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Long-Term Effects of Lifestyle Changes on Well-Being and Cardiac Variables Among Coronary Heart Disease Patients

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Objective: To focus on psychological well-being in the Lifestyle Heart Trial (LHT), an intensive lifestyle intervention including diet, exercise, stress management, and group support that previously demonstrated maintenance of comprehensive lifestyle changes and reversal of coronary artery stenosis at 1 and 5 years. ***Design and Main Outcome Measures:*** The LHT was a randomized controlled trial using an invitational design. The authors compared psychological distress, anger, hostility, and perceived social support by group (intervention group, $n = 28$; control group, $n = 20$) and time (baseline, 1 year, 5 years) and examined the relationships of lifestyle changes to cardiac variables. ***Results:*** Reductions in psychological distress and hostility in the experimental group (compared with controls) were observed after 1 year ($p < .05$). By 5 years, improvements in hostility tended to be maintained relative to the control group, but reductions in psychological distress were reported only by experimental patients with very high 5-year program adherence. Improvements in diet were related to weight reduction and decreases in percent diameter stenosis, and improvements in stress management were related to decreases in percent diameter stenosis at both follow-ups (all $p < .05$). ***Conclusion:*** These findings illustrate the importance of targeting multiple health behaviors in secondary prevention of coronary heart disease.

Keywords: lifestyle changes, psychological well-being, cardiac variables

Coronary heart disease (CHD) remains the leading cause of death in most industrialized countries (American Heart Association, 2007). Intensive efforts have been made to identify risk factors of CHD. In the INTERHEART Study, nine potentially modifiable risk factors have been identified that play a major role in the etiology and prognosis of CHD, accounting for 90% of CHD risk in men and 94% in women (Yusuf et al., 2004). Among these are psychosocial factors such as depression and stress. Similarly, several reviews have examined the evidence for causal relationships of psychosocial factors to CHD (Rozanski, Blumenthal, Davidson, Saab, & Kubzansky, 2005; Schneiderman, Antoni, Saab, & Ironson, 2001). Psychosocial factors such as hostility, depression, and anxiety, which are often summarized as "psychological distress," are regarded as risk factors for CHD morbidity and mortality (Chaput et al., 2002; Hemingway & Marmot, 1999; Kuper, Marmot, & Hemingway, 2002; Matthews, Gump, Harris, Haney, & Barefoot, 2004; Rasul, Stansfeld, Hart, & Davey Smith, 2005). Social support, on the other hand, appears to act as a buffer for stress (Hemingway & Marmot, 1999), and sense of coherence plays a role in the adoption and maintenance of health behaviors relevant to secondary prevention of CHD (Kuuppelomäki & Utriainen, 2003; Lindmark, Stegmayr, Nilsson, Lindahl, & Johansson, 2005).

It remains unclear whether secondary prevention programs for CHD that target psychosocial risk factors are effective in improving psychological well-being. For example, patients with ischemic heart disease significantly reduced psychological distress after participation in cardiac rehabilitation including regular stress management and exercise compared with patients receiving usual care over a 4-month follow-up (Blumenthal et al., 2005). Exercise-based cardiac rehabilitation has also been shown to be beneficial in reducing hostility in patients with high levels of hostility over a similar length of follow-up (Lavie & Milani, 1999, 2005) and in patients with depression for up to 1 year (Lett, Davidson, & Blumenthal, 2005). However, a few studies testing psychological

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or stress management interventions in cardiac rehabilitation have found only minimal reductions in anxiety and depression (Frasure-Smith et al., 1997; Grace et al., 2005; Hofman-Bang et al., 1999; Kuper et al., 2002; Lisspers et al., 1999; Rees, Bennett, West, Davey, & Ebrahim, 2004). Indeed, two large randomized clinical trials did not show any differences in psychological status between rehabilitation group patients participating in psychological interventions and control group patients (Berkman et al., 2003; Jones & West, 1996).

It should be noted that follow-up in the majority of these studies was limited to 3–12 months. Only two studies reported findings beyond 1 year. One study included a 9-year follow-up after a 3-month behavioral intervention (exercise, psychosocial group intervention, and individual psychological therapy) that did not indicate that changes in lifestyle led to further reductions in negative affect beyond 3 months (Denollet & Brutsaert, 2001). However, improvements in affect during the first 3 months of follow-up seemed to have a beneficial effect on prognosis in CHD patients over 9 years. Another study included a 4.5-year follow-up and investigated whether an intervention that included intensive cardiac and Type A counseling for 4–6 months and monthly meetings for the remainder of the study would alter Type A behavior and CHD prognosis in post–myocardial infarction patients (Friedman et al., 1986). The authors found that the intervention reduced not only Type A behavior but also cardiac morbidity and mortality over 4.5 years in post–myocardial infarction patients when compared with a control group that only received cardiac counseling or with a no-treatment comparison group. In sum, there is limited knowledge about long-term effects (i.e., more than 1 year) of maintained lifestyle changes on psychological well-being.

The goals of the present analyses were (a) to evaluate the long-term effects of comprehensive lifestyle changes (i.e., diet, exercise, stress management, and group support) on psychological well-being and (b) to identify associations of individual lifestyle changes with changes in specific cardiac variables in patients with CHD over 5 years who participated in the Lifestyle Heart Trial (LHT). The main focus of the LHT was to evaluate whether comprehensive lifestyle changes could halt or reverse the progression of heart disease. Previous reports demonstrated significant reductions in coronary plaque burden and improvements in health behaviors and coronary risk factors at 1- and 5-year follow-ups in the lifestyle intervention group relative to a control group receiving usual care (Gould et al., 1995; Ornish et al., 1990, 1998). However, recent interest in psychosocial variables in cardiac research has increased (e.g., Berkman et al., 2003; Rozanski et al., 2005), and findings of our two recent demonstration projects, the Multicenter Lifestyle Demonstration Project and the Multisite Cardiac Lifestyle Intervention Program, both observational studies, indicate that patients who make comprehensive lifestyle changes experience improvements in psychosocial risk factors (Daubenmier et al., 2007; Koertge et al., 2003; Pischke et al., 2006). This prompted us to analyze the psychosocial variables that had been assessed in the LHT. Thus, we compared psychosocial outcomes over the course of 5 years in 38 CHD patients who were randomly assigned either to an experimental group participating in a 1-year lifestyle intervention or to a control group receiving usual care during the same time period.

Method

The study was approved by the Human Research Committees of both Pacific Medical Center and the University of California, San Francisco, and fully informed written consent was obtained from each patient. The design, recruitment, and study population, including eligibility criteria, have been described previously (Gould et al., 1992, 1995; Ornish et al., 1990; Scherwitz & Ornish, 1994). Briefly, the LHT was a randomized controlled trial using an invitational design (Zelen, 1979). Men and women with coronary atherosclerosis documented by quantitative coronary arteriography (40–74 years of age) were recruited from the San Francisco Bay Area (Ornish et al., 1998). At baseline, there were 28 patients in the experimental group and 20 patients in the control group. Analyses of coronary risk factors, clinical events, and coronary artery percent diameter stenosis at the 5-year follow-up are based on 35 patients who had 5-year follow-up quantitative coronary arteriography (Ornish et al., 1998) and 38 patients with complete psychosocial and health behavior questionnaires.

Psychosocial Measures

All psychosocial questionnaires were administered at baseline, 1 year, and 5 years.

Goldberg's (1972) 30-item General Health Questionnaire, a screening tool for psychological distress originally developed to screen for psychiatric disorders (O'Rourke, MacHale, Signorini, & Dennis, 1998), assesses anxiety and depression, social dysfunction, and insomnia (e.g., "Have you recently been feeling mentally alert and wide awake?"). Psychometric properties have been reported elsewhere (Stansfeld, Fuhrer, Shipley, & Marmot, 2002; Stansfeld & Marmot, 1992). Strong associations of the General Health Questionnaire with clinical psychiatric disorder and depression suggest that it is a good proxy for depression and the quality of social interactions (Goldberg, Rickels, Downing, & Hesbacher, 1976; Stansfeld & Marmot, 1992). The Insomnia subscale of the General Health Questionnaire contains items similar to the Vital Exhaustion scale by Appels and colleagues (2006).

An adapted version of the Social Support Questionnaire (Berkman & Syme, 1979; Seeman & Syme, 1987) was administered to assess instrumental social support (e.g., help with household tasks, a ride, or a loan of money) and adequacy of social support.

The Sense of Coherence questionnaire is a 13-item scale assessing patients' perceptions of the degree to which their lives are comprehensible, manageable, and meaningful (Antonovsky, 1987). Sense of coherence is associated with subjective state of health (Suominen, Helenius, Blomberg, Uutela, & Koskenvuo, 2001) and plays a major role in the adoption and maintenance of health behaviors relevant to secondary prevention of CHD (Kuuppelomäki & Utriainen, 2003; Lindmark et al., 2005). Information on validity and reliability of this measure has been reported previously (Antonovsky, 1993).

Spielberger's state and trait anger scales (Spielberger, Jacobs, Russell, & Crane, 1983) were used to assess proneness to anger. This measure consists of two subscales measuring anger–reaction and anger–temperament. An angry temperament has been associated with an increased risk for cardiac events (Williams, Nieto, Sanford, & Tyroler, 2001). Psychometric information has been reported elsewhere (Moreno, Fuhriman, & Selby, 1999).

Type A behavior was assessed using a clinical Hostility and Time Urgency Interview (Friedman & Powell, 1984). Each interview was videotaped and scored for 35 separate observable characteristics that were subsequently categorized as either time urgency or hostility by a trained interviewer whose ratings had been shown to be reliable in the Western Collaborative Group Study (Ragland & Brand, 1988).

Intervention: The Lifestyle Change Program

To acquaint patients with the lifestyle program, the treatment intervention began with a weeklong residential retreat at a local resort hotel. Patients' spouses or partners were invited to attend. During the retreat, patients and partners attended daily lectures on the rationale for the lifestyle intervention, nutrition lectures, cooking classes, and grocery store tours. Patients received 3 hr of stress management training, 1 hr of aerobic exercise, and 1 hr of group support meetings per day led by a clinical psychologist. Following the retreat, patients attended program sessions in groups two times per week for 1 year. Sessions focused on the four program components in 1-hr blocks. In addition, they were instructed to follow the diet, exercise, and practice stress management on their own (for further detail, see Billings, 2000; Ornish et al., 1990, 1998). Thus, 104 sessions (4 hr each) were offered during the 1-year intervention. After 1 year of intensive lifestyle intervention, patients were given the option to continue the Ornish program lifestyle on their own in a self-directed community (Billings, 2000), which was not part of the research protocol. Patients paid for their own transportation and for potluck food they brought to the group meetings. Yoga instruction, group support, and the meeting space were paid for by the Preventive Medicine Research Institute. Five years after study entry, all patients were invited for systematic reassessment (Ornish et al., 1998).

Adherence to the Individual Components of the Lifestyle Change Program

Detailed information of the components of the lifestyle change program has been reported previously and is therefore described here only briefly (Billings, 2000; Ornish et al., 1998). *Diet.* Percentage of calories from fat; goal: 10%. Adherence to the dietary guidelines was calculated using a formula that was validated by previous research (based on 3-day food diary; for more detail, see Daubenmier et al., 2006; Ornish et al., 1998). *Moderate exercise.* Hours per week; goal: 3 hr/week (e.g., brisk walking; according to the guidelines of the American College of Sports Medicine, 1986). *Stress management.* Hours per week; goal: 1 hr/day (Ornish et al., 1990, 1998). Specifically a 1-hr practice included 30 min of stretching based on the asanas (English: poses) in hatha yoga, 15 min of progressive relaxation, 5 min of breathing, 8 min of meditation, and 2 min of visualization of patient's arteries dilating with increased blood flow to the heart, in that order (Billings, 2000; Billings, Scherwitz, Sullivan, & Ornish, 1996; Ornish et al., 1990); *Smoking cessation.* Smokers ($N = 4$) in the experimental group agreed to quit smoking when entering the study. *Group support.* The two weekly groups were designed to provide support to help patients adhere to the lifestyle change program. Group members were encouraged to express their feelings and to avoid problem solving and giving advice or finding solutions, but instead to listen to each other with empathy and compassion (Billings, 2000; Billings et al., 1996; Schulz et al., in press).

Overall Adherence to the Lifestyle Change Program

A lifestyle index, based on a formula validated in previous research (Daubenmier et al., 2006; Ornish et al., 1998), measured overall adherence to intervention guidelines and was calculated as the mean percentage of adherence to each lifestyle behavior. Zero equaled no compliance, and 1 equaled 100% compliance. A score was created for each of the four elements, as well as a cumulative score for the entire program adherence divided by the four elements: $[t + (u/35 + v/420)/2 + (x/3 + y/180)/2 + z]/4$, where t is smoking compliance, u is stress management (times/week), v is also stress management (minutes/week), x is exercise (times/week), y is also exercise (minutes/week), and z is the dietary compliance score (see also Daubenmier et al., 2006; Ornish et al., 1998). Some of the patients did more than the recommended level and thus had a score greater than 100%.

Statistical Analysis

Comparisons of group differences at baseline (experimental vs. control group; 5-year graduate vs. drop-out) were performed with two-sample t tests for continuous variables and with chi-square tests for categorical variables. Analyses of variance (ANOVAs) for repeated measures with one within factor at three levels (time: baseline, 1 year, and 5 years) and one between factor (experimental vs. control group) were computed to test for the effects of time, group, and their interactions on psychosocial outcomes and on health behaviors. Significant interactions were followed up by multiple comparisons testing for group differences ($p < .05$; Bonferroni adjusted). For exploratory purposes, we also followed marginally significant interactions with multiple comparisons in this rather small sample. In addition, we computed two sets of multivariate analysis of variance (MANOVA) including group as the independent variable and change scores (baseline − 1 year and baseline − 5 years, respectively) for the seven psychological outcomes (i.e., psychological distress, social support, sense of coherence, trait anger, state anger, hostility, time urgency) as dependent variables. To test for differences in changes in psychological outcomes over 5 years by adherence, patients in the experimental group were divided into two adherence groups on the basis of a median split, and ANOVAs for repeated measures were performed. Bivariate Pearson's correlations were used to analyze associations between changes in health behaviors and changes in psychosocial outcomes and cardiac variables over 1 year and 5 years in the entire sample. SPSS (Version 14.0, 2005; SPSS, Inc., Chicago, IL) was used to perform the statistical analysis.

Results

Baseline Characteristics

Medical and demographic characteristics in this predominantly male sample (96% male in the experimental group; 80% male in the control group) have been reported previously (Ornish et al., 1998). Patients in the two groups did not significantly differ in age, income, and marital status (see Table 1). Patients in the experimental group were more likely to be employed outside the home

Table 1
Baseline Characteristics: Lifestyle Heart Trial (N = *48*)

Measure	Experimental group ($M \pm SD$ [N])	Control group ($M \pm SD$ [N])	p
Age (years)	57 ± 8 (28)	59 ± 10 (20)	493
Education (years)	16 ± 3 (28)	14 ± 3 (20)	068
Married/living with someone (N [%])	22 (79)	15 (75)	.497
Employed outside the home (N [%])	22 (79)	9 (45)	.017
Psychosocial outcomes			
Psychological distress	27.5 ± 10.6 (26)	23.9 ± 9.0 (17)	.247
Depression & anxiety	6.0 ± 3.5 (26)	4.7 ± 3.6 (17)	.236
Social dysfunction	4.1 ± 1.8 (26)	3.8 ± 1.0 (17)	.534
Insomnia	5.8 ± 2.5 (26)	4.9 ± 1.5 (17)	.197
Social support	19.7 ± 4.1 (27)	20.3 ± 5.2 (16)	.683
Instrumental support	4.2 ± 2.6 (27)	4.5 ± 2.9 (16)	.744
Adequacy of social support	15.4 ± 2.5 (27)	15.8 ± 3.6 (17)	.730
Sense of coherence	43.9 ± 6.9 (27)	47.7 ± 6.4 (17)	.082
State anger	21.4 ± 9.4 (25)	20.0 ± 7.5 (16)	.618
Trait anger	29.9 ± 8.0 (27)	26.7 ± 6.8 (17)	.175
Type A behavior	35.3 ± 12.0 (27)	35.1 ± 11.7 (20)	.953
Time urgency	25.7 ± 8.7 (27)	26.2 ± 8.3 (20)	.873
Hostility	9.9 ± 5.3 (26)	8.9 ± 5.7 (20)	.550
Health behaviors			
Diet (% calories from fat)	30.8 ± 8.1 (28)	29.3 ± 10.9 (20)	.594
Exercise (hours/week)	2.4 ± 3.8 (27)	2.1 ± 3.2 (17)	.848
Stress management (hours/week)	.74 ± 1.6 (27)	.21 ± .51 (17)	.189

($p < .05$) and tended to be more educated ($p < .10$) than controls. No significant group differences in health behaviors and psychosocial outcomes were found at baseline.

Participant Characteristics at Follow-Ups

Psychosocial outcomes and adherence to health behaviors of patients with complete data at 1 year and 5 years can be seen in Table 2. At 1 year, patients in the experimental group reduced psychological distress more than did control group patients ($p < .05$). Specifically, reductions in insomnia ($p < .05$) and a trend for improvements in social dysfunction ($p < .08$) were observed in experimental group patients compared with control group patients. Reductions in hostility were marginally greater in the experimental group compared with the control group. Regardless of group, sense of coherence, state anger, time urgency, and social support remained constant over 1 year.

At 5 years, reductions in psychological distress reverted to baseline. However, improvements in hostility tended to be maintained in the experimental group relative to the control group. Reductions in time urgency were observed in all patients regardless of group from baseline to 5 years ($p < .01$). Sense of coherence remained constant in the experimental group over the 5-year follow-up and was increased in the control group from 1-year to 5-year follow-up ($p < .01$). State anger and social support remained constant over the 5-year follow-up in both groups.

Results of the two sets of MANOVAs confirmed findings from the individual ANOVAs. That is, significant group differences for 1-year changes in psychological distress and hostility indicated that the experimental patients reduced psychological distress, $F(1, 33) = 4.64$, $p < .05$, and hostility, $F(1, 33) = 4.97$, $p < .05$, more than did controls. No significant changes in psychological outcomes were noted from baseline to 5 years.

Changes in health behaviors and medical outcomes over 1 year and 5 years have been reported previously (Ornish et al., 1998). Briefly, patients in the experimental group significantly reduced dietary fat intake and improved exercise and stress management relative to controls at 1 year and 5 years (all $ps < .001$). Experimental group patients met program requirements in regard to diet and exercise at 5 years. They fell 1 hr short of the recommended stress management at 5 years.

Beneficial effects of comprehensive lifestyle changes on coronary risk factors (i.e., weight, total cholesterol, low-density lipoprotein), clinical events, and coronary artery percent diameter stenosis for at least 4 years after participation in the LHT have been reported elsewhere (Ornish et al., 1998). We correlated changes in health behaviors with changes in the improved cardiac variables only (i.e., weight, blood pressure, total cholesterol, low-density lipoprotein, percent diameter stenosis) over 1 year and 5 years.

Associations of health behavior changes to changes in cardiac variables over 1 year and 5 years for all patients can be seen in Table 3. The most robust relationships (i.e., significant at $p < .05$ at both follow-ups) were observed for improvements in diet to weight reduction and to decreases in percent diameter stenosis and for improvements in stress management to decreases in percent diameter stenosis (all $p < .05$). The association between improvements in stress management and reductions in percent diameter stenosis remained significant after controlling for improvements in diet ($p < .01$), whereas the association between improvements in diet and reductions in percent diameter stenosis was rendered nonsignificant after controlling for improvements in stress management (not shown).

Associations between changes in health behaviors and changes in psychological well-being over 1 year (not shown) were noted as follows: Reductions in dietary fat were associated with reductions in psychological distress ($r = .39$, $p < .05$), and improvements in