Biologic and Quality-of-Life Outcomes From the Mediterranean Lifestyle Program

A randomized clinical trial

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OBJECTIVE — Few multiple lifestyle behavior change programs have been designed to reduce the risk of coronary heart disease in postmenopausal women with type 2 diabetes. This study tested the effectiveness of the Mediterranean Lifestyle Program (MLP), a comprehensive lifestyle self-management program (Mediterranean low–saturated fat diet, stress management training, exercise, group support, and smoking cessation), in reducing cardiovascular risk factors in postmenopausal women with type 2 diabetes.

RESEARCH DESIGN AND METHODS — Postmenopausal women with type 2 diabetes ($n = 279$) were randomized to either usual care (control) or treatment (MLP) conditions. MLP participants took part in an initial 3-day retreat, followed by 6 months of weekly meetings, to learn and practice program components. Biological end points were changes in HbA_{1c}, lipid profiles, BMI, blood pressure, plasma fatty acids, and flexibility. Impact on quality of life was assessed.

RESULTS — Multivariate ANCOVAs revealed significantly greater improvements in the MLP condition compared with the usual care group on HbA_{1c}, BMI, plasma fatty acids, and quality of life at the 6-month follow-up. Patterns favoring intervention were seen in lipids, blood pressure, and flexibility but did not reach statistical significance.

CONCLUSIONS — These results demonstrate that postmenopausal women with type 2 diabetes can make comprehensive lifestyle changes that may lead to clinically significant improvements in glycemic control, some coronary heart disease risk factors, and quality of life.

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The prevalence of diabetes, which places women between 45 and 55 years of age at risk for coronary heart disease (CHD), has increased from <2% in the 1960s to nearly 6% in the early 1990s (1). Mortality from CHD is 2.5 times higher in women with diabetes than in women without diabetes and is greater for women with diabetes than for men with diabetes (2,3).

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Abbreviations: CHD, coronary heart disease; EPA, epicosapentaenoic acid; MANCOVA, multivariate analysis of covariance; MLP, Mediterranean Lifestyle Program; MOS, Medical Outcomes Study; PAID, Problem Areas in Diabetes; UC, usual care.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Consumption of a high-fat diet is a key modifiable CHD risk factor for women and men (4). Sedentary habits also account for a substantial portion of deaths due to CHD (5), whereas regular moderate to vigorous physical activity is associated with reduced morbidity and mortality due to cardiovascular disease and reduced risk factors for CHD (6). Exaggerated stress responses (7) also may affect CHD outcomes.

Behavior change interventions may promote healthful lifestyles, reduce the incidence of type 2 diabetes more effectively than metformin (8), reduce CHD risk (9), and improve glycemic control (8). The Lyon diet heart study (10) reduced coronary events and cardiac deaths by nearly 70% for participants using the Mediterranean diet, yet few studies have related lifestyle change to coronary risk reduction in women with diabetes.

Behavioral risk factor intervention trials rarely address multiple lifestyle risk factors. Yet, there is convincing evidence that improvements in multiple lifestyle behaviors (e.g., diet, physical activity, stress management, social resources, and tobacco use) (11) can help reduce further risks from heart disease. Three randomized trials, one using multiple CHD risk factor reduction (12) and two using coronary angiography (13) as end points, employed lifestyle interventions similar to those implemented in the current study. These trials not only promoted weight loss, reductions in angina symptoms, and reduced use of lipid- and blood pressure–lowering medications (12), but also aided in the regression of coronary lesions (13).

The Mediterranean Lifestyle Program (MLP) is a randomized controlled trial to test the effectiveness of a comprehensive behavioral risk factor reduction program for postmenopausal women with type 2 diabetes, using similar procedures shown to be successful in middle-aged men (10,14) and with women in our Women's

Lifestyle Heart Trial (12). The purpose of this report is to evaluate improvements at the 6-month follow-up of the MLP intervention, relative to control subjects, on a variety of biologic outcomes and quality of life. Quality of life is as important as biologic or behavior change outcomes but is rarely reported (15). Our hypothesis was that participants randomized to the MLP condition would show greater improvement than those randomized to the usual care (UC) control condition on both biologic and quality-of-life measures.

RESEARCH DESIGN AND METHODS

Participants

Participants were 279 postmenopausal women with type 2 diabetes who received their medical care from participating primary care clinics located in Lane County, Oregon. Recruitment took place between February 2000 and January 2001. Inclusion criteria were female sex, diagnosis of type 2 diabetes for at least 6 months, postmenopausal, living independently (e.g., not in an institution), having a telephone, able to read English, not developmentally disabled, and living within 30 miles of the intervention site in Eugene, Oregon. Exclusion criteria included being >75 years of age or planning to move from the area within the study's time span. All patients who met the above eligibility criteria were sent a letter from their primary care providers, followed by a phone call inviting them to participate. Of the eligible women, 51% who were contacted agreed to participate. Recruitment procedures, a participant flow diagram, and participation rates are presented in more detail in a separate article (15a). Participants represented patients of 59 participating primary care providers and the population of the state and were stratified by *1*) physician practice, *2*) smoking status, and *3*) type of diabetes medication. They were randomized to either the control condition (UC; $n = 116$) or the treatment condition (MLP; $n = 163$).

Intervention

Intervention lasted 6 months and addressed diet, physical activity, stress management, social support, and smoking. The program context, materials, logo, music, intervention space, and key components (including the diet) were designed to produce a "Mediterranean feel." To build a sense of community, a social support intervention delivered by professional and lay leaders was included. The program began with a 3-day nonresidential retreat (beginning Friday evening and running through Sunday) followed by weekly meetings lasting 6 months and consisting of 1 h each of physical activity, stress management, group Mediterranean potluck dinner, and support groups.

Eating patterns. The project's registered dietitian taught participants the Mediterranean α-linolenic acid–rich diet, which is low in saturated fat but moderately high in more healthful monounsaturated fats as well as n-3 fatty acids (10). The dietitian individualized carbohydrate and fat intake to optimize blood glucose and lipid concentrations using the dietary patterns of the MLP. The diet recommended increased amounts of bread, root vegetables, green vegetables, legumes, and fish; less red meat (e.g., beef, lamb, and pork), substituting poultry; no day without fruit; and avoidance of butter and cream, substituting olive oil/canola oil or commercially available olive oil/canola oil–based margarine.

Physical activity. The physical activity goal was consistent with the recent American College of Sports Medicine guidelines (16). Participants were advised to follow a physical activity program including *1*) moderate aerobic activity (e.g., walking, low-impact aerobic dance, or stationary cycling) for 30 min most, preferably all, days of the week; *2*) 10 strength-training exercises performed twice per week, building to three sets of 12 repetitions; and *3*) formal warm-up/cooldown routines 10 min before and 10 min after all activity sessions.

Stress management. Using procedures from Toobert et al. (12), participants were instructed in stress management (yoga, progressive deep relaxation, meditation, and directed or receptive imagery) and asked to practice these techniques at least 1 h per day. Participants received videotapes to assist them.

Outcomes

Biochemical measurements. After fasting overnight, venous blood samples were drawn to measure cholesterol and triglyceride in whole plasma. In addition, a nonsegmented continuous flow method was used to quantify cholesterol in lipoprotein classes separated by single vertical ultracentrifugation. With this technique, a detailed quantitative profile of lipoprotein fractions not reflected in the standard lipid measurements was obtained. Lipoprotein fractions were assayed by Atherotech Laboratories in Birmingham, Alabama.

HbA_{1c}. HbA_{1c} was assayed with ion-exchange high-performance liquid chromatography using the BioRad Variant II Instrument and conducted at Oregon Medical Laboratories in Eugene, Oregon.

Plasma fatty acids. To measure the plasma n-3 fatty acid profile, including the monounsaturated, n-6, and n-3 fatty acids, a 500-μl aliquot of plasma was extracted twice with 5 ml chloroform/methanol (2:1 [vol/vol]) and transesterified with boron trifluoride and methanol. The methyl esters were analyzed on a Hewlett Packard 5890 gas chromagraph (Avondale, PA). Individual fatty acids were identified using eicosatrienoic acid as an internal standard.

BMI and central obesity (waist-to-hip) measurements. Measures of height and weight were taken in the morning in stocking feet on a sensitive digital scale (Detecto Electronics), and these measurements were converted to BMI (kg/m^2). Girth measurement was estimated as the average of duplicate measures taken to the nearest 0.5 cm using a steel tape. Minimum waist circumference was measured on bare skin during mid-respiration level with the umbilicus. Hip girth was measured at the maximum circumference of the buttocks. To compute waist-to-hip ratio, waist measured in centimeters was divided by hip measured in centimeters.

Blood pressure. A random-zero sphygmomanometer was used to determine resting blood pressure using the Heritage protocol (17). Readings were taken in the morning before 11:00 A.M. in a room with temperatures between 21 and 25°C. The women were asked to refrain from smoking or ingesting caffeine for 30 min before measurements. A measurement was considered valid as long as artery pulsations could be heard clearly and protocol was followed. The entire procedure was repeated 1 week later. An average of the six valid blood pressure measures was used for analyses.

Flexibility. Trunk flexion (16) and shoulder range-of-motion (18) tests were conducted to assess changes in flexibility resulting from the yoga practices.

Quality of life. A general measure of functioning, the Medical Outcomes Study

(MOS) Short-Form General Health Survey (19), was administered. This 12-item instrument produces highly reliable and valid scores on several important dimensions of functioning and well-being and has extensive normative data with which to compare results for patients with chronic disease, including heart disease and diabetes, and the general population. The Problem Areas in Diabetes (PAID) scale, a diabetes-specific measure of quality of life, was also used. Respondents rated the degree to which common barriers to adherence was problematic for them. This scale assessed diabetes-specific overall emotional distress, interpersonal distress, regimen-related distress, and physician-related distress. A recent 32-item revision of the PAID scale (20) produces subscales on these four dimensions as well as an overall score. The PAID scale has good construct and criterion validity and has been shown to be responsive to psychosocial intervention. We used two of the four PAID scales: the regimen-related and interpersonal distress scales.

Statistical analysis

ANOVAs were conducted to evaluate the baseline equivalence of conditions and characteristics of individuals present versus absent at the 6-month follow-up. Multivariate analyses of covariance (MANCOVAs) were used to control the experiment-wide error rate in evaluating program outcomes. Six separate MANCOVAs were conducted to evaluate 6-month intervention effects on *1*) the biological outcomes of serum lipids (e.g., total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides) and HbA_{1c}, *2*) body composition (BMI and waist-to-hip ratio), *3*) blood pressure (systolic and diastolic), *4*) plasma fatty acids, *5*) flexibility (range of motion and sit-and-reach), and *6*) quality of life (MOS-12 and PAID). When the overall MANCOVA was significant, follow-up ANCOVAs were conducted to identify specific variables accounting for the differential change. In all analyses, baseline scores on the dependent variable served as covariates.

RESULTS — Comparisons of study participants and individuals declining participation indicated no statistically significant differences in self-reported age, BMI, age diagnosed with diabetes, type of diabetes medication, or percent of smokers. However, relative to nonparticipants, participants reported taking diabetes medications for fewer years (4.9 vs. 6.7, $P = 0.006$) and had been diagnosed with diabetes for fewer years (8.5 vs. 10.2, $P = 0.027$). Analysis of baseline characteristics of women assigned to UC versus MLP indicated that, with the exception of the percent of women on estrogen replacement therapy (59.3% in MLP vs. 46.6% in UC, $P = 0.037$), no differences between conditions were found on any of the demographic and medical history variables. All of the MANCOVAs were reanalyzed using estrogen replacement therapy as a covariate. Significance and conclusions from these reanalyses were identical to those without this covariate. Most women had lived with diabetes for a number of years and had other chronic diseases (most commonly arthritis and hypertension).

Biologic outcomes

As shown in Table 1, the MANCOVA for HbA_{1c} and serum lipids revealed significant differences in favor of the MLP participants [Wilks' $\lambda = 0.94$, $F(5,224) = 2.77$; $P = 0.019$]. For the MLP women, HbA_{1c} decreased from a baseline level of 7.43 to 7.07 mg/dl ($P = 0.001$) at 6 months (a 0.4% reduction), whereas that of the control subjects remained at 7.4 mg/dl during the same period. The 6-month differences between UC and MLP on total cholesterol, triglycerides, and LDL and HDL cholesterol did not achieve statistical significance but favored the MLP condition (Table 1).

Other favorable changes in risk factor status occurred for women in the MLP condition. The overall MANCOVA for body composition was significant [Wilks' $\lambda = 0.96$, $F(2,229) = 4.20$; $P = 0.015$]. There was a significant decrease in BMI in MLP women compared with UC. The follow-up analysis revealed a drop of 0.37 in BMI from baseline to the 6-month follow-up in the MLP women and an increase of 0.20 in BMI for the UC group. There was a corresponding significant decrease in weight in favor of the MLP condition (covariate-adjusted 6-month follow-up scores of 91.6 kg for MLP vs. 93.4 kg for UC). Body fat distribution, assessed using the waist-to-hip ratio, did not reach statistical significance.

Quality of life

The MANCOVA across all quality-of-life dimensions revealed overall improvement in favor of the MLP participants [Wilks' $\lambda = 0.95$, $F(4,234) = 2.95$; $P = 0.021$]. Follow-up analyses revealed significantly greater improvement in quality of life as measured by the PAID regimen-related distress dimension (covariate-adjusted 6-month follow-up scores of 14.8 for MLP vs. 16.2 for UC). A score ≥ 16 on a PAID scale indicates the area is likely to represent a problem area. The interpersonal distress PAID scale and the two scales of the MOS Short-Form 36 were nonsignificant.

Blood pressure and flexibility

While the MLP condition improved and the UC condition slightly worsened on blood pressure and flexibility, the overall MANCOVAs for these 6-month differences did not achieve statistical significance (Table 1).

Plasma fatty acids

The MANCOVA for the plasma fatty acid profile neared statistical significance ($P = 0.059$). It is interesting to note that this change was produced by a small but significant increase in the plasma level of epicosapentaenoic acid (EPA) (EPA 20:5 n-3). The level of the other major n-3 fatty acids, α-linolenic acid (18:3 n-3) and docosahexaenoic acid (22:6 n-3), was not changed by the intervention.

Impact of attrition

Six-month follow-up data were collected on 245 (88%) of the randomized participants. It was not possible to collect 6-month data on 6.9% of the participants from UC and 16% from MLP. Two-way ANOVAs of the baseline characteristics of dropouts versus participants present and treatment condition revealed no significant main effects or interactions with treatment condition on any of the following characteristics: age, number of years diagnosed with diabetes or taking diabetes medications, smoking status, level of education, living arrangement, ethnicity, type of diabetes medication, number of comorbidities, diabetes complications, employment status, BMI, waist-to-hip ratio, or baseline HbA_{1c}.

We tested the robustness of all significant findings by conducting a second analysis using the last-observation-carried-forward method for imputing

Table 1—*Physiological outcomes*

	Group	Assessments		Significance of MANCOVA*	
		Baseline	6 months	Individual (6 months)	Overall (6 months)
HbA_{1c} and serum lipids					0.019
HbA_{1c} (%)	MLP (Tx)	7.43 ± 1.30	7.07 ± 1.11	0.000	
	UC (control)	7.40 ± 1.48	7.38 ± 1.33		
Triglycerides (mg/dl)	MLP (Tx)	202.38 ± 149.06	176.82 ± 113.98	0.982	
	UC (control)	171.59 ± 110.56	157.93 ± 88.82		
Total cholesterol (mg/dl)	MLP (Tx)	191.57 ± 37.84	187.61 ± 35.60	0.963	
	UC (control)	181.77 ± 36.69	180.72 ± 39.73		
HDL cholesterol (mg/dl)	MLP (Tx)	43.12 ± 11.06	43.49 ± 10.14	0.823	
	UC (control)	44.05 ± 12.69	43.46 ± 11.99		
LDL cholesterol (mg/dl)	MLP (Tx)	118.64 ± 31.97	118.43 ± 30.64	0.987	
	UC (control)	113.33 ± 30.78	114.22 ± 32.86		
BMI/waist-to-hip ratio					0.015
BMI (kg/m^2)	MLP (Tx)	35.34 ± 7.93	34.97 ± 7.85	0.009	
	UC (control)	34.87 ± 8.20	35.07 ± 8.48		
Waist-to-hip ratio	MLP (Tx)	0.91 ± .07	0.90 ± .07	0.318	
	UC (control)	0.90 ± .08	0.88 ± .08		
Quality of life					0.021
PAID social summary (score)	MLP (Tx)	12.96 ± 5.22	11.63 ± 4.33	0.871	
	UC (control)	12.55 ± 5.05	11.31 ± 4.83		
PAID self-care summary score	MLP (Tx)	19.14 ± 5.53	15.04 ± 4.68	0.005	
	UC (control)	18.03 ± 5.80	15.94 ± 5.33		
MOS-12 physical health (score)	MLP (Tx)	40.28 ± 10.60	40.68 ± 11.34	0.601	
	UC (control)	40.46 ± 12.41	41.32 ± 12.62		
MOS-12 mental health (score)	MLP (Tx)	46.60 ± 9.30	46.67 ± 9.71	0.438	
	UC (control)	46.99 ± 9.27	46.13 ± 9.45		
Blood pressure					0.069
Average systolic (mmHg)	MLP (Tx)	136.06 ± 13.91	134.21 ± 14.30	0.483	
	UC (control)	134.01 ± 14.17	131.83 ± 14.63		
Average diastolic (mmHg)	MLP (Tx)	79.29 ± 9.49	77.15 ± 8.77	0.204	
	UC (control)	77.38 ± 9.20	76.94 ± 8.33		
Plasma fatty acids					0.059
18:2 (n-6) (relative weight percent)	MLP (Tx)	23.88 ± 4.83	25.99 ± 3.91	0.573	
	UC (control)	25.20 ± 5.87	26.80 ± 5.35		
20:5 (n-3) (relative weight percent)	MLP (Tx)	0.47 ± .29	0.68 ± .40	0.022	
	UC (control)	0.51 ± .37	0.56 ± .26		
22:6 (n-3) (relative weight percent)	MLP (Tx)	0.97 ± .38	1.14 ± .47	0.864	
	UC (control)	1.00 ± .41	1.13 ± .47		
Flexibility					0.095
Sit-and-reach (percentile)	MLP (Tx)	31.91 ± 23.47	34.21 ± 27.51	0.093	
	UC (control)	32.30 ± 25.73	29.66 ± 26.80		
Range of motion (percentile)	MLP (Tx)	14.01 ± 23.10	14.23 ± 24.17	0.136	
	UC (control)	11.16 ± 22.10	9.45 ± 19.88		

Data are means ± SD. *Significance of two-tailed MANCOVA comparing MLP (treatment) and UC (control) nonadjusted follow-up scores, covarying out the effects of baseline scores and social desirability. Tx, treatment.

missing values in an intent-to-treat analysis. Baseline values were brought forward to replace missing 6-month values. With the imputed data, the analyses were repeated to include women who were not present at the 6-month follow-up. Significance and conclusions from analyses were unaltered.

CONCLUSIONS — Our earlier Women's Lifestyle Heart Trial (12) demonstrated that an intensive lifestyle change program was feasible for women with CHD, but it remained a question whether women who were at risk for, but did not have, CHD would be as motivated to complete such an intense program. Although the participation and attendance rates were not as high as the earlier program, these rates indicate that, despite the time commitment, women with type 2 diabetes viewed the MLP as attractive and feasible. We have speculated that the disproportionately higher loss to follow-up in the MLP may be due to the more demanding nature of the program for the MLP participants compared with the UC participants.

Whereas the reductions in HbA_{1c} may seem modest, the MLP condition reduced HbA_{1c} by 0.4%, significantly more than the UC condition. Epidemiological analysis of the U.K. Prospective Diabetes Study data (21) showed that for every percentage point decrease in HbA_{1c}, there was a 35% reduction in risk of complications. In our study, this would translate into a 14% reduction in risk of diabetes complications.

Fish consumption has been linked to a decreased risk of CHD in women (22). This decreased risk is associated with an increase in plasma EPA and docosahexaenoic acid content. It is interesting to note that, in this study, modest dietary intervention increased plasma EPA concentration. Because the increase in the concentration of EPA occurred without an accompanying increase in the concentration of docosahexaenoic acid, the change may have been produced by the consumption of α-linolenic acid rather than increased fish consumption.

The behavioral outcomes of this study are the focus of a separate article (D.J.T., L.A.S., R.E.G., M.B., L. Angell, unpublished data). Briefly, the MLP intervention produced consistent and significantly greater improvements than the UC in all of the five targeted behavioral risk factors: eating patterns, physical activity, social support, stress management/coping, smoking cessation (36% cessation rate in the MLP vs. 8% cessation rate in the UC), and psychosocial variables (self-efficacy, social support, and problem-solving ability). The present report indicates significantly greater improvements in the areas of weight, HbA_{1c}, eicosapentaenoic plasma fatty acid, and quality of life. Taken together, this pattern of changes could have a considerable public health impact, given the high risk for CHD and other illnesses among women with diabetes, and may justify the program's intensity. Future research is needed to evaluate the cost-effectiveness of the MLP and alternative interventions for this high-risk population.

Given their significant lifestyle, BMI, fatty acids, and HbA_{1c} improvements, it is unclear why the MLP women did not show significant improvements in lipids. In the Lyon heart study (10), reduction in coronary events and reduction in cardiac deaths of close to 70% were achieved using the Mediterranean diet, but without a reduction of total cholesterol or triglycerides, or an increase in HDL cholesterol when compared with control subjects. Similarly, we did not see a significant improvement in serum lipids in our earlier study (12). The Mediterranean diet, rich in carbohydrates and fiber, does not restrict dietary fat as severely as the Ornish diet (23), but does restrict saturated fat, which recently has been shown to reduce the incidence of CHD.

An important limitation of our earlier study was the moderate-sized sample of motivated women, which limited generalizability of results. In this trial, we addressed these earlier problems by using a population-based approach to recruitment. The study was successful in recruiting a much larger and less motivated sample of women (as evidenced by the lower participation rate in this study). In the first 6 months, the MLP showed similar improvements in diet, exercise, stress management, weight, and glycemic control as our earlier study. However, the present study lacked an ethnically diverse population. Although we recruited a sample that was heterogeneous on socioeconomic status, income, and education and representative of the local area in terms of race and ethnicity, participants were 94% Caucasian with 96% covered by medical insurance. The intensity of this program was reduced from our earlier trial because of the typically inverse relation between program intensity and reach (24). This project attempted to deliver a moderately intensive intervention in a way that attracted a high percentage of the target population. Despite this reduced intensity, the program still calls for an initial retreat and at least 6 months of weekly meetings. Even this level of intensity, plus the concurrent management of multiple lifestyle behaviors, may not be feasible for some health care systems. The women who participated in this trial were at high risk for CHD-related diseases, which are major contributions to health care costs as well as mortality. For this population, a program with this level of intensity may be warranted.

The current study has both methodological strengths and weaknesses. Strengths include the reasonably large sample size, the randomized design, the focus on multiple risk factors, the variety of biological outcomes assessed, the inclusion of quality-of-life outcomes, the multivariable analyses, and procedures to account for missing data. Limitations include the largely Caucasian sample (although a broad range of socioeconomic status was represented) and the need for longer-term follow-up. It remains for future research to determine the replicability of the intervention, especially with more diverse populations, and its cost-effectiveness relative to other programs.

We believe there are three important research questions remaining that must be addressed before this program is ready for translation to practice: *1*) Can successful outcomes be achieved in a different and more representative setting, having a larger percentage of minority participants and using regular health plan staff? *2*) How should the theory, structure, and content of the MLP be modified to make it appealing and appropriate for ethnically diverse populations? *3*) What are the costs, cost-effectiveness, and economic implications of a program like this for other ethnicities?

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