Effects of a Behavioral Weight Loss Program Stressing Calorie Restriction Versus Calorie Plus Fat Restriction in Obese Individuals With NIDDM or a Family History of Diabetes

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OBJECTIVE — The aim of this randomized trial was to compare the effects of a behavioral intervention focusing on either calorie restriction alone or calorie plus fat restriction on weight loss and changes in lipids and glycemic control in individuals with non-insulin-dependent diabetes mellitus (NIDDM) or a family history of diabetes.

RESEARCH DESIGN AND METHODS — We recruited 44 obese women with NIDDM and 46 obese women with a family history of NIDDM and randomly assigned these subjects to calorie restriction (CAL) or to calorie plus fat restriction (CAL+FAT). All subjects participated in a 16-week behavioral weight loss program, with training in diet, exercise, and behavior modification. Subjects assigned to the CAL condition were given a 1,000–1,500 kcal/day goal and self-monitored calories consumed. Subjects assigned to the CAL+FAT condition had the same calorie goal, but were also given a fat goal (grams of fat/day), to produce a diet with <20% of calories from fat; this group monitored both calories and fat grams.

RESULTS — Among NIDDM subjects, weight loss of the subjects in the CAL+FAT condition was significantly greater than subjects in the CAL condition (7.7 vs. 4.6 kg) and the CAL+FAT condition group also maintained their weight loss better at the 1-year follow-up (5.2 vs. 1.0 kg). Significant decreases in glucose, high-density lipoprotein (HDL) cholesterol, and total cholesterol were seen after 16 weeks of treatment among NIDDM subjects; these changes were similar in CAL and CAL+FAT groups, but a greater proportion of subjects in CAL condition required oral hypoglycemic medication. At the 1-year follow-up, all parameters had returned to baseline in NIDDM subjects, except HDL cholesterol, which continued to be significantly below baseline. No significant differences in weight loss or physiological changes were seen between CAL and CAL+FAT conditions in subjects with a family history of diabetes.

CONCLUSIONS — These results suggest that using the combination of calorie and fat restriction may help promote weight loss in obese NIDDM patients. No other long-term benefits of this regimen were observed.

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ANOVA, analysis of variance; CAL, calorie restriction; CAL+FAT, calorie plus fat restriction; CHD, coronary heart disease; FH, family history of diabetes; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NIDDM, non-insulin-dependent diabetes mellitus.

Weight loss is the treatment of choice for obese patients with non-insulin dependent diabetes mellitus (NIDDM). However, few patients are successful in maintaining weight losses of the magnitude necessary to bring about long-term improvements in glycemic control and coronary heart disease (CHD) risk, particularly if the treatment goal is normalization of these values (1). Thus, it is crucial to improve weight loss interventions so that more patients experience long-term improvements in glycemic control and CHD risk profiles.

Another important role for behavioral weight control interventions may be in the prevention of NIDDM. Obese individuals, particularly those with a history of gestational diabetes, a positive family history of diabetes, or impaired glucose tolerance, are at risk of developing diabetes (2–5). Although lowering body weight may decrease the risk of diabetes (6), there has been no research comparing different approaches to weight loss and maintenance in these individuals.

To date, most behavioral approaches to weight reduction have focused on calorie reduction and exercise, with little attention given to the proportion of calories consumed as fat (7,8). Such treatment programs have been shown to produce modest improvements in body weight, but the percentage of calories consumed as fat usually remains high. For example, in one recent clinical trial, hypertensive subjects in the weight reduction condition decreased their dietary fat intake from 37% of total calories at baseline to 35% after intervention (9); other weight loss studies that have focused on calorie restriction have likewise not reduced fat intake below 35% of calories (10,11).

Dietary interventions that limit consumption of fat may improve weight loss by increasing the satiety value of the diet and by influencing fat storage and use (12,13). Several recent studies provide evidence to support the value of low-fat

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Table 1—*Characteristics of subjects before treatment*

	NIDDM	FH	*P* value
n	44	46	
Age (years)	56.5 ± 8.4	42.7 ± 8.4	0.001
Weight (kg)	94.6 ± 12.7	96.2 ± 13.0	>0.10
Body mass index (kg/m^2)	36.3 ± 4.7	35.9 ± 4.7	>0.10
Total cholesterol (mmol/l)	6.0 ± 0.89	4.97 ± 0.82	0.001
HDL cholesterol (mmol/l)	1.27 ± 0.23	1.44 ± 0.32	0.005
LDL cholesterol (mmol/l)	3.80 ± 0.80	2.98 ± 0.64	0.001
Triglycerides (mmol/l)	2.38 ± 1.68	1.18 ± 0.82	0.001
Fasting glucose (mmol/l)	13.42 ± 4.54	5.81 ± 1.20	0.001
HbA_1 (%)	10.9 ± 2.2	— —	—
No. on diet only/oral medication	16/28	— —	—
Subjects reporting history of			
Heart attack (%)	7	0	>0.10
Angina (%)	11	2	0.08
Hypertension (%)	52	9	0.001

Data are means ± SD. The sample size for LDL cholesterol was 39 with NIDDM and 45 with FH.

diets for weight loss; for example, subjects instructed to lower their fat intake, but given ad libitum access to complex carbohydrates, have been found to lose weight (14,15), and in one study lost as much weight as those on calorie-restricted regimens (16).

Concern has been raised, however, about possible negative effects of low-fat (high-carbohydrate) diets on glycemic control and serum lipids in people with NIDDM (17–21). In contrast, other studies showed no adverse effects or even improvements in glycemic control and lipids in subjects following a low-fat diet (22–27). It should be noted that these investigations have relied on isocaloric substitution of carbohydrates for fat, promoting a state of weight maintenance. A recent study (28) reported results for 652 patients with NIDDM who participated in the Pritikin Longevity Center 26-day residential program. These participants consumed a <10% fat diet and participated in supervised exercise. Weight loss over the 26 days averaged 4.5 kg; total cholesterol decreased by 21–23%, low-density lipoprotein (LDL) cholesterol by 20–26%, and HDL cholesterol by 11–14%. Fasting glucose concentration decreased from 9.1 to 6.9 mmol/l in those participants who were not taking diabetes medication. To date, there have been no studies comparing weight loss regimens that differ in the dietary fat content on changes in weight, lipids, or glycemic control in individuals with NIDDM.

The present study was conducted to determine whether focusing on dietary fat restriction, in addition to calorie restriction, would promote greater long-term weight reduction and improvements in glycemic control and CHD risk than focusing on calorie reduction alone. Two groups of obese women were studied: women with NIDDM, and those with a family history of diabetes. It was hypothesized that a low-calorie/low-fat diet would produce greater weight losses, and, therefore, greatly improve glycemic control and serum lipids in both diabetic and high-risk subjects.

RESEARCH DESIGN AND METHODS

Subjects

Newspaper advertisements were used to recruit obese women with NIDDM and those who were at risk of developing NIDDM. To be eligible for the program, patients were required to be ≥20% above ideal body weight based on the 1983 Metropolitan Life Insurance norms. High-risk subjects were required to have at least one biological parent with NIDDM (determined from a history regarding the age of onset, body weight, and initial treatment regimen of the parent). Individuals with diabetes were required to meet the criteria specified by the National Diabetes Data Group for NIDDM and had to be using diet only or oral medications to control their blood glucose levels. All subjects signed a consent form approved by the Institutional Review Board for Biomedical Research at the University of Pittsburgh.

Forty-six high-risk women (having a family history of diabetes [FH]) and 44 NIDDM subjects started the program. Table 1 shows the baseline characteristics for these FH and NIDDM subjects. As expected, there were marked differences at baseline between subjects with diabetes and those with FH. Thus, all subsequent analyses were done for NIDDM and FH subjects separately.

Design

Subjects were randomly assigned to calorie restriction (CAL) or calorie restriction plus fat restriction (CAL+FAT). Subjects assigned to the CAL condition (n = 22 NIDDM, 23 FH) did not differ from those in the CAL+FAT condition (n = 22 NIDDM, 23 FH) on any baseline characteristic (data not shown). Both groups participated in a 16-week treatment program that differed only in the dietary prescription that was given. All subjects were assessed at baseline, after the 16-week program, and at the 1-year follow-up.

Treatment groups

Both the CAL and CAL+FAT condition groups met weekly for 16 weeks of group treatment sessions, with follow-up meetings held 1, 2, 4, and 6 months after treatment. The treatment program for subjects in both conditions focused on the modification of eating and exercise habits through the use of behavioral strategies and self-management skills. The two

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treatment groups differed only in the type of diet regimen that was prescribed.

Patients in the CAL restriction group consumed 1,000–1,500 kcal/day (those subjects whose entry weight was <200 pounds were instructed to consume 1,000 kcal/day, whereas those weighing >200 pounds were instructed to consume 1,500 kcal/day, decreasing to 1,200 kcal/day after 10 weeks). These subjects were given general information about healthy eating and encouraged to keep their fat intake at <30% of calories/day. However, the emphasis in the CAL condition was on staying below the calorie goal. Subjects in the CAL condition recorded their calorie intake daily throughout the 16-week program. Their diaries were reviewed by trained therapists, and advice was given to subjects on strategies for lowering caloric intake while maintaining a nutritionally balanced diet.

Subjects in the CAL+FAT group were given similar individualized calorie goals, set at levels identical to those in the CAL condition. However, these subjects were also given a goal for the number of fat grams they should consume each day. The number of fat grams was set at a level corresponding to 20% of total calories consumed as fat. Subjects in the CAL+FAT condition recorded both the calories and the number of grams of fat in each food they ate and were encouraged to achieve both goals. Their diaries were reviewed weekly as above.

Patients in both groups were taught about the benefits of exercise on weight, glycemic control, and other CHD risk factors. Graded goals for programmed activity (i.e., structured walking) were used throughout the program, and patients monitored the number of calories expended on a daily basis. The importance of increasing lifestyle activity (e.g., using stairs, parking farther away from entrances to stores) was also emphasized, and patients were encouraged to gradually increase lifestyle activity throughout the program. Patients in each group were also taught behavior modification principles to enhance self-management of caloric intake and expenditure. Weekly sessions included discussions of stimulus control, problem solving, social skills training, goal setting, and the relationship between thoughts and eating.

Oral hypoglycemic medication

Patients taking oral hypoglycemic medication stopped their diabetes medication for 1 week before the program. Subjects were taught to monitor their blood glucose levels and to record fasting glucose levels on three mornings/week throughout the program. Medication was restarted in subjects whose average fasting glucose levels exceeded 240 mg/dl for 2 weeks.

Measures

Assessments were conducted at baseline, at the conclusion of the 16-week program (posttreatment), and at the 1-year follow-up. Oral hypoglycemic medication was stopped for 1 week before these assessments. Patients were weighed on a calibrated balance beam scale, while wearing street clothes without shoes. Body mass index (kg/m^2) was calculated to provide an estimate of body fat. Caloric intake was determined by having subjects complete 3-day diaries, including 2 weekdays and 1 weekend day. Subjects received extensive training in portion size estimation and were encouraged to record all intake in as much detail as possible. All food diaries were documented by trained nutritionists. Analyses of the food diaries were done by trained dietary personnel at the Obesity/Nutrition Research Center of the University of Pittsburgh using the Minnesota Nutrition Data System. All diary analyses were done blinded to subjects' treatment condition and the time point of the assessments. Glucose and lipid levels were obtained after an overnight fast. Plasma glucose was measured with a YSI autoanalyzer. Total serum cholesterol, total HDL cholesterol, and triglycerides were assessed by electroimmunoassay. LDL cholesterol was determined by calculation (29); subjects who had triglyceride levels ≥400 mg/dl were not included in this computation.

Statistical analysis

Repeated-measures analyses of variance (ANOVA) were performed to determine whether the changes in weight, lipids, and glycemic control that occurred throughout treatment and the follow-up period differed between the two treatment conditions. Due to non-normal distributions of triglycerides, this variable was log-transformed before ANOVA. Values reported in the text represent means and SD.

RESULTS — The results are presented for the FH subjects and NIDDM subjects separately because, as noted above, these two groups of subjects differed at baseline on almost all parameters measured.

NIDDM subjects

Of the 44 NIDDM subjects, 31 subjects (70%) completed both the posttreatment and 1-year assessments: 16 of 22 subjects in the CAL condition and 15 of 22 in the CAL+FAT condition. No significant baseline differences were observed between those who completed the study and those who dropped out or between those in the CAL or CAL+FAT conditions who completed the study (Table 2).

Self-reported dietary data are shown in Table 3. No significant differences were observed between groups at baseline. Analysis of covariance, comparing 16-week and 1-year dietary intake adjusted for baseline, indicated that the CAL+FAT group had significantly lower self-reported intake of total calories, grams of fat, and percentage of calories from fat at week 16 than did the CAL group. At the end of the 16-week program, subjects in the CAL+FAT condition reported consuming 22.4% of calories as fat vs. 30% in CAL alone ($P < 0.01$). Only the difference in percentage of calories from fat remained significant at 1 year, with subjects in the CAL+FAT condition continuing to consume only

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Table 2—*Baseline characteristics of those subjects who completed all assessments*

	NIDDM		FH	
	CAL	CAL+FAT	CAL	CAL+FAT
n	16	15	13	16
Weight (kg)	93.1 ± 13.0	94.4 ± 9.5	95.3 ± 13.3	94.5 ± 14.6
Body mass index (kg/m^2)	36.4 ± 4.7	36.3 ± 4.2	35.0 ± 4.4	36.1 ± 5.6
Total cholesterol (mmol/l)	6.09 ± 0.60	6.09 ± 1.01	4.92 ± .93	4.92 ± 0.84
HDL cholesterol (mmol/l)	1.35 ± 0.13	1.29 ± 0.27	1.53 ± .28	1.47 ± 0.39
LDL cholesterol (mmol/l)	3.93 ± 0.70	3.96 ± 0.83	2.96 ± 0.72	2.82 ± 0.51
Triglycerides (mmol/l)	2.00 ± 1.12	2.35 ± 1.99	0.93 ± 0.28	1.30 ± 1.07
Glucose (mmol/l)	12.74 ± 5.13	12.69 ± 3.63	5.53 ± 0.63	5.85 ± 1.09
HbA_1	10.9 ± 2.7	10.4 ± 1.9	—	—
No. on diet only/oral medication	6/10	5/10	—	—

Data are means ± SD. Sample sizes for LDL-cholesterol are 15, 13, 13, and 15 for NIDDM in CAL and CAL+FAT and FH in CAL and CAL+FAT, respectively.

26% of calories from fat vs. 34% in CAL alone.

Weight losses also differed significantly between the two treatment conditions (Fig. 1); subjects in the CAL+FAT group lost 7.7 ± 3.6 kg during the 16-week program, whereas subjects in the CAL program lost only 4.6 ± 4.0 kg ($P < 0.05$). Weight losses at the 1-year follow-up were also somewhat greater in the CAL+FAT group than in the CAL group (−5.2 ± 7.3 kg vs. −1.0 ± 3.9 kg, $P = 0.06$). The overall changes from baseline to 1 year were significant for the CAL+FAT group ($P < 0.05$) but not for the CAL group.

Changes in lipids and glycemic control are presented by group in Table 4. The time × treatment group interactions were not significant for any of these measures, indicating that the magnitude of change was similar in the two treatment groups. However, there was a significant effect of time on many of the measures; participation in the 16-week program led to significant decreases in total cholesterol, HDL cholesterol, fasting glucose, and HbA_1. At the 1-year follow-up, only HDL cholesterol levels remained significantly lower than baseline; all other physiological variables had returned to baseline levels.

Because NIDDM subjects in the CAL+FAT condition lost significantly more weight than those in CAL condition, the changes in glucose and lipids in the two treatment conditions were also compared after adjusting for weight loss. These analyses continued to show no significant differences between CAL and CAL+FAT conditions at 16 weeks or 1 year on any of the physiological parameters.

Ten subjects in each treatment condition were taking oral medication at the start of the study. At the end of the 16-week treatment, 7 of the 10 patients (70%) from the CAL+FAT group were able to be treated with diet only vs. 2 of the 10 patients (20%) from the CAL group ($\chi^2(1) = 5.05$, $P < 0.03$). At the 1-year follow-up, however, no difference in medication status between the two groups was observed (4 of 10 patients in the CAL+FAT group and 2 of 10 patients in the CAL group were treated with diet only, $\chi^2(1) = 0.95$, $P > 0.10$).

FH subjects

A total of 29 FH subjects completed the full study (63% of the original cohort). As shown in Table 2, those in the CAL condition ($n = 13$) and in the CAL+FAT condition ($n = 16$) who completed the study did not differ on any baseline variables.

Among FH subjects, it is apparent that the CAL+FAT condition again produced significantly greater reductions in dietary fat intake than did the CAL alone condition (Table 3). These differences were significant at both 16 weeks and 1 year for measures of both total grams of fat and percentage of calories from fat. Subjects in the CAL+FAT condition reported that they were consuming a diet with 22% of calories from fat vs. 30.8% in

Table 3—*Self-reported dietary intake for NIDDM and FH subjects in CAL and CAL+FAT conditions*

	NIDDM		FH	
	CAL	CAL+FAT	CAL	CAL+FAT
Calories				
Pretreatment	1,837 ± 496	1,658 ± 673	2,220 ± 646	2,024 ± 680
16 weeks	1,392 ± 243	1,201 ± 242*	1,190 ± 252	1,246 ± 251
1 year	1,614 ± 419	1,420 ± 421	1,535 ± 230	1,430 ± 229
% calories from fat				
Pretreatment	35.5 ± 8.3	32.2 ± 6.9	36.5 ± 6.0	39.2 ± 6.6
16 weeks	30.1 ± 6.7	22.4 ± 6.7†	30.8 ± 6.3	22.2 ± 6.3†
1 year	34.0 ± 6.1	26.1 ± 6.1†	34.0 ± 6.7	26.1 ± 6.7*
Fat (g)				
Pretreatment	75.7 ± 30.2	61.9 ± 30.4	95.2 ± 3.9	90.4 ± 39.9
16 weeks	48.2 ± 14.8	30.5 ± 14.8†	41.8 ± 12.7	30.8 ± 12.7*
1 year	64.1 ± 24.3	44.1 ± 24.7	60.1 ± 15.8	43.1 ± 15.7*

Data are means ± SD. *$P < 0.05$; †$P < 0.01$.

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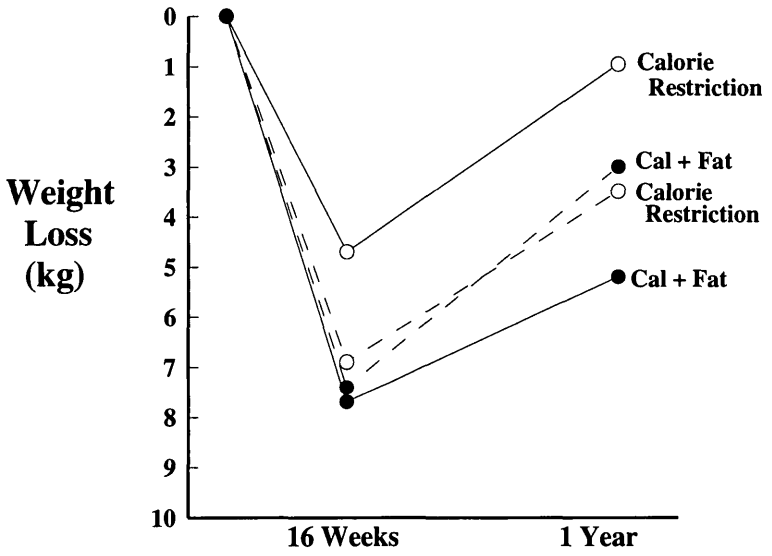

Figure 1—*Weight loss of NIDDM subjects (——) and FH subjects (– – –) in the CAL condition and in the CAL+FAT condition.*

CAL alone subjects at the end of the 16-week program; at 1 year, the reported levels were 26% and 34%, respectively. Despite the differences in reported fat intake, no differences between the two treatment groups were seen for total caloric intake.

Moreover, the greater reductions in self-reported dietary fat intake were not associated with greater weight losses in CAL+FAT subjects. At the end of the 16-week program, subjects in the CAL+FAT condition had lost 7.5 ± 4.0 kg vs. 6.9 ± 4.5 kg for CAL alone subjects ($P < 0.10$). Overall weight losses from baseline to 1-year follow-up were 3.1 ± 8.9 kg for CAL+FAT subjects versus 3.2 ± 7.2 kg for CAL subjects.

Changes in lipids and fasting glucose levels are shown in Table 5. The only significant difference between the two treatment conditions (i.e., time × group interaction) was for changes in total cholesterol at 1 year. Subjects in the CAL+FAT group had significantly greater improvements on this parameter than those in CAL alone ($P < 0.02$). There were no significant effects of treatment on LDL cholesterol or triglyceride levels at either time period, and changes in fasting glucose were significant only at 16 weeks. HDL cholesterol levels decreased significantly from pretreatment to posttreat-

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Table 4—*Changes in lipids and glucose by treatment group for patients with NIDDM*

			P values	
	CAL	CAL+FAT	Time effect	T × G
n	16	15	—	—
Pretreatment to the end of the 16-week program				
Weight (kg)	−4.7 ± 3.9	−7.7 ± 3.6	<0.05	0.04
Body mass index (kg/m^2)	−1.85 ± 1.49	−2.97 ± 1.4	<0.05	0.04
Total cholesterol (mmol/l)	−0.23 ± 0.61	−0.33 ± 0.70	<0.05	NS
HDL cholesterol (mmol/l)	−0.14 ± 0.14	−0.12 ± 0.17	<0.05	NS
LDL cholesterol (mmol/l)	−0.03 ± 0.54	−0.27 ± 0.72	NS	NS
Triglycerides (mmol/l)	−0.27 ± 0.59	−0.24 ± 1.24	NS	NS
Glucose (mmol/l)	−2.80 ± 3.90	−2.85 ± 2.24	<0.05	NS
HbA_1 (%)	−1.1 ± 1.8	−0.7 ± 1.5	<0.05	NS
Pretreatment to 1-year follow-up				
Weight (kg)	−0.96 ± 3.7	−5.2 ± 7.3	<0.05	<0.05
Body mass index (kg/m^2)	−0.38 ± 1.4	−2.02 ± 2.8	<0.05	<0.05
Total cholesterol (mmol/l)	+0.08 ± 0.52	+0.15 ± 0.59	NS	NS
HDL cholesterol (mmol/l)	−0.12 ± 0.13	−0.05 ± 0.21	<0.05	NS
LDL cholesterol (mmol/l)	+0.12 ± 0.58	+0.02 ± 0.59	NS	NS
Triglycerides (mmol/l)	+0.16 ± 0.71	−0.16 ± 1.79	NS	NS
Glucose (mmol/l)	−0.48 ± 2.11	−1.11 ± 3.42	NS	NS
HbA_1 (%)	+0.21 ± 1.7	−0.03 ± 1.9	NS	NS

Data are means ± SD. Sample sizes for LDL cholesterol are $n = 13$ (CAL) and $n = 15$ (CAL+FAT). Data for triglycerides have been log-transformed for analysis. T × G, time × treatment group.

Table 5—*Changes in lipids and glucose by treatment group for FH patients*

			P values	
	CAL	CAL+FAT	Time effect	T × G
n	13	16	—	—
Pretreatment to the end of the 16-week program				
Weight (kg)	−6.9 ± 4.7	−7.4 ± 4.0	<0.05	NS
Body mass index (kg/m^2)	−2.6 ± 1.8	−2.8 ± 1.5	<0.05	NS
Total cholesterol (mmol/l)	−0.23 ± 0.56	−0.42 ± 0.65	<0.05	NS
HDL cholesterol (mmol/l)	−0.14 ± 0.13	−0.25 ± 0.20	<0.05	NS
LDL cholesterol (mmol/l)	−0.06 ± 0.39	−0.02 ± 0.46	NS	NS
Triglycerides (mmol/l)	−0.06 ± 0.36	−0.25 ± 0.82	NS	NS
Glucose (mmol/l)	−0.32 ± 0.59	−0.36 ± 0.83	<0.05	NS
Pretreatment to 1-year follow-up				
Weight (kg)	−3.5 ± 7.4	−3.0 ± 8.4	<0.05	NS
Body mass index (kg/m^2)	−1.3 ± 2.8	−1.1 ± 3.1	<0.05	NS
Total cholesterol (mmol/l)	+0.24 ± 0.56	−0.18 ± 0.28	NS	<0.05
HDL cholesterol (mmol/l)	−0.12 ± 0.22	−0.13 ± 0.22	<0.05	NS
LDL cholesterol (mmol/l)	+0.31 ± 0.48	−0.08 ± 0.60	NS	NS
Triglycerides (mmol/l)	+0.11 ± 0.40	−0.03 ± 0.99	NS	NS
Glucose (mmol/l)	−0.68 ± 0.74	−0.38 ± 1.70	NS	NS

Data are means ± SD. Sample sizes for LDL cholesterol are n = 13 (CAL) and n = 15 (CAL+FAT). Data for triglycerides have been log-transformed for analysis.

ment, and remained significantly lower at follow-up. These changes was observed in both treatment conditions.

CONCLUSIONS— In this study, a 16-week behavioral treatment program focusing on reducing calories and dietary fat produced significantly greater weight loss in women with NIDDM than a program focusing on calorie restriction alone. Moreover, NIDDM patients in the CAL+FAT condition maintained a significant amount of weight loss at 1 year, whereas patients who focused on calorie restriction alone regained almost all of their weight loss. For nondiabetic women, however, the emphasis on dietary fat in addition to calorie restriction did not improve weight loss or maintenance.

It is unclear why this difference between NIDDM patients and those with a family history of diabetes was observed. Perusal of the weight loss data in Fig. 1 suggests that this difference resulted from the fact that NIDDM patients in the CAL alone condition did particularly poorly. The diabetic subjects were older (Table 1), had all had a significant health problem (diabetes) diagnosed, and >50% reported having hypertension. Thus, it is reasonable to suggest that these individuals may have received greater encouragement in the past to lose weight and may have tried calorie restriction, unsuccessfully; thus, they may have found the CAL+FAT modification approach more novel. Unfortunately, data were not collected on the number of prior attempts at weight loss. Previous studies have suggested that individuals who have made no previous efforts to lose weight are more successful than those who have tried before (30), and subjects often do better on their first experience with a specific dietary intervention, such as a very-low-calorie diet, than on repeated efforts with the same exact diet (31). The finding that NIDDM subjects in the CAL alone condition reported consuming more calories after 16 weeks in the program than NIDDM subjects in the CAL+FAT condition and also more than FH subjects in either condition supports the suggestion that this intervention was less motivating to these subjects.

The self-reported dietary data suggested that the two treatment regimens produced very different levels of fat intake. In the CAL condition, fat intake remained ≥30% of calories at all time points in both NIDDM and FH subjects, confirming prior studies with calorie-counting diets (9–11). In contrast, subjects in the CAL+FAT condition reported consuming 22–26% of their calories as fat. Concern has been raised about the accuracy of self-reported dietary intake (32), and thus these findings should be interpreted with caution. Moreover, the small sample size may have obscured possible differences in baseline intake.

The current study found no adverse effects of a low-calorie/low-fat diet in individuals with NIDDM and suggests that these regimens may be useful in improving glycemic control and lowering CHD risk factors in such individuals. Both the calorie restriction regimen and the low-calorie/low-fat regimen produced significant improvement in total choles-

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terol, fasting glucose, and HbA_1 levels at the end of the 16-week program, but a far greater percentage of the NIDDM subjects in the calorie restriction plus low-fat diet regimen were able to control their blood glucose levels with diet alone through the end of the 16-week treatment. Previous studies indicating adverse effects of low-fat/high-carbohydrate diets in NIDDM patients have ensured that patients maintained stable weight on the different diet protocols. Because the natural tendency for patients on low-fat diets is to lose weight (14,33), this maintenance of body weight may obscure one of the major benefits of a low-fat regimen. Moreover, for obese patients with NIDDM, a low-fat diet may be most helpful when used in combination with calorie restriction as a means of promoting weight loss, rather than as a sole dietary modification.

The changes in lipids and glucose seen in both treatment conditions were, however, poorly maintained. At the 1-year follow-up, the only significant long-term change was a significant decrease in HDL cholesterol, observed in both FH and NIDDM subjects in both treatment conditions. Previous studies have shown that women often experience decreases in HDL cholesterol initially with weight loss (34,35) but show increases in HDL cholesterol in the long-term. For example, Wing et al. (1) reported significant increases in HDL cholesterol at the 1-year follow-up in NIDDM subjects who maintained weight losses of 6.9 kg or more. Wood et al. (36) found that weight loss resulting from calorie restriction alone lowered HDL cholesterol in women, but the combination of diet plus exercise prevented this decrease. The failure to observe long-term increases in HDL cholesterol in the present study may thus be due to the modest weight losses that were achieved or may indicate that subjects in this study focused on calorie restriction more than on increasing exercise.

In conclusion, adding dietary fat restriction to the calorie counting diet improved weight loss and maintenance among NIDDM subjects with no adverse effects on lipids or glycemic control. Use of the low-calorie/low-fat regimen should thus be considered as an approach to improving weight loss in these patients. However, this regimen was still only modestly successful. On average, subjects in the low-calorie/low-fat regimen maintained weight losses of only 3.5 to 5.2 kg at the 1-year follow-up, and only 33% of NIDDM patients and 44% of FH patients maintained a weight loss of 5 kg or more. There were no significant long-term improvements in lipids or glycemic control. Further research is clearly needed to develop more effective strategies for long-term weight loss and maintenance in individuals with NIDDM and those at risk of developing diabetes.

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