

Oregon Research Institute

Project Name ...

Mediterranean Lifestyle Program

Principal Investigator ...

*Deborah J. Toobert, Ph.D.
Research Scientist, Diabetes and Heart Disease Lifestyle Trials
Oregon Research Institute
1715 Franklin Blvd.
Eugene, OR 97403
tel. 541-484-4421 (x 2407) ; fax. 541-434-1502*

Background / Significance of Problem ...

Coronary heart disease (CHD) is the leading cause of death and functional limitations among women in the U.S. Postmenopausal women with diabetes are at especially high risk of CHD, but CHD research with this population is very limited. Epidemiological and clinical studies suggest that diabetes is associated with increased risk for CHD that is greater in women than in men. CHD is a major cause of death and functional limitations in women, but the vast majority of CHD studies have primarily involved middle-aged men. There is convincing research evidence that healthy lifestyle behaviors, including low-fat diet, physical activity, stress management, smoking cessation, and social support, can reduce CHD risk.

Research Question ...

The overall goal of this project was to test a practical, theory-based intervention to achieve long-term behavior change for women with type 2 diabetes at high risk for developing coronary heart disease (CHD). We conducted a randomized trial to compare short-term (6-month) outcomes in women receiving usual care compared to a modified Ornish-type comprehensive lifestyle management (CLM) intervention. After 6 months, women in the CLM condition were randomized to one of two approaches for providing support – either lay-led group support or personalized computer-based support – to evaluate these strategies in enhancing longer-term maintenance of effects. Outcomes included multiple CHD lifestyle behaviors (e.g., dietary intake, exercise levels, stress management, smoking cessation), physiological risk factors associated with CHD (e.g., serum lipids, hypertension, weight, vascular reactivity), HbA1c, and quality of life (e.g., depression, functioning).

Findings To-Date ...

- [•] **BEHAVIORAL OUTCOMES:** In intent-to-treat analyses, Mediterranean Lifestyle Program (MLP) participants showed significantly greater improvement in dietary behaviors, physical activity, stress management, at 6 and 12 months compared to a usual care (UC) control condition.
- [•] **PHYSIOLOGICAL OUTCOMES:** Multivariate analyses of covariance revealed significantly greater improvements in the MLP condition compared to the usual care group on hemoglobin A1c, body mass index, plasma fatty acids, and quality of life at 6-month follow-up.

-] **PSYCHOSOCIAL OUTCOMES:** At the 6- and 12-month assessments, MLP participants made significantly greater improvements than UC participants on measures of diet behavior self-efficacy, exercise behavior self-efficacy, and confidence in overcoming challenges to illness management. Those treatment effects are important because self-efficacy has a significant influence on self-management and clinical outcomes, even after controlling for the strong predictive effect of past levels of self-care. Clinical depression occurs in 15-20% of people with type 2 diabetes, and interferes with adequate self-treatment and glycemic control. While we did not specifically intervene on depression and did not select a clinically depressed sample to study, the MLP condition showed decreases and the UC condition showed increases in depression, and the between-group difference in depression was marginally significant ($p=.053$) at 6-month follow-up.
-] **SOCIAL RESOURCES:** Compared to UC, MLP participants reported significant improvements in social support following the first 6 months of intervention. This effect was maintained at 12 months. Those improvements included increases in the amount of perceived emotional and tangible support, and increases in support from friends and family members. Our measure of personal, social, and community resource use, the Chronic Illness Resources Survey, also showed a significant treatment effect at the 6- and 12- month assessments. We conducted analyses to determine if the MLP intervention was differentially effective for women who varied on education, income, employment status, comorbid illness, and several indicators of pretreatment levels of social support. Results showed no indication that the effects of the MLP intervention on diet, exercise, or stress management were affected by a large number of background characteristics.

Implications ...

[for multibehavioral and multi-theoretical approaches to behavior change]

-] The next step in this research is to investigate the poorly understood natural history of long-term maintenance of change in multiple behaviors (i.e., dietary, physical activity, and stress management) related to CHD risk, as well as the effects of theoretically important mediating variables on relapse and maintenance. This research could rely on a framework that synthesizes social-cognitive, social-ecologic, and goal-systems theories. It should also provide important scientific and theoretical information about the patterns of maintenance/relapse among multiple risk factors, and about the relative importance of theoretical mediating variables (e.g., self-efficacy, problem-solving, peer and community support). This natural history of maintenance may be examined using a variety of statistical approaches, including mediational and latent growth modeling techniques.
-] In addition, the potential for translating this program into the real world could be assessed using the RE-AIM evaluation framework, a cost-effectiveness analysis should be conducted, and, if the approach is cost effective, the intervention should be disseminated.