Enhancing support for health behavior change among women at risk for heart disease: the Mediterranean Lifestyle Trial

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Abstract
This paper describes a randomized study to evaluate the effects of a comprehensive lifestyle management intervention for 279 postmenopausal women with type 2 diabetes who are at elevated risk for coronary heart disease (CHD). The intervention, called the Mediterranean Lifestyle Trial, is focused on dietary factors, physical activity, social support and stress management. The Mediterranean Lifestyle Trial relies on a synthesis of Social Cognitive Theory and Social Ecologic Theory, as well as goal-systems theory, to explicitly inform the lifestyle intervention and to address maintenance. Thus, the trial should help illuminate the theoretical mechanisms responsible for lifestyle change. Primary outcome variables are dietary, stress management and physical activity behavior change, quality of life, and CHD-related biological risk factors. Hypothesized mediating variables include self-efficacy, coping, and social and environmental support. Following the initial 6-month intervention, participants in the intervention condition are randomized to one of two groups designed to enhance maintenance of effects: either a peer-led support group or a personalized multilevel community resources maintenance condition. Unlike the peer group, the personalized approach focuses on multiple levels of community resources to promote healthful lifestyle change. Because this research focuses on issues of generalization and translation to practice, the RE-AIM evaluation framework is being used to evaluate Reach, Effectiveness, Adoption, Implementation and Maintenance. This framework will help to translate research into practice by directing researchers’ attention to important but seldom-investigated strategies for enhancing longer-term maintenance. Specifically, the study tests how long-term maintenance may be improved through the use of existing community resources, an intervention based on multiple environmental factors and multiple lifestyle behaviors, and lay leaders versus personalized professional support.

Introduction
As the leading cause of death among women in the US, coronary heart disease (CHD) (Khaw, 1997) exacts a high toll both in human suffering and cost (Graboyes et al., 1987). Postmenopausal women who have diabetes typically are overweight and are at particularly high risk for morbidity and mortality from CHD (Barrett-Connor et al., 1991; National Diabetes Data Group, 1995). Mortality from CHD is 3- to 5-fold higher in women with type 2 diabetes than in non-diabetic women and reaches coronary event rates similar to those of men with diabetes (Kannel and McGee, 1979; American Diabetes Association Consensus Statement, 1992). However, few studies have focused on the CHD problems unique to women with type 2 diabetes (Howard et al., 1997).

A number of behavior-related CHD risk factors

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have been identified for women, including high-fat diet (Jeppesen et al., 1997), smoking (Brownson et al., 1998), sedentary lifestyle (Kannel, 1990), exaggerated stress responses (Weidner and Messina, 1995) and social isolation (Case et al., 1992; Berkman et al., 1992; Williams et al., 1992). Behavioral changes, such as reduced fat intake, smoking cessation, increased physical activity, stress management and social support, are thought to promote healthy lifestyles and reduce CHD risk [see (Toobert et al., 1998b) for review]. Although most studies designed to address CHD behavioral risk factors have concentrated on a single health practice (e.g. smoking cessation), data suggest multiple risk factor interventions could be a powerful method for addressing the complex interactions between lifestyle behaviors, the social environment, and maintenance effects (Ornish et al., 1983; Haskell et al., 1994; Toobert et al., 1998a).

Another intervention dilemma addressed by this project is 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 (Haskell et al., 1994; Lowrie et al., 1995), especially for women (Boogaard, 1984; Oldridge et al., 1990; Ades et al., 1992). This project attempted to deliver a moderately intensive intervention in a way that attracted a high percentage of the target population. Finally, the project addressed the well-documented maintenance/relapse problem (Orleans, 2000a) by experimentally testing two different maintenance interventions, focusing on peer social support and community resources.

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 very few published accounts of interventions specifically designed to train adults, especially women, at risk for CHD in obtaining or maintaining social support. In those that do exist (Wilson and Pratt, 1987; Chesney, 1996; Barrera et al., 2002), rarely has it been possible to identify the separate influences of social support factors. This project experimentally investigated whether ongoing support group sessions over 24 months enhanced the practice and maintenance of healthful lifestyle behaviors relative to usual care. A second maintenance condition adopted a broader perspective on support, focusing on multiple levels of community resources (Glasgow et al., 2000a) to enhance maintenance of treatment outcomes.

**Purpose**

This project had two primary objectives. The first was to test a practical, theory-based Comprehensive Lifestyle Management (CLM) intervention to reduce CHD risk in postmenopausal women with type 2 diabetes, using procedures shown to be successful in middle-aged men (Ornish et al., 1990) that we have previously successfully modified for our Women’s Lifestyle Heart Trial (Toobert et al., 2000). Second, to promote long-term maintenance of initial changes associated with the CLM intervention, the study evaluated two approaches for providing support—either lay-led group support or tailored, computer-based support to enhance use of existing community resources, such as family, friends, the health care system and media.

The RE-AIM evaluation framework, which our group has developed and described elsewhere (Glasgow et al., 1999, 2001), was used to evaluate Reach, Effectiveness, Adoption, Implementation and Maintenance of the intervention. This framework was selected to guide the evaluation because it explicitly focuses on issues related to representativeness and replication in applied settings, which were primary concerns of the investigation. RE-AIM expands on work by Abrams et al. (Abrams et al., 1994), who proposed that the impact of an intervention was a function of its Reach times its Efficacy. As specified in Methods, RE-AIM extends this thinking to include other setting and intervention agent factors of Adoption, Implementation and Maintenance—all of which combine with Reach and Effectiveness to determine the overall public health impact of an intervention (Glasgow et al., 1999, 2001).
Fig. 1. Our intervention model incorporates a combination of SCT, SET and goal-systems theories.

**Process used to select theoretical model**

Historically, our work was guided by a Social Cognitive Theory (SCT)-based (Bandura, 1986, 1997) conceptual model of diabetes management and education (Glasgow, 1991; Glasgow and McCaul, 1982). This model has become more complex over time, reflecting our research findings. We began by seeking to identify and to understand, from the perspective of persons having diabetes, the social-environmental, psychological, economic and biomedical factors related to diabetes self-management. We worked to translate the results of our research into efficient, tailored interventions to help patients better manage their diabetes diet and, in some cases, improve physical activity.

Our current model (see Figure 1) has evolved into a combination of SCT, goal-systems theory (Karoly, 1993; Glasgow, 1995; Glasgow et al., 1995; Glasgow and Eakin, 1998) and social ecological theories (SETs) (Moos, 1979; McLeroy et al., 1988; Stokols, 1996; Glasgow et al., 2000a) 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 support resources (Glasgow et al., 1995; Glasgow and Eakin, 2000). In previous studies, our research group and others identified multiple system and social-environmental factors that influence self-management of chronic illness (Glasgow et al., 2000a). Some of the social-environmental factors we have documented include social support (Glasgow and Toobert, 1988), barriers to adherence (Glasgow et al., 2000a) and problem-solving skills (Toobert and Glasgow, 1991).

We have combined this model with interactive technology to develop assessment and treatment procedures that both address these features and are: (1) feasible to use in medical offices and other settings frequented by patients; (2) applicable to and capable of reaching a large percentage of persons with diabetes; (3) helpful to both patients and health care providers; and (4) potentially generalizable to self-management of other chronic diseases (Glasgow et al., 1995). We chose SCT and the social-ecological framework to inform our intervention and evaluation out of our desire to focus on the interaction between individual and the environmental factors. We believe these issues were best addressed by the reciprocal determinism aspect of SCT and the explicit multilevel perspective of SET.

More recently, we incorporated several aspects of the Ornish et al. comprehensive lifestyle management program into our approach (Ornish et al., 1990). One of Ornish’s main contributions was suggesting 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. The current study was based on our previous work aimed at women with CHD (Toobert et al., 1998a, 2000), in which we intervened simultaneously on a combination of factors (i.e. diet, exercise, smoking cessation, stress management and social support).

For the maintenance phase of the trial, we turned to SET, which addressed the complex and multilevel factors that have been shown to influence lifestyle behaviors (Orleans, 2000; Emmons, 2000). We conceived of these multiple levels as a ‘pyramid of influences’, with a range from proximal and relatively well-studied influences on self-management, such as personal self-efficacy, family support and health care provider–patient communication, to more distal and much less researched community-level factors, such as...
workplace, neighborhood and media. Each level contains both barriers to behavior change/disease management and supportive resources that can enhance outcomes.

This research is novel in that it integrates (1) practical theory-based interventions derived from the above, (2) a focus on, and measures of, social/community support, (3) high-risk women with a chronic disease (diabetes), (4) use of the RE-AIM evaluation framework, and (5) an explicit focus on maintenance issues.

Method

Population
Participants were 279 postmenopausal women with type 2 diabetes, at high risk for CHD, who received their medical care from participating primary care clinics. Participants were stratified on (1) physician practice, (2) smoking status and (3) type of diabetes medication. Inclusion criteria were: female sex, diagnosis of type 2 diabetes for at least 6 months using the Welborn criteria (Welborn et al., 1983), postmenopausal, under age 75, 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. All patients who met the above eligibility criteria were sent a letter from their primary care provider, followed by a phone call inviting them to participate, and records were kept of the percent and representativeness of those who participated.

A total of 1162 women were mailed recruitment letters, of whom 184 (15.8%) returned postcards declining further contact. Of those remaining, 850 women (87%) were contacted by phone. Of those women reached by phone, 544 (64%) met eligibility criteria. A total of 279 (51%) women eligible for the program agreed to participate and completed the initial assessment.

Design
A total of 123 participants were assigned to usual care (UC) and 156 were initially randomized to the CLM program. CLM participants were randomized again 6 months later to one of two different maintenance conditions (78 each to lay-led peer group support or computer-based tailored community resources support) (see Figure 2). We projected a moderate to large effect size of $f = 0.30$ (Cohen, 1988) for between-condition effects. Although this effect may appear ambitious for a lifestyle change program, it is actually conservative, given our own previous findings and results from other researchers in this area. Cohen indicates that with an $f = 0.30$, a final sample size of 210 (90 for UC and 60 each for the treatment conditions) results in a power of 0.85 ($\alpha = 0.05$, one-tailed) (Cohen, 1988). Thus, 279 baseline participants allowed for more than 15% attrition.

Variables
Organized according to the RE-AIM assessment framework, including the following measures.

Reach
Reach was assessed by measuring participation rate among eligible patients, as described above. Reach measures also included representativeness by comparing participant versus non-participant characteristics.

Effectiveness
Effectiveness was measured using:

(a) Behavioral endpoints, including dietary intake and eating habits [Kristal Fat and Fiber Behavior Questionnaire (Kristal et al., 1990, 2000)], NIH Fat Screener (Thompson et al., 1998), physical activity self-report [CHAMPS Activities Questionnaire for older adults (Stewart et al., 1998)], and fitness and flexibility testing; smoking self-report and carbon monoxide testing; and self-monitoring of stress management practice.

(b) Physiologic endpoints, including carotid artery intimal-media thickness (a non-invasive ultrasonographic marker of atherosclerosis), lipid (e.g. apolipoprotein B, a detailed quantitative profile of lipoprotein fractions) and HbA1c levels, blood pressure, and body mass.
(c) Psychosocial outcomes, including quality of life and degree of depression.
(d) Process measures and potential mediating variables related to our theoretical model, including: perceived social support (both interpersonal and broader community resources), perceived stress, obstacles or barriers to lifestyle change, self-efficacy, problem solving, depression, coping and, for the intervention conditions, group cohesion.

**Adoption**
Assessed at the setting/provider level, adoption concerned the participation rate and representativeness of clinics (e.g. medical offices and physicians).

**Implementation**
Implementation indices assessed the consistency with which different intervention components are delivered (by different intervention agents) over time. Measures included intervention checklists, and the percent of participants receiving mailings and follow-up calls.

**Maintenance**
Maintenance was measured at both the individual and the setting levels. Individual-level maintenance referred to the longer-term effectiveness measures at 12- and 24-month follow-ups, including attrition. At the setting level, maintenance referred to whether an innovation or program was retained (became institutionalized) or was dropped over time. We surveyed participating physician practices at the end of the study to gather feedback on the CLM program and to investigate their commitment to this program if it were to be offered as a service.

**Intervention**
The CLM program was conducted with participants in four successive waves, with 35–40 women in each wave. It lasted 6 months and addressed the
primary behavioral risk factors affecting CHD in postmenopausal women (i.e. diet, physical activity, stress management and smoking), and included a generic social support intervention delivered by professional leaders. After 6 months, CLM participants were randomized to either: (1) CLM with support delivered by lay leaders and program components led by non-professional leaders or videotapes or (2) the CLM program plus tailored social support, described below.

**Eating patterns**
During a 3-day retreat and as part of the weekly sessions, study participants were taught by the project registered dietitian to follow the Mediterranean ω-linolenic acid-rich diet that is low in saturated fat but moderately high in more healthful monounsaturated fats (de Lorgeril *et al.*, 1994; Renaud *et al.*, 1995). The dietitian individualized carbohydrate and fat requirements to optimize blood glucose and lipid concentrations within the parameters of the lifestyle program. The diet recommended more bread; more root vegetables, green vegetables and legumes; more fish; less red meat (beef, lamb, pork), replaced by poultry; no day without fruit; and avoidance of butter and cream, to be replaced by olive oil or margarine with a composition comparable to olive oil.

**Physical activity**
The physical activity goal was consistent with the recent ACSM/CDC guidelines for physical activity (*Pate et al.*, 1995) and developed in consultation with the project exercise physiologist. Women who engaged in no, or very little, activity were advised to gradually increase activity about 5 min per session and/or increase the number of days per week they engaged in moderate aerobic activity. The eventual physical activity goal of the project was to engage in a 1-h session per day at least 3 days per week.

**Stress management**
Stress management was also a key component of the CLM program. Using procedures from Ornish (1990) and Toobert *et al.* (*Toobert et al.*, 1998a), participants were taught to engage in the following stress management techniques each day: (1) 20 min of yoga, (2) 15 min of progressive deep relaxation techniques, (3) 15 min of meditation and (4) 5 min of directed or receptive imagery (e.g. visualizing improvements occurring in the heart). The purpose of each technique was to increase the participant’s sense of relaxation, concentration, and awareness. Participants were asked to practice these stress management techniques for at least 1 h per day and received an audiocassette tape to assist them.

**Retreat**
The CLM program began with a 3-day retreat to provide an experience of the new lifestyle, build camaraderie, and teach program components. The Women’s Lifestyle Heart Trial (*Toobert et al.*, 1998a, 2000) and the Lifestyle Heart Trial (Ornish, 1990) program began with a week-long residential retreat to teach the lifestyle intervention to the experimental group. In an effort to ease the burden of such an intense program, in this trial we developed a shorter, non-residential retreat (3 instead of 7 days).

The daily retreat schedule included lectures by the project registered dietitian featuring components of the Mediterranean diet. Retreat meals were planned by the project dietitian and were prepared by local caterers under her direction. Participants received 3 months’ worth of recipes. Study participants received instruction in, and had an opportunity to practice, stress management techniques twice per day during the retreat. Physical activity included warm-up, walking or other aerobics and a cool-down led by an ACSM-certified exercise physiologist.

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.
Weekly meetings
Immediately following the 3-day retreats, participants began attending weekly 4-h meetings to provide social support. Each weekly meeting followed a similar sequence: physical activity, group yoga and relaxation, a Mediterranean potluck dinner, and small group support sessions.

Support group leaders
Individual support group leaders were trained interventionists. The lay leaders received co-leadership experience and supervision from the professional group leaders during the 6-month intervention phase and both were supervised by a clinical psychologist. After re-randomization at 6 months, the professional leaders ended their involvement and the lay leaders assumed primary responsibility for the support groups.

Attendance
The first 6 months of the intervention was designed to teach the program components and to build group cohesion. A variety of motivational techniques derived from SCT and SET were employed to keep the meetings interesting and to boost attendance including contests, and group and individual rewards. Average attendance for the four waves of study participants ranged from 66 to 83%.

Program adherence
During the weekly meetings, several techniques for encouraging compliance with the dietary, physical activity and stress management program recommendations were employed. These techniques were derived from a combination of social-cognitive features, and systems-based and SETs, and included incentives (monetary awards, contests), self-monitoring and feedback on goal achievement.

Maintenance conditions
The two maintenance conditions were not equally intense. The lay-led support group was more intense in solidifying the peer interpersonal support established in the initial intervention phase. Continuity and familiarity were advantages for this condition. This study evaluated two strategies for enhancing longer-term maintenance: the continuity of a known (but relatively narrow) intervention with lay leaders (CLM + LL) and a broad-based interactive approach to enhance community resources (CLM + CR).

CLM intervention with lay leaders (CLM + LL)
Participants randomized to the CLM + LL condition continued the weekly meetings led by exercise assistants and lay support group leaders. After 6 months post re-randomization, weekly meetings were faded to twice per month for 6 months and then to once per month for 6 months.

CLM intervention with tailored social support (CLM + CR)
The CLM + CR intervention used a broad-based social-environmental approach to increase social support and community resources to enhance maintenance of their healthy lifestyle practices. This condition (1) used a computer-assisted interactive version of the Chronic Illness Resources Survey (Glasgow et al., 2000a) to identify personally relevant support resources at multiple levels (e.g. friends, neighborhood, media) and help participants set goals for increasing use of social support and community resources; (2) broadened the support enhancement intervention to include work, health care providers, the community/neighborhood, media and other social environmental contextual factors in addition to personal, family and peer support; and (3) took advantage of the computer’s ability to rapidly score assessments and provide immediate feedback to both participants and interventionists, and to periodically revise support targets.

Individual support enhancement sessions were scheduled four times during the 18 months following re-randomization for each woman in the CLM + CR group. At each session, (1) Motivational Interviewing techniques (Miller and Rollnick, 1991; Rollnick et al., 1995) were used to assist the participant in choosing one lifestyle area (i.e. diet, physical activity or stress management) to focus on for the next 3 months and (2) participants completed a computer-assisted CD-ROM assess-
Fig. 3. Our logic model of intervention effects shows the contextual and mediating variables that influenced, and were incorporated into, our initial and maintenance interventions.

ment to develop a plan for enhancing support in that lifestyle area. In keeping with SCT and systems-based SETs, we explicitly considered factors supportive of, and interfering with, behavior change at each of the different levels (e.g. empowerment at the personal level, collaborative goal-setting at the health care team level). These factors were addressed in the CD-ROM developed for this project, entitled ‘A Healthy Village: Building Support for Lifestyle Change’. The CD-ROM helped participants set specific goals to increase support for diet, physical activity or stress management for the following 3 months. For example, a goal from the neighborhood or community area is, ‘Visit a community or senior center to take cooking classes or eat healthful meals’. Participants also selected specific actions they would take to address the chosen goal. An example of an action item for the goal listed above is, ‘Volunteer to help serve healthful meals at community centers to others. By serving others, you will help yourself. Ask for volunteer opportunities at community centers, senior centers, or homeless shelters’.

In keeping with a social-cognitive approach to behavior change, at the conclusion of this brief session, patients received a personalized printout containing four sets of information: (1) their chosen goal for achieving support in one lifestyle area, (2) their chosen action items for achieving their support enhancement goal, (3) space to list the difficult situations in each area for which to be prepared (generated together with the interventionist) and (4) space to list specific problem-solving strategies for these situations. Participants in the CLM + CR condition received community resource newsletters and a brief follow-up phone call from an interventionist in months without goal-setting sessions.
Hypothesized intervention model

Our logic model of intervention effects is presented in Figure 3. The model shows the contextual and mediating variables from the theoretical models that influenced, and were incorporated into, both the initial and the maintenance interventions and hypothesized outcomes. The approach is novel in part because it tests two different types of support for maintenance of intervention effects. This study will test the extent to which the social-cognitive factors of self-efficacy and problem-solving skills, and social-ecologic factors of social support and community resource utilization, (1) are impacted by the experimental conditions and (2) mediate treatment outcomes. We hypothesize that the effects of both CLM interventions will be mediated by the variables described above, with the exception that at long-term follow-up, CLM + LL (but not CLM + CR) will be mediated by group cohesion; and that CLM + CR (but not CLM + LL) will be mediated by community resource utilization.

Discussion

This study makes several important contributions to existing behavior-change intervention research. First, it addresses a gender gap in CHD and diabetes research (Toobert et al., 1998b). Based on our earlier promising preliminary findings (Toobert et al., 1998a, 2000) and other research targeting postmenopausal CHD women, we have modified procedures developed by Ornish (Ornish, 1990) to improve self-care among women with type 2 diabetes who are at high risk for CHD. Second, this project combined features of SCT and SET to increase the effectiveness of our intervention and maintenance conditions. We have used multiple behavioral strategies to modify multiple lifestyle behaviors designed to reduce CHD risk (e.g., improvement in diet, stress management, social support, smoking and physical activity) and avert costly and invasive medical procedures. Third, this project has brought together two promising lines of research: the work of Ornish et al. (Ornish et al., 1990), which is a more practical and less theoretical comprehensive lifestyle management program for heart disease patients, and the work of Glasgow and Toobert (Glasgow and Toobert, 2000), which has focused on diabetes self-management and the psychosocial processes that produce changes in self-care. While there is strong research linking social support and CHD risk, few interventions have been designed to enhance social support in women at risk for CHD. Several facets of social support are pertinent to the understanding of lifestyle change in women. These include: (1) the measurement of social support as a multifaceted construct, (2) the link between social support (in its many forms) and the ability to successfully engage in healthful lifestyle practices, and (3) the link between social support and CHD risk factors. Our previous comprehensive lifestyle program for women with CHD, (Toobert et al., 1998a) was effective in improving perceptions of supportive and non-supportive behaviors directed toward study participants by their families specific to health-related eating and exercise behaviors. The prior work suggested that social support components were important, leading us to evaluate two conceptually distinct approaches to enhance maintenance/prevent relapse that focus on different types and levels of social support. The project also uses the RE-AIM framework to investigate critical but under-researched factors, such as Reach, Adoption and Implementation, which are vitally important for dissemination and closing the gap between research and practice. Explicitly studying issues of participation and representativeness at both participant and provider levels should lead to better estimates of the likely rates of adoption, impact, and sustainability in later, non-research settings. Finally, the study provides the opportunity to relate theoretical processes or mechanisms of change (e.g. self-efficacy, perceptions of support, group cohesion and community resource utilization) to outcomes to advance our theoretical understanding of how interventions work.
Acknowledgements

The work reported here was supported by grant R01 HL62156-01 from the National Heart, Lung and Blood Institute.

References


Received on February 14, 2001; accepted on November 13, 2001