

 HEALTHWAYS

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**Scientifically Proven Research for the Dr. Dean Ornish
Program for Reversing Heart Disease™**



Dr. Dean Ornish continues to establish himself as a pioneer in the medicine of the future. He breaks well-established myths in the field of biology by showing scientifically that heart disease is reversible, that certain types of cancer are preventable, and that even your genes can be made to change their blueprint for your destiny by lifestyle changes that are fun and enjoyable and energizing.

Deepak Chopra

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Executive Summary and Literature Review

For more than 35 years, Dr. Ornish has championed lifestyle modification as a proven approach for reversing heart disease in patients with pre-existing coronary artery disease. Based on in-depth scientific research, Dr. Ornish’s approach actually reverses the progression of cardiovascular disease and reduces the need for interventional revascularizations and costly medications for patients with one of several risk indicators, including a prior acute myocardial infarction, CABG surgery, a PCI procedure or stable angina. Recognizing the extraordinary results that Dr. Ornish achieved in reversing heart disease, Congress and the Centers for Medicare and Medicaid Services (CMS) in 2010 provided for Medicare reimbursement for individuals enrolled

in The Dr. Dean Ornish Program for Reversing Heart Disease™. Dr. Ornish and Healthways are now deploying a scalable solution that is unmatched in its impact on outcomes and costs.

Using the following four core elements equally; (1) A very low-fat, whole foods diet, (2) Moderate aerobic exercise, (3) Stress management techniques, and (4) Support groups, the program has proven results documented in peer-reviewed research journals.

In these published studies, CHD patients showed greater changes in diet and lifestyle and better clinical outcomes than have ever before been reported for various lifestyle change interventions. These studies showed, for the first time, that the progression of coronary atherosclerosis could be stopped or reversed by making comprehensive lifestyle changes.

Specifically, these studies demonstrated the following benefits of the lifestyle modification program:

- Regression of coronary artery stenosis using quantitative coronary arteriography;
- Decreased size and severity of ischemic myocardial perfusion abnormalities (blood flow to the heart) using cardiac positron emission tomography (PET), exercise thallium scintigraphy, and exercise radionuclide ventriculography;
- Safe avoidance of revascularization procedures such as coronary bypass surgery, angioplasty, and intracoronary stents in almost 80% of those who were eligible for these procedures, with comparable clinical outcomes;
- Significantly greater exercise capacity;
- Substantial cardiac risk factor improvements, e.g., reductions in LDL-cholesterol comparable to what can be achieved with statin drugs without the costs and potential side-effects as well as significant reductions in weight, BMI, blood pressure and fasting blood glucose;
- Marked, rapid, and often dramatic decreases in the frequency and severity of angina;
- Substantial improvements in quality of life by a variety of measures (including decreased emotional stress and depression and increased vitality, physical function, and well-being);
- 2.5 times fewer cardiac events.

In addition, we measured significant improvements in other chronic diseases prevalent in the population, including obesity, diabetes, hypertension, hypercholesterolemia, depression, arthritis, prostate cancer, and related illnesses.

Follow-up analyses revealed even more reversal after five years than after one year. In contrast, patients in the usual-care randomized control group showed worsening (progression) of coronary atherosclerosis after one year and even more worsening after five years. Also, there was a direct correlation between degree of adherence to this lifestyle

modification program and changes in coronary atherosclerosis after one year and also after five years.

Full text versions of the articles presented in this booklet can be found at:
ornishspectrum.com/proven-program/the-research/

Avoiding Revascularization With Lifestyle Changes: The Multicenter Lifestyle Demonstration Project

Ornish D, et al.

American Journal of Cardiology. 1998;82:72T-76T.

The Multicenter Lifestyle Demonstration Project was designed to determine if comprehensive lifestyle changes (as above) can be a direct alternative to revascularization for selected patients without increasing cardiac events. A total of 333 patients completed this demonstration project (194 in the experimental group and 139 in the control group). We found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality. These patients reported reductions in angina comparable with what can be achieved with revascularization.

Can Lifestyle Changes Reverse Coronary Heart Disease? The Lifestyle Heart Trial

Ornish D, Brown SE, Scherwitz LW, et al. *Lancet*. 1990;336:129-133.

In a prospective, randomized, controlled trial to determine whether comprehensive lifestyle changes affect coronary atherosclerosis after 1 year, patients were assigned to an experimental group asked to follow the Lifestyle Modification Program or to a usual-care control group. 195 coronary artery lesions were analyzed by quantitative coronary angiography. The average percentage diameter stenosis regressed from 40.0 (SD 16.9)% to 37.8 (16.5)% in the experimental group yet progressed from 42.7 (15.5)% to 46.1 (18.5)% in the control group. When only lesions greater than 50% stenosed were analyzed, the average percentage diameter stenosis regressed from 61.1 (8.8)% to 55.8 (11.0)% in the experimental group and progressed from 61.7 (9.5)% to 64.4 (16.3)% in the control group. Overall, 82% of experimental-group patients had an average change towards regression. Comprehensive lifestyle changes may be able to bring about regression of even severe coronary atherosclerosis after only 1 year, without use of lipid-lowering drugs.

Changes in Myocardial Perfusion Abnormalities by Positron Emission Tomography After Long-Term, Intense Risk Factor Modification

Gould KL, Ornish D, Scherwitz L, et al. *JAMA*. 1995;20:274(11):894-901.

OBJECTIVE: To quantify changes in size and severity of myocardial perfusion abnormalities by positron emission tomography (PET) in patients with coronary artery disease after 5 years of risk factor modification. **DESIGN:** Randomized controlled trial. **SETTING:** Outpatient community setting. **INTERVENTION:** Randomization of patients to risk factor modification consisting of the Lifestyle Modification Program or to usual care by their own physicians, consisting principally of antianginal therapy. **MAIN OUTCOME MEASURES:** Quantitative coronary arteriography and PET at baseline and 5 years after randomization. Automated, objective measures of size and severity of perfusion abnormalities on rest-dipyridamole PET images and of stenosis severity on arteriograms were made by computer algorithms. **RESULTS:** Size and severity of perfusion abnormalities on dipyridamole PET images decreased (improved) after risk factor modification in the experimental group compared with an increase (worsening) of size and severity in controls. The percentage of left ventricle perfusion abnormalities outside 2.5 SDs of those of

normal persons (based on 20 diseasefree individuals) on the dipyridamole PET image of normalized counts worsened in controls (mean +/- SE, + 10.3% +/- 5.6%) and improved in the experimental group (mean +/- SE, -5.1% +/- 4.8%) (P = .02); the percentage of left ventricle with activity less than 60% of the maximum activity on the dipyridamole PET image of normalized counts worsened in controls (+13.5% +/- 3.8%) and improved in the experimental group (-4.2% +/- 3.8%) (P = .002); and the myocardial quadrant on the PET image with the lowest average activity expressed as a percentage of maximum activity worsened in controls (-8.8% +/- 2.3%) and improved in the experimental group (+4.9% +/- 3.3%) (P = .001). The size and severity of perfusion abnormalities on resting PET images were also significantly improved in the experimental group as compared with controls. The relative magnitude of changes in size and severity of PET perfusion abnormalities was comparable to or greater than the magnitude of changes in percent diameter stenosis, absolute stenosis lumen area, or stenosis flow reserve documented by quantitative coronary arteriography. **CONCLUSIONS:** Modest regression of coronary artery stenoses after risk factor modification is associated with decreased size and severity of perfusion abnormalities on rest-dipyridamole PET images. Progression or regression of coronary artery disease can be followed noninvasively by dipyridamole PET reflecting the integrated flow capacity of the entire coronary arterial circulation.

Intensive Lifestyle Changes for Reversal of Coronary Heart Disease

Ornish D, Scherwitz LW, Billings JH, et al. *JAMA*. 1998;280(23):2001-7.

CONTEXT: The Lifestyle Heart Trial demonstrated that intensive lifestyle changes may lead to regression of coronary atherosclerosis after 1 year. **OBJECTIVES:** To determine the feasibility of patients to sustain intensive lifestyle changes for a total of 5 years and the effects of these lifestyle changes (without lipid-lowering drugs) on coronary heart disease. **DESIGN:** Randomized controlled trial conducted from 1986 to 1992 using a randomized invitational design. **PATIENTS:** Patients with moderate to severe coronary heart disease were randomized to the Lifestyle Modification Program or to a usual-care control group. **SETTING:** Two tertiary care university medical centers. **INTERVENTION:** Intensive lifestyle changes (10% fat whole foods diet, aerobic exercise, stress management training, and group psychosocial support) for 5 years. **MAIN OUTCOME MEASURES:** Adherence to intensive lifestyle changes, changes in coronary artery percent diameter stenosis assessed by quantitative coronary arteriography, and cardiac events. **RESULTS:** Experimental group patients made and maintained comprehensive lifestyle changes for 5 years, whereas control group patients made more moderate changes. In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement)

and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening) (P=.001 between groups. More than twice as many cardiac events occurred in the control group (risk ratio for any event for the control group, 2.47 [95% confidence interval, 1.48-4.20]). CONCLUSIONS: More regression of coronary atherosclerosis occurred after 5 years than after 1 year in the experimental group. In contrast, in the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred.

The Effectiveness and Efficacy of an Intensive Cardiac Rehabilitation Program in 24 Sites

Silberman, A, Banthia, R, Estay I, Kemp, C, Studley, J, Hareras, D, Ornish, D *American Journal of Health Promotion*. 2010;4:260-266.

The purpose of this study is to test the efficacy and effectiveness of an intensive cardiac rehabilitation program in improving health outcomes in multiple sites. This study employs a non-experimental design to investigate changes in cardiovascular disease in 2,974 men and women from 24 socioeconomically diverse sites who participated in an intensive cardiac rehabilitation program at baseline, 12 weeks and 1 year and values after each time point. Results, 88% of patients remained enrolled in the program after 12 weeks and 78.1% remained enrolled in the program after 1 year. Patients showed statistically significant improvements after 12 weeks in BMI, triglycerides, LDL, Tchol, HbA1c, systolic blood pressure, diastolic blood pressure, depression, hostility, exercise, and functional capacity. These differences also remained significant after 1 year. There were additional significant improvements between 12 weeks and significant recidivism between 12 weeks and 1 year in all other measures (except triglycerides) and depression, yet improvements from baseline to 1 year remained significant in all measures (except HSL, which was unchanged) (p<0.005). Conclusion, this intensive cardiac rehabilitation program was feasible and sustainable for most patients who enrolled and was associated with the numerous subjective and objective improvements in health outcomes. It demonstrates that the intervention works when it is administered by staff at multiple clinical/community sites in four different states. These improvements were also seen in patients 65 years of age or older.

Lifestyle Changes are Related to Reductions in Depression in Persons With Elevated Coronary Risk Factors

Pischke, C, Frenda, S, Ornish, D, Weidner. *Psychology and Health*. 2010;25:1077-1100.

This observational study investigates whether persons with elevated coronary risk factors (CRFs 43 and/or diabetes) and depression [i.e., ≥ 16 on the Center for Epidemiological Scale – Depression (CES-D)] can make changes in health behaviors over 3 months and improve depressive symptoms and other CRFs. Analyses were based on data from 310 men and 687 women enrolled in the high-risk arm of the Multisite Cardiac Lifestyle Intervention Program, targeting diet (10% fat), exercise (3 h per week) and stress management (7 h per week). As expected, at study entry, depressed persons had a more adverse medical status, consumed more dietary fat and practiced less stress management than non-depressed persons. To examine 3-month changes, participants were grouped into (1) depressed persons who became non-depressed (CES-D ≤ 16 , n=248; 73%), (2) persons who remained or became depressed (CES-D ≥ 16 , n=476) and (3) non-depressed persons who remained nondepressed (n=597). All persons, regardless of group, met program goals. The greatest improvements (i.e., diet, exercise, perceived stress, hostility and mental health) were observed in Group 1 relative to Groups 2 and 3, which did not differ from each other. Comprehensive lifestyle changes appear to be feasible and beneficial for initially depressed persons with elevated CRFs.

Socioeconomic Status and Improvements in Lifestyle, Coronary Risk Factors, and Quality of Life: The Multisite Cardiac Lifestyle Intervention Program

Govil, S, Weidner, G, Merritt-Worden, T, Ornish, D.
American Journal Public Health. 2009;99:1263-1270.

We sought to clarify whether patients of low socioeconomic status (SES) can make lifestyle changes and show improved outcomes in coronary heart disease (CHD), similar to patients with higher SES. We examined lifestyle, risk factors, and quality of life over 3 months, by SES and gender, in 869 predominantly White, nonsmoking CHD patients (34% female) in the insurance-sponsored Multisite Cardiac Lifestyle Intervention Program. SES was defined primarily by education. At baseline, less educated participants were more likely to be disadvantaged (e.g., past smoking, sedentary lifestyle, high fat diet, overweight, depression) than were higher-SES participants. By 3 months, participants at all SES levels reported consuming 10% or less dietary fat, exercising 3.5 hours per week or more, and practicing stress management 5.5 hours per week or more. These self-reports were substantiated by improvements in risk factors (e.g., 5-kg weight loss, and improved blood pressure, low-density lipoprotein cholesterol, and exercise capacity; $P < .001$), and accompanied by improvements in wellbeing (e.g., depression, hostility, quality of life; $P < .001$). The observed benefits for CHD patients with low SES indicate that broadening accessibility of lifestyle programs through health insurance should be strongly encouraged.

Long-Term Effects of Lifestyle Changes on Well-Being and

Cardiac Variables Among Coronary Heart Disease Patients

Pischke, C, Scherwitz, L, Weinder, G, Ornish, D. *Health Psychology*. 2008;27:58-592.

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. The LHT was a randomized controlled trial using an individual 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. Reductions in psychological distress and hostility in the experimental group (compared with controls) were observed after 1 year ($p < 0.5$). By 5 years, 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 followups (all $p < 0.5$). These findings illustrate the importance of targeting multiple health behaviors in secondary prevention of coronary heart disease.

Angina Pectoris and Atherosclerotic Risk Factors in the Multisite Cardiac Lifestyle Intervention Program

Frattaroli, J, Weidner, G, Merritt-Worden, T, Frenda, S, Ornish, D. *American Journal of Cardiology*. 2008;101:911-918.

Cardiovascular symptom relief is a major indicator for revascularization procedures. To examine the effects of intensive lifestyle modification on symptom relief, we investigated changes in angina pectoris, coronary risk factors, quality of life, and lifestyle behaviors in patients with stable coronary artery disease enrolled in the multisite cardiac lifestyle intervention program, an ongoing health insurance-covered lifestyle intervention conducted at 22 sites in the United States. Patients with coronary artery disease (nonsmokers; 757 men, 395 women; mean age 61 years) were asked to make changes in diet (10% calories from fat, plant based), engage in moderate exercise (3 hours/week), and practice stress management (1 hour/day). At baseline, 108 patients (43% women) reported mild angina and 174 patients (37% women) reported limiting angina. By 12 weeks, 74% of these patients were angina free, and an additional 9% moved from limiting to mild angina. This improvement in angina was significant for patients with mild and limiting angina at baseline regardless of gender ($p < 0.01$). Significant improvements in cardiac risk factors, quality of life, and lifestyle behaviors were observed, and

patients with angina who became angina free by 12 weeks showed the greatest improvements in exercise capacity, depression, and health-related quality of life ($p < 0.05$). In conclusion, the observed improvements in angina in patients making intensive lifestyle changes could drastically reduce their need for revascularization procedures.

I had a massive heart attack in 1985 when I was 53 years old. Dean called me and he had called my doctor; and actually my doctor told him not to take me in the program because he didn't think I would last the year. Dean didn't care. He knew that the thing worked. He had the book and he explained what it was. And it was a complete change from the life that I was living. But I had to do it. I knew I had to do it 'cause I couldn't walk across the street in time for the light or I would get a chest pain. But almost immediately—I would say within 2 or 3 weeks—I noticed the difference. As soon as I noticed the difference, I knew that this thing was . . . it was possible for me to live.

Mel Lefer, participant

The Contribution of Changes in Diet, Exercise, and Stress Management to Changes in Coronary Risk in Women and Men in the Multisite Cardiac Lifestyle Intervention Program

Daubenmier, J, Weidner, G, Sumner, M, Mendell, N, Merritt-Worden, T, Studley, J, Ornish, D. *Annals of Behavioral Medicine*. 2007;33(1):57-68.

The relative contribution of health behaviors to coronary risk factors in multicomponent secondary coronary heart disease (CHD) prevention programs is largely unknown. Our purpose is to evaluate the additive and interactive effects of 3-month changes in health behaviors (dietary fat intake, exercise, and stress management) on 3-month changes in coronary risk and psychosocial factors among 869 non-smoking CHD patients (24% female) enrolled in the health insurance-based Multisite Cardiac Lifestyle Intervention Program. Analyses of variance for repeated measure were used to analyze health behaviors, coronary risk factors and psychosocial factors at baseline and 2-months. Multiple regression analysis evaluated changes in dietary fat intake and hours per week of exercise and stress management as predictors of changes in coronary risk and psychosocial factors. Significant overall improvement in coronary risk was observed. Reductions in dietary fat intake predicted reductions in weight, total cholesterol, low-density lipoprotein cholesterol and interacted with increased exercise to predict reduction in perceived stress. Increase in exercise predicted improvements in total cholesterol and exercise capacity (for women). Increased stress management was related to reductions in weight, total cholesterol/ high-density lipoprotein cholesterol (for men), triglycerides, hemoglobin A1c (in patients with diabetes), and hostility. Improvements in dietary fat intake, exercise, and stress management were individually, additively and interactively related to coronary risk and psychosocial factors, suggesting that multicomponent programs focusing on diet, exercise, and stress management may benefit patients with CHD.

Lifestyle Changes and Clinical Profile in Coronary Heart Disease Patients with an Ejection Fraction of $\leq 40\%$ or $>40\%$ in the Multicenter Lifestyle Demonstration

Pischke, C, Weidner, G, Elliott-Eller, M, Ornish, D. *European Journal of Heart Failure*. 2007:928-934.

Lifestyle changes are recommended for coronary heart disease (CHD) patients at risk for heart failure (HF) [ACC/AHA stage B; left ventricular ejection fraction (LVEF) $<40\%$]. However, it is not clear whether changes in lifestyle are feasible and beneficial in these patients. We investigated the feasibility of intensive lifestyle changes for CHD patients at risk for HF. We compared 50 patients (18% female) with angiographically documented LVEF $\leq 40\%$ (mean= 33.4 ± 7.3 ; range: 15–40%) to 186 patients (18% female) with LVEF $>40\%$ (mean= 58.2 ± 9.6 ; range: 42–87%), who were participants in the Multicenter Lifestyle Demonstration Project (MLDP). All were non-smoking CHD patients. The MLDP was a community-based, insurance-sponsored intervention (lowfat, plant-based diet; exercise; stress management) implemented at 8 sites in the US.

Coronary risk factors, lifestyle and quality of life (SF-36) were assessed at baseline, 3 and 12 months. Regardless of LVEF, patients showed significant improvements (all $p < .05$) in lifestyle behaviours, body weight, body fat, blood pressure, resting heart rate, total and LDL-cholesterol, exercise capacity, and quality of life by 3 months; most improvements were maintained over 12 months. CHD patients at risk for heart failure with an LVEF $\leq 40\%$, can make changes in lifestyle to achieve similar medical and psychosocial benefit to patients with an LVEF $> 40\%$.

Comparison of Coronary Risk Factors and Quality of Life in Coronary Artery Disease Patients With Versus Without Diabetes Mellitus

Pischke, C, Weidner, G, Elliott-Eller, M, Scherwitz, L, Merritt-Worden, T, Marlin, R, Lipsenthal, L, Finkel, R, Saunders, D, McCormac, P, Scheer, J, Collins, R, Guarneri, E, Ornish, D. *American Journal of Cardiology*. 2006;97:1267-1273.

This study assessed medical characteristics, lifestyle, and quality of life by diabetic status and gender in the Multicenter Lifestyle Demonstration Project (MLDP), a study of 440 nonsmoking patients with CAD (347 men, 55 with DM; 15.9%; 93 women, 36 with DM; 38.7%). Patients met in groups to improve lifestyle (plant-based, low-fat diet; exercise; stress management) for 1 year. Follow-ups were conducted at 3 and 12 months. At baseline, body mass and systolic blood pressure were significantly higher among patients with DM. Men with DM had a worse medical history (e.g., hypertension, hyperlipidemia, and family history of CAD) than did those without DM. Patients with DM, especially women, reported poorer quality of life than did patients without DM. The 2 groups of patients were able to adhere to the recommended lifestyle, as demonstrated by significant improvements in weight (mean=5 kg), body fat, low-density lipoprotein cholesterol, exercise capacity, and quality of life. No significant changes in triglycerides and high-density lipoprotein cholesterol were noted. By the end of 12 months, improvements in glucose-lowering medications (i.e., discontinuation or a change from insulin to oral hypoglycemic agents) were noted for 19.8% ($n=18$) of patients with DM. In conclusion, patients with CAD and DM are able to follow a comprehensive lifestyle change program and show similar improvements in coronary risk factors and quality of life as those without DM.

Improvement in Medical Risk Factors and Quality of Life in Women and Men With Coronary Artery Disease in the Multicenter Lifestyle Demonstration Project

Koertge J, Weidner G, Elliott-Eller M, et al. *American Journal of Cardiology*. 2003;91:1316-22.

This study examined medical and psychosocial characteristics of 440 patients (mean age 58 years, 21% women) with coronary artery disease at baseline and at 3-month and 12-month follow-ups. All patients were participants in the Multicenter Lifestyle Demonstration Project, aimed at improving diet (low fat, whole foods, plant-based), exercise, stress management, and social support. Spousal participation was encouraged. Both genders evidenced significant improvements in their diet, exercise, and stress management practices, which they maintained over the course of the study. Both women and men also showed significant medical (e.g., plasma lipids, blood pressure, body weight, exercise capacity) and psychosocial (e.g., quality of life) improvement. Despite their worse medical, psychosocial, and sociodemographic status at baseline, women's improvement was similar to that of men's. These results demonstrate that a multi-component lifestyle change program focusing on diet, exercise, stress management, and social support can be successfully implemented at hospitals in diverse regions of the United States. Furthermore, this program may be particularly beneficial for women with coronary artery disease who generally have higher mortality and morbidity than men after a heart attack, angioplasty, or bypass surgery.

Marked Improvements in Biomedical and Psychosocial Cardiac Risk Factors From a Community-Based Lifestyle Change Program

Merritt-Worden T, Ornish D, Pettengill E. *Circulation*. 2003;17:IV-758.

We assessed 12-week clinical outcomes from 13 sites and 250 participants who completed a community based comprehensive lifestyle change program during the year 2002. Fifty-eight percent of participants had primary cardiac diagnoses of CHD, twenty-two % had hypertension, and others had one or more risk factors. Forty-six percent of the participants were women, and the average age was 56 years. Participants were instructed to eat a plant-based, low fat diet, exercise 180 min/wk, practice stress management for an hour a day, and to attend bi-weekly group support sessions. All data are mean \pm SEM. At 12 weeks, there were significant improvements in biomedical outcomes ($p < .001$ unless otherwise noted). For example, participants lost an average of $13 \pm .74$ lbs, BMI decreased by $2.0 \pm .12$, exercise capacity increased by $1.5 \pm .14$ METs, and systolic and diastolic pressures declined by $9.6 \pm .18$ mmHg and $6.1 \pm .10$ mmHg respectively. Total cholesterol dropped by 25 ± 2.4 mg/dl, LDL dropped by 18.2 ± 2.0 mg/dl, cholesterol/HDL ratio decreased by $0.2 \pm .07$ mg/dl ($p = .006$), and triglycerides decreased by 19.6 ± 7.1 mg/dl ($p = .006$). Improvements in psychosocial risk factors were also significant (p 's $< .001$), with a 36% drop in CES-D depression scores and a 20% decrease in Cook-Medley Hostility scores. Most notably, the greatest improvements occurred among those with

the highest risk at baseline. For example, obese participants (BMI ≥ 30) lost an average of $16 \pm .85$ lbs and hypertensive participants dropped systolic and diastolic blood pressures by 24 ± 2.6 mmHg and 17 ± 1.2 mmHg respectively. The subset of participants with Type 2 diabetes decreased fasting blood sugar by 30.1 ± 7.0 mg/dl and reduced hemoglobin a1C from 7.3 to 6.3. In addition, most diabetics achieved these changes while either reducing or discontinuing diabetic medications. What's more, the risk reductions we observed could not be attributed to medication changes, which were carefully documented throughout program participation. In conclusion, these ambulatory patients were able to make comprehensive changes in diet and lifestyle that resulted in greater reductions in risk factors than have ever before been reported from a community based lifestyle change program.

Gender Comparisons in an Intensive Comprehensive Risk Factor Reduction Program

Merritt-Worden T, Pettengill E, Ornish D. *JCR*. 2003;23:376.

In order to evaluate possible gender differences among participants in a multi-site community-based lifestyle change program, we analyzed baseline and 12-week outcomes on 107 women (W) and 126 men (M) consecutively enrolled in an intensive comprehensive lifestyle programs that provided a diet, exercise, stress management, and group support intervention. Men and women were similar in age, employment, and education, but fewer women were married (71% vs. 93% for men), and women were more likely to have annual household incomes of \$35,000 or less (30% vs. 18% for men). At baseline, women had poorer scores than men on nearly all biomedical variables, including higher BMI's (W=35, M=31), lower functional capacity (W=8.0, M=9.3 METS), higher total cholesterol (W=203, M=170 mg/dl), higher LDL cholesterol (W=114, M=96 mg/dl), more severe shortness of breath (W=1.35, M=.98), and less exercise (W=71, M=136 minutes per week) (p 's $<.005$). Also, while men had higher hostility scores at baseline (M = 9.5, W = 8.0), women reported higher levels of perceived stress (W=17.8 M=14.2), higher depression scores (W=14.9, M=11.0), poorer quality of life (on six of eight SF-36 subscales), and lower levels of social support (W=70, M=79), with all p 's $<.05$. After three months of program participation, there were statistically significant improvements in nearly all outcomes in both genders. However, there were significant gender differences in the magnitude of change on some variables. While women improved significantly more than men in reducing BMI, reducing calories from fat, and lowering dietary cholesterol, men had significantly larger drops in systolic

blood pressure, total and LDL cholesterol, and greater increases in dietary fiber. Thus, balanced program enrollment allowed us to identify possible relationships between gender differences at enrollment and differential risk factor reduction at 12 weeks, with implications for other cardiac rehabilitation and prevention programs.

Community-Based Lifestyle Change Program Produces Substantial Reductions in Biomedical and Psychosocial Cardiac Risk Factors

Pettengill E, Pearson J, Pifalo B, et al. *Circulation*. 2002;106:76e-123.

Numerous studies report the benefits of lifestyle changes on cardiac risk factors, yet there are few reports on the efficacy of lifestyle change programs outside of a research protocol. We are presenting program evaluation clinical outcomes collected at baseline and 12-weeks from 349 participants in a community based comprehensive lifestyle change program. Fifty-nine percent of participants had CHD (others had one or more risk factors), 41% were women, and the average age was 59 years (SD \pm 9.8). Participants were instructed to eat a plant-based, low fat diet, exercise 180 min/wk, practice stress management for an hour a day, and to attend group support sessions. There were significant improvements in biomedical outcomes from baseline to 12 weeks ($p < .000$ unless otherwise noted). Exercise capacity increased by 2.1 METs \pm 1.7 (SD), ($t = -21.4$), systolic and diastolic pressures declined by 9.3 mmHg (\pm 17.0, $t = 9.8$) and 7.2 mmHg (\pm 10.7, $t = 12.0$) respectively, and participants lost an average of 9.8 lbs (\pm 7.9, $t = 22.9$). Total cholesterol declined from 192.8 mg/dl to 170.5 mg/dl (\pm 29.4, $t = 13.8$), LDL-C dropped from 112.3 mg/dl to 95.5 mg/dl (\pm 16.5, $t = 11.1$), and triglycerides declined from 186.7 mg/dl to 177.8 mg/dl (\pm 80.9, $t = 2.0$, $p = .047$). There was a slight drop in HDL-C from 44.1 mg/dl to 39.7 mg/dl (\pm 7.4, $t = 7.5$).

Improvements in psychosocial risk factors were also highly significant ($p < .000$), with a 48% drop in CES-D depression scores (11.8 to 6.1, $t = 13.6$), a 35% drop in Perceived Stress Scale scores (14.9 to 9.6, $t = 15.5$), a 18% decrease in Cook-Medley Hostility scores (8.5 to 6.9, $t = 7.5$), and a 7.5% increase in perceived social support (Preferred Support Profile scores increased from 75 to 82, $t = -6.5$). Gender-related differences in program benefits included a larger drop in systolic pressure for men (11.0 vs. 7mmHg, $t = -2.3$, $p < .032$), and larger drops in depression scores for women (7.5 vs. 4.5, $t = 3.4$, $p < .001$). In conclusion, participants in this community-based program successfully implemented lifestyle changes and thereby achieved marked improvements in cardiac risk factors associated with primary and secondary prevention of CHD.

Effects of Intensive Lifestyle Changes on Coronary Heart Disease Risk Factors and Clinical Status in Self-Selected Heart Patients

Merritt, T, Ornish, D, Scherwitz, L, et al. *JCR*. 1995;15:353.

This study was designed to answer the question of whether the lifestyle modification program will reduce risk factors and improve clinical status. Four program clinical sites provided baseline and three month follow-up data on risk factors and clinical status for 107 lifestyle-change patients. Mean body weight decreased from 188 to 179 pounds, % body fat from 24.1 to 21.9, total cholesterol from 203.4 to 186.2 mg/dl, LDL-C from 125.2 to 109.4 mg/dl, HDL-C from 37.6 to 32.4 mg/dl, and triglycerides increased from 220.4 to 227.8 mg/dl. Functional capacity, as measured by graded exercise testing, increased from 9.25 to 10.6 METS. The percentage of patients reporting angina decreased from 44% to 26%. All changes, except for the triglycerides, were statistically significant, $p < .05$. Preliminary results show that motivated patients in an intensive lifestyle change program can substantially reduce cardiovascular risk factors and improve clinical status.

Preliminary Results From the Multicenter Lifestyle Heart Trial: Can Self-Selected Heart Patients Maintain Intensive Lifestyle Changes?

Merritt, T, Ornish, D, Scherwitz, L et al. *JCR*. 1995;15:354.

Previous research has shown that patients with coronary heart disease who followed an intensive risk factor reduction programming improved remarkably in every area measured, including improvements in angina, lipids, coronary artery stenosis and myocardial perfusion. To assess whether a larger sample of heart patients could be motivated by different teams to maintain intensive lifestyle changes, a demonstration project has been implemented at eight medical centers across the United States. Patients undergoing lifestyle changes are asked to consume a low fat diet, exercise moderately three hours per week, practice stress management techniques one hour per day, and attend two group support meetings per week for the first twelve weeks and then once per week for the next nine months. Adherence data are available

at baseline and three month follow-up from four sites for 107 patients. During the first three months, 6 patients dropped out of the program. Attendance at meetings where each component of the program is practiced was 91%. Aerobic exercise increased from 3.6 times/wk and 26.4 min/session at baseline to 6.0 times/wk and 39.3 min. after 3 months. Stress management practice increased from .83 times/wk and 4.9 min/ session to 6.0 times/wk and 51.9 min/session. These preliminary results suggest that a diverse but self-selected population of motivated patients will comply fairly well with a program of intensive lifestyle changes for the initial three months.

Improved Stenosis Geometry by Quantitative Coronary Arteriography After Vigorous Risk Factor Modification

Gould KL, Ornish D, Kirkeeide R, et al.

American Journal of Cardiology. 1992;69:845-53.

This study is a randomized, controlled, blinded, arteriographic trial to determine the effects of the Lifestyle Modification Program on geometric dimensions, shape and fluid dynamic characteristics of coronary artery stenosis in humans. Complex changes of different primary stenosis dimensions in opposite directions or to different degrees cause stenosis shape change with profound effects on fluid dynamic severity, not accounted for by simple percent narrowing. Accordingly, all stenosis dimensions were analyzed, including proximal, minimal, distal diameter, integrated length, exit angles and exit effects, determining stenosis shape and a single integrated measure of stenosis severity, stenosis flow reserve reflecting functional severity. In the control group, complex shape change and a stenosis-molding characteristic of statistically significant progressing severity occurred with worsening of stenosis flow reserve. In the treated group, complex shape change and stenosis molding characteristic of significant regressing severity was observed with improved stenosis flow reserve, thereby documenting the multidimensional characteristics of regressing coronary artery disease in humans.

Changes in Lifestyle and Exercise Capacity

Merritt T, Scherwitz L, Brown S, et al.

Journal of Cardiopulmonary Rehabilitation. 1990;10:354.

In a controlled clinical trial, patients with CHD were randomly assigned to an experimental group asked to follow the Lifestyle Modification Program or to a usual medical care control group (UC). Exercise treadmill testing was performed at baseline and after 15 months. The groups did not differ at baseline in exercise capacity. After 15 months, experimental group patients improved exercise capacity (difference in time to max baseline rate-pressure product) by 0.9 minutes whereas UC patients decreased exercise capacity by 0.6 minutes ($P=0.002$). Overall program adherence was correlated with increased exercise capacity ($r=.32$, $P=0.05$). Exercise capacity was related to diet ($r=.42$, $P=0.01$) and stress management adherence ($r=.37$, $P=0.3$), but surprisingly not related to exercise adherence ($r=.11$, $P=0.5$). However, exercise adherence was strongly related to increased exercise capacity for those with lower functional capacity at baseline ($r=.5$, $P=0.04$), but not for those with higher exercise capacity ($r=.09$, $P=0.75$), suggesting that exercise helped more for those in poorer physical condition. We conclude that adherence to comprehensive lifestyle changes improves exercise capacity greater than exercise alone, especially for those with lower functional capacity.

Effects of Stress Management Training and Dietary Changes in Treating Ischemic Heart Disease

Ornish DM, Scherwitz LW, Doody RS, et al. *JAMA*. 1983;249:54-59.

To evaluate the short-term effects of the Lifestyle Modification Program in patients with coronary heart disease, this study compared the cardiovascular status of 23 patients who received this intervention with a randomized control group of 23 patients who did not. After 24 days, patients in the experimental group demonstrated a 44% mean increase in duration of exercise, a 55% mean increase in total work performed, significantly improved left ventricular regional wall motion during peak exercise, and a net change in the left ventricular ejection fraction from rest to maximum exercise of +6.4%. Also, there was a 20.5% mean decrease in plasma cholesterol levels and a 91.0% mean reduction in frequency of anginal episodes. In this selected sample, short-term improvements in cardiovascular status seem to result from these adjuncts to conventional treatments of coronary heart disease.

Hillary asked Dr. Dean Ornish to consult with us on improving our health and well-being and to train the chefs who cooked for us at The White House, Camp David, and Air Force One. I felt better and lost weight when I followed his recommendations. And his work shows, my genes may have been improving as well.

President Bill Clinton

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