Clinical and cost outcomes of medical nutrition therapy for hypercholesterolemia: A controlled trial

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ABSTRACT

Objective To compare the results and cost-effectiveness of a cholesterol lowering protocol implemented by registered dietitians with cholesterol lowering advice by physicians.

Design Six month randomized controlled trial, cost-effectiveness analysis. Subjects included 90 ambulatory care patients (60 men, 30 women), age range 21 to 65 years, with hypercholesterolemia and not taking hypolipidemic drugs. Patients were randomly assigned to receive medical nutrition therapy (MNT) from dietitians using a NCEP based lowering protocol or usual care (UC) from physicians. Outcome measures were plasma lipid profiles, dietary intake, weight, activity, patient satisfaction, and costs of MNT. Changes from baseline for each variable of interest were compared between treatment groups using analysis of covariance controlling for baseline value of the variable and gender.

Results MNT achieved a 6% decrease in total and LDL cholesterol levels at 3 and 6 months compared with a 1% increase and a 2% decrease in both values at 3 and 6 months with UC ($P<.001$ and $P<.05$, respectively). Weight loss (1.9 vs 0 kg, $P<.001$) and dietary intake of saturated fat (7% of energy vs 10%, $P<.001$) were better in the MNT than the UC group. The additional costs of MNT were $217 per patient to achieve a 6% reduction in cholesterol and $98 per patient to sustain the reduction. The cost-effectiveness ratio for MNT was $36 per 1% decrease in cholesterol and LDL level.

Applications/conclusions MNT from registered dietitians is a reasonable investment of resources because it results in significantly better lipid, diet, activity, weight, and patient satisfaction outcomes than UC. *J Am Diet Assoc. 2001:101: 1012-1016, 1021-1023.*

Coronary heart disease (CHD) costs the nation between $50 and $100 billion per year for medical treatment and lost wages. The second Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II or ATP II) targeted diet therapy as the first line of treatment of high blood cholesterol, a recognized risk factor for CHD, and recommended that drug therapy be reserved for patients who are at high risk for CHD. These guidelines for dietary treatment of hypercholesterolemia are based on total blood cholesterol and HDL cholesterol levels and an assessment of other non-lipid CHD risk factors (1). The NCEP guidelines suggest that a "physician and other involved health professionals" should implement the Step I diet and that the involvement of a "registered dietitian or other qualified nutrition professional is very useful, particularly for intensive dietary therapy such as the Step II diet" (1). The cost-effectiveness of this approach in a clinical ambulatory care setting has not been adequately evaluated.

The primary objective of this study was to compare the cost-effectiveness of a cholesterol lowering protocol implemented by registered dietitians with the implementation of cholesterol lowering advice by physicians in a clinical ambulatory setting. Our hypothesis was that it would be more cost-effective for dietitians than for physicians to implement a cholesterol lowering protocol for volunteers with hypercholesterolemia.

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METHODS

Volunteers

Based on our data we estimated that the standard deviation of the change from baseline in cholesterol was 0.49 mmol/L[1]. With 30 volunteers in each treatment group there was an 80% chance of detecting a .33 mmol/L difference in the change from baseline, at a one sided P=0.05 significance level. We anticipated a 10% dropout rate; therefore, a minimum of 35 volunteers would need to be enrolled in each group.

Potential study candidates included 1,493 adults (identified through the Massachusetts General Hospital (MGH) Clinical Laboratory Information Center), age range 21 to 65 years, with total cholesterol levels greater than 5.2 mmol/L and less than 8.84 mmol/L. After medical record review, 422 remained eligible after the following exclusion criteria were applied: presence of secondary medical conditions that can influence lipid levels (such as pregnancy, perimenopausal condition, diabetes, thyroid disease or renal failure); use of medications that influence lipid levels (such as hypolipidemic drugs, thiazide diuretics, beta blockers or estrogen therapy); hypertriglyceridemia (>4.52 mmol/L[2]); or nutrition counseling for hypercholesterolemia by a registered dietitian in the previous year. Thirteen primary care physicians who agreed to participate in this study enrolled 90 of their patients as study volunteers (30 men and 15 women in each treatment group) between June 1996 and April 1997.

Research Design

The 90 eligible study volunteers were randomly assigned, using a Permuted Block randomization to receive either medical nutrition therapy (MNT) from registered dietitians or usual care (UC) from physicians. Volunteers randomized to MNT received cholesterol lowering nutritional counseling and treatment according to a NCEP–based cholesterol lowering protocol developed by the Ambulatory Nutrition Service at the Massachusetts General Hospital. The protocol required volunteers with hypercholesterolemia to meet with registered dietitians for a minimum of 2 to 3 visits in a 2- to 3-month period. If lipids were not in the target range after initial treatment, volunteers had an additional 2 to 3 follow-up visits to provide a full 6-month diet intervention as recommended in the NCEP guidelines. The number of visits was based on an assessment of each volunteer's eating habits, lifestyle, capabilities and motivation for change. MNT volunteers also continued to receive usual care from their physicians.

Volunteers randomly assigned to UC from physicians received the customary cholesterol-lowering advice from their healthcare provider in the ambulatory care setting, which did not include contact with a dietitian. During the 6-month intervention period, physicians and volunteers agreed not to use lipid-lowering drugs or seek additional dietary counseling or therapy. After the 6-month intervention period, hypolipidemic medications and additional dietary counseling could be added at the discretion of the volunteer's physician.

Table 1
Baseline anthropometric and demographic characteristics

	Medical Nutrition Therapy group (n=45)		Usual Care group (n=45)	
	← *mean±standard deviation* →			
Age (y)	49±10		49±9	
BMI (kg/m2)	27±4		28±4	
	n	%	*n*	%
Male sex	30	67	30	67
Caucasian	42	93	44	96
Income >$40,000[a]	37	84	36	80
College graduate	37	82	30	67
Smoker	5	11	2	4

[a]Percent based on 37 out of 44 because 1 person in MNT did not report income.

The entire cohort was evaluated again at 1 year, 6 months after the end of the study intervention.

Outcome Measures

Body weight was measured (with the subject wearing a hospital gown and after fasting) and recorded to the nearest 0.1 kg. Height was measured with a wall-mounted stadiometer to the nearest 0.1 cm. Body mass index (BMI) was calculated.

Fasting (after at least 12 hours) plasma lipid profiles including total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides were measured (Hitachi 917 analyzer with reagents supplied by BMD/Roche Diagnostics, Indianapolis, Ind) at baseline, 3 months, 6 months, and 1 year for all volunteers. LDL-cholesterol levels were determined using the Friedewald calculation (2). The total cholesterol assay is an enzymatic colorimetric assay using cholesterol esterase and cholesterol oxidase (3-5) and was calibrated against isotopic dilution/mass spectrometry. The HDL-cholesterol assay is a homogenous enzymatic colorimetric assay (6,7) and has been calibrated against the Roche PTA (phosphotungstic acid) precipitation method (8,9). This standardization meets the requirements of the "HDL Cholesterol Method Evaluation Protocol for Manufacturers" of the US National Reference System for Cholesterol, CRMLN (Cholesterol Reference Method Laboratory Network), November 1994.

Nutrition analysis of energy, total fat, saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, and fiber intake was performed at baseline, 3 months, 6 months, and 1 year based on random 24-hour recalls (Nutrition Data System [NDS], University of Minnesota, Minneapolis, Minn, NDS 2.91, Food Database version 12A, Nutrient version 2.7)(10).

Nutrition interviewers, masked to treatment assignment, conducted 24-hour recalls using the multiple pass interview methodology and a 2-dimensional food portion visual aid (10). After the baseline visit, the nutrition interviewers conducted 24-hour recalls either via telephone within 2 weeks prior to the follow-up visit or in person at the visit.

Study volunteers also reported via recall their total minutes of exercise per week and the number of visits and the time spent with their physician discussing their cholesterol level at each follow-up visit. Time spent with the dietitian was assessed via nutrition clinic records and the office computer scheduling system. A patient satisfaction survey, adapted from the Diabetes Quality of Life measure for the Diabetes Control and Complications Trial, was administered at baseline

[1]To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7 to convert mg/dL cholesterol to mmol/L multiply mg/dL by 0.026. Cholesterol of 5.00 mmol/L=193 mg/dL

[2]To convert mmol/L triglycerides to mg/dL, multiply mmol/L by 88.6. To convert mg/dL triglycerides to mmol/L multiply mg/dl by 0.0113. Triglycerides of 1.80 mmol/L=159 mg/dL.

Table 2
Comparison of nutrient intake between treatment groups based on 24-hour recall

Diet	Baseline	3 month	6 month	1 year
N				
MNT[a]	45	45	44	42
UC[a]	45	43	43	44
	← mean±standard deviation →			
Kcal[a]				
MNT	1,987±841	1,554±544*	1,679±796	1,462±472†††
UC	1,888±585	1,847±706	1,850±675	1,675±522†
% Fat				
MNT	32±12	24±8***	25±10**	26±10†
UC	31±11	30±10	29±10	28±9†
% Sat Fat[a]				
MNT	11±6	7±3***	7±4***	8±4††
UC	11±4	10±4	10±4	10±4
% MFA[a]				
MNT	12±5	9±4**	9±4**	10±4†
UC	12±5	11±5	11±4	10±4†
% PFA[a]				
MNT	6±4	5±3	7±4	5±3
UC	6±3	6±3	5±2	6±2
Cholesterol (mg)				
MNT	235±191	154±103	165±132*	166±154†
UC	242±229	189±120	239±199	179±123
Dietary fiber (g)				
MNT	16±9	20±12*	18±8	16±7
UC	18±10	16±7	16±6	19±9

Difference between treatment groups, using analysis of covariance controlling for baseline and gender. *$P<.05$, **$P<.01$, ***$P<.001$.
Difference within treatment groups using paired *t* tests baseline versus 1 year. †$P<.05$, ††$P<.01$, †††$P<.001$.
[a]MNT=medical nutrition therapy, UC=usual care, Kcal=kilocalories, PFA=polyunsaturated fatty acids, Sat fat=Saturated fatty acids, MFA=monounsaturated fatty acids.

Table 3
Comparison of lipid levels, weight and activity between treatment groups[a]

	Baseline	3 month	6 month	1 year
N				
MNT[b]	45	45	44	43
UC[b]	45	44	44	44
	← mean±standard deviation →			
Chol[c] (mmol/L)				
MNT	6.19±0.73	5.77±0.70***	5.77±0.60*	5.98±0.70
UC	6.16±0.75	6.19±0.70	6.03±0.65	5.90±0.73††
LDL[c,d] (mmol/L)				
MNT	4.29±0.60	4.00±0.62*	3.98±0.55	4.00±0.57†
UC	4.24±0.68	4.21±0.68	4.13±0.60	3.90±0.68†††
HDL[c] (mmol/L)				
MNT	1.22±0.42	1.12±0.39**	1.14±0.36	1.30±0.47
UC	1.14±0.31	1.14±0.31	1.09±0.31	1.22±0.42
Triglycerides[e] (mmol/L)				
MNT	1.46±0.61	1.38±0.66*	1.47±0.73	1.54±0.86
UC	1.71±0.89	1.81±0.90	1.85±1.27	1.72±0.95
Weight (kg)				
MNT	79.6±15.4	77.7±15.4***	77.7±15.4***	78.2±15.4
UC	83.2±15.0	83.2±15.0	83.2±15.0	83.2±15.0
Activity[f] (min/wk)				
MNT	119±126	160±161*	144±130	148±102
UC	92±97	94±93	108±109	135±185

[a]Difference between treatment groups using analysis of covariance controlling for baseline and gender. *$P<.05$, **$P<.01$, ***$P<.001$.
Difference within treatment groups using paired *t* tests baseline vesus 1 year. †$P<.05$, ††$P<.01$, †††$P<.001$.
[b]MNT=medical nutrition therapy, UC=usual care.
[c]To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. Cholesterol of 5.00 mmol/L=193 mg/dL.
[d]Number of subjects is reduced because of inability to calculate low-density lipoprotein cholesterol with triglycerides >4.52 mmol/L. At 6 months n=43 for UC and MNT, at 1 year n=42 for MNT.
[e]To convert mmol/L triglycerides to mg/dL, multiply mmol/L by 88.6. To convert mg/dL triglycerides to mmol/L multiply mg/dL by 0.0113. Triglycerides of 1.80 mmol/L=159 mg/dL.
[f]Number of subjects is reduced due to missing value (at 3 months n=43 for UC.)

Table 4
Volunteers' satisfaction[a]

	MNT (n=44)	UC (n=44)	P^c
	← *mean score at six months*[b] →		
How satisfied are you with your ability to manage your cholesterol	2.2	3.1	<.001
How satisfied are you with the amount of time you spend exercising?	3.0	3.3	.35
How satisfied are you with your knowledge about your cholesterol?	1.5	2.3	<.001
How satisfied are you with your doctor's/dietitian's understanding of your lifestyle and the way you eat?	1.4	2.6	<.001
How satisfied are you with your visits with the dietitian/doctor to discuss your cholesterol?	1.5	2.4	<.001
How satisfied are you with the amount of food you are currently eating?	1.8	2.8	<.001
How satisfied are you with the way you are currently eating?	1.9	2.8	<.001

[a]as adapted from the "Diabetes Quality of Life Measure" (11).
[b]Data obtained from rankings on Likert scale: very satisfied=1, moderately satisfied=2, neither=3, moderately dissatisfied=4, very dissatified=5.
[c]*P* value determined using the Wilcoxon test.

and 6-month visits (11).

The additional cost of medical nutritional therapy was calculated according to the standard charges at the MGH using Transition Systems Inc, TSI, data from 1995 and changes in the consumer price index for medical care services for urban consumers between 1995 and 1997. TSI produces unit cost information from monthly analyses of each department's fixed and variable costs, staffing, and volume of services produced. The additional cost per percent decrease in mean cholesterol was calculated for MNT (12). The number of volunteers who required drug therapy after 6 months of MNT vs 6 months of UC was tallied and associated costs, based on wholesale costs (1997) of the actual drugs (13), dosages prescribed, and associated lab work ordered to monitor side effects (ie, SGOT, CPK) were compared. These costs do not include lipid panels or extra physicians' visits. Lab costs were based on the 1997 MGH rate book.

Statistical analysis

Analysis of covariance controlling for baseline value of the variable and gender was used to assess group differences in the change in dietary intake and lipid levels at 3 months, 6 months, and 1 year. Baseline comparisons were made using *t* tests for continuous variables and Fisher's exact test for categorical variables. Within group changes were calculated using paired *t* tests. Pearson product moment correlations were computed to correlate dietary intake and clinical outcomes. The Wilcoxon test was used to compare differences in patient satisfaction between groups at baseline and 6 months. SAS was used for all of the analyses (SAS Institute, Inc, Cary, NC, SAS version 6.12). All inter-group comparisons were based on intention-to-treat analyses.

RESULTS

Of the 90 volunteers (60 men and 30 women) who enrolled in the study, 2 men (one in each group) dropped out after the 3-month visit. Table 1 presents baseline characteristics of volunteers who received MNT vs UC. There were no significant differences between the two groups.

Adherence to the Study Regimen and Nutrient Intake

During the 6-month study intervention, 98% of the MNT volunteers adhered to the study regimen, attending a minimum of 2 nutrition counseling sessions. One of the volunteers assigned to UC saw a dietitian for 1 session. None of the study volunteers was prescribed hypolipidemic drugs. After the 6-month study intervention period ended, 29% of the UC volunteers were prescribed hypolipidemic drugs (statins) (n=7) or received further dietary intervention (n=6) compared with none in the MNT group ($P<.001$).

At baseline, there were no significant differences in diet, assessed by 24 hour recall, between treatment groups (Table 2). At 3 and 6 months, the MNT group was more likely to meet the goals for NCEP Step 2 diets than the UC group and achieved lower fat intakes (24% vs 30% fat at 3 months, $P<.001$; and 25% vs 29% fat at 6 months, $P<.01$; 7% vs 10% saturated fat, $P<.001$). Compared with baseline, the MNT group sustained a 7% to 8% decrease in total fat intake and a 4% decrease in saturated fat intake at 3 months and 6 months; significant reductions from baseline in reported total fat ($P<.01$), saturated fat ($P<.01$), cholesterol ($P<.05$), and energy intake ($P<.001$) persisted at 1 year. However, the differences in the changes between treatment groups were no longer significant at 1 year as the UC group also reported significant reductions in energy intake (P <.05) and total fat intake (P <.05) compared with baseline.

Serum Lipids, Weight, and Activity

At baseline, lipid levels, weight, BMI, and activity level were not significantly different for the MNT and UC groups (Table 3). The MNT group had a 6% decrease in serum total and LDL-cholesterol levels at 3 months and 6 months, whereas the UC group had no significant change in total or LDL-cholesterol levels (Table 3). The difference in the change in total cholesterol levels between the groups was significant at 3 months (P<.001) and at 6 months (P<.05). Moreover, 82% (n=37) of MNT volunteers vs 43% (n=19) of UC volunteers had lower total cholesterol levels at 3 months with 38% (n=17) of MNT volunteers vs 14% (n=6) of UC volunteers achieving at least a 10% reduction in total cholesterol levels at 3 months. Volunteers receiving MNT lost 1.9 kg at 3 months, which was sustained at 6 months compared with no weight loss in the UC group (P<.001). In addition, the MNT group reported higher activity levels (160 ± 161 min/wk) at 3 months compared with UC volunteers (94 ± 93 min/wk) (P<.05).

Weight reduction at 3 months was correlated with reductions in serum cholesterol (r= 0.38, P=.0002) and triglyceride levels (r=0.29, P=.005), and with increased activity (r=-0.29, P=.007) in the entire cohort. Change in percentage of energy from saturated fat at 3 months was correlated with reductions in serum cholesterol (r=0.52, P=.0001), LDL-cholesterol (r=0.50, P=.0001), and HDL-cholesterol levels (r=0.26, P=.02). Reduction in percentage of energy from total fat was associated with changes in weight, (r=0.21, P<.05), LDL (r=0.34, P=.001), and total cholesterol (r=0.33, P=.001).

At 1 year, the differences in the changes between treatment groups for serum lipids, weight, and activity were no longer significant. MNT volunteers received no additional interventions between 6 months and 1 year, but sustained significant reductions in LDL-cholesterol (P<.01) compared with baseline. By comparison, 13 of 45 UC volunteers received additional drug or diet intervention between 6 months and 1 year and had significant reductions in total cholesterol (P<.01) and LDL cholesterol (P<.001).

Time Spent Counseling Volunteers

Dietitians providing MNT spent an average of 90 minutes (range 60 to 140 minutes) per volunteer in the first 3 months [mean=2.5 visits ± 0.5 (standard deviation)] and 30 minutes (1.5 visits ± 0.8) in the second 3 months. Time spent with the dietitian by month 3 was correlated with reductions in serum total cholesterol (r=-0.47, P=.001) and LDL-cholesterol (r=-0.39, P=.008), and with weight reduction (r=-0.34, P=.02). Because the average amount of time that primary care physicians spent discussing total cholesterol levels and diet therapy was similar in both treatment groups (1 to 2 minutes per volunteer between baseline and 3 months and between 3 and 6 months), we could not compare the costs of UC vs MNT. Therefore, only the incremental costs of MNT were calculated.

Cost Outcomes/Cost-Effectiveness

The calculated cost of dietitians' effort for 90 minutes per volunteer during the first 3 months was an average of $217 to achieve a 6% reduction in total and LDL-cholesterol levels and an extra 3% reduction in saturated fat intake. In the second 3 months, dietitians spent an average of 30 minutes per volunteer, at an average cost of $98, which sustained the decrease in total and LDL-cholesterol levels and the extra reduction in saturated fat intake. The cost-effectiveness ratio for MNT was $36 for each 1% decrease in total and LDL-cholesterol level and $72 for each extra 1% decrease in saturated fat intake.

> Dietitians need to convey that the impact of MNT on health outcomes may extend beyond the reduction of total cholesterol levels: the increased physical activity, decreased fat intake and greater weight loss may provide additional health benefits

Satisfaction

At baseline, there were no significant differences in satisfaction except that volunteers in MNT were more satisfied with the amount of food they were eating (MNT=2.4, UC=2.9, P=.03; 1=very satisfied, 5=very dissatisfied). At the 6-month evaluation, the MNT group reported significantly higher satisfaction levels with clinic visits, dietitian's vs physician's understanding of lifestyle and eating habits, their knowledge about cholesterol, ability to manage cholesterol levels, and eating habits than the UC group (Table 4).

Cost of Lipid-Lowering Drugs

The average cost associated with lipid-lowering drugs for the 7 UC volunteers was $443.93 per person over 6 months. The average reduction in cholesterol was 14.14%, resulting in an average cost of $31.40 for each 1% reduction of total cholesterol for a 6-month period.

DISCUSSION

The MNT group had a 6% decrease in total and LDL-cholesterol levels at month 3 compared with the UC group, which had no reduction in total cholesterol or LDL levels. More than one third of the MNT group showed a more than 10% decrease in total cholesterol levels at month 3. The changes in total cholesterol levels were significantly greater in the MNT volunteers at 3 months and at 6 months compared with UC volunteers.

In addition to reducing total cholesterol levels by 6%, the MNT group lost more weight (1.9 vs 0 kg) at 3 and 6 months and reported more activity at 3 months compared with the UC group. At baseline, fat and cholesterol intake were similar to a Step 1 NCEP diet and less than the average American diet (14), with 31% to 32% fat, 11% saturated fat, and 235 to 242 mg cholesterol. The MNT group met the NCEP Step 2 recommended diet guidelines at 3 months and 6 months, whereas the UC group was more likely to maintain a diet consistent with Step 1 criteria of NCEP. The MNT group achieved and sustained an 8% decrease in total fat (from 32% to 24%) and a 4% decrease in saturated fat intake (from 11% to 7%), which was statistically significant at both 3 and 6 months. To achieve the MNT results, dietitians spent an average of 90 minutes per volunteer during the first 3 months and 30 minutes in the next 3 months of therapy. This contrasts with the average of 1 to 2 minutes per volunteer spent by the physicians in providing cholesterol-lowering advice.

Volunteers assigned to MNT were counseled with individualized approaches evidenced by the use of as many as 5 different strategies. These included: verbal advice, brochures, handwritten instructions, preprinted materials, and recipes. At least 3 to 5 different counseling strategies were used with 80% of MNT volunteers, compared with 4% of UC volunteers, suggesting that dietitians who provide MNT use a more customized approach for cholesterol lowering.

Although physicians and dietitians were not masked to study assignment, the staff collecting outcome data, ie GCRC (General Clinical Research Center) staff weighing the volunteers and collecting the diet recalls, and the staff performing laboratory measures, were masked to treatment assignment. Moreover, while the physicians could have preferentially begun specific hypolipidemic therapies on one group vs another, they had all agreed to and refrained from doing so during the first 6 months, so any potential bias introduced through their unmasking was trivial at most.

The results of our study can be compared with the results of other published studies. At 6 months, the 6% decrease in total cholesterol levels is comparable to the 5.3% mean decrease recently reported in a review of randomized trials of dieting advice to lower blood cholesterol levels in free-living subjects (15). Our results also parallel, in at least some respects, a randomized trial (comparing MNT by dietitians with UC provided by nurses and physicians) in which MNT resulted in a greater decrease in total cholesterol levels: 10% (from 6.97 to 6.27 mmol/L) compared with a 7% decrease with UC (16). The greater decrease in total cholesterol levels in this study may be partially explained by the higher baseline cholesterol levels compared to the current study (17).

The results of the Cholesterol Lowering Intervention Program (CLIP) (18), a randomized study designed to develop and evaluate approaches for physicians to implement the NCEP STEP 1 guidelines, also support our results. CLIP examined whether office assisted and nutrition center models would be more effective in lowering serum cholesterol than UC, which served as the control. After 2 months, serum cholesterol levels declined by 2.2% with Usual Care Model; by 4.6% in the Office Assisted Model; and by 7.8% in the Nutrition Center Model, similar in magnitude to the 6% decrease in our study.

Our results are also consistent with the findings of Stefanick et al (19), who reported an 8% and 3% decrease in total and saturated fat, respectively, after a NCEP Step 2 diet and exercise program. Lipid responses to diet and exercise were also similar to our study. The time spent with dietitians who advised changes in diet and exercise in the Stefanick study, was greater than in our study, including one individual session, 8 one-hour group sessions, and 6 to 8 monthly contacts for diet counseling thereafter via mail, phone, group or private meeting. In addition, volunteers received 6 weeks of 1-hour exercise sessions 3 times per week and a 7- to 8-month maintenance phase during which participants could attend exercise sessions 3 times per week with a goal of 10 miles of brisk walking per week.

In our study, the 12-month data, approximately 6 months after MNT sessions were completed, showed no significant differences in the changes from baseline between treatment groups in diet, exercise, or lipid outcomes. A study by Henkin et al also showed a similar trend, but they found that both dietitian and physician groups lost half of the beneficial effects on LDL-cholesterol levels at one year compared with 3 months (20). In our study, however, the 1-year results were largely a function of improvement in lipid levels in the UC group, rather than worsening status in the MNT group. Almost one third of the UC group was given either hypolipidemic medications (n=7) or had joined formal diet programs (such as Weight Watchers) or sought out a dietitian (n=6). By comparison, none of the MNT volunteers were prescribed hypolipidemic agents or further dietary intervention.

Because volunteers in the UC group were less satisfied with their ability to manage their cholesterol levels at 6 months, this might explain the extra attention to diet, hypolipidemic medications and cholesterol lowering that subsequently occurred in this group.

Although we could not directly compare the costs of UC vs MNT, we examined the costs and potential clinical benefits of ongoing MNT. The additional average cost of MNT per volunteer was $217 in the first 3 months for 2.5 visits and $98 in the second 3-month period for 1.5 visits, which sustained the 6% decrease in total cholesterol. The cost-effectiveness ratio for MNT was $36 per 1% decrease in total cholesterol and LDL levels. Sikand et al (21) demonstrated a 13% lowering in total cholesterol levels (from 7.06 to 6.14 mmol/L) using MNT and calculated the average cost to be $165 for 3 visits (144 minutes) over a 7-week period. This contrasts with the calculated annualized cost of statin therapy, including monitoring, of $2,648.59. For each dollar spent on MNT, a cost savings of $4.28 was noted.

Sikand also reported that "after dietitian intervention, only 15 of 30 eligible patients required antihyperlipidemic medications, which led to an annual cost savings of $27,449 or $638.35 per patient" (22). MNT also produced and sustained an extra 3% reduction in saturated fat intake. The ongoing cost of $98 per 3-month period to sustain reductions in saturated fat intake and total cholesterol and LDL levels appears to be worth the benefits when one compares an annualized cost of MNT of $511 to the $2,648.59 annual cost of statin therapy.

The potential clinical benefits of ongoing MNT can be examined from several perspectives. First, every 1% reduction in total cholesterol levels is associated with a 2% to 3% reduction in coronary heart disease (23). Second, Oster and Thompson (24) estimate that reducing saturated fat intake by one to three percentage points would reduce CHD incidence by 32,000 to 99,700 events and yield combined savings in medical expenditures and lost earnings ranging $4.1 to $12.7 billion over 10 years (estimates in 1993 US dollars). Finally, MNT not only helps reduce lipid levels but also encourages lifestyle modifications that result in weight loss, reduction in fat intake, and increases in activity levels. Medications are only effective at lipid lowering.

APPLICATIONS

Dietitians can use these research results with physicians, third party payers, and decision makers in health systems to substantiate the effectiveness of MNT in reducing fat intake and decreasing cholesterol levels compared with physicians' advice in the usual care setting. Dietitians need to convey that the impact of MNT on health outcomes may extend beyond the reduction of total cholesterol levels: the increased physical activity, decreased fat intake and greater weight loss may provide additional health benefits (25,26). Moreover, the greater patient satisfaction that occurred with MNT provides evidence that the quality of the counseling process is also important. The significant improvement in all of these outcomes provides evidence that MNT is a reasonable investment of healthcare resources and supports our recommendation that NCEP dietary guidelines should be implemented by registered dietitians as much as possible and in an ongoing manner to achieve and sustain maximum health benefits.

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