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Effects of the Mediterranean Lifestyle Program on Multiple Risk Behaviors and Psychosocial Outcomes Among Women at Risk for Heart Disease

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Abstract

Background—The Mediterranean Lifestyle Program was evaluated for its effects on multiple behavioral risk factors for coronary heart disease (CHD) among postmenopausal women with diabetes.

Methods—Participants (N=279) were randomized to usual care (UC) or Mediterranean Lifestyle Program, a lifestyle change intervention aimed at the behavioral risk factors (eating patterns, physical activity, stress management, and social support) affecting risk for CHD in postmenopausal women with type 2 diabetes.

Results—In original and intent-to-treat analyses, Mediterranean Lifestyle Program participants showed significantly greater improvement in dietary behaviors, physical activity, stress management, perceived support, and weight loss at 6 months compared to UC.

Conclusions—This study demonstrated the effectiveness of the Mediterranean Lifestyle Program in improving self-care among women with type 2 diabetes, showed that postmenopausal women could make comprehensive lifestyle changes, and provided evidence that a program using social-cognitive strategies and peer support can be used to modify multiple lifestyle behaviors.

Keywords

Coronary Heart Disease; Diet; Exercise; Stress Management; Social Support; Type 2 Diabetes; Randomized Controlled Trial; Women's Health

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Coronary heart disease (CHD) is the leading cause of death among women in the United States (1). Relative risk of and death from CHD is significantly higher among postmenopausal women and is 2.5 times higher among women with vs. without diabetes (2). With rising rates of obesity, and evidence that obesity increases risk for type 2 diabetes, effective lifestyle management has become a core issue for diabetes control and prevention of CHD. Although CHD is a major cause of death and functional limitations in older women (3), a gender gap exists in CHD research (4). The vast majority of studies of CHD risk factors, drug intervention trials,

prevention regimens, and health care strategies have involved primarily middle-aged men, although numerous studies show that data from middle-aged men cannot be extrapolated to women of all ages (5). To address this concern, the present trial targeted postmenopausal women with type 2 diabetes who are at risk for coronary heart disease.

A number of behavior-related CHD risk factors have been identified for women with and without diabetes, including high-fat diet (6), smoking (7), sedentary lifestyle (8), exaggerated stress responses (9), and social isolation (10). Despite numerous hypotheses about underlying mechanisms, and a large body of evidence emphasizing the prognostic importance of social support for heart disease morbidity and mortality, there are few published accounts of interventions specifically designed to assist adults, especially women, *at risk* for CHD in obtaining or maintaining social support. In those that do exist (11), rarely has it been possible to identify the separate influences of social support factors. This project experimentally investigated whether an ongoing behavior change intervention and support group sessions over 6 months enhanced the practice and maintenance of healthful lifestyle behaviors relative to usual care.

Behavior change may promote healthful lifestyles, reduce CHD risk (12), and improve glycemic control (13). The Lyon diet heart study (14), using the Mediterranean diet, reduced coronary events and cardiac deaths by nearly 70%. However, until recently (15), chronic illness trials have typically addressed diet alone (16) or, less frequently, physical activity alone (17) or diet combined with physical activity (18). Rarely are multiple lifestyle risk factors targeted in either diabetes or general health prevention studies (19) despite the potential for the additive effect of combining lifestyle interventions. Recent multiple lifestyle risk factor trials for hypertension, including PREMIER (15) and DASH (20), have investigated the effects of combining weight loss, physical activity, and sodium and alcohol restriction on hypertension, anticipating that the combined interventions would be additive. Pickering (21) noted that the net changes in these trials were smaller than expected. The current study, addressed the extent to which individuals were able to make comprehensive lifestyle changes.

Theoretical Model

The conceptual basis for the program was a combination of Social Cognitive Theory (22), Goal Systems (23), and Social Ecological Theory (24,25). Our current theoretical model has evolved to explicitly address barriers and factors that support behavior change. This model suggests an ongoing self-management cycle in which participants are helped to target behaviors, collaboratively set goals, identify barriers to lifestyle change, select personally relevant coping strategies, and arrange follow-up supportive resources (26,27). In previous studies, our research group and others identified multiple system and social-environmental factors, including social support, that influence self-management of chronic illness (24). In this intervention, individually tailored goal-setting took place at an initial 2½-day retreat, after which participants attended 6 months of weekly meetings and received support for their lifestyle change goals.

This project also addressed the inverse relation between program intensity and reach. Most studies have found that more intensive interventions produce better outcomes. Unfortunately, intensive interventions usually have very low participation rates (28), especially for women (29). This project delivered a moderately intense intervention that attracted a high percentage of the target population. The RE-AIM evaluation framework, which our group has developed and described elsewhere (30), was used to evaluate Reach, Effectiveness, Adoption, Implementation, and Maintenance of the intervention. This framework explicitly focuses on issues of representativeness and generalization, which were primary concerns of the investigation. The RE-AIM approach was used to assess the potential of the Mediterranean Lifestyle Program for broader translation.

This study tests a theory-based comprehensive lifestyle management intervention to reduce CHD risk in postmenopausal women with type 2 diabetes, using procedures similar to successful programs for middle-aged men (31) and women in our Women's Lifestyle Heart Trial (32). The main hypothesis was that those randomized to the Mediterranean Lifestyle Program compared to a randomized usual care condition would make significantly larger improvements in targeted lifestyle behaviors, including eating patterns, physical activity, stress management, perceived social support, and body weight. Biological endpoints have been previously presented (33) and revealed significant improvements in hemoglobin A_{1c}, body mass index, plasma fatty acids, and quality of life at 6-month follow-up. Patterns favoring intervention were seen in lipids, blood pressure, and flexibility, but did not reach statistical significance.

Methods

Participants

Participants were 279 postmenopausal women with type 2 diabetes who were patients of participating primary care clinics. Inclusion criteria were: type 2 diabetes for at least 6 months, being postmenopausal, living independently (e.g., not in an institution), having a telephone, ability to read English, not being developmentally disabled, and living within 30 miles of the intervention site (Eugene, OR). Exclusion criteria included being older than 75 or planning to move from the area within the study's time span. All patients meeting eligibility criteria were sent letters from their primary care providers, followed by phone calls inviting them to participate. Fifty-one percent of eligible women contacted agreed to participate. Recruitment procedures and participation rates are presented in more detail separately (34). Enrollees were representative of patients in participating primary care offices and the diabetes population of the state, and were stratified on physician practice, smoking status, and type of diabetes medication.

Design and Intervention

A total of 116 participants were randomized to usual care and 163 to the Mediterranean Lifestyle Program. The usual care condition participated in all assessments and received ongoing diabetes care from their physicians. The Mediterranean Lifestyle Program was conducted in four successive waves of approximately 40 women each. Intervention lasted 6 months and addressed primary behavioral risk factors affecting CHD in postmenopausal women (i.e., diet, physical activity, stress management, and social support). The intervention began with a 2½-day nonresidential retreat (Friday evening, Saturday, and Sunday), followed by 6 months of weekly meetings. The retreats jumpstarted the behavior change process and promoted camaraderie among the women. The retreats also provided the opportunity to learn the diet, stress-management, social support, and physical activity aspects of the program. Retreats were followed by 6 months of weekly 4-hour meetings consisting of 1 hour each of physical activity, stress management, Mediterranean potluck, and support groups.

Eating patterns—The project registered dietitian taught participants the Mediterranean alpha-linolenic acid-rich diet, which is low in saturated fat but moderately high in more healthful monounsaturated fats (14). The dietitian individualized carbohydrate and fat requirements to optimize blood glucose and lipid concentrations within the parameters of the Mediterranean Lifestyle Program. The diet recommended more bread; more root vegetables, green vegetables, and legumes; more fish; less red meat (e.g., beef, lamb, pork), replaced by poultry; daily fruit; and avoidance of butter and cream, to be replaced by olive/canola oil or olive/canola-based margarine. Mediterranean Lifestyle Program participants were asked each week to complete and bring to weekly meetings a simple self-monitoring log of their adherence to four of the Mediterranean diet components.

Physical activity—The initial physical activity goal, developed in consultation with the project's exercise physiologist, was consistent with the recent Centers for Disease Control and Prevention and the American College of Sports Medicine guidelines for physical activity (35): 30 minutes of moderate physical activity on most days of the week. Once they achieved that goal, participants were advised to build up to 1 hour of moderate aerobic activity per day. Women who had engaged in little or no activity before the program were helped to set individualized goals to gradually increase activity about 5 minutes per session or increase the number of days per week they exercised.

Stress management—Using procedures from Ornish (36) and Toobert et al. (12), participants were instructed in yoga, progressive deep relaxation, meditation, and directed or receptive imagery. The purpose of each technique was to increase the sense of relaxation, concentration, and awareness. Participants were asked to practice all of these techniques for at least 1 hour per day and received a videotape to assist them.

Attendance—The first 6 months of the intervention was designed to teach the program components and build group cohesion. Numerous motivational techniques were employed to keep meetings interesting and boost attendance, such as contests, self-monitoring, and group and individual rewards. Small incentives, such as candles, refrigerator magnets, and pins, were given to women for recording adherence to program dietary, physical activity, and stress-management components. In addition, a \$100 cash prize was given to the person with the best attendance in each wave. Of all the motivational techniques used, we believe the most effective was telephone calls from support group leaders and other group members if participants missed a meeting.

Measures

The following measures were collected from participants in both conditions to evaluate the impact of the intervention. Women were assessed in groups of 6-8 at Oregon Research Institute in Eugene, OR. Some demographic measures were collected on the telephone for screening purposes prior to randomization; all other measures were collected at baseline prior to randomization and at 6 months following introduction of the lifestyle program. The measures are described below. A large number of measures was necessary in this study to capture the many and varied anticipated effects of the multiple-risk-factor intervention. Each behavioral target required its own set of measures. Because there is no one feasible gold standard for measuring most of the behaviors, we adopted a convergent multi-method (self-monitoring, interview, paper-and-pencil questionnaires) approach to measurement. Our analyses used constructs evaluated by multivariate analysis of covariance (MANCOVA), which is a stronger, more robust approach than the arbitrary selection of one behavioral or process measure.

Behavioral Endpoints

Dietary—Our diet measures included a behavioral measure of fat intake, a Food Frequency Questionnaire (FFQ), and a global self-rating of diet. To measure behaviors related to low-fat and high-fiber eating patterns, the Fat and Fiber Behavior Questionnaire (FFB) (37) was collected. The FFB provides five behavioral fat intake dimensions and a total score which averages the five dimensions. The total score ($\alpha = .59$) was used in the current analyses. We have shown that the test-retest reliability for the FFB compares favorably with measures from a 4-day food record and that the FFB correlated highly with other dietary measures and with biologic measures of serum cholesterol, body mass index (BMI), and HbA_{1c} (38). We used the semi-quantitative FFQ developed at the Fred Hutchinson Cancer Center (39) to document percent of calories from fat, saturated fat, and fruit and vegetable servings. This FFQ has been validated with 4-day food records and 24-hour dietary recalls (average correlation $r = .5$). The Summary of Diabetes Self-Care Activities Questionnaire (SDSCA) diet scale (40)

is a brief, self-report questionnaire of diabetes self-management. A scale of just the seven SDSCA diet items ($\alpha = .74$) was included in the Diet MANCOVA, along with the other dietary measures. Normative data (means and standard deviations), inter-item and test-retest reliability, correlations between the SDSCA subscales and a range of criterion measures, and sensitivity to change scores have been examined for seven different studies and the instrument was found to be a reliable and valid self-report measure of diabetes self-management (27). A 7-day Mediterranean Lifestyle Program self-monitoring log was also developed for this project. The self-monitoring log asked participants to record for 7 days their daily adherence to four components of the Mediterranean diet: whether they (1) had any fruit, (2) ate at least two vegetable servings, (3) limited fat to either canola oil, olive oil, or olive/canola-based margarine, and (4) avoided red meat. The number of days respondents adhered to each component was summed, and a mean of all components was used to compute the self-monitoring diet adherence score ($\alpha = .48$).

Physical activity—Multiple measures of exercise self-care behaviors were collected. The CHAMPS Activities Questionnaire for Older Adults (41) provided an estimate of total kilocalories expended. The 3-month stability coefficient for expended calories per week was .84. A composite score from the SDSCA (40) was computed as the mean of the two exercise items (e.g., how often participants exercised at least 20 minutes) ($\alpha = .80$). The 7-day Mediterranean Lifestyle Program self-monitoring log provided data on the intensity, type, and duration of activities, which were incorporated into a composite score for the Physical Activity MANCOVA equation.

Stress management—Since objective measures of stress-management practices are not well established, we designed a self-monitoring form for participants. They monitored their daily performance of at least 20 minutes of yoga, 5 minutes of breathing exercises, 15 minutes of progressive relaxation, and 5 minutes each of meditation and visualization. The α s for the Stretching, Breathing, and Meditation/Visualization scales respectively were .88, .84, and .91.

Social resources—Social support was a key outcome, but it is complex and there are no objective measures of this construct. We assessed support using multiple methods (paper-and-pencil questionnaires and self-monitoring). Since our intervention targeted different sources of support (e.g., friends, family, health care providers) and behavior-specific measures of support, we included measures that would address each of these components. A 7-day self-monitoring log of supportive resources from friends, family, health care provider, neighborhood, and church was developed for this project. Only sources of support targeted in the first 6 months of the intervention were used in these analyses: friends ($\alpha = .86$), family ($\alpha = .91$), and health care provider ($\alpha = .96$). Four scales measuring sources of support from the UCLA Social Support Inventory (UCLA) (42) were also used. The four scales included support from support group ($\alpha = .97$), friends ($\alpha = .91$), health care provider ($\alpha = .81$), and spouse/partner/other family members ($\alpha = .87$). The Brief Chronic Illness Resources Survey (CIRS) (24) provided a profile of an individual's support for behavior-specific disease management, ranging from more proximal support (e.g., support from family and friends) to more distal factors (e.g., support from neighborhood or community). Respondents rated on a 1 (not at all) to 5 (a great deal) Likert scale the extent to which each item over the past 6 months was a resource for them. In these analyses, we used the CIRS scales for support for diet ($\alpha = .63$) and physical activity ($\alpha = .67$).

Body weight—Measures of height and weight were taken in the morning in the fasting state, in stocking feet on a sensitive digital scale (Detecto Electronics).

Program evaluation—Besides attendance, which was recorded by project staff, two other types of process evaluations were used. Participants were asked to rate the helpfulness of, and their satisfaction with, program structure (e.g., amount of contact and support received, personal coaches, handouts and written materials) and the behavioral (diet, physical activity, support groups, and stress management) components. A 5-point Likert scale was used for each item with larger numbers representing more satisfaction or helpfulness. In addition, the Group Environment Survey (43) was administered to treatment condition participants to measure group cohesion. This survey asked participants to rate their feelings about their involvement with the Mediterranean Lifestyle Program and with their support group. Items included enjoyment of social interactions, feelings about the other people in the support group, and the importance of the group compared with other social experiences in their life. Ratings were on a 9-point scale ranging from very strongly disagree (1) to very strongly agree (9).

Analyses

A series of one-way analyses of variance (ANOVA) was conducted to evaluate baseline equivalence of conditions and subject attrition. MANCOVAs were used to evaluate intervention effects on the behavioral outcomes (adherence to dietary, physical activity, and stress-management components, and perceived social support). Multivariate analyses were chosen to reduce the number of comparisons conducted and limit type 1 error. Separate MANCOVA equations were developed for behavior-specific supportive resources and source of social resources. The Sources of Support MANCOVA included measures from friends, family, health care provider, and support group. Only when the overall MANCOVA was significant were follow-up analyses of covariance (ANCOVAs) used to identify variables accounting for the differential change. In all analyses, baseline scores on the dependent variable and the Socially Desirable Responding Scale (71) served as covariates. The adjusted results are reported in the tables.

Results

Participants vs. decliners—Comparisons of study participants (N=279; 51% of eligible) and those who were eligible and declined (N=217) indicated no statistically significant differences in self-reported age, income, employment status, body mass, age diagnosed with diabetes, type of diabetes medication, amount of diabetes education, heart disease status including myocardial infarctions and coronary bypass surgeries, existence of medical insurance, or percent of smokers. However, relative to nonparticipants, participants reported taking diabetes medications for fewer years (4.9 vs. 6.7, $p = .006$) and had been diagnosed with diabetes for fewer years (8.5 vs. 10.2, $p = .027$). More details are provided in Toobert et al. (34).

Usual care vs. Mediterranean Lifestyle Program—Table 2 presents the baseline characteristics of women assigned to usual care vs. the Mediterranean Lifestyle Program.

Participants vs. dropouts—Six-month follow-up data were collected on 245 (88%) of the randomized participants. Analyses of the characteristics of dropouts vs. participants present at 6-month follow-up revealed no significant main effects or interactions with treatment condition on a number of baseline characteristics (age, weight, waist/hip ratio, age diagnosed with diabetes, years taking diabetes medications, years diagnosed with diabetes, smoking, type of medication, income, education level, living arrangement, ethnicity, and comorbidities).

Missing data analysis—The robustness of all significant findings was tested by conducting a second analysis using the last observation carried forward (LOCF) method for imputing missing values. Baseline values were brought forward to replace missing 6-month values.

Although no one strategy for missing values is adequate for all dropout patterns, Unnebrinke and Windeler (45) suggest that for low dropout rates, missing values may be imputed by common substitution methods (e.g., LOCF). Significance and conclusions from imputed analyses were identical to those using only participants present at follow-up. The non-imputed results are presented here.

Intraclass correlations (ICCs)—ICCs were computed for key dependent variables to determine whether there was significant clustering by wave of the study participants. All ICCs were less than .003 (median = .001), indicating an absence of wave effects.

Behavioral Outcomes (Table 2)

Diet—The overall MANCOVA for dietary measures was highly significant in favor of the Mediterranean Lifestyle Program condition. Follow-up analyses revealed a significantly greater improvement in adherence to the Mediterranean diet in the Mediterranean Lifestyle Program compared to the usual care condition on all of the measures in the MANCOVA equation. Mediterranean Lifestyle Program participants adhered to all aspects of the diet more days per week than the usual care condition. Data from the FFQ indicated significantly greater reductions in total fat and saturated fat consumption, and significant increases in daily fruit and vegetables servings in favor of the Mediterranean Lifestyle Program participants. On the FFB, Mediterranean Lifestyle Program participants demonstrated significantly more improvement in behavioral patterns related to low-fat eating. There was significantly greater improvement on the diet scale of SDSCA and there was a significant decrease in weight in Mediterranean Lifestyle Program women (loss of .87 kg) compared to usual care (gain of .90 kg).

Physical activity—Physical activity results paralleled those reported for dietary self-care. There was a highly significant overall effect on the MANCOVA for physical activity outcomes (See Table 2). Follow-up univariate ANCOVAs revealed that this was due to substantial increases in the Mediterranean Lifestyle Program compared to usual care on the frequency, duration, and intensity of activity reported in the 7-day self-monitoring log; number of exercise sessions and number of minutes spent engaged in physical activity each day as measured by the SDSCA; and caloric expenditure per week for all activities as measured by the CHAMPS.

Stress management—Stress-management results from the 7-day self-monitoring log indicated the Mediterranean Lifestyle Program condition significantly increased the number of minutes per day and days per week engaged in stress-management activities compared to usual care. Follow-up univariate ANCOVAs revealed the Mediterranean Lifestyle Program participants practiced these techniques a greater number of minutes on more days per week than the usual care participants.

Social Resources

There was a significant increase in the *behavior-specific perceived supportive* resources favoring the Mediterranean Lifestyle Program condition (see Table 3). Follow-up univariate ANCOVAs revealed the Mediterranean Lifestyle Program participants increased their perception of support for diet and exercise more than participants in the usual care condition. Overall MANCOVAs (or ANCOVA for support group) for three of the four *sources of support* were significant, indicating increases in perceived social resources from friends, family, and support group, but not from health care providers.

Social desirability, which was a covariate in all of the analyses presented, did not significantly contribute to any of the equations.

Attendance

Attendance averaged 74% and was relatively constant over the 6-month period.

Program Evaluation

Helpfulness of the program structure and materials (e.g., amount of contact and support received, personal coaches, handouts and written materials) were all rated similarly and ranged from a mean low of 3.77 on a 5-point scale ($SD = 1.39$) (moderately helpful) for the exercise and stress-management videotapes to an average high of 4.51 ($SD = .63$) (quite helpful) for the program personal coaches. Participants also rated all of the behavioral program components from moderately to quite helpful. The diet component ($M = 4.09$, $SD = .86$) was rated more helpful than the other components, followed by physical activity ($M = 3.98$, $SD = .91$) support groups ($M = 3.92$, $SD = 1.21$), and stress management ($M = 3.75$, $SD = 1.11$). On the Group Environment Survey, participants rated all aspects of the program highly, agreeing most with the statement that they “liked meeting the people who came to the program” ($M = 7.80$, $SD = 1.1$) and agreeing least with the statement, “In terms of the social experiences in my life, this group was very important” ($M = 7.03$, $SD = 1.8$). When rating the support group only rather than the program as a whole, participants were highly satisfied with all aspects, agreeing most with the statement that they “liked meeting the people who came to the program” ($M = 7.60$, $SD = 1.47$) and agreeing least with the statement, “I was happy with all of the activities we did in this group” ($M = 6.80$, $SD = 2.01$).

Discussion

Relatively little research has been conducted to test interventions for changing multiple lifestyle behaviors simultaneously (46). Many studies that have taken on this challenge have (1) examined at most two health practices at a time (e.g., depression and low perceived social support) (47) despite complex interactions between various health habits (e.g., (48)); (2) focused mostly on men (28,31); or (3) used a more intensive and time-consuming intervention than the Mediterranean Lifestyle Program (31,32). Historically, scientists have shied away from real-world, multiple-lifestyle interventions, in part because of perceived problems with recruitment and retention, treatment fidelity, intervening on multiple risk factors, time and expense, and dissemination. Studies of this kind are difficult, but necessary to develop behavioral programs powerful enough to truly help people prevent or cope with chronic illnesses. Multiple-risk-factor interventions may produce more CHD risk reduction than single-factor interventions (49), and are critical for older adults because of the multiple chronic medical conditions typical in this age group. Such interventions are especially critical in diabetes because of the myriad of complications associated with it, the complexity of the treatment regimen, and the enhanced CHD risk, especially among women with diabetes.

Results of the Mediterranean Lifestyle Program suggest that many of the challenges associated with a multiple-behavior intervention may be successfully overcome. This study demonstrates that it is possible to deliver an appealing, moderately intense program to a relatively high and representative percentage of older, chronically ill women. The program consistently produced significant improvements from baseline to 6 months compared to usual care across a variety of measures, encompassing all of the four diverse CHD risk factors targeted: eating patterns, physical activity, social support, and stress management. While some of the changes were small (i.e., servings of fruit and vegetables increased by only .5 servings) and of debatable clinical significance, the intervention succeeded in changing multiple behaviors.

The effects of the Mediterranean Lifestyle Program were produced by an intervention consisting of (1) an initial, nonresidential weekend retreat to teach program components and (2) weekly 4-hour group meetings lasting 6 months. On the face of it, such a program may

seem demanding for staff and onerous for participants. In fact, it was neither. Though health professionals were used at the retreat to teach program components, weekly meetings were conducted by trained but relatively inexpensive research assistants. Their role was not to teach, but to ensure a safe and orderly group experience. Participants gladly invested time for the program, expressing gratitude for the opportunity to learn and practice healthy habits, and to make social connections with other women struggling with similar health issues.

Taken together, the pattern of changes produced by the Mediterranean Lifestyle Program could have considerable public health impact, given the high risk for CHD and other illnesses among women with diabetes (3). The criticism that “no one would ever participate or adopt this program” was frequently heard when we launched the intervention 5 years ago. However, the **data** on adoption (70% among primary care physicians approached) and participation rate (a representative 51% of eligible patients) do not support such a criticism. Our goal was to provide the intensity and support necessary to produce major lifestyle changes. Moderately intense lifestyle management programs may not seem feasible given the resources of many health care systems. However, such a program may be warranted for people at high risk for CHD-related diseases, such as the women who participated in this trial.

Besides intensity, the primary threat to disseminability is presumed cost. An explicit cost and cost-effectiveness analysis to determine precisely how costly this intervention is ! and how that compares to alternatives and CHD treatment options ! is indicated. The likely costs of our program are much less than those of the Diabetes Prevention Program (50) and Look Ahead (which relies on highly trained leaders and medications; see (51)). The costs are also vastly lower than coronary bypass surgery, which consumes more health dollars than any other medical procedure in the U.S. (52).

There are other practical and public health implications of our results. Our participation rates may be influenced by the fact that participants were not charged for the program. If it were to be widely adopted, either patients or their health plans would have to pay, which could reduce participation. On the other hand, participants in this study had to agree to randomization, and to complete lengthy surveys and biological assessments, which would not be required in clinical settings.

This study has both methodological strengths and limitations. Strengths include the relatively large and generally representative sample, broad-based recruitment, the randomized design, the use of varied and valid measures, multivariate analytic procedures, the targeting of multiple risk behaviors, the consistent results, and the use of the RE-AIM framework to evaluate potential for translation.

Limitations include the lack of an ethnically diverse population (though representative of the local area) and use of self-report measures. The consistency of findings across methods and formats suggests results were not simply due to demand characteristics, however.

The primary intent of the first 6 months of this intervention was to increase support by means of a shared experience with others in changing important lifestyle behaviors and participation in a support group. The one source of support that did not improve, but seemed to worsen in both conditions, was health care provider. While not a specific study target in the first 6 months, an increased perception of support was anticipated because many support group sessions focused on stress and lack of support from family, friends, and health care providers. It is possible that the support groups empowered the women to demand more of their health care providers – and to be dissatisfied if the level of care did not measure up.

A final limitation of this study was that the comparison, usual care condition likely varied across participants in the ways that behavioral issues were addressed. Future studies should

address the replicability and robustness of these findings across different settings, intervention agents, and levels of intensity compared to different control conditions, and with more diverse populations. Future studies also should explore alternate strategies for targeting multiple behaviors, such as sequencing the introduction of each behavior and examining “spillover effects” of change in one lifestyle behavior on change in other behaviors. More research is needed to establish maintenance of effects and long-term cardiovascular health improvements from multiple-risk-factor trials such as the Mediterranean Lifestyle Program.

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Table 1
 Characteristics of Participants by Treatment Condition

Characteristic	Mean (SD) or Percent		p
	Usual Care (N=116)	MLP (N=163)	
Age	60.7 (7.8)	61.1 (8.0)	.70
Weight (kg)	93.9 (23.8)	92.3 (21.2)	.55
Waist/hip ratio	0.90 (.08)	0.91 (.08)	.35
Body mass index (kg/m ²)	35.6 (8.8)	35.1 (7.7)	.62
Age diagnosed with diabetes	52.5 (10.7)	53.0 (10.0)	.71
Years taking medications	5.0 (6.3)	4.9 (4.9)	.90
Years diagnosed with diabetes	8.5 (8.3)	8.2 (7.3)	.77
Smoker (% yes)	10.3	8.7	.59
Income			.22
% \$0 to \$ 9,999	14.9	5.8	
% \$10,000 to \$19,999	21.9	24.5	
% \$20,000 to \$29,999	17.5	23.9	
% \$30,000 to \$39,000	17.5	14.2	
% \$40,000 to \$49,000	10.5	11.0	
% \$50,000 to \$59,999	9.5	5.8	
% \$60,000 to \$69,999	0.9	5.2	
% \$70,000 to \$79,999	1.7	3.9	
% \$80,000 plus	5.2	5.8	
Type of medication			.62
% none	17.2	24.7	
% oral medication only	61.2	54.9	
% insulin only	12.1	7.4	
% insulin and oral medication	9.5	13.0	
Present living arrangement			.43
% with spouse	49.1	51.5	
% with spouse and children	11.2	9.8	
% with children or others	9.4	14.7	
% alone	30.2	23.9	
Level of education achieved			.72
% 0 to 11th grade	11.2	8.5	
% high school graduate	25.0	25.2	
% some college	39.7	43.6	
% college/university graduate	24.1	22.7	
% Caucasian	94.8	92.0	.59
Hemoglobin A1c (%)	7.6 (1.6)	7.4 (1.3)	.35
Medications			
% taking lipid-lowering	40.5	38.9	.79
% taking blood pressure-lowering	47.4	46.3	.86
% taking estrogen replacement therapy	46.6	59.3	.04
Number of comorbidities			.27
% with no other disease	4.3	4.9	
% with 1–2 other diseases	43.1	50.9	
% with ≥3 other diseases	52.6	44.2	
Most prevalent comorbidities			
% having CHD	15.0	14.0	.26
% having arthritis	50.9	56.4	.36
% having high blood pressure	72.4	70.6	.74
% having back problems	37.9	33.1	.41

Table 2

Behavioral Outcomes

Measure	Assessments Covariate adjusted 6-month means and standard errors	Significance of MANCOVA [/]	
		Individual 6 months	Overall 6 months
Diet outcomes		Wilks' $\lambda = .72$, $F(8,209) = 10.44$, $p < .001$	
Adherence to Mediterranean diet (7-Day Self-Monitoring Log)	MLP	5.65 (.09)	
FFQ daily fruit consumption	UC	4.79 (.10)	
	MLP	2.15 (.10)	<.001
FFQ daily vegetable consumption	UC	1.62 (.11)	
	MLP	2.62 (.11)	<.001
FFQ total fat (g.)	UC	2.03 (.11)	
	MLP	46.56 (2.26)	<.001
FFQ total saturated fat (g.)	UC	62.13 (2.40)	
	MLP	14.56 (.83)	<.001
Summary of Diabetes Dietary Self-Care Activities	UC	20.53 (.88)	
	MLP	4.60 (.09)	<.001
Fat and Fiber Behavior Questionnaire	UC	3.94 (.10)	
	MLP	1.75 (.03)	<.001
Weight (kg)	UC	2.04 (.03)	
	MLP	91.73 (.40)	.004
	UC	93.44 (.43)	
Physical activity outcomes		Wilks' $\lambda = .86$, $F(3,215) = 12.17$, $p < .000$	
MET's X duration X days from 7-Day Self-Monitoring Log	MLP	80.90 (6.41)	
Number days exercise in past 7 days from Summary	UC	55.90 (6.89)	<.009
Diabetes Exercise Self-Care Activities	MLP	3.9 (.17)	<.000
Caloric expenditure per week for all activities from the CHAMPS	UC	2.53 (.18)	
	MLP	4763 (255)	<.001
Stress-management outcomes		Wilks' $\lambda = .85$, $F(4,219) = 9.7$, $p < .000$	
Average number of minutes per week engaged in stress-management stretching	UC	3459 (274)	.007
	MLP	7.57 (.76)	
Average number of minutes per week engaged in stress-management breathing	UC	4.50 (.82)	
	MLP	7.12 (.59)	<.000
Average number of minutes per week engaged in stress-management visualization	UC	3.93 (.63)	
	MLP	7.43 (.77)	.006
Average number of days practiced all stress-management techniques	UC	4.23 (.83)	
	MLP	4.97 (.24)	<.001
	UC	2.78 (.25)	

[/] Significance of two-tailed multivariate analysis of covariance (MANCOVA) comparing Mediterranean Lifestyle Program (MLP) and usual care (UC) follow-up scores, covarying out the effect of baseline scores and social desirability.

Table 3
Social Support Outcomes

Measure		Covariate-adjusted Means and standard errors at 6 months	Significance of MANCOVA ¹	
			Individual 6 months	Overall 6 months
Behavior-specific support for diet and exercise			Wilks' $\lambda = .94$, $F(2,236) = 7.87$; $p < .001$	
CIRS support for diet	MLP	2.82 (.06)	<.001	
	UC	2.49 (.07)		
CIRS support for exercise	MLP	2.45 (.06)	.004	
	UC	2.17 (.06)	Wilks' $\lambda = .94$, $F(3,222) = 4.69$; $p = .003$	
Source of support: friends	MLP	3.63 (.05)		
UCLA support from friends	UC	3.45 (.06)		
CIRS support from friends	MLP	2.75 (.07)		
	UC	2.37 (.08)	.001	
7-Day Self-Monitoring support from friends	MLP	.75 (.03)		
	UC	.71 (.03)	Wilks' $\lambda = .95$, $F(3,222) = 3.63$; $p = .014$	
Source of support: family	MLP	2.74 (.08)		
CIRS support from family	UC	2.39 (.08)		
UCLA support from relatives	MLP	3.95 (.05)		
	UC	3.90 (.06)	.525	
7-Day Self-Monitoring support from family	MLP	.86 (.02)		
	UC	.82 (.02)	Wilks' $\lambda = .99$, $F(3,222) = .433$; $p = .729$	
Source of support: health care provider	MLP	3.56 (.08)		
CIRS support from health care provider	UC	3.64 (.09)		
UCLA support from health care provider	MLP	3.08 (.06)		
	UC	3.12 (.07)	.518	
7-Day Self-Monitoring support from health care provider	MLP	.41 (.04)		
	UC	.37 (.04)	.471	
Source of support: support group	MLP	3.40 (.08)		
	UC	1.59 (.09)	<.001	

¹ Significance of two-tailed multivariate analysis of covariance (MANCOVA) comparing Mediterranean Lifestyle Program (MLP) and usual care (UC) follow-up scores, covarying out the effect of baseline scores and social desirability.