



## Center for Medical Consumers

# HEALTHFACTS

For Informed Decision Making

## Three Weight-Loss Diets Compared: Low-Fat Diet is the Loser

Three weight loss diets were compared over the course of two years in a newly published clinical trial conducted in Israel. The “winners” are the Mediterranean and the Atkins diets. People on one of these two diets lost more weight than the people on the low-fat diet long recommended by the American Heart Association and many physicians.

The differences and the amounts of weight lost were not great, ranging from 6.5 to 11 pounds. The results, however, call into question the dire health warnings about going on the Atkins diet, which is high in fat and protein and represented in this study as the low-carbohydrate diet. Published last month in *The New England Journal of Medicine*, the study was partially funded by the Dr. Robert C. and Veronica Atkins Research Foundation.

The Dietary Intervention Randomized Controlled Trial (DIRECT) Group was led by Iris Shai, RD, PhD, Ben-Gurion University of the Negev. They designed their trial to overcome the usual problems associated with diet studies that rely solely on the participants filling out extensive food-frequency questionnaires. (Who among us can accurately remember how many cups of broccoli were eaten in the last 6-12 months, much less the amount and type of fat used in the cooking?) DIRECT was conducted at a workplace in a semi-isolated location (fewer chances to stray beyond the diet) in a country

where lunch is the main meal. It lasted longer and had a much lower dropout rate (15% ) than other diet studies.

The 322 moderately obese, mostly male participants worked at a nuclear research center in Dimona, Israel, with a self-service cafeteria and an on-site medical clinic. The foods they were instructed to eat had been marked with stickers color-coded according to each participant’s assigned diet.

Each food item also had a label showing the number of calories and the number of grams of carbohydrates, fat, and saturated fat. Each food item was also labeled with a full circle (indicating “feel free to consume”) or a half circle (indicating “consume in moderation”). Here’s how the three diets were described in the study: “low-fat, restricted-calorie; Mediterranean, restricted-calorie; or low-carbohydrate, non-restricted-calorie [Atkins diet].”

Food-frequency questionnaires were used in this study, but just as a back-up to validate the participants’ adherence to their assigned diets. The questionnaires had to be filled out three times during the two-

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## Three Weight-Loss Diets continued

year duration of the study. And lastly, the participants received telephone pep talks from dieticians six times. Even their spouses received support.

After all that effort, here's what was accomplished after two years: The people on the Mediterranean diet and the people on the Atkins diet lost 9 and 11 pounds, respectively. And the people on the low-fat, restricted-calories diet lost 6 1/2 pounds. The small number of women who participated in this study tended to lose more weight on the Mediterranean diet (14 pounds) than on the other diets.

Dr. Shai and colleagues concluded that the Mediterranean diet may be better for people with type 2 diabetes because it showed more favorable effects on glucose and insulin levels, which the researchers attributed high consumption of monounsaturated fats like olive oil. The high-fat, high-protein Atkins diet had the best effects on cholesterol levels, though the Mediterranean diet was a close second. Both diets were described as effective alternatives to the American Heart Association low-fat diet.

The DIRECT study was supported by the Nuclear Research Center Negev, the Dr. Robert C. and Veronica Atkins Research Foundation, and the S. Daniel Abraham International Center for Health and Nutrition, Ben-Gurion University, Israel.

### For More Information:

-Go to The New England Journal of Medicine Web site ([www.nejm.org](http://www.nejm.org)), July 17, 2008 issue, "Weight Loss with a Low-Carbohydrate, Mediterranean or, Low-Fat Diet."

-Read about the "fat and fit" research conducted by Dr. Steven Blair, University of South Carolina at our Web site ([www.medicalconsumers.org](http://www.medicalconsumers.org)). See "Walk More."

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## Off-Label Drug Promotion —New Report

For seven years, Johnson & Johnson ran a false advertising campaign for its anti-anemia drug, Procrit. The TV and print ads gave the impression that Procrit would instantly cure the fatigue that afflicts cancer patients undergoing chemotherapy.

If Procrit—and its sister drugs, Aranesp and Epoprostan—had not begun to cause death and life-threatening blood clots in some cancer patients participating in clinical trials, the Procrit ads might be with us today. In March 2007, however, the FDA announced at a press briefing that there is no evidence for the fatigue-treatment claim. Procrit had been approved by the FDA solely to reduce the need for blood transfusions in anemic cancer patients and to treat people with kidney disease. Any other uses of this drug is called "off-label." Doctors can prescribe drugs off-label (though it is unethical not to warn patients). Drug companies, however, are not permitted to promote off-label uses of their drugs, as J&J did.

The Procrit campaign is but one horrendous example of why the FDA must strengthen its regulatory authority. The U.S. Government Accountability Office released a report entitled, "FDA's Oversight of the Promotion of Drugs for Off-Label Uses," confirming what FDA watchdogs have long known. Because of the sheer volume of promotional materials, the agency is overwhelmed and further hampered by the lack of a standardized system that consistently tracks the receipt and review of submitted materials. When drug companies were cited for serious violations, they took an average of 4 months to take corrective action, according to the report.

The Center for Medical Consumers has asked Congress for "corrective action" to mean more than withdrawing the offending ad. J&J, for example, should be made to run a seven-year corrective ad campaign in the TV and print media.

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