low Carb
Energy	restricted	restricted	Non-restricted
Total fat	≤ 30%	≤ 35%	Non-restricted
Saturated fat	≤ 10%	≤ 10%	not specifically restricted, but moderation recommended, as well as reduced <i>trans</i> fat
Dietary cholesterol	≤ 300 mg	≤ 300 mg	not specifically restricted
Carbohydrates	Not restricted, whole grains recommended	Not restricted, whole grains recommended	Restricted ≤ 20gr in induction phases. Gradually added to maximum of 120gr/day to maintain achieved weight loss
Specific food items added		a. 30-45gr extra virgin olive oil/day b. a handful (5-7) of nuts /day c. 2 fish meals/wk	
No specific recommendations for alcohol and vitamin supplements			

2b. Daily food color labeling in the cafeteria



Food labels:
Energy (kcal), total fat (gr), saturated fat (gr), carbohydrates (gr) per portion size