PHYSIOLOGIC AND RELATED BEHAVIORAL OUTCOMES FROM THE WOMEN'S LIFESTYLE HEART TRIAL[1,2]

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ABSTRACT

The Women's Lifestyle Heart Trial was a small (N = 28) randomized controlled trial to evaluate the effects of a comprehensive lifestyle self-management program (very low-fat vegetarian diet, stress-management training, exercise, group support, and smoking cessation) on reduction of cardiovascular risk factors in postmenopausal women with coronary heart disease (CHD). Women assigned to the treatment condition (Prime Time) participated in a week-long retreat followed by twice-weekly 4-hour meetings. Endpoints were program adherence; changes in lipid profiles, body mass, blood pressure, hypolipidemic and antihypertensive medications; and quality of life. Risk factor and psychosocial evaluations were conducted at baseline and at 4, 12, and 24 months. Repeated measures analyses of covariance revealed that the dietary, stress management, and physical activity changes made by intervention women were dramatic and lasting. There were significantly greater improvements in the Prime Time condition compared to the usual care control group on body mass, angina symptoms, and quality of life, and a tendency for a greater reduction in blood pressure-lowering medications. Similar patterns were seen in lipids, blood pressure, and lipid-lowering medications, but did not reach significance. These results demonstrate that postmenopausal CHD women can make lasting lifestyle changes, and that these changes may reduce the need for cardiac medications and improve CHD risk factors and quality of life.

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INTRODUCTION

Coronary heart disease (CHD) is the leading cause of death among women in the United States (1). In 1990, it accounted for 236,574 deaths in females and approximately 197,680 (75%) mortalities per year among postmenopausal females (2,3). Exclusion of females, especially older women, from CHD research has been commonplace (4). Relatively little research has focused on strategies to promote healthier lifestyles for women with CHD (5). Of the reports on treatment of CHD that have included women, most have focused on drug therapy and invasive interventions such as coronary bypass surgery or coronary angioplasty (6). Resource intensive technologies such as coronary bypass surgery have become focal points for the debate over cost control and adequate access to health care (7). Strategies to promote healthier lifestyles for health care consumers—as opposed to surgical or medical procedures—may ultimately reduce the use of medical services and help to contain costs, as well as prevent initial or recurrent heart attacks (8).

There is convincing evidence that improvements in lifestyle behaviors, which include smoking cessation (9), diet (10), exercise (11), and stress management (12,13), can reduce further heart disease problems. However, it is clear that an individual's risk for developing heart disease is not a result of one risk factor in isolation, but rather a product of a complex set of risk factors, and the contribution of each to overall risk varies from person to person (14,15). While available data strongly implicate the contribution of these risk factors to heart disease, investigations aimed at intervening simultaneously on combinations of factors are practically nonexistent (13,16–18).

Few investigators (19–23) have studied a comprehensive lifestyle program for treating CHD. Compared to their control group counterparts, patients participating in these studies have generally had slower rates of progression, and even regression, of coronary lesions. Ornish et al. (24) performed a prospective randomized controlled trial of multiple lifestyle changes versus usual care in patients with clinically manifest coronary disease. The Comprehensive Lifestyle Program (CLP) consisted of a very low-fat diet, smoking cessation, stress-management training, moderate aerobic exercise, and group support. Of 48 patients randomized to experimental or control groups, 41 had undergone repeat coronary arteriography at Year 1. Their average percent diameter stenosis regressed from 40.0% to 37.8% in the experimental group and progressed from 42.7% to 46.1% in the control group ($p < 0.001$).

The purpose of the PrimeTime program was to develop and evaluate an intervention to improve self-care and reduce secondary CHD risk among postmenopausal CHD women, using the procedures developed by Ornish (13,25) for the Lifestyle Heart Trial. This report presents the effects of the PrimeTime program on lowering cardiovascular risk factors and improving quality of life in these women.

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METHODS

Study Design and Participants

The PrimeTime program was promoted extensively among local physicians and through presentations, mailings, individual meetings, and the local media. Persons interested in the project called to receive a description of the project and to determine eligibility. Eligibility requirements included being a postmenopausal female and having documented CHD defined as atherosclerosis, myocardial infarction (MI), percutaneous transluminal coronary angioplasty, and/or coronary bypass graft surgery. Exclusion criteria employed by Ornish et al. (24,25), including having other life-threatening illnesses, infarction during the preceding 6 weeks, receiving streptokinase or alteplase, or being scheduled for bypass surgery, were used. CHD documentation and permission from one's primary care physician and cardiologist were required. Participants completing baseline assessment (75% of those expressing interest and eligible) were stratified and then randomized to either the PrimeTime program or to usual care (UC). Stratification was by: (a) total/HDL cholesterol ratios of greater than versus less than 6.0, (b) smoking status, and (c) presence or absence of diabetes. Since these are major risk factors for CHD in women and given the small sample size, we anticipated that a predominance of one of these risk factors in either the treatment or control group could overpower the effects of the intervention. Participants were assessed at baseline and at 4, 12, and 24 months.

PrimeTime Intervention

Participants randomized to the PrimeTime program began the intervention with a 7-day retreat (24). Each woman was encouraged to bring her spouse or a support partner who had agreed to assist her in carrying out the program. The daily schedule for the retreat included cooking classes, and meals were planned by the project dietician to follow the Reversal Diet (13) guidelines (e.g. vegetarian, less than 10% calories from fat).

Study participants received instruction in, and had an opportunity to practice, stress-management techniques twice per day during the retreat led by a certified Yoga instructor. The stress-management techniques included Hatha Yoga stretches, progressive deep relaxation, deep breathing, meditation, and directed or receptive imagery (i.e. visualizing improvements occurring in the heart). The women were asked to practice these techniques 1 hour per day and were given audiocassette tapes to assist them.

Daily group physical activity sessions included warm-up, walking or aerobics, and a cool-down led by an American College of Sports Medicine certified exercise physiologist. Participants were individually prescribed exercise intensity based on their treadmill exercise test performance. Following the retreat, the intervention exercise program required participants to engage in a 1-hour session per day at least 3 days each week.

Retreat evenings ended with small, relatively unstructured group sessions for sharing feelings. Participants discussed difficulties with program components and emotional issues as they arose, practiced communication skills, and engaged in exercises to build group support and decrease feelings of social isolation. Group leaders emphasized unconditional positive regard and encouraged participants to share feelings rather than thoughts and to refrain from offering advice.

Twice-weekly 4-hour meetings followed the retreat. Each meeting followed a sequence similar to the retreat schedule: (a) supervised exercise training, (b) Yoga and relaxation led by a trained instructor, (c) one prepared meal and one potluck per week, and (d) small group discussions similar to those held during the retreat.

PrimeTime participants were instructed to adhere to the Reversal Diet (13), which contains no animal products other than egg whites and nonfat yogurt and no added oils or other concentrated fats. The high-fiber diet contains less than 10% of calories from fat, 70% to 75% of calories from carbohydrates, 15% to 20% of calories from protein, and 5 milligrams of cholesterol per day. After 15 months, the twice-weekly group meetings were reduced to 2-week intervals for 6 months, then reduced to once per month for the final 3 months.

Measures

A demographic/medical history questionnaire was administered in which participants identified the presence or absence of 15 comorbidities. The behavioral measures have been previously described (23). Dietary measures consisted of the Kristal Food Habits Questionnaire (FHQ) (26), a 4-day food record (27), and a paper-and-pencil dietary fat intake screener (28). The FHQ, a 20-item questionnaire, was employed to measure behaviors associated with eating low-fat foods. Participants' 4-day food records were scored to determine average daily percent of calories consumed from fat and saturated fat, using the Minnesota Nutrition Data System (NDS) software (29). The fat screener (28) provided an estimate of daily grams of fat.

Exercise measures consisted of the Stanford 7-Day Recall (30), which provided average kilocalories expended per day, and a composite score from our Summary of Self-Care Activities Questionnaire (31).

Stress-management activities were assessed using the Summary of Self-Care Activities Questionnaire (31).

Current medications, including antihypertensive and hypolipidemic medications, a reflection of physiological outcomes, were obtained by interview.

Serum lipid profiles (mg/dl), blood pressure, and body mass index (BMI) were the physiological endpoints to document changes in CHD risk. The serum lipid profile was measured once at each endpoint to contain costs and lessen the demand on the participant's time. Fasting plasma total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), and triglycerides (Tg) were measured directly, and low-density lipoprotein cholesterol (LDL-C) was calculated using the formula: LDL-C = TC − (TG/5 + HDL-C). The Colin STBP-680 automated blood pressure unit was used to determine resting blood pressure, using the Heritage protocol (32). An average of six valid blood pressure readings was used for analyses.

A measure of weight (kg) was taken in the morning in the fasting state, in stocking feet on a calibrated Cardinal Detecto Electronics digital readout scale. The scale, which has a capacity of 400 pounds (by 2 graduation values), is accurate to plus or minus 1 graduation. The scale was situated on a tile floor. Height, measured using a height bar attached to the scale and with participants standing without shoes and with head straight, was rounded to the nearest 0.5 cm. Measurements were converted to BMI (kg/m^2). Frequency, duration, and severity of angina were reported using the Rose Chest Pain Questionnaire (33). Also calculated was a Framingham Heart Study (34) score for CHD women, which corresponds with an estimated percent risk of having another heart attack, stroke, or death from CHD in the next 2 years. This score calculates heart disease risk in terms of age, HDL cholesterol, systolic blood pressure, cigarette smoking, and presence or absence of diabetes.

A general measure of functioning, the Medical Outcomes Study (MOS) Short-Form General Health Survey (SF-36) (35) was administered to assess quality of life.

Statistical Analyses

A series of one-way analyses of variance (ANOVA) were conducted to evaluate baseline equivalence of conditions and subject attrition. Given the small sample size and large number of measures, multivariate analyses of covariance (MANCOVA) were used to control experiment-wide error rate in evaluating program outcomes. MANCOVAs were conducted to evaluate intervention effects on three behavioral components (PrimeTime program adherence to dietary, physical activity, and stress management) and serum lipids (cholesterol, LDL, HDL, and triglycerides). Where the overall MANCOVA was significant, follow-up analyses of covariance (ANCOVAs) were conducted to identify variables accounting for the differential change. In all analyses, baseline scores on the dependent variable, the Social Desirable Responding Scale (36) (for psychosocial measures), and number of comorbid chronic diseases served as covariates. The MANCOVAs were repeated on data collected at the 4-, 12-, and 24-month assessments.

RESULTS

Twenty-eight participants who completed baseline assessments were randomized into the study. After the retreat, three PrimeTime participants were lost to follow-up. Of those, two experienced discomfort with the program and one died of an acute myocardial infarction prior to the 12-month follow-up. Twenty-five participants completed the 24-month follow-up.

The baseline sample reported here is comprised of the 25 participants who completed the 24-month follow-up. As can be seen in Table 1, no differences between conditions were found on any of the demographic and medical history variables with the exception of number of comorbid chronic diseases. Most patients had lived with their heart disease for a number of years, and 97% of the baseline sample also had other chronic diseases, most commonly arthritis, hypertension (each affecting 68% of subjects), and diabetes (44%). The UC group had an average of 4.1 comorbid chronic illnesses and the PrimeTime group had an average of 2.6 ($F = 5.1, p < .02$). The mean age was 63 with 32% of participants older than 70 years of age. Thirty-six percent of the participants were treated with cholesterol-lowering medication at baseline, and 40% were receiving hormone replacement therapy.

Program Adherence

Attendance: Attendance at the twice-weekly 4-hour meetings for the duration of the 15-month treatment phase was good, with PrimeTime women attending an average 81% and support partners attending an average 70% of the sessions ($SD = 13$; range = 64 to 104 of 118 total). During the maintenance phase, attendance for PrimeTime women at the 16 sessions ranged from 1 to 16 sessions (Mean = 10).

Behavioral Outcomes: A series of three multivariate repeated measures analyses of covariance were conducted to evaluate the intervention effects on the following sets of measures: (a) dietary behavior, (b) physical activity, and (c) stress management. As shown in Table 2, the PrimeTime group showed significantly greater improvement on percent of dietary total and saturated fat than did the UC group, but not on total caloric intake. Data from 4-day food records indicated that the intervention produced large,

TABLE 1
Baseline Comparisons of the Usual Care Versus the PrimeTime Participants

Patient Characteristic	PT ($n = 14$) Mean (*SD*) or *n*	UC ($n = 11$) Mean (*SD*) or *n*	Significance*
Years diagnosed with CHD, mean (*SD*)	11 (10)	12 (10)	.92
Clinical characteristics			
Coronary angiographic indication of disease progression, *n*	7	6	.74
Previous acute myocardial infarction, *n*	7	6	.83
Percutaneous transluminal coronary angioplasty, *n*	5	4	.98
Coronary artery bypass graft surgery, *n*	3	4	.43
Average number of comorbidities, mean (*SD*)	2.6 (1.7)	4.1 (1.9)	.03
Presence of diabetes, *n*	5	6	.37
Age, mean (*SD*)	64 (10)	63 (11)	.80
Medications, *n*			
Lipid-lowering	4	5	.65
Blood pressure-lowering	10	9	.73
Estrogen replacement therapy	5	5	.64
Marital status, *n*			
Married	9	8	.67
Divorced/single	1	1	.87
Widowed	4	2	.57
Having a partner to attend program, *n*	11	7	.35
Present living arrangement, *n*			
With spouse	7	7	.52
With spouse and children	2	1	.71
With children	1	1	.87
Alone	4	2	.57
Level of education achieved, *n*			.17
7th to 11th grade	0	2	
High school graduate	4	3	
Partial college	7	5	
College/University graduate	3	1	
Ethnicity, *n*			.57
White, not Latino	13	10	
Latino	0	1	
Native American or Alaskan	1	0	
Glycosylated hemoglobin, mean % (*SD*)	6.3 (1.4)	6.6 (1.4)	.67
Weight, mean kg (*SD*)	80 (10)	79 (15)	.83
Body mass index, mean kg/m^2 (*SD*)	32 (4.2)	32 (5.5)	.98
Waist/hip ratio, mean (*SD*)	.91 (.1)	.92 (.1)	.83
Systolic blood pressure, mean mm Hg (*SD*)	145 (21)	142 (21)	.70
Diastolic blood pressure, mean mm Hg (*SD*)	78 (11)	70 (10)	.64
Total cholesterol, mean mg/dl (*SD*)**	233 (39)	234 (54)	.95
LDL cholesterol, mean mg/dl (*SD*)**	147.9 (35.1)	137.3 (34.4)	.50
HDL cholesterol, mean mg/dl (*SD*)**	40.3 (13.5)	41.0 (13.6)	.90
Plasma triglycerides, mean mg/dl (*SD*)**	227.3 (115.5)	346.6 (321.3)	.21
Ratio of total to HDL cholesterol, mean (*SD*)	6.3 (2.3)	6.2 (2.3)	.90

* Significance of one-way analysis of variance (ANOVA) comparing treatment and control at baseline.

** To convert values for cholesterol to millimoles per liter, multiply by 0.02586; for triglycerides, multiply by 0.01129.

TABLE 2
Behavioral Outcome Results

Measure	Condition	Baseline Mean (*SD*)	4 Months Mean (*SD*)	12 Months Mean (*SD*)	24 Months Mean (*SD*)	Significance of MANCOVA* or Follow-up ANCOVA
Dietary fat						$F = 15.8; p = .000$
Percent calories from fat	PT	25 (10)	11 (3)	13 (7)	12 (6)	$p < .000$
	UC	29 (8)	26 (9)	27 (8)	28 (9)	
Percent calories saturated fat	PT	7.8 (4.1)	2.7 (.9)	3.7 (2.4)	3.1 (2.4)	$p < .000$
	UC	9.5 (3.3)	8.2 (3.0)	8.7 (3.3)	8.7 (3.0)	
Caloric intake						$F = 1.01; p = .164$
Mean total caloric intake	PT	1664 (422)	1340 (285)	1480 (489)	1349 (284)	
	UC	1358 (253)	1263 (321)	1362 (408)	1394 (477)	
Physical activity						$F = 8.00; p = .005$
Summary of self-care	PT	3.9 (1.8)	4.8 (1.0)	4.6 (1.5)	3.7 (2.0)	
	UC	2.3 (1.5)	2.5 (1.1)	2.5 (1.7)	2.7 (1.6)	
Stress management						$F = 6.12; p < .005$
Structured interview	PT	2.8 (2.6)	5.8 (2.1)	5.4 (2.1)	5.4 (2.2)	$p = .000$
	UC	2.8 (2.7)	3.3 (2.6)	1.5 (2.0)	2.8 (2.4)	
Summary of self-care	PT	1.5 (1.8)	4.6 (1.6)	3.6 (1.8)	3.0 (1.9)	$p = .04$
	UC	1.4 (1.7)	3.1 (1.9)	2.6 (1.9)	2.9 (1.6)	

* Significance of one-tailed repeated measures multivariate analysis of covariance (MANCOVA) comparing the PT and UC follow-up scores, controlling for baseline scores. When overall MANCOVA is significant, follow-up ANCOVA results are provided.

TABLE 3
Levels of Antihypertensive and Lipid-Lowering Medications by Condition Over Time

	Assessments				Significance of ANCOVA*		
	Baseline	4 Month	12 Month	24 Months	Individual Time Points		
Measure	Mean (*SD*)	Mean (*SD*)	Mean (*SD*)	Mean (*SD*)	4 Months	12 Months	24 Months
Antihypertensive medications (mg)						$F = 3.56; p = .037$	
PT	97 (121)	21 (77)	75 (161)	92 (207)	.016	.089	.083
UC	120 (115)	240 (345)	236 (374)	262 (354)			
Lipid lowering medications (mg)						$F = 2.19; p = .077$	
PT	95 (318)	43 (160)	91 (325)	101 (340)	.054	.070	.140
UC	175 (539)	282 (617)	317 (607)	126 (357)			

* Significance of one-tailed analyses of covariance (ANCOVA), using baseline level of medication as covariate, comparing treatment and control groups.

significant, and consistent improvements in mean percent calories from fat (24-month follow-up scores of 12% for PrimeTime versus 28% for UC) and mean percent calories from saturated fat (24-month follow-up scores of 3.1% for PrimeTime versus 8.7% for UC). Improvements were most substantial at the 4-month assessment.

Physical activity results parallel those reported above for dietary self-care. There was a significant overall effect on the repeated measures MANCOVA for physical activity ($F = 8.0$; $p = .01$). PrimeTime participants substantially increased their number of exercise sessions and number of minutes spent engaged in physical activity each day compared to the UC group.

Stress-management results indicated the PrimeTime group significantly increased the number of times per week they engaged in stress-management activities compared to the UC condition (see Table 2). These increases were detected by both the Structured Interview and the Summary of Self-Care Questionnaire. The PrimeTime participants showed a slight, nonsignificant decrease in practice of stress-management techniques at the 12- and 24-month follow-ups.

The one smoker in the PrimeTime group successfully quit during the retreat and remained abstinent for the remainder of the program. This was confirmed by carbon monoxide and saliva continine analyses. The one smoker in the UC group has continued to smoke.

Medication Changes

Antihypertensive drugs were substantially reduced in the PrimeTime women from baseline to the 4-month follow-up (from 97 mg per person per day on average to 21 mg per person per day), compared to a substantial increase among the UC condition (120 mg at baseline to 240 mg at 4-month follow-up). The repeated measures ANCOVA on change in medication from baseline was significant ($F = 3.56$; $p = .037$). The PrimeTime women maintained some of their improvement at the 12- and 24-month follow-ups (see Table 3).

At baseline, the UC group was taking an average 175 mg of lipid medications, compared to an average 95 mg in the PrimeTime condition. At the 4-month follow-up, the PrimeTime women were taking an average of 52 mg less than they had at baseline, while the UC group had increased an average of 107 mg ($p = .054$). The repeated measures ANCOVA revealed that the PrimeTime women did not maintain these improvements at the 24-month follow-up (see Table 3).

TABLE 4
Changes in Physiologic Risk Factors

Measure	Assessements: Baseline Mean (*SD*)	4 Months Mean (*SD*)	12 Months Mean (*SD*)	24 Months Mean (*SD*)	Significance of MANCOVA*
Serum lipids					$F = 1.34; p = .13$
Total cholesterol					
PT	233 (39)	242 (40)	227 (36)	224 (32)	$p = .257$
UC	234 (54)	255 (92)	288 (275)	213 (63)	
LDL cholesterol					
PT	156 (30)	155 (31)	137 (21)	137 (19)	$p = .477$
UC	138 (32)	138 (32)	127 (32)	131 (51)	
HDL cholesterol					
PT	40 (14)	39 (11)	40 (11)	43 (13)	$p = .343$
UC	41 (14)	40 (10)	40 (11)	40 (9)	
Triglycerides					
PT	227 (116)	262 (112)	254 (111)	233 (106)	$p = .378$
UC	347 (321)	456 (514)	284 (191)	263 (210)	
Total/HDL cholesterol					$F = 2.14; p = .080$
PT	6.1 (2.1)	6.5 (1.8)	6.1 (1.7)	5.9 (2.6)	
UC	5.9 (2.1)	6.1 (2.0)	5.3 (1.6)	5.2 (1.5)	
Body mass index					$F = 3.34; p = .041$
PT	32 (4)	30 (3)	30 (4)	31 (4)	
UC	32 (6)	32 (6)	32 (6)	32 (6)	
Blood pressure					Overall $F = .89, p = .213$
Systolic					
PT	142 (21)	140 (21)	145 (20)	135 (22)	$p = .081$
UC	145 (21)	149 (17)	151 (23)	147 (28)	
Diastolic					
PT	70 (10)	66 (12)	68 (13)	64 (15)	$p = .239$
UC	72 (7)	71 (8)	71 (10)	67 (15)	
Chest pain frequency (episodes)					
PT	2.5 (3.6)	.77 (1.1)	.50 (1.1)	.39 (.51)	$F = 6.68; p = .01$
UC	2.8 (3.2)	2.3 (2.8)	.90 (1.1)	3.0 (5.5)	
Chest pain duration (minutes)					
PT	9.7 (10.9)	14.6 (27.7)	3.4 (4.8)	3.0 (5.5)	$F = 2.72; p = .06$
UC	6.0 (2.8)	9.2 (8.7)	7.0 (7.0)	10.1 (12.4)	
Chest pain severity (1–7 scale)					
PT	.85 (1.6)	2.1 (2.0)	1.6 (1.7)	1.2 (1.6)	$F = .81; p = .19$
UC	1.6 (1.7)	2.5 (2.2)	2.3 (2.1)	2.6 (2.2)	
Framingham risk score					
PT	12.06 (6.1% risk)	12.25 (6.6% risk)	11.36 (6.0% risk)	10.86 (4.9% risk)	$F = 2.8; p = .055$
UC	11.63 (6.1% risk)	11.8 (6.3% risk)	12.0 (5.9% risk)	11.9 (6.5% risk)	

* Significance of one-tailed repeated measures multivariate analyses of covariance (MANCOVA) comparing treatment and control follow-up scores covarying the effect of baseline scores.

Physiologic Outcomes

Some favorable changes in risk factor status occurred for women in the PrimeTime condition. These results are summarized in Table 4. There was a small but significant decrease in BMI in PrimeTime women compared to UC ($p = .041$). The repeated measures ANCOVA revealed a 2-point drop in BMI from baseline to the 4- and 12-month follow-ups in the PrimeTime women, with no change for the UC group. The PrimeTime women gained 1 point in BMI at 24-month follow-up.

On the Rose questionnaire (33), PrimeTime women reported a reduction in frequency of chest pain episodes in the past 7 days from an average of 2.5 at baseline to 0.4 at the 24-month follow-up. The frequency of chest pain episodes rose over the 2-year period for the UC group from an average of 2.8 at baseline to 3.0 at 24 months (repeated measures ANCOVA, $F = 6.68$; $p = .01$). Duration and severity of angina symptoms were similarly improved for the PrimeTime women, but did not reach statistical significance (see Table 4).

The PrimeTime women improved their heart disease risk score over the course of the 2 years. Their risk of further heart disease, stroke, or cardiovascular death decreased from 12.06 (6.1% risk) at baseline to 10.86 (4.9% risk) ($p = .04$) at 24 months, while that of the control group rose from 11.63 (6.1%) to 11.9 (6.5%) during the same period. The repeated measures ANCOVA comparing conditions was marginally significant ($p = .055$).

Differences between the PrimeTime and UC conditions in average changes in plasma lipid concentrations and blood pressure did not achieve statistical significance (see Table 4).

While the PrimeTime group made impressive improvements in dietary fat intake, it is interesting to examine how closely they matched their counterparts in the Ornish Lifestyle Heart Trial. As

TABLE 5
Comparison of Guidelines and Actual Results: Ornish Lifestyle Heart Trial versus Women's Lifestyle Heart Trial

		Actual Results				
			Women's Lifestyle Heart Trial			
			Months after Baseline			
Program Requirement	Ornish Guidelines	Ornish at 12 Months	0	4	12	24
Calories from fat (%)	10%	6.8%	25%	11%	13%	12%
Polyunsaturated/saturated fat ratio	Greater than 1	Not available	.76	1.4	1.2	1.2
Calories from protein (%)	15%–20%	Not available	18%	16%	16%	16%
Calories from complex carbohydrates (%)	70%–75%	Not available	57%	76%	74%	75%
Dietary cholesterol (mg/day)	5	12.4	174	27	34	41
Stress management (times/week)	7	5.94	.43	.71	.71	.71
Technique practice (minutes/day)	60	82.1	N/A	N/A	N/A	N/A
Physical activity (minutes/week)	120	184	34	172	188	144

shown in Table 5, the group approached, but did not on average meet, the recommended Ornish guidelines or the levels reported of his study participants.

Given the discrepancies between the Ornish guidelines and the PrimeTime women's program achievements, how did the PrimeTime women fare in terms of changes in CHD risk factors? Table 6 compares key risk factors between the two programs for baseline and 12-month follow-up.

Quality of Life

The repeated measures MANCOVA for all quality of life dimensions revealed overall improvement in favor of the PrimeTime participants ($F = 4.28$; $p = .026$). Follow-up analyses revealed significantly greater improvements in quality of life in the areas of general health (PrimeTime condition improved an average 4 points, while the UC condition decreased 23 points) and social functioning (PrimeTime condition improved an average 22 points, while the UC condition decreased 4 points). The other four scales of the MOS SF-36 were nonsignificant.

Impact of Attrition

The results were reanalyzed to include women who dropped out of the study after the retreat. For each construct tested, baseline scores were substituted for the missing 4-, 12-, and 24-month follow-ups. The analyses made very little difference in the final outcomes. Of the 13 variables tested, differences on two outcomes were positively affected and one outcome was adversely affected. Significance levels improved for between-condition differences on the ratio of total cholesterol to HDL cholesterol (from $p = .080$ to $p = .033$) and for Chest Pain Duration (from $p = .06$ to $p = .05$), and caused one variable, Chest Pain Frequency, to become nonsignificant.

DISCUSSION

The Lifestyle Heart Trial (25), the St. Thomas' Atherosclerosis Regression Study (37), the Heidelberg Study (38), the Leiden Intervention Trial (39), and the Stanford Coronary Risk Intervention Project (21) have demonstrated that lifestyle can have a major influence on progression of coronary artery atherosclerosis. However, participants in these trials were primarily male or included too few women to allow detection of gender effects. The Women's Lifestyle Heart Trial, despite a small sample size, demonstrated that a lifestyle intervention could produce marked, consistent behavioral differences sustained over 2 years in postmenopausal CHD females. Although this regimen placed heavy demands on participants, adherence and participation levels were good, and the intervention was moderately effective in producing improvements in BMI, angina symptoms, use of antihypertensive and lipid-lowering medications, coronary risk, and quality of life.

It is worth noting that in the Ornish Lifestyle Heart Trial, total cholesterol and LDL cholesterol improved significantly, while triglyceride and HDL cholesterol levels did not. Significant serum lipid improvements did not accrue in the Women's Lifestyle Heart Trial, but both studies achieved significant reductions in body weight (a 10 kg reduction in the Ornish program versus a 3.9 kg reduction in the PrimeTime program). Given their significant dietary improvements, especially compared to national averages (39), it remains unclear why the PrimeTime women did not show significant improvements in lipids. Gender differences, the small sample size, lack of precision in serum lipid measurements, or perhaps the reduction in their lipid-lowering medication may explain this. In the Lyon heart study (40), reduction in coronary events and reduction in cardiac deaths of close to 70% were achieved using the Mediterranean diet, without a reduction of total cholesterol or triglycerides, or an increase in HDL-C compared to controls. The Mediterranean diet, rich in carbohydrates and fiber, does not restrict dietary fat as severely as the Ornish diet, but does restrict saturated fat, which recently has been shown to reduce incidence of CHD (41).

Although PrimeTime participants engaged in stress-management activities to a much greater degree than did the UC group, there is a large discrepancy in the frequency of their practices compared to their male counterparts in the Ornish Lifestyle Heart Trial. Regularly practicing stress-reduction techniques appeared to be challenging for the women. There were many difficulties cited by the PrimeTime participants, mostly stemming from structural problems with their bodies, other chronic diseases, and the feeling they lacked the time to relax.

The PrimeTime women appeared to engage in physical activity on average about 44 minutes less at 24 months compared to 12 months. The reduction in physical activity by the PrimeTime women at the 24-month follow-up may reflect their greatly reduced contact with the program (from twice per week to once per month) by the end. It is possible that group support for exercise is extremely important. The PrimeTime women also engaged in less physical activity than the men in the Ornish study. This is not surprising since, compared to men, fewer women enroll in cardiac rehabilitation programs (42,43). In an assessment study of self-management of heart disease, the women were significantly less

TABLE 6
Changes in Risk Factors: PrimeTime Program versus Ornish Lifestyle Heart Trial

	Baseline Assessment		12-Month Assessment		
	Experiment	Control	Experiment	Control	
Measure	Mean (*SD*)	Mean (*SD*)	Mean (*SD*)	Mean (*SD*)	Significance*
Serum lipids (mg/dl)**					
Total cholesterol					
PrimeTime	233 (39)	234 (54)	227 (36)	288 (275)	.195
Ornish	277 (50)	245 (39)	172 (44)	232 (60)	.019
LDL cholesterol					
PrimeTime	155 (27)	137 (34)	137 (25)	127 (32)	.409
Ornish	152 (48)	167 (30)	95 (60)	157 (45)	.007
HDL cholesterol					
PrimeTime	40 (14)	41 (14)	40 (11)	40 (14)	.495
Ornish	39 (10)	52 (20)	38 (15)	51 (15)	.832
Triglycerides					
PrimeTime	227 (116)	347 (321)	254 (111)	284 (191)	.237
Ornish	211 (112)	217 (219)	258 (130)	198 (159)	.247
Lipid ratios					
Total/HDL					
PrimeTime	6.34 (2.28)	5.89 (2.10)	6.06 (1.66)	5.31 (1.59)	.151
Ornish	6.33 (2.14)	5.32 (1.89)	5.15 (2.23)	4.93 (1.59)	.173
LDL/HDL					
PrimeTime	4.33 (1.76)	3.28 (1.18)	3.76 (1.54)	3.03 (1.17)	.490
Ornish	4.18 (1.53)	3.59 (1.37)	2.89 (1.92)	3.33 (1.42)	.035
Blood pressure (mm/Hg)					
Systolic					
PrimeTime	142 (21)	145 (21)	145 (20)	151 (23)	.289
Ornish	134 (13)	140 (26)	127 (13)	131 (20)	.755
Diastolic					
PrimeTime	70 (10)	72 (7)	68 (13)	71 (10)	.328
Ornish	83 (8)	82 (13)	79 (7)	77 (11)	.899
Weight (kg)					
PrimeTime	80.3 (9.6)	79.3 (15.0)	76.4 (7.6)	79.24 (16.3)	.045
Ornish	91.1 (15.5)	80.4 (22.8)	81.0 (11.4)	81.8 (25.0)	.0001
Angina symptoms					
Chest pain frequency					
PrimeTime	2.40 (3.5)	2.80 (3.23)	0.50 (1.09)	.90 (1.10)	.099
Ornish	5.10 (14.1)	2.35 (3.77)	0.45 (0.76)	6.24 (12.9)	.058
Chest pain duration					
PrimeTime	9.57 (10.44)	6.20 (2.74)	3.14 (4.72)	6.70 (6.65)	.094
Ornish	2.73 (4.69)	3.47 (7.95)	1.58 (4.48)	6.97 (14.5)	.139
Chest pain severity					
PrimeTime	.79 (1.58)	1.60 (1.65)	1.50 (1.65)	2.30 (2.10)	.184
Ornish	2.30 (1.60)	1.80 (1.10)	1.70 (1.20)	2.50 (1.20)	.001

* Significance of one-tailed multivariate analysis of covariance (MANCOVA) comparing the 12-month PrimeTime and Usual Care follow-up scores, controlling for baseline scores. *P* values from Ornish Lifestyle Heart Trial (24) are two-tailed.
** To convert values for cholesterol to millimoles per liter, multiply by 0.02586; for triglycerides, multiply by .01129.

likely than men to report close adherence to prescription for exercise (22).

An important limitation of this study is the small sample of motivated women and generalizability of results to all CHD women over 50. It is possible that we have recruited a sample of highly motivated CHD women and that using a population-based approach to recruitment would have produced a different set of results. However, other investigators have used similar recruitment techniques in several major CHD clinical trials, including the Multiple Risk Factor Intervention Trial (Mr. FIT) (44), a CHD diet and lifestyle trial conducted by Singh et al. (10), and the large Diabetes Control and Complications Trial (45). Other CHD behavioral investigations have experienced higher rates of nonparticipation than in our study, including the Take Pride project (22) and Kane et al.'s (46) work with heterozygous familial hypercholesterolemia. Still, selection bias is a major threat to external validity. Investigators whenever possible should use recruitment strategies that provide samples reflecting general population characteristics. This was unfortunately not possible in the current investigation. A larger sample (at least 200, including adequate numbers of minority participants) would have permitted a better demonstration of the feasibility of implementing this program with larger, more diverse, and possibly less-motivated populations.

The goals of this research and that of Ornish et al. (24,25) differed. The major goal of the Lifestyle Heart Trial was to determine whether a comprehensive lifestyle program could by itself reverse heart disease, which it did in mostly male study participants. The main goal of the present project was to test whether the same procedures would produce substantial reductions in CHD risk factors in women. Given the small sample size, there

were a surprising number of significant physiologic and quality of life benefits accruing to the PrimeTime women. Overall lifestyle change appeared to have beneficial effects on general health, social functioning, and role functioning in women with CHD as measured by the SF-36. Our past experience with the SF-36 indicated that this measure has been relatively resistant to change (47). The results showing improvement in quality of life for PrimeTime participants are particularly strong. The extent to which results obtained may apply to changes in coronary lesions is not known.

Future research, with larger sample sizes and more sensitive measures, is needed to more thoroughly investigate lipid and blood pressure changes. The lipid measures were only collected once at each assessment point, which considerably inflates the error variance compared to the average of two or three measurements used in most lipid reduction studies (21,41).

Intensive, concurrent management of multiple lifestyle behaviors may not seem feasible given the resources of many health care systems. The women who participated in this trial were at extremely high risk for further CHD-related diseases, which are major causes of health care expenditures as well as mortality. For them, a program with this level of intensity may be warranted. Still, the overall cost of the intervention is considerably less than invasive surgical or even some intensive pharmacologic or cardiac rehabilitation interventions (7). Future research should address ways to reduce and more thoroughly evaluate costs of this intervention approach. It is possible that less frequent meetings and lay/peer led groups would be as effective (48,49). It may be that some of the intervention components are less essential than others. Our clinical impression is that the social support component is as critical for women with CHD as it appears to be in managing other diseases (50,51). More research is also needed to understand how comprehensive lifestyle change affects quality of life, which may be the ultimate outcome (52,53). Results of the current study are encouraging.

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