Long-Term Comparison of Three Dietary Prescriptions in the Treatment of NIDDM

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OBJECTIVE — To compare three sets of dietary guidelines for the treatment of non-insulin-dependent diabetes (NIDDM) in free-living individuals and to observe the effects on metabolic control over an 18-month period.

RESEARCH DESIGN AND METHODS — Seventy volunteer subjects with NIDDM were randomly assigned to one of three diets, a weight-management diet, a high-carbohydrate/fiber diet, or a modified-lipid diet and followed for 18 months. Nutrient intakes, weight, blood lipids, and glycemic control were measured.

RESULTS — In all diet groups, glycated hemoglobin (HbA_1) fell significantly before diet intervention began, remaining lower throughout the study and at follow-up 9 months later. Low-density lipoprotein (LDL) cholesterol showed a sustained fall in all groups after diet intervention. Apart from transient changes in high-density lipoprotein (HDL) cholesterol and triglyceride (TG) in the diet groups with the higher carbohydrate intake, no lasting differences were found between the three diet groups.

CONCLUSIONS — In the long term, there were few differences in the outcome of the three dietary prescriptions. Even with intensive instruction, participants found it difficult to meet recommended nutrient intakes; however, specific dietary advice did result in an improvement in LDL cholesterol. Adverse changes in HDL cholesterol and TG because of diet intervention were transient. The significant improvement in glycemic control during the recruitment phase may have been the result of participants' previous dietary knowledge and the increased attention that they received during the intervention.

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NIDDM, non-insulin-dependent diabetes mellitus; LDL, low-density lipoprotein; HDL, high-density lipoprotein; TG, triglyceride; BMI, body mass index; TC, total cholesterol; ANOVA, analysis of variance; CHO, carbohydrate; SFA, saturated fatty acids; PUFA, polyunsaturated fatty acids; MUFA, monounsaturated fatty acids.

Dietary treatment is accepted as an integral part of the management of non-insulin-dependent diabetes mellitus (NIDDM). Adjustment of energy intake to achieve optimal body weight is uncontroversial, but universal agreement regarding the appropriate distribution of nutrients in the diabetic dietary prescription has not been achieved (1–5). Current recommendations are based on epidemiological data and short-term dietary studies (usually 4-12 weeks). Therefore, we compared three dietary prescriptions that have all been suggested for the treatment of NIDDM over an 18-month period.

RESEARCH DESIGN AND METHODS

Seventy people with no major illnesses other than NIDDM and its complications were recruited from the Dunedin Hospital Diabetes Clinic and through local general practitioners. During the study, 2 participants moved from the region, 2 started insulin treatment, 1 was diagnosed with cancer, and 1 died. Details of the 64 participants who completed the 18-month study are provided in Table 1. The project was approved by the Otago Area Health Board Ethical Committee, and informed consent was given by all participants.

Experimental design

After stratification for age, sex, body mass index (BMI) (weight kg/height m^2), and duration of diabetes, participants were randomly allocated to one of three diet groups an average of 3 months after recruitment. Dietary, clinical, and laboratory measurements were made at recruitment (baseline), at the time of randomization to diet groups (month 0), 1 and 3 months after randomization, and then every 3 months for 18 months. Nine months after completion of the study, an attempt was made to reassess all participants.

Experimental diets

The three diets are summarized in Table 2. Daily energy requirements were calcu-

Table 1—*Characteristics at recruitment of the 64 participants who completed the 18-month study*

	Study groups		
	Diet group	Modified-lipid	High-carbohydrate/fiber
n	21	22	21
Age (years)	58 ± 2	59 ± 2	60 ± 2
BMI (kg/m^2)	29 ± 1	29 ± 1	30 ± 1
Duration of diabetes (years)	3.7 ± 0.66	5.6 ± 1.2	5.0 ± 0.94
Sex (F/M)	12/9	12/10	11/10
Medication diet only (n)*	4	5	0
Hypoglycemic drugs	11	11	12
Other medication†	6	3	8

Data are means ± SE.
*No medication data was available for 4 participants.
†Medication for asthma, insomnia, and migraine.

lated for each participant on the basis of a 4-day weighed-food record completed at recruitment. An energy deficit of 500 kcal/day was applied to those with a BMI >25 kg/m^2. Detailed dietary advice was given at the time of randomization and was reinforced at regular intervals throughout the study. Food displays, exchange lists, and recipes were provided, and participants' favorite recipes were adapted. Several evening meals were organized in a social context in a further attempt to aid compliance.

Dietary, clinical, and laboratory measurements

At each visit, a 24-h diet recall was completed by a dietitian (A.C.), and information on current medication was recorded. Participants were weighed, and blood pressure was measured using a random zero sphygmomanometer. Blood samples were collected after a 12-h overnight fast. Glycated hemoglobin (HbA_1) was analyzed by column separation using an ion-exchange resin (6), and plasma total cholesterol (TC) and triglyceride (TG) were analyzed using enzymatic kits (Boehringer Mannheim, Mannheim, Germany). High-density lipoprotein (HDL) cholesterol was determined using the manganese-heparin precipitation method (7), and low-density lipoprotein (LDL) cholesterol was calculated using the Friedewald equation (8).

Statistical methods

Differences in clinical and laboratory measurements between the three diet groups were analyzed by analysis of variance (ANOVA) with Bonferroni's adjustment to maintain significance at 95% (9). Data were adjusted using linear interpolation, as the blood samples for each individual were not collected at precisely 3-month intervals. The data were analyzed for changes over time by randomization ANOVA as described by Zerbe (10). Significant changes were then tested using the ANOVA test for repeated measures. Nutrient data were obtained from the New Zealand Food Composition Tables (11) and the soluble fiber content of foods from Englyst et al. (12,13). Nutrient data were compared by ANOVA.

RESULTS— Within each diet group, HbA_1, TC, and LDL cholesterol did not change significantly between months 1 to 6 or between months 9 to 18. Therefore, the results for these time intervals have been combined and presented as averages. No significant differences were observed between the diet groups for weight, HbA_1, TC, and LDL cholesterol at each sampling time, so diet groups were combined. However, significant differences were detected between the diet groups for HDL cholesterol and TG, and analyses were performed separately for each diet group. Results are presented for the 64 participants who completed the 18-month study (Table 3).

Table 2—*Description of the diet treatment groups*

Study group		
Weight-management	Modified-lipid	High-carbohydrate/fiber
Achieve and/or maintain BMI ≤25 kg/m^2	Achieve and/or maintain BMI ≤25 kg/m^2	Achieve and/or maintain BMI ≤25 kg/m^2
Restrict extrinsic simple sugars and energy-dense foods	19% energy from protein	15% protein
	36% energy from fat	30% energy from fat
No advice on the specific distribution of nutrients	SFA:PUFA:MUFA = 1	≤10% SFA
	45% energy from CHO	55% CHO
		≥30 g fiber/day
		Increase soluble fiber

Table 3—*Changes in glycemic control and lipid profile during the 18-month study*

	Recruitment	Randomization	Average month 1 to month 6	Average month 9 to month 18	Repeated measure ANOVA
Weight (kg)					
Weight-management	79.1 ± 2.6	78.3 ± 2.6	79.8 ± 2.7	79.8 ± 2.7	
Modified-lipid	82.8 ± 3.3	83.1 ± 3.6	82.1 ± 3.2	82.1 ± 3.2	
High-carbohydrate	80.9 ± 2.6	80.8 ± 1.7	80.7 ± 1.7	80.7 ± 3.0	
All	81.0 ± 1.7	80.8 ± 1.7	80.5 ± 1.7	80.5 ± 1.7	NS
GHb (%)					
Weight-management	9.5 ± 0.43	9.0 ± 0.44	8.3 ± 0.38	8.9 ± 0.54	
Modified-lipid	10.9 ± 0.79	9.8 ± 0.65	9.5 ± 0.56	9.7 ± 0.56	
High-carbohydrate	9.4 ± 0.52	8.7 ± 0.49	8.5 ± 0.44	8.5 ± 0.44	
All	10.0 ± 0.35	9.2 ± 0.31	8.8 ± 0.27	9.1 ± 0.30	$P < 0.001$
TC (mM)					
Weight-management	6.7 ± 0.27	6.4 ± 0.29	6.2 ± 0.21	6.1 ± 0.18	
Modified-lipid	6.4 ± 0.24	6.0 ± 0.20	5.9 ± 0.14	5.7 ± 0.15	
High-carbohydrate	6.8 ± 0.27	6.6 ± 0.33	5.9 ± 0.26	6.2 ± 0.20	
All	6.7 ± 0.15	6.3 ± 0.16	6.0 ± 0.12	6.0 ± 0.12	$P < 0.001$
LDL-cholesterol (mM)					
Weight-management	4.5 ± 0.26	4.5 ± 0.28	4.2 ± 0.22	4.2 ± 0.14	
Modified-lipid	4.0 ± 0.24	4.2 ± 0.20	3.8 ± 0.14	3.6 ± 0.15	
High-carbohydrate	4.4 ± 0.24	4.2 ± 0.31	3.8 ± 0.24	4.0 ± 0.19	
All	4.3 ± 0.14	4.2 ± 0.15	3.9 ± 0.12	3.9 ± 0.10	$P < 0.001$
HDL-cholesterol (mM)					
Weight-management	1.42 ± 0.07	1.24 ± 0.05	1.31 ± 0.04	1.18 ± 0.05	$P < 0.001$
Modified-lipid	1.44 ± 0.07	1.15 ± 0.10*†	1.33 ± 0.10	1.22 ± 0.06	$P = 0.0001$
High-carbohydrate	1.33 ± 0.06	1.23 ± 0.07	1.30 ± 0.10	1.19 ± 0.06	$P = 0.05$
All	1.40 ± 0.04	1.21 ± 0.03	1.32 ± 0.03	1.20 ± 0.03	$P = 0.0001$
TG (mM)					
Weight-management	2.0 ± 0.27	1.7 ± 0.24†	1.9 ± 0.24†	1.6 ± 0.15†	$P = 0.04$
Modified-lipid	2.1 ± 0.22	1.8 ± 0.29†	2.0 ± 0.20†	2.0 ± 0.19	NS
High-carbohydrate	2.7 ± 0.25	2.5 ± 0.34	2.8 ± 0.34	2.4 ± 0.21	NS
All	2.3 ± 0.14	2.0 ± 0.17	2.2 ± 0.16	1.9 ± 0.11	$P < 0.01$

Data are means ± SE.
*Significantly lower than the weight-management group at the 95% level.
†Significantly lower than the high-carbohydrate at the 95% level.

Weight

No overall significant changes were observed in weight during the study. Changes in weight were not correlated with changes in any other measured variable.

Glycemic control

No differences were found in HbA_1 between the three diet groups at any time throughout the study. When all diet groups were considered together, levels fell significantly between recruitment and randomization, and the decrease was maintained throughout the study period (Table 3).

TC and LDL cholesterol

TC levels fell significantly between recruitment and randomization when all groups were combined, with a further decrease during the first 6 months. No differences were observed between the three diet groups during the experimental period. No change was observed in LDL cholesterol between recruitment and randomization, however, concentrations were significantly lower throughout the diet intervention period than at recruitment or randomization.

HDL cholesterol and TG

A significant decrease was observed in HDL-cholesterol levels between recruitment and randomization in all three diet groups (Table 3). HDL cholesterol increased in the modified-lipid diet group after dietary intervention but continued to decline in the weight-management and high-carbohydrate groups. However, by month 3, these HDL-cholesterol levels had risen again, and there were no

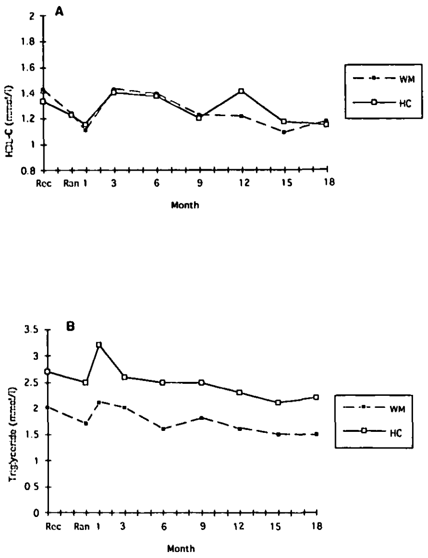

Figure 1—*HDL-cholesterol (A) and TG (B) levels for weight-management (WM) and high-carbohydrate (HC) groups.*

significant differences between the diet groups (Fig. 1*A*).

Between recruitment and randomization, a decline was detected in TG levels reaching significance only for the weight-management group (Table 3). The high-carbohydrate group showed a significant increase in TG over the first month, but by month 3, TG levels had decreased again (Fig. 1*B*). However, TG levels remained significantly higher in the high-carbohydrate group than other groups throughout the study (Table 3).

Data for the modified-lipid group are not presented in Fig. 1 because no significant changes were found in HDL cholesterol or TG during the first 6 months. No differences were observed in lipid levels between those on medications known to influence lipid metabolism and those not taking these preparations.

Follow-up

Results from 45 of the 64 participants who were available for follow-up are presented in Table 4. No significant demographic or metabolic differences were detected between those available for follow-up and those who were unavailable. Improvements in HbA_1, TC, and LDL cholesterol observed earlier in the study were maintained.

Nutrient intake

At recruitment, no significant differences were experienced in nutrient intake between the three diet groups as calculated from 4-day weighed food records (Table 5). A complete set of 4-day weighed-food records was not available for the full study, so nutrient intakes from 24-h diet recalls are presented in Table 6. Relatively small differences in reported nutrient intake were noted during the study. On average over the 18 months, the weight-management and high-carbohydrate groups had a significantly higher proportion of energy from carbohydrate (CHO), whereas the modified-lipid group had a higher proportion from fat.

Table 5—***Nutrient intakes at recruitment from 4-day weighed-food records***

Diet group	Recruitment
Energy (kJ)	
Weight-management	6399 ± 474
Modified-lipid	6623 ± 705
High-carbohydrate	7393 ± 525
CHO (% of energy)	
Weight-management	45.0 ± 1.4
Modified-lipid	44.7 ± 1.0
High-carbohydrate	44.3 ± 1.8
Fiber (g/day)	
Weight-management	21.6 ± 1.4
Modified-lipid	21.8 ± 1.9
High-carbohydrate	22.6 ± 1.7
Soluble fiber (g/day)	
Weight-management	6.2 ± 0.4
Modified-lipid	6.3 ± 0.6
High-carbohydrate	6.6 ± 0.4
Sucrose (g/day)	
Weight-management	21.5 ± 2.7
Modified-lipid	19.4 ± 4.2
High-carbohydrate	18.8 ± 1.8
Fat (% of energy)	
Weight-management	31.9 ± 1.2
Modified-lipid	34.1 ± 1.3
High-carbohydrate	34.7 ± 1.7
SFA (% of energy)	
Weight-management	13.1 ± 0.7
Modified-lipid	12.9 ± 0.6
High-carbohydrate	14.0 ± 0.9
P/S ratio	
Weight-management	0.39 ± 0.04
Modified-lipid	0.48 ± 0.05
High-carbohydrate	0.44 ± 0.06
MUFA (% of energy)	
Weight-management	10.7 ± 0.5
Modified-lipid	11.6 ± 0.6
High-carbohydrate	11.6 ± 0.6

Data are means ± SE.

Table 4—***Results from the 43 participants available for follow-up***

	Recruitment	Randomization	Average month 1 to month 18	Follow-up	Repeated measure ANOVA
Weight (kg)	79.9 ± 2.1	79.8 ± 2.1	79.4 ± 2.0	79.4 ± 1.9	NS
GHb (%)	9.9 ± 0.48	9.3 ± 0.48	8.9 ± 0.4	9.2 ± 0.54	P = 0.02
TC (mM)	6.6 ± 0.18	6.4 ± 0.21	6.0 ± 0.11	6.0 ± 0.16	P = 0.0002
LDL-cholesterol (mM)	4.2 ± 0.19	4.4 ± 0.20	3.9 ± 0.11	3.8 ± 0.15	P = 0.002
HDL-cholesterol (mM)	1.41 ± 0.05	1.25 ± 0.04	1.27 ± 0.03	1.23 ± 0.06	P = 0.0009
TG (mM)	2.2 ± 0.19	1.8 ± 0.21	2.0 ± 0.16	2.1 ± 0.24	NS

Data are means ± SE.

Table 6—*Nutrient intakes during the study from 24-h diet recalls*

	Average nutrient intakes		
	During study	Months 1–6	Months 9–18
Energy (kJ)			
Weight-management	5,382 ± 164	5,481 ± 218	5,289 ± 246
Modified-lipid	5,941 ± 271	5,894 ± 408	6,001 ± 338
High-carbohydrate	5,621 ± 215	5,554 ± 252	5,702 ± 366
CHO (% of energy)			
Weight-management	48.9 ± 1.1	50.4 ± 1.5	47.6 ± 1.6
Modified-lipid	44.5 ± 1.1*†	43.1 ± 1.5*†	46.4 ± 1.6
High-carbohydrate	47.2 ± 1.1	47.8 ± 1.4	46.6 ± 1.6
Fiber (g/day)			
Weight-management	19.3 ± 0.9	21.3 ± 1.4	17.3 ± 1.3
Modified-lipid	20.1 ± 1.6	19.2 ± 2.2	21.4 ± 2.3
High-carbohydrate	21.4 ± 1.0	21.7 ± 1.1	21.1 ± 1.7
Soluble fiber (g/day)			
Weight-management	5.5 ± 0.3†	6.1 ± 0.4	5.0 ± 0.4†
Modified-lipid	5.4 ± 0.4†	4.8 ± 0.5*†	6.2 ± 0.6
High-carbohydrate	6.4 ± 0.4	6.2 ± 0.4	6.8 ± 0.6
Sucrose (g/day)			
Weight-management	19.0 ± 1.7	17.8 ± 2.3	20.1 ± 2.5
Modified-lipid	22.4 ± 3.2	18.3 ± 3.2	27.6 ± 5.9
High-carbohydrate	15.8 ± 1.3‡	16.2 ± 1.8	15.4 ± 1.9‡
Fat (% of energy)			
Weight-management	32.3 ± 1.0‡	31.1 ± 1.4‡	33.6 ± 1.4
Modified-lipid	35.7 ± 1.0	37.0 ± 1.4	33.9 ± 1.3
High-carbohydrate	31.5 ± 0.9‡	30.7 ± 1.2‡	32.4 ± 1.5
SFA (% of energy)			
Weight-management	12.6 ± 0.6‡	12.2 ± 0.8‡	13.1 ± 0.8
Modified-lipid	14.3 ± 0.4	14.8 ± 0.6	13.6 ± 0.5
High-carbohydrate	11.8 ± 0.5‡	11.3 ± 0.6‡	12.4 ± 0.9
P/S ratio			
Weight-management	0.5 ± 0.04†	0.5 ± 0.10	0.5 ± 0.10†
Modified-lipid	0.4 ± 0.03†	0.4 ± 0.05	0.4 ± 0.03†
High-carbohydrate	0.6 ± 0.04	0.5 ± 0.05	0.6 ± 0.10
MUFA (% of energy)			
Weight-management	10.8 ± 0.4	10.7 ± 1.0	12.6 ± 1.1
Modified-lipid	11.4 ± 0.4	11.3 ± 1.0	10.5 ± 0.8
High-carbohydrate	10.6 ± 0.4	10.8 ± 1.0	9.2 ± 1.0*

Data are means ± SE.
*Significantly lower than the weight-management group at the 95% level.
†Significantly lower than the high-carbohydrate group at the 95% level.
‡Significantly lower than the modified-lipid group at the 95% level.

Soluble fiber intake was higher on the high-carbohydrate diet than on the other two diets.

CONCLUSIONS— The aims of this study were to determine whether different sets of dietary advice produced different effects on glycemic control and plasma lipids and whether a group of free-living individuals with NIDDM were able to adhere to dietary recommendations over a prolonged period. The results were unexpected but permitted conclusions relevant to clinical practice and further research in this field.

Overall, an 8% reduction in HbA_1 was achieved between the times of recruitment and randomization before dietary instructions were given. Advice regarding the specific distribution of nutrients resulted in only a small additional improvement, with little difference among the three diet groups. However, the initial improvement was sustained throughout the 18-month study and was still evident at follow up after a further 9 months with no intervention. These changes are unlikely to have occurred because of regression to the mean as levels remained constant following the initial improvement and because the downward trend was apparent at all concentrations of HbA_1. We believe that the improvement in glycemic control following recruitment resulted from the fact that all but 2 participants had visited a dietician and received advice regarding a low–saturated fat, high-CHO diet, with particular emphasis on soluble fiber. Nutrient intakes at recruitment suggest that some of the participants were already consuming this type of diet. Also this study occurred at a time of major promotion of the general health benefits of such a diet by the National Heart Foundation and various food stores. It seems likely that these influences, along with the fact that they were in a research project provided the stimuli for these well-motivated individuals with NIDDM to apply information already available to them. Worth et al. (14) reported an improvement in glycemic control in patients with insulin-dependent diabetes as a result of the increased attention associated with participating in a research project.

A decrease in TC was also observed between recruitment and randomization, but this was caused by a fall in HDL cholesterol. In contrast with the changes in HbA_1, which occurred mainly during entry to the study, TC and LDL cholesterol fell in all groups following diet intervention, and the improvement was sustained throughout the 18-month study and 9-month follow-up. In the two groups with higher intakes of CHO, weight-management and high-carbohydrate, HDL-cholesterol and TG showed transient adverse changes after diet intervention, but these were no longer apparent by month 3 (Fig. 1). A reduction in HDL cholesterol and elevation of TG has been reported previously in association with high-CHO diets with insufficient fiber and are regarded as major reasons for not recommending such diets to diabetic individuals (15–17). Our data suggest that with prolonged intake of a moderately raised CHO intake, the changes in HDL cholesterol and TG are transient, however, if fiber intakes in this study had been higher, the undesirable changes in HDL cholesterol and TG may not have been observed (18,19).

Disappointingly, a greater change in dietary intake was not seen among the groups, as participants received intensive, regular instruction and encouragement. Despite considerable effort to achieve dietary change, almost none of the participants succeeded in achieving currently recommended intakes of either CHO or unsaturated fat. A similar finding has been reported from a 15-month diet-intervention study in individuals recently diagnosed with NIDDM (20). New approaches may be required to achieve more marked dietary changes in the long term, and these changes may result in more striking metabolic differences between the different diet regimes than those observed in this study.

Further research is needed to confirm the suggestion of Grundy (21) that different dietary prescriptions are appropriate at different stages of NIDDM and for those with varying metabolic abnormalities. Until such studies are completed, it seems most appropriate to adopt the compromise suggestion of Riccardi and Rivellese (22). They argue in favor of a moderate increase in fiber-rich CHO combined with an increased intake of unsaturated fat, especially monounsaturated fat, to partly replace saturated fat.

Our findings suggest that focusing on increasing CHO and fiber intake in the diet or replacing saturated fatty acids with unsaturated fats both result in improvement. However, because participants found it difficult to meet either of these recommendations in full, advice to achieve moderate changes in both CHO and fat intake may be more acceptable, more realistic, and, therefore, a more effective long-term dietary treatment for diabetes.

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