Improvement in Medical Risk Factors and Quality of Life in Women and Men With Coronary Artery Disease in the Multicenter Lifestyle Demonstration Project

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This study examined medical and psychosocial characteristics of 440 patients (mean age 58 years, 21% women) with coronary artery disease at baseline and at 3-month and 12-month follow-ups. All patients were participants in the Multicenter Lifestyle Demonstration Project, aimed at improving diet (low fat, whole foods, plant-based), exercise, stress management, and social support. Spousal participation was encouraged. Both genders evidenced significant improvements in their diet, exercise, and stress management practices, which they maintained over the course of the study. Both women and men also showed significant medical (e.g., plasma lipids, blood pressure, body weight, exercise capacity) and psychosocial (e.g., quality of life) improvement. Despite their worse medical, psychosocial, and sociodemographic status at baseline, women's improvement was similar to that of men's. These results demonstrate that a multi-component lifestyle change program focusing on diet, exercise, stress management, and social support can be successfully implemented at hospitals in diverse regions of the United States. Furthermore, this program may be particularly beneficial for women with coronary artery disease who generally have higher mortality and morbidity than men after a heart attack, angioplasty, or bypass surgery.

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Changes in lifestyle and psychosocial status can decrease morbidity, mortality, and even reverse the course of coronary artery disease (CAD).[1–4] One example is the Lifestyle Heart Trial (LHT), in which a predominantly male sample of patients was asked to make comprehensive lifestyle changes (diet, exercise, stress management, group support). Substantial decreases of cardiovascular risk factors and events, reversal of coronary atherosclerosis, and improvement in myocardial perfusion in the intervention group were reported.[2–4] To address the question of "generalizability" of this lifestyle change program to different geographic regions in the United States and to women with heart disease, the Multicenter Lifestyle Demonstration Project (MLDP) was implemented at 8 hospital sites across the United States. The MLDP asked patients with CAD to make the same intensive lifestyle changes as in the LHT.[5] Clinical improvements and substantial cost savings (due to safely avoiding revascularization for 3 years) were evident in a subsample of MLDP patients with angiographically documented CAD severe enough to be eligible for revascularization.[5] This investigation reports the medical and psychosocial characteristics of all patients enrolled in the MLDP at baseline and at 3 and 12 months into the program.

METHODS

Recruitment and procedure: Hospital site selection was based on location in geographically diverse areas with sufficient population density (>500,000 people within a 60-minute drive time of the site); a sizeable cardiology program; the demonstration of interest and support from key physicians; and the ability to convince large health insurance providers of the value of including the program in their benefit plan. Accordingly, MLDP teams were trained at 8 sites: Omaha, Nebraska; New York, New York; Des Moines, Iowa; Ft. Lauderdale, Florida; Columbia, South Carolina; Concord, California; Boston, Massachusetts; and La Jolla, California. Intervention teams consisted of a program director, medical director, exercise physiologist, stress management specialist, registered nurse as case manager, group support leader, registered dietitian, chef, and data manager.

A program staff member contacted potential participants after referral to the program either by their physicians or by self-referral as a result of local media pub-

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licity. A brief description of the program was given and demographics and health history were obtained. Eligible patients (determined by interview) were sent a description of data collection activities, a release of medical records form, a medical history questionnaire (including medication), and an informed consent form to be completed before an intake interview. Spouses were requested to accompany the patient at the intake interview. A baseline physical assessment (anthropometrics) was completed during the interview. A second interview was scheduled with the hospital team after the intake interview and records review; this included the administration of psychosocial and behavioral questionnaires, instructions for completion of a 3-day diet diary, a blood draw for baseline lipid profile, and a treadmill exercise stress test using the Bruce protocol. Medical and behavioral variables and quality of life were reassessed at 3 and 12 months.*

Participants: The research protocol was approved by the Committee on the Protection of Rights of Human Subjects, and written informed consent was obtained from participants before entering the program. The patients in this study consisted of 347 men and 93 women enrolled in the intervention arm of the MLDP.† Patients were classified into either "Group 1" or "Group 2." Group 1 consisted of men and women who had been diagnosed with CAD angiographically or by a positron emission tomography (PET) scan, or by using stress thallium or echo tests that showed myocardial ischemia sufficient to provide a clinical indication by Mutual of Omaha Insurance Company's (Omaha, Nebraska) coverage policy standards for coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA). Medical indications for angiography were determined by local medical practice standards. The policy standards for CABG or PTCA authorization were: (1) ischemia with 3-vessel coronary disease and exercised-induced left ventricular dysfunction with ejection fraction of $<50\%$; or (2) an episode of unstable angina pectoris within the previous 3 months that responded to inpatient medical management, now recurring despite maximal pharmacomedical therapy, and an angiogram showing $\geq$2-vessel disease; or (3) an acute myocardial infarction within the last 6 months with $>50\%$ residual stenosis in a single vessel after successful thrombolytic reperfusion; or (4) unstable or stable angina that persists despite pharmacologic therapy with nitrates, β blockers, or calcium antagonists and a $\geq 50\%$ stenosis in ≥ 1 vessel or in an aortocoronary graft.

Patients who met any of the previously mentioned criteria were further screened to determine whether they would be medically safe if deferring a revascularization procedure. Patients were excluded from the study if they had ≥ 1 of these conditions: (1) left main CAD with $>50\%$ occlusion or left main equivalent CAD; (2) CABG within the past 6 weeks; (3) angioplasty within the previous 6 months; (4) myocardial infarction within the last month; (5) chronic congestive heart failure with New York Heart Association class symptoms III or greater and unresponsive to medications; (6) malignant uncontrolled ventricular arrhythmias; (7) hypotensive blood pressure response to exercise testing; and (8) diagnosed homozygous hypercholesterolemia. Group 2 patients consisted of those who had previous CABG or PTCA and were in stable condition. One case management specialist at Mutual of Omaha made all group determinations to ensure uniformity of group classification across hospital sites. Furthermore, all patients had to be ambulatory, free of life-threatening co-morbidities and psychiatric disturbances, and not currently using tobacco or abusing alcohol or narcotics.

Medical variables: Height was measured at baseline. The following variables were assessed at all 3 time points. Weight was measured with clothing and without shoes. Blood pressure and heart rate were measured by a trained health professional using a calibrated sphygmomanometer.[6] Angina was assessed using a modified version of the Rose Questionnaire.[7] Plasma lipids and lipoproteins were based on fasting blood samples. The frozen batches were sent to a central laboratory (Baylor College of Medicine, Houston, Texas). Standard laboratory methods of the Baylor School of Medicine Atherosclerosis Laboratory used enzymatic and colorimetric measurement procedures of Boehringer Mannheim, Mannheim, Germany (Monotest cholesterol procedure, GPO triglyceride procedure, high-density lipoprotein [HDL] magnesium sulfate extraction [Mg2+], and low-density lipoprotein [LDL] was calculated [total cholesterol $-$ HDL $+$ 0.16 $\times$ triglycerides]). Exercise capacity, or functional capacity, was assessed by symptom-limited maximal graded exercise testing using the Bruce protocol. Indications for stopping the test were provided by the American College of Sports Medicine's Guidelines for Exercise Testing and Prescription.[8] Metabolic equivalents, a measure of energy expenditure, were automatically calculated by the testing device. One metabolic equivalent equals approximately 3.5 mg of oxygen consumed per minute per kilogram of body weight. Diet assessment was based on a 3-day food diary.[9] Nutrient content was determined using a standard software program and database (Professional Diet Analyzer version 4.1; The CBORD Group, Inc., Ithaca, New York)

Psychosocial and behavioral variables: Quality of life was measured by the 8 subscales of the Medical Outcomes Study (MOS) 36-item Short-Form Health Survey (SF-36)[10] : (1) physical functioning; (2) role–

*Participation in the 1-year, hospital-based program was financially supported by the patient privately or by third-party insurance reimbursement. During this time period, medical tests and quality-of-life assessments were administered to all participants in a rigorous manner. After 1 year, participation in a self-directed program was offered to patients for another 2 years. Participation in this self-directed program was optional, inexpensive, and paid for by the patients. Only major medical variables were tracked during these 2 additional years.[5]

†The Multicenter Demonstration Project also included a control group that consisted largely of group 1 patients who were identified from the Mutual of Omaha database and matched to intervention group participants' characteristics, such as age, gender, and left ventricular ejection fraction. The main purpose of this comparison group was to determine whether comprehensive lifestyle changes would decrease primary outcomes. Results from this comparison have been reported previously.[5]

TABLE 1 Demographic and Medical Characteristics at Baseline

Variable	Men (n = 347)	Women (n = 93)	p Value
Age (yrs)	58 ± 10	59 ± 10	0.32
Education (yrs)	16 ± 3	15 ± 3	0.006
Married or cohabitating	302 (87%)	58 (62%)	0.000
Employed outside the home	236 (68%)	42 (45%)	0.000
Spousal participation	168 (49%)	23 (25%)	0.000
Family history of CAD*	198 (57%)	58 (63%)	0.09
Previous cigarette smoker	240 (69%)	52 (56%)	0.02
Diabetes mellitus	55 (16%)	36 (39%)	0.000
Systemic hypertension	163 (47%)	52 (56%)	0.25
Hyperlipidemia†	206 (59%)	66 (71%)	0.07
Previous myocardial infarction	182 (52%)	54 (58%)	0.34
Previous coronary angioplasty	159 (46%)	47 (51%)	0.42
Previous coronary bypass	171 (49%)	31 (33%)	0.006
Angina pectoris (during past 30 d)	146 (42%)	49 (53%)	0.08
Medication			
Nitrates	100 (29%)	33 (35%)	0.22
β blockers	170 (49%)	45 (48%)	0.92
ACE inhibitors	70 (20%)	21 (23%)	0.61
Calcium antagonists	161 (46%)	60 (65%)	0.002
Diuretics	30 (9%)	23 (25%)	0.000
Antihypertensives	18 (5%)	2 (2%)	0.21
Lipid-lowering therapy	179 (52%)	52 (56%)	0.48

*Family history of CAD was considered positive if a male (<60 years of age) or female (<70 years of age) first-degree relative had CAD, myocardial infarction, or a cerebrovascular accident.

†Hyperlipidemia was defined as LDL cholesterol >100 mg/dl, or HDL cholesterol ≤35 mg/dl, or triglycerides ≥200 mg/dl (National Cholesterol Education Program guidelines Adult Treatment Panel II for individuals with established CHD).

Values expressed as mean ± SD or as number of patients (%).

ACE = angiotensin-converting enzyme.

physical (limitations in usual role activities because of physical health problems); (3) bodily pain; (4) general health; (5) vitality; (6) social functioning; (7) role–emotional (limitations in usual role activities because of emotional problems); and (8) mental health. Program attendance was based on the number of meals, lectures, exercise, stress management, and group support sessions that were attended divided by the number of sessions offered. Diet adherence was measured in percent of total calories from dietary fat. Adherence to exercise and stress management were measured in hours per week during the last week. Adherence goals were 10% of total calories from dietary fat, ≥3 hours of moderate aerobic exercise per week, and ≥1 hour of stress management per day.

The following variables were assessed by standardized questionnaires at baseline only: optimism (Life Orientation Test[11]); sense of coherence,[12] measuring the extent life is perceived as comprehensible, manageable, and meaningful; perceived stress[13] during the last month; and positive and negative effect[14] experienced during the last week. Perceived self-efficacy was assessed by a questionnaire based on the "Theory of Planned Behavior[15]" on which participants rate 9 items on a 1 to 7 scale that measure their perceived effort, control, and likelihood to adhere to exercise, stress management, and diet components of the program. An overall self-efficacy factor was created using the following formula: intention + control − effort.

The lifestyle change program: The lifestyle change program included a low-fat, whole foods, plant-based diet with no more than 10% of total calories from fat (predominantly fruits, vegetables, grains, legumes, nonfat dairy, and egg whites), moderate exercise (for ≥3 hours/week according to guidelines of the American College of Sports Medicine,[8] stress management for ≥1 hour per day, and group support sessions twice a week. Details of this program have been described previously.[16–17]

Statistical analysis: The comparison of men and women in terms of baseline demographic, medical, and psychosocial factors was performed with *t* (for continuous variables) and chi-square tests (for categoric variables). These statistics were also used to evaluate baseline characteristics of patients who completed the 1-year follow-up compared with those who failed to complete the study for any reason. Analyses of variance for repeated measures were run to test for the effects of gender and time (and their interaction) on medical and psychosocial measures, program attendance, and health behaviors. Statistical analyses were performed using SPSS 11.0 (SPSS Inc., Chicago, Illinois).

RESULTS

Baseline characteristics: Demographic characteristics, medical history, and medications of the 440 patients (79% men) are listed in Table 1. One hundred ninety-four patients (44% of all men and 43% of all women) were approved for a revascularization procedure (Group 1) and 246 (56% of all men and 57% of all women) had a previous revascularization procedure and were in stable condition (Group 2). There was no significant difference in age between men and women. On average, women were socially more disadvantaged than men, evidenced by having fewer years of education and being less often employed outside the home. Women also were more likely to live alone. Women were less likely to have their partner participate in the program compared with men (25% vs 49%). They also reported more adverse health histories than men; they were more likely to be diabetic. There were trends for women to be more hyperlipidemic ($p = 0.067$) and to report more angina symptoms in the past 30 days ($p = 0.078$). Women had less often undergone CABG, had less often been smokers, and were more often prescribed calcium antagonists and diuretics. Additionally (not shown in table), women consumed less alcoholic drinks per week (mean 1.2) than men (mean 3.3; $p = 0.000$). Twenty-six percent of the women were receiving hormone replacement therapy.

Table 2 lists medical characteristics, plasma lipids and lipoproteins, and exercise capacity. Women had higher body mass index, higher heart rates at rest, and

TABLE 2 Medical Risk Factors of Men and Women at Baseline

Variable	Men	Women	p Value
Systolic blood pressure (mm Hg)	132 ± 19	135 ± 19	0.11
Diastolic blood pressure (mm Hg)	79 ± 10	78 ± 10	0.42
Heart rate at rest (beats/min)	69 ± 13	75 ± 13	0.000
Body mass index (kg/m^2)	27.8 ± 5.4	29.5 ± 6.6	0.01
Total serum cholesterol			
mmol/L	5.0 ± 1.4	5.7 ± 1.2	0.000
mg/dl	195 ± 53	221 ± 45	
LDL			
mmol/L	3.1 ± 1.2	3.5 ± 1.1	0.001
mg/dl	118 ± 45	136 ± 41	
HDL			
mmol/L	0.9 ± 0.3	1.2 ± 0.3	0.000
mg/dl	34 ± 10	44 ± 12	
Triglycerides			0.72
mmol/L	2.6 ± 2.6	2.5 ± 1.3	
mg/dl	230 ± 225	221 ± 112	
Exercise capacity (metabolic equivalents)	10.0 ± 3.0	7.5 ± 2.3	0.000

TABLE 3 Psychosocial and Behavioral Characteristics at Baseline

Variable	Men (n = 347)	Women (n = 93)	p Value
MOS SF-36*			
Physical functioning	76.8 ± 20.0	60.7 ± 22.5	0.000
Role–physical	65.5 ± 38.4	48.1 ± 41.3	0.000
Bodily pain (reverse-scored)	70.2 ± 23.4	63.1 ± 24.2	0.01
General health	58.7 ± 21.3	53.7 ± 19.6	0.04
Vitality	55.9 ± 21.6	46.6 ± 20.0	0.000
Social functioning	78.9 ± 23.0	72.6 ± 25.3	0.02
Role–emotional	74.6 ± 36.5	64.5 ± 39.6	0.02
Mental health	70.5 ± 17.0	67.1 ± 16.0	0.09
Perceived stress	14.8 ± 6.3	17.9 ± 6.4	0.001
Sense of coherence	66.9 ± 11.6	65.8 ± 12.4	0.49
Optimism	21.6 ± 4.9	20.0 ± 5.2	0.02
Positive effect	15.1 ± 4.8	15.1 ± 4.9	0.92
Negative effect	7.7 ± 4.4	8.4 ± 4.7	0.29
Self-efficacy—diet†	8.7 ± 3.3	8.0 ± 3.2	0.05
Self-efficacy—exercise†	9.3 ± 3.1	8.1 ± 3.2	0.001
Self-efficacy—stress management†	7.0 ± 3.5	7.4 ± 3.6	0.29
Diet (% of total calories from fat)	13.1 ± 8.4	16.9 ± 8.8	0.000
Exercise (h/wk)	2.36 ± 2.1	1.4 ± 1.4	0.000
Stress management (h/wk)	0.5 ± 1.3	0.6 ± 1.3	0.46

*Values range from 0 to 100; greater scores indicate better quality of life.
†Values range from −5 to +13; greater scores indicate greater perceived self-efficacy.

lower exercise capacity, but did not differ significantly with regard to blood pressure compared with men. Women had a more adverse lipid profile with respect to total cholesterol and LDL cholesterol than men but had higher levels of HDL cholesterol.

Table 3 lists psychosocial and behavioral characteristics. Overall, women's psychosocial profile was more adverse than men's, with the exception of "sense of coherence" and "positive and negative affect," which were similar for both genders. Women reported more physical, social, and emotional dysfunction, more bodily pain, less vitality, and poorer overall health than men did on the MOS SF-36. Women also perceived more stress, were less optimistic, and saw themselves as less efficacious than men in regard to following the diet and exercise components, but not the stress management component. Women's current health practices mirrored these gender differences: women exercised less, consumed more calories from dietary fat, but did not differ in time spent managing their stress.

Participant characteristics at follow-up (medical risk factors and health behaviors): Changes in medical risk factors and health behaviors are listed in Table 4. In both genders, body weight, blood pressure, heart rate at rest, total cholesterol, and LDL cholesterol significantly decreased, and exercise capacity was improved. Improvements in most of these risk factors were evident by 3 months and were maintained at 12 months. In regard to HDL cholesterol, there was a decrease at 3 months for both genders, but a return to baseline levels by 12 months. Triglyceride levels remained unchanged. Reports of angina in men decreased from 42% at baseline to 29% 3 months later, to 20% after 1 year (for women, the corresponding percentages were 53%, 35%, and 27%). Both genders improved at comparable rates. Changes in lipid-lowering medications are unlikely to explain the decreases in total cholesterol or LDL cholesterol because their use was similar at all time points (about 50% of patients used these medications). Both genders improved their health behaviors over the study period. Although women's intake of dietary fat was higher than men's at baseline, both genders met the program criteria of limiting their total percentage of calories from fat to no more than 10% at the 2 follow-ups. Similarly, at 3 months, men and women met the program criteria of exercising ≥3 hours/week. However, at all 3 time points, women exercised significantly less than men ($p < 0.001$). There was no significant gender by time interaction, suggesting that exercise improved similarly for both genders. Finally, with regard to stress management, men and women fell short (by about 2.5 hours/week) of the recommended guidelines. However, both genders did increase time spent in stress management by approximately 4 hours/week. Attendance of program sessions (not shown) was higher at 3 months (ranging from 89% to 93%, depending on component) than at 12 months (ranging from 74% to 79%). Overall, women attended fewer exercise and group support sessions than men (exercise 81% vs 85%, group support 82% vs 85%; $p < 0.05$). No significant gender differences were found for stress management (women 83%, men 85%).

Psychosocial variables: Only the MOS SF-36 was administered at the follow-ups, allowing for comparisons of changes in quality of life between time points and gender (Table 5). Men and women had signifi-

TABLE 4 Medical Risk Factor Profile and Health Behaviors of Patients With Complete Data at Baseline and 3 and 12 Months

Variable	Baseline	3 Mo	1 Yr	p Value Time	p Value Gender	p Value Time/Sex
Systolic blood pressure (mm Hg)						
Men	132 ± 18	127 ± 18	129 ± 19	0.001	0.18	0.81
Women	135 ± 18	129 ± 18	133 ± 17			
Diastolic blood pressure (mm Hg)						
Men	79 ± 10	74 ± 11	76 ± 11	0.000	0.60	0.76
Women	79 ± 9	76 ± 12	76 ± 11			
Heart rate at rest (beats/min)						
Men	69 ± 13	65 ± 12	68 ± 13	0.000	0.000	0.95
Women	76 ± 13	72 ± 14	75 ± 12			
Body weight (kg)						
Men	86.8 ± 17.7	82.8 ± 14.3	82.4 ± 13.9	0.000	0.000	0.37
Women	77.1 ± 17.7	72.5 ± 16.3	71.5 ± 16.2			
Total serum cholesterol						
Men						
mmol/L	5.1 ± 1.5	4.6 ± 1.5	4.6 ± 1.0	0.000	0.000	0.51
mg/dl	195 ± 56	177 ± 57	179 ± 37			
Women						
mmol/L	5.6 ± 1.0	5.3 ± 1.0	5.2 ± 1.1			
mg/dl	218 ± 39	204 ± 40	200 ± 43			
LDL						
Men						
mmol/L	3.1 ± 1.2	2.6 ± 1.0	2.7 ± 0.9	0.000	0.03	0.31
mg/dl	120 ± 46	101 ± 40	104 ± 33			
Women						
mmol/L	3.4 ± 1.0	3.0 ± 1.0	2.9 ± 0.9			
mg/dl	132 ± 37	115 ± 37	111 ± 33			
HDL						
Men						
mmol/L	0.9 ± 0.3	0.8 ± 2.1	0.9 ± 0.2	0.000	0.000	0.79
mg/dl	35 ± 10	31 ± 8	34 ± 9			
Women						
mmol/L	1.2 ± 0.3	1.1 ± 0.4	1.2 ± 0.4			
mg/dl	44 ± 12	41 ± 14	45 ± 14			
Triglycerides						
Men						
mmol/L	2.6 ± 2.8	2.7 ± 2.1	2.6 ± 2.2	0.20	0.85	0.48
mg/dl	231 ± 247	238 ± 183	232 ± 189			
Women						
mmol/dL	2.5 ± 1.3	2.9 ± 1.9	2.5 ± 1.5			
mg/dl	215 ± 112	250 ± 165	221 ± 128			
Exercise Capacity (metabolic equivalents)						
Men	10.1 ± 3.0	11.8 ± 2.7	12.2 ± 2.8	0.000	0.000	0.10
Women	7.8 ± 2.6	8.8 ± 2.8	9.4 ± 3.0			
Diet (% of total calories from fat)						
Men	12.8 ± 7.8	6.3 ± 2.2	6.3 ± 2.6	0.000	0.000	0.01
Women	16.9 ± 8.5	6.9 ± 2.4	7.6 ± 4.1			
Exercise (h/wk)						
Men	2.3 ± 1.9	4.0 ± 2.3	3.7 ± 2.2	0.000	0.000	0.84
Women	1.4 ± 1.4	3.2 ± 1.4	3.0 ± 1.6			
Stress management (h/wk)						
Men	0.5 ± 1.3	5.60 ± 2.5	4.8 ± 2.9	0.000	0.39	0.76
Women	0.5 ± 1.0	5.4 ± 2.4	4.5 ± 2.7			

cantly improved all areas of quality of life during the study. Women had made even greater progress than men with regard to physical functioning, role–physical, and role–emotional.

Participants lost during follow-up: Twenty-seven percent of women and 21% of the men did not complete the 1-year follow-up. Women completing the follow-up (n = 68) were younger (p = 0.009) and more likely to be employed (p = 0.044). Men completing the follow-up (n = 274) were more likely to have a history of PTCA (p = 0.026) and a family history of CAD (p = 0.004), were more often previous smokers (p = 0.033), consumed less alcohol (p = 0.042), were living with someone (p = 0.020), and cohabitating men tended to have their partner participate (p = 0.054). Men who completed the program also expressed greater self-efficacy toward adherence to the program components (p = 0.071 for diet; p = 0.005 for exercise; and p = 0.012 for stress management). There were no other statistically significant differences in demographic, medical, or psychosocial characteristics between those who completed the follow-up and those who did not.

TABLE 5 Quality of Life (MOS SF-36) at Baseline and at 3 and 12 Months*

Variable	Baseline	3 Mo	12 Mo	p Value Time	p Value Sex	p Value Time/Sex
Physical functioning						
Men	77.9 ± 19.5	86.7 ± 14.1	87.8 ± 15.6	0.000	0.000	0.02
Women	61.7 ± 22.4	74.0 ± 20.0	78.1 ± 18.3			
Role–physical						
Men	66.6 ± 38.1	79.0 ± 33.2	81.4 ± 31.7	0.000	0.03	0.006
Women	48.1 ± 41.2	75.0 ± 34.5	77.7 ± 34.3			
Bodily pain (reverse-scored)						
Men	70.7 ± 22.9	76.2 ± 21.9	79.5 ± 20.3	0.000	0.005	0.61
Women	63.3 ± 23.8	70.9 ± 21.8	71.4 ± 20.4			
General health						
Men	59.5 ± 21.0	70.2 ± 19.7	71.7 ± 21.7	0.000	0.03	0.95
Women	53.5 ± 20.7	65.0 ± 19.0	66.3 ± 21.3			
Vitality						
Men	56.1 ± 21.8	68.9 ± 17.0	68.1 ± 18.6	0.000	0.001	0.35
Women	46.0 ± 22.2	62.2 ± 20.6	60.5 ± 21.4			
Social functioning						
Men	79.4 ± 22.8	87.1 ± 19.0	86.7 ± 21.0	0.000	0.07	0.18
Women	72.2 ± 24.8	85.4 ± 20.2	83.0 ± 20.3			
Role–emotional						
Men	75.7 ± 35.0	83.4 ± 32.4	85.4 ± 29.2	0.000	0.03	0.05
Women	61.6 ± 39.3	81.8 ± 30.5	77.3 ± 34.2			
Mental–health						
Men	71.1 ± 16.5	79.6 ± 13.3	79.0 ± 14.9	0.000	0.02	0.61
Women	65.2 ± 16.6	76.2 ± 16.3	75.3 ± 17.2			

*Values range from 0 to 100; higher scores indicate better quality of life.

DISCUSSION

The results of this study indicate that this program of comprehensive lifestyle changes can be successfully implemented at hospitals across the country. By the end of 1 year, participants of both the LHT[2] and the MLDP reported similar levels of dietary fat intake (LHT, 6.8% of total calories from fat; MLDP, 6.3% for men, 7.6% for women). However, MLDP participants spent fewer hours per week exercising (men 3.7; women 3.0) and practicing stress management (men 4.8; women 4.5) than LHT patients (exercise 4.4; stress management 9.6). Risk factor levels in the MLDP were similar to those observed in LHT patients after participating in the program for 1 year. For example, total cholesterol and LDL cholesterol levels in the MLDP were 4.6 mmol/L (179 mg/dl) and 2.7 mmol/L (104 mg/dl) for men, and 5.2 mmol/L (200 mg/dl) and 2.9 mmol/L (111 mg/dl) for women. In the LHT these values were 4.5 mmol/L (171 mg/dl) for total cholesterol and 2.5 mmol/L (95 mg/dl) for LDL cholesterol. HDL cholesterol and triglyceride levels did not change from baseline to the 1-year follow-up in either study. Both systolic and diastolic blood pressure dropped significantly in the MLDP for both genders. These decreases in blood pressure were of the same magnitude in the LHT, but the number of observations in the LHT was too low to reach statistical significance. Mean weight loss in the LHT was larger than in the MLDP (10.1 kg in the LHT; 4.4 kg for men and 5.6 kg for women in the MLDP), which may be attributable to the higher levels of exercise in the LHT. The observed improvements in the MLDP were already evident at 3 months and were maintained (or improved even further) by the end of 12 months.

Consistant with other studies,[18–23] women in our sample had poorer socio-demographic, medical, and psychosocial characteristic than men. These characteristics did not appear to contribute much to women's slightly higher drop-out rate. Comparisons of baseline characteristics of all patients who stayed in the program with those who dropped out revealed that barriers to program completion in women were older age and not being employed outside the home (which was primarily due to older age). Barriers to program completion in men included single marital status, lack of spousal support, and lack of self-efficacy regarding program adherence.

Our findings indicate that the benefits of this program accrue to women with heart disease, despite their worse status at baseline. Women adhered to the prescribed treatment guidelines, made significant improvements regarding diet and exercise, and increased their hours of exercise per week as much as men did. Moreover, unlike other studies,[24] women in this study had participation rates only slightly lower than men. Considering that women have a worse prognosis after a heart attack, angioplasty, or bypass surgery than men do,[25] this lifestyle change program may be particularly beneficial for women with heart disease.

Unfortunately, very few women (some estimate as low as 5%[21]) participate in cardiac rehabilitation programs. One explanation may be that women are less likely to be referred to the programs.[26] Given that a physician's recommendation is a very important factor in a patient's decision to participate in a rehabilitation program,[24] every effort should be made to increase women's confidence toward program adherence and to educate physicians on the benefits for women. In addition to lack of physician referral, current cardiac

rehabilitation programs may not be meeting women's needs.[24,27] One major criticism of traditional programs is their almost exclusive focus on exercise, which, by itself, appears to be of limited value in cardiac rehabilitation[28] and may not appeal very much to women with CAD.[28,29] Our findings appear to support the previously mentioned criticisms. Women in the MLDP exercised less than men, had lower exercise capacity, and expressed less confidence in following the exercise component.[‡] Programs combining exercise recommendations with dietary instruction appear to have a larger percentage of female participants.[21,30] The additional program components of stress management and group support in the MLDP may have been responsible for our comparatively high participation rates (21%) among women. The results of the MLDP demonstrate that a multi-component cardiac rehabilitation program focusing on diet, exercise, stress management, and social support can be successfully implemented at hospitals in diverse regions of the United States, with demonstrated benefits for both genders.

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APPENDIX

Multicenter Lifestyle Demonstration Research Group:

Preventive Medicine Research Institute, Sausalito, California: Dean Ornish, MD—President and Director; James H. Billings, PhD, MPH—Director of Clinical Services; Lee Lipsenthal, MD—Medical Director; Melanie Elliott-Eller, RN, MSN—Hospital Liason, Director of Nursing Services; Terri Merritt-Worden, MS—Hospital Liaison, Director of Exercise Science Services; Nischala Devi—Director of Stress Management Services; Sarah Ellis, RD—Director of Nutrition Services; Helen Roe, RD—Former Director of Nutrition Services; Larry Scherwitz, PhD—Director of Research; Jean-Marc Fullsack—Director of Food Services; Glenn Perelson—Director of Network Development; Patty McCormac, RN—Hospital Liaison; Ruth Marlin, MD—Hospital Liaison; Ana Regalia, CPA—Director of Grants and Contracts; Bryce Williams, MS—Controller; *Massachusetts General Hospital Data Coordinating Center, Charlestown, Massachusetts:* Alexander Leaf, MD—Director; Judy Scheer, MPH, RN—Center Coordinator; David Schoenfeld, PhD—Consulting Statistician.

Program Sites:

Alegent Immanuel Medical Center/Alegent Heart Institute, Omaha, Nebraska: Richard Collins, MD—Medical Director; Sheila McGuire—Program Director; *Alegent Bergen Mercy Medical Center, Omaha, Nebraska:* Dennis Tierney, MD—Medical Director; Steve Luppes—Program Director; *Beth Israel Medical Center, New York, New York:* Steven Horowitz, MD—Medical Director; Roberto Roberti, MD—Co-Medical Director; Laurie Jones—Program Director; *Mercy Hospital Medical Center/Iowa Heart Center, Des Moines, Iowa:* William Wickemeyer, MD—Medical Director; Philip Bear, MD—Co-Medical Director; Shakun Advani, MD—Co-Medical Director; Diane McIlhon, RD—Program Director; *Broward General Medical Center, Ft. Lauderdale, Florida:* Brenda Sanzobrino, MD—Medical Director; Carroll Moody, MD—Co-Medical Director; Michael Chizner, MD—Co-Medical Director; Terry Ray, RN—Program Director; *Palmetto Richland Memorial Hospital, Columbia, South Carolina:* Donald Saunders, MD—Medical Director; Joseph Hollins, MD—Co-Medical Director; Donna Greenwold, RN—Program Director; *Mt. Diablo Medical Center/Heart Health Center, Concord, California:* Peter Kunkel, MD—Medical Director; Lynn Olison, PhD—Program Director; *Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, Massachusetts:* Jackie Hart, MD—Medical Director; Caitlin Hosmer, RD—Program Director; *Scripps Health, Shiley Sports & Health Center, La Jolla, California:* Erminia Guarneri, MD—Medical Director; Betty Christensen—Program Director.

[‡]Both genders attended >80% of exercise sessions and had significant increases in exercise capacity.

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