*Behavior Change*

# The Effects of an Intensive Lifestyle Modification Program on Carotid Artery Intima-media Thickness: A Randomized Trial

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***Abstract***

***Purpose.*** *This study evaluated the effect of the Dr. Dean Ornish Program for Reversing Heart Disease on cardiovascular disease as measured by the intima-media thickness of the common carotid artery and compared this effect to outcomes from patients participating in traditional cardiac rehabilitation.*

***Design.*** *Randomized clinical trial.*

***Setting.*** *SwedishAmerican Health System.*

***Subjects.*** *Ninety three patients with clinically confirmed coronary artery disease were randomly assigned to the intervention ($n = 46$) or traditional cardiac rehabilitation ($n = 47$).*

***Intervention.*** *Dr. Dean Ornish Program for Reversing Heart Disease.*

***Measures.*** *Ultrasound of the carotid artery and other cardiovascular risk factors were measured at baseline, 6, and 12 months.*

***Analysis.*** *Intent-to-treat analysis.*

***Results.*** *There was no significant reduction in the carotid intima-media thickness of the carotid artery in the Ornish group or the cardiac rehabilitation group. Ornish Program participants had significantly improved dietary habits ($p < .001$), weight ($p < .001$), and body mass index ($p < .001$) as compared with the rehabilitation group. The decrease in the number of patients with angina from baseline to 12 months was 44% in Ornish and 12% in cardiac rehabilitation.*

***Conclusions.*** *The Ornish Program appears to causes improvements in cardiovascular risk factors but does not appear to change the atherosclerotic process as it affects the carotid artery. (Am J Health Promot 2007;21[6]:510–516.)*

***Key Words:*** Lifestyle, Carotid Artery, Prevention Research, Nutrition, Exercise; Format: research; Research purpose: intervention testing/program evaluation; Study design: randomized trial; Outcome measure: biometric; Setting: clinical/health care; Health focus: nutrition; Strategy: skill building/behavior change; Target population age: adults; Target population circumstances: geographic location

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## INTRODUCTION

It is estimated that 686,040 Americans died of cardiovascular diseases in 2003.[1] Findings from the Nurses Health Study[2] estimated that 82% of coronary events could be prevented through following lifestyle guidelines involving diet, exercise, body weight, and abstinence from smoking. Hence, lifestyle changes have the potential to dramatically impact the cardiovascular disease process and mortality.

The carotid artery intima-media thickness measured by ultrasound imaging is a valid indicator of atherosclerosis. It correlates well with the incidence of stroke, myocardial infarction, and other cardiovascular events.[3–5] It is also a useful predictor of the severity and extent of coronary artery disease[6] and cardiovascular risk factors.[7] Intima-media thickness is influenced by a variety of cardiovascular risk factors,[8] including cholesterol,[9] triglycerides,[10] glucose tolerance,[11,12] physical activity,[13–15] dietary saturated fat,[16] body fat,[17] and hypertension.[18] Consumption of certain phytochemicals has also been linked with reductions in intima-media thickness.[19,20] The links among unhealthy behaviors, elevated cardiovascular risk, and intima-media thickness are convincing.

The Dr. Dean Ornish Program for Reversing Heart Disease[21] is an aggressive, comprehensive lifestyle modification program with the goal of improving cardiovascular risk factors. It includes a vegetarian, very low-fat diet, exercise, stress management, and group support. Previous studies of the Ornish Program have been able to demonstrate significant reductions of risk factors for program participants.[22,23] The Lifestyle Heart Trial reported that the Ornish Program decreased coronary artery stenosis in the experimental group, while coronary artery stenosis increased in the control group.[24] This trial had a limited

number of subjects (15 control and 20 experimental subjects), and more than 50% of those that began the study dropped out because they did not wish to do an additional angiogram. The rationale for the Ornish Program is that lifestyle change can impact cardiovascular disease in a systemic manner. All vessels of the body, including those of the heart, could potentially be impacted by a healthy lifestyle. With the use of a noninvasive intima-media thickness measure, more participants would be willing to tolerate the outcome data collection and data could be gathered from the carotid artery of the neck, rather than just coronary arteries. In addition, there are no published data that show that the Ornish Program offered at a site without the presence of Dr. Dean Ornish can alter the atherosclerotic process.

The objective of this study was to evaluate the effect of the Ornish Program on cardiovascular disease as measured by the intima-media thickness of the common carotid artery and to compare this effect to outcomes from patients participating in traditional cardiac rehabilitation.

## METHODS

### Participants

From August 2000 to July 2003 a total of 93 patients with clinically confirmed coronary artery disease from the metropolitan Rockford, Illinois area were recruited into the study. Potential participants were recruited through analysis of SwedishAmerican Hospital's admission and discharge information sheets and community-wide marketing through the print and radio media. Participants were included if they had at least two of the following three criteria: chest pain lasting at least 30 minutes continuously, electrocardiogram changes typical of an evolving myocardial infarction (ST segment elevation or depression, evolving Q waves, or symmetric inversion of T waves), or elevated levels of cardiac enzymes. Patients were also accepted into the study if they demonstrated any of the following: myocardial infarction within the past 12 months, coronary artery bypass graft surgery, stent placement, rotoblator within the prior 12 months, stable angina, or pacemakers associated with one or more of the above diagnoses. Exclusion criteria included history of substance abuse disorder without documentation of at least 1 year of abstinence, history of psychiatric disorder without documentation of at least 1 year of stability, impaired cognitive function such as dementia or delirium, participation in other lipid-lowering or lifestyle modification trials, and others which were previously documented.[24]

Prior to program assignment, all interested patients were oriented by a physician or nurse concerning the Ornish and traditional cardiac rehabilitation programs. Following this brief orientation each patient completed the informed consent form before participation in the study. Participants were randomly assigned to either the Ornish (n = 49) or traditional cardiac rehabilitation program (n = 49). The study was approved by the institutional review board of the SwedishAmerican Health System. Participation in the study was free of charge to the patients, and patients in both groups received standard care as prescribed by their doctors.

### Ornish Program

The Dr. Dean Ornish Program for Reversing Heart Disease combines diet, exercise, stress management, and group support to lower risk of cardiovascular disease. This program was delivered in three separate stages. Stage 1 included an intensive 12-week component in which participants met for two 4-hour sessions each week. This began once the patient was discharged from the hospital. The sessions included supervised exercise, stress management, a meal, lifestyle-related lecture, and group support.

Before beginning stage 2 participants were evaluated and compared with a risk-stratification assessment model. This aided in determining the level of intervention appropriate for stage 2 by assessing the participants' ability to adhere to the program and the severity of their disease. Most of the activity in stage 2 was self-directed, but participants were encouraged to attend weekly support groups. Stage 2 consisted of one 4-hour session each week including stress management, group support, exercise, lecture, and a meal. The length of stage 2 was variable depending on medical status and program adherence lasting from 3 to 9 months. Each participant's progress was managed in person or by telephone for 1 year.

Stage 3 included participation in an alumni-based community of previous program participants, designed to continue encouragement and support to reinforce lifestyle modifications learned in the program. Participants were encouraged to attend monthly alumni meetings for as long as they liked.

The program encouraged a plant-based diet composed of 75% of total calories from complex carbohydrates, at least 15% calories from protein, and less than 10% of total calories from fat. The diet recommended liberal consumption of fruit and vegetables, whole grains, and legumes; a daily serving of soy food; a multivitamin and a flax source of omega-3-fatty acids; and moderate sugar intake.

Participants met with an exercise physiologist who prescribed an individualized exercise program that was medically appropriate according to a baseline exercise treadmill test. During stage 1 an exercise physiologist and a nurse supervised participants twice a week for 1 hour of group exercise. Daily independent exercise of at least 30 minutes was also greatly encouraged. During stage 3 of the program participants were expected to continue to exercise on their own. Being physically active for the remainder of their lifetime was the ultimate goal of this component.

Participants met for 2 hours each week in stage 1 and 1 hour each week in stage 2 to increase relaxation, concentration, and awareness through stress management. The stress management techniques, taught by a certified instructor, were partially based on Hatha yoga.

Participants attended a 1-hour group support meeting twice a week during stage 1 and once a week during stage 2. The sessions were led by licensed mental health professionals.

### Traditional Cardiac Rehabilitation

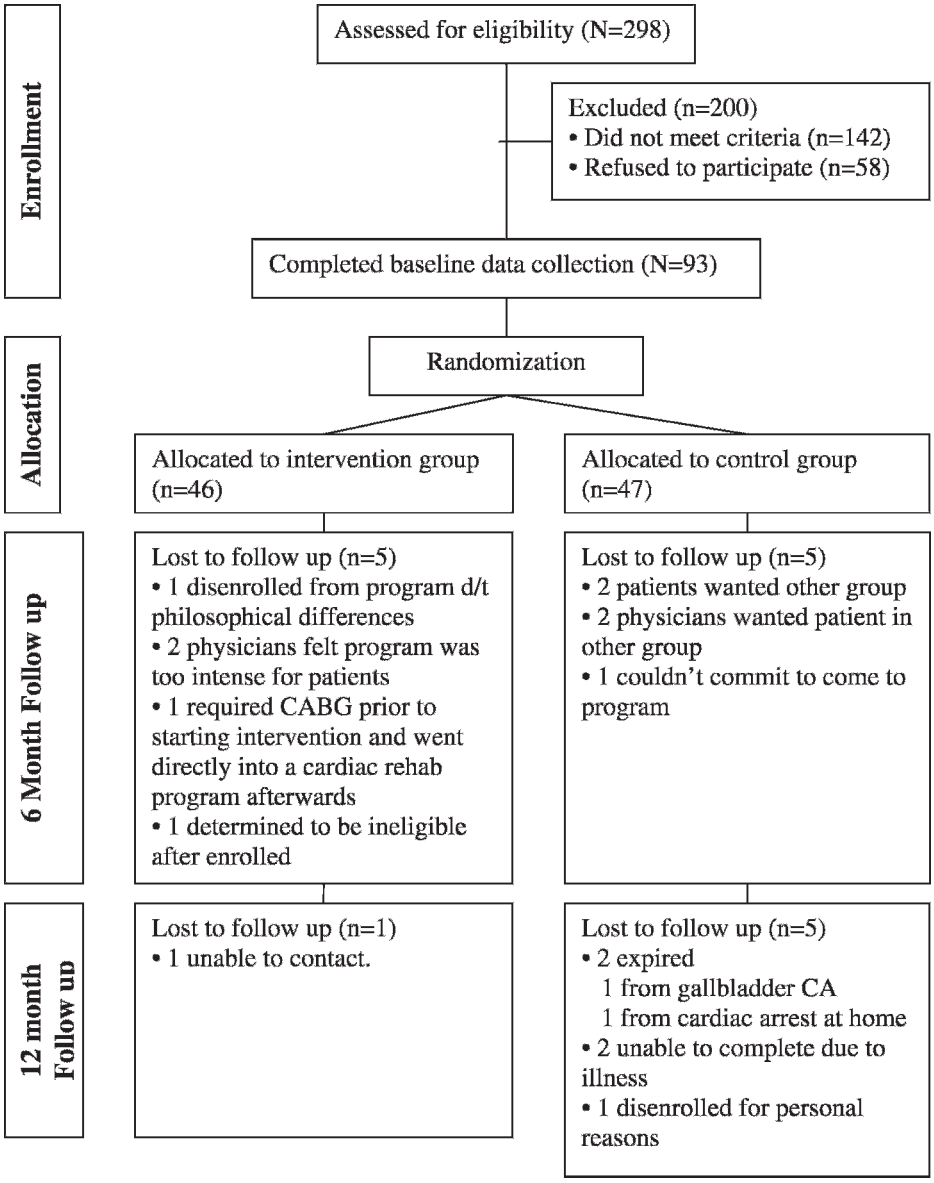
The five main components of traditional cardiac rehabilitation are medical evaluation, prescribed exercise, cardiac risk factor modification, edu-

cation, and counseling. Medical professionals, including a medical director, consulting cardiologist, and cardiac rehabilitation registered nurse developed individualized programs to help the participants return to a normal and physically active lifestyle.

The cardiac rehabilitation program at the SwedishAmerican Health System consisted of three phases. Phase I took place 5 to 14 days following the coronary event and included bed exercises and easy walking while the patient was in the hospital. Phase II was an outpatient program which began 3 to 4 weeks after discharge from the hospital. The medical director and cardiac rehabilitation coordinator developed a specific exercise program for each participant. Participants exercised three times a week in a supervised setting with advanced cardiac life support certified staff and electrocardiogram monitoring. Individual nutrition consultations with a dietician were also included in phase II. Participants were given the option to attend phase III, which involved exercise in a community setting. Heart rate and blood pressure were monitored each session.

**Figure 1**

**Flow Diagram of Participant Progress**




**Carotid Ultrasound Measures**

The automated ultrasound methodology used in this study was described and validated by Fritz et al.[25] Longitudinal images of the common carotid artery were taken on both the left and right sides using a General Electric high-resolution B-mode ultrasonograph equipped with an 8-MHz transducer. Two certified technicians, trained by the same individual, performed the ultrasounds. Technicians were blinded to group allocation and time measurement. Images were recorded on a super VHS videotape. Quality control was regularly monitored.

Images from the super VHS videotapes were converted to digital files. For both the left and right arteries, 10 1-cm common carotid segments were captured from the digital video 1 cm proximal to the common carotid bifurcation. Every image was captured by the same technician. Intima-media thickness was measured at the far wall automatically using SonoCalc computer software (Sonosite Inc., Bothell, Washington), and the 10 measures from the right and left sides were combined and averaged. In some cases the tortuosity of the internal segment was unclear and the software was unable to automatically identify the intima/lumen interface. In these cases the internal segment from the near wall was evaluated. If neither the far nor the near wall provided a clear 1-cm image, the measure was made manually using the caliper process described by Fritz et al.[25] Intima-media thickness measures were taken at baseline, 6 months, and 12 months.

**Other Clinical Measures**

Baseline measures included age, gender, height, weight, body mass index (BMI), income, medical history, medications, blood pressure, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, blood glucose, blood triglycerides, C-reactive protein, homocysteine, ferritin, fibrinogen, diet composition, and angina. Measures at 6 and 12 months included weight, BMI, medications, blood lipids, blood glucose, C-reactive protein, ferritin,

fibrinogen, diet composition, program adherence, quality of life, and angina. Medications were measured by grouping all medications into major classes such as cholesterol medications, hypertensive medications, heart medications, etc. Within each class, medication initiation or termination was tracked and evaluated. Participants were compensated $50 at the 6- and 12-month data collection times. Demographic information, income, diet, adherence, and angina were self-reported. Adherence in this study was similar to participation. It is expressed as the percentage of classes, exercise sessions, activities, and support group sessions each participant attended. Quality of self-reports was achieved through a minimal number of questions and having a technician present during survey completion. Venous blood samples were taken and analyzed at SwedishAmerican Hospital's laboratory following a 12-hour fast to obtain hemostatic variables.

### Statistical Analyses

Cross-tabulations were used to perform bivariate analyses between selected variables, with statistic significance based on the $\chi^2$ test for independence.[26] Results are based on the intent-to-treat method in which all participants were retained in the analyses. When data were lost to follow-up, the participant's most recent available data used the last test carry forward method. The *t*-test method was used for testing differences in means.[27] Because multiple pairwise tests were performed, an adjusted alpha should be used to minimize the overall probability of committing a type I error. The modified alpha based on the Bonferroni correction,[28] pairwise tests, and alpha = 0.05 is 0.001. Statistic significance of change scores were evaluated using 95% confidence intervals. Change scores were significant when they did not overlap zero. Analyses were performed using SAS version 9.0 (SAS Institute Inc., Cary, North Carolina). Procedure statements used in SAS for assessing the data were PROC CORR, PROC FREQ, PROC REG, PROC TTEST, and PROC UNIVARIATE.

**Table 1**

**Clinical Characteristics of Study Participants**

| | Ornish (n = 46) Means (SD) | Cardiac Rehabilitation (n = 47) Mean (SD) | *p* |
|---|---|---|---|
| Age | 60.9 (9.7) | 62.2 (8.9) | 0.5747 |
| Sex (males) | 47.8% | 64.6% | 0.1015 |
| Weight (pounds) | 193.8 (41.3) | 202.3 (52.1) | 0.3893 |
| Body mass index | 31.0 (5.7) | 31.0 (6.6) | 0.9918 |
| % calories from fat | 20.8 (10.1) | 22.8 (10.8) | 0.3671 |
| % calories from protein | 17.0 (4.6) | 17.4 (3.2) | 0.6364 |
| % calories from simple carbohydrates | 21.1 (13.3) | 22.8 (11.9) | 0.5246 |
| % calories from complex carbohydrates | 42.0 (12.1) | 37.1 (10.2) | 0.0351 |
| Systolic BP (mm Hg) | 132.3 (19.9) | 132.2 (21.8) | 0.9801 |
| Diastolic BP (mm Hg) | 76.8 (10.7) | 75.0 (10.7) | 0.4378 |
| Total cholesterol (mm/dL) | 174.8 (43.1) | 165.7 (43.9) | 0.3145 |
| HDL cholesterol (mm/dL) | 44.7 (11.4) | 42.1 (14.3) | 0.3337 |
| LDL cholesterol (mm/dL) | 100.8 (37.9) | 90.1 (26.7) | 0.1185 |
| Triglycerides (mg/dL) | 146.6 (75.1) | 167.4 (137.0) | 0.3654 |
| Glucose (mg/dL) | 112.1 (30.5) | 111.0 (28.4) | 0.8590 |
| Carotid intima-media thickness (mm) | 0.82 (0.16) | 0.80 (0.21) | 0.7569 |

BP indicates blood pressure; HDL, high-density lipoprotein; and LDL, low-density lipoprotein.

## RESULTS

Participant age ranged from 40 to 80 years (mean = 62; SD = 9.1). Fifty-three men and 40 women participated in the study. These 93 participants were randomly assigned to the Ornish (n = 46) and traditional cardiac rehabilitation (n = 47) groups (Figure 1). During the first 6 months Ornish Program participants attended an average of 30.27 of the 37 possible program sessions (82%). Traditional cardiac rehabilitation participants' program attendance averaged 42.6 sessions out of a possible 63 exercise sessions or 68% session attendance.

Participants were comparable at baseline across selected clinical variables in all but the percentage of calories in complex carbohydrates, being higher in the Ornish group (Table 1). The distribution of income was similar between both groups: $\chi^2(4) = 2.77$, $p = .5976$. There were no significant differences in medication use between groups at baseline.

After 6 months the Ornish group showed significantly better improvement in weight, BMI, percentage of calories from dietary fat, and percentage of calories from complex carbohydrates compared with the traditional cardiac rehabilitation group. Significant improvements were observed in both groups for weight, BMI, and systolic blood pressure. After 12 months the Ornish group continued to show significantly better improvements in percent calories from fat and percent calories from complex carbohydrates. There were no differences in medication use between groups across time. After both 6 and 12 months there were no significant changes in intima-media thickness in either group nor were there any between-group differences (Table 2).

The prevalence of angina among patients did not significantly differ at entry into the study between Ornish and traditional cardiac rehabilitation groups. Eighteen of the 46 Ornish group participants (39%) had angina at baseline while 16 of the 47 traditional cardiac rehabilitation group participants (33%) reported having angina at baseline. After 6 months the number of patients with angina in the Ornish group dropped to four, a 78% reduction, and the number of traditional cardiac rehabilitation group participants with angina at 6 months dropped to 11, a 22.9% decline ($\chi^2[3] = 4.74$, $p = .0598$). This significant between-group difference disappeared at 12 months. At 12 months 10 Ornish group participants and 14 traditional cardiac rehabilitation group participants reported having angina.

**Table 2**

**Clinical Indices at Baseline, 6 Months, and 12 Months**

| | Baseline | 6 Months | Change | 95% CI | 12 Months | Change | 95% CI |
|---|---|---|---|---|---|---|---|
| Weight (pounds) | | | | | | | |
| Ornish | 193.78 | 183.14 | −10.64 | −13.57, −7.84* | 186.92 | −6.86 | −10.93, −2.79* |
| Cardiac rehabilitation | 202.26 | 198.67 | −3.59‡ | −6.65, −0.54* | 199.86 | −2.40 | −5.58, 0.50 |
| BMI | | | | | | | |
| Ornish | 30.97 | 29.30 | −1.67 | −2.18, −1.29* | 29.82 | −1.15 | −1.78, −0.52* |
| Cardiac rehabilitation | 30.96 | 30.40 | −0.56‡ | −1.03, −0.08* | 30.56 | −0.40 | −0.85, 0.07 |
| % calories in fat (%) | | | | | | | |
| Ornish | 20.80 | 10.81 | −9.99 | −13.17, −6.10* | 12.95 | −7.85 | −10.66, −3.92* |
| Cardiac rehabilitation | 22.77 | 26.13‡ | 3.36‡ | 1.28, 6.32* | 26.19‡ | 3.42‡ | 0.88, 6.48* |
| % calories in protein (%) | | | | | | | |
| Ornish | 17.02 | 17.21 | 0.19 | −1.69, 2.08 | 16.35 | −0.67 | −2.11, 0.77 |
| Cardiac rehabilitation | 17.42 | 18.22 | 0.80 | −0.58, 2.13 | 18.81* | 1.39 | −0.56, 3.67 |
| % calories in simple carbohydrates | | | | | | | |
| Ornish | 21.07 | 22.60 | 1.53 | −3.71, 5.76 | 23.07 | 2.00 | −3.58, 7.10 |
| Cardiac rehabilitation | 22.80 | 19.71 | −3.09 | −7.01, −0.14* | 18.85 | −3.95† | −7.39, −0.61* |
| % calories in complex carbohydrates | | | | | | | |
| Ornish | 42.04 | 49.55 | 7.51 | 2.85, 12.37* | 47.02 | 4.98 | −0.49, 9.73 |
| Cardiac rehabilitation | 37.06‡ | 36.16‡ | −0.90‡ | −3.84, 2.24 | 36.11‡ | −0.95 | −5.00, 2.71 |
| Systolic BP (mm Hg) | | | | | | | |
| Ornish | 132.33 | 125.65 | −6.68 | −11.77, −1.58* | 127.37 | −4.96 | −10.35, 0.70 |
| Cardiac rehabilitation | 132.22 | 126.41 | −5.81 | −10.89, −0.72* | 126.70 | −5.52 | −10.7, −0.34* |
| Diastolic BP (mm Hg) | | | | | | | |
| Ornish | 76.76 | 74.06 | −2.70 | −6.15, 0.76 | 71.72 | −5.04 | −8.87, −1.22* |
| Cardiac rehabilitation | 75.02 | 72.04 | −2.98 | −6.14, 0.18 | 72.56 | −2.46 | −5.60, 0.69 |
| Total cholesterol (mg/dL) | | | | | | | |
| Ornish | 174.78 | 163.24 | −11.54 | −23.79, 0.70 | 176.70 | 1.92 | −11.89, 15.71 |
| Cardiac rehabilitation | 165.66 | 167.85 | 2.19† | −8.36, 13.84 | 166.78 | 1.12 | −8.10, 11.45 |
| HDL cholesterol (mg/dL) | | | | | | | |
| Ornish | 44.67 | 42.74 | −1.93 | −3.88, 0.01 | 44.00 | −0.67 | −3.37, 2.02 |
| Cardiac rehabilitation | 42.06 | 42.91 | 0.85 | −1.49, 3.23 | 42.89 | 0.83 | −1.69, 3.38 |
| LDL cholesterol (mg/dL) | | | | | | | |
| Ornish | 100.85 | 94.13 | −6.72 | −16.8, 3.37 | 106.37 | 5.52 | −5.78, 16.83 |
| Cardiac rehabilitation | 90.15 | 92.92 | 2.77 | −6.31, 12.18 | 98.43 | 8.28 | 2.24, 14.67* |
| Triglycerides (mg/dL) | | | | | | | |
| Ornish | 146.61 | 132.20 | −14.41 | −35.49, 6.67 | 131.98 | −14.63 | −34.61, 5.34 |
| Cardiac rehabilitation | 167.42 | 157.52 | −9.9 | −27.46, 11.33 | 130.78 | −36.64 | −66.67, −2.94* |
| Glucose (mg/dL) | | | | | | | |
| Ornish | 112.13 | 108.06 | −4.07 | −15.01, 6.88 | 112.98 | 0.85 | −7.39, 9.09 |
| Cardiac rehabilitation | 111.04 | 111.39 | 0.35 | −5.93, 6.58 | 114.39 | 3.35 | −3.49, 10.14 |
| Carotid IMT (mm) | | | | | | | |
| Ornish | 0.815 | 0.799 | −0.016 | −0.035, 0.012 | 0.787 | −0.028 | −0.051, 0.007 |
| Cardiac rehabilitation | 0.803 | 0.807 | 0.004 | −0.020, 0.021 | 0.778 | −0.025 | −0.078, 0.007 |

Confidence intervals indicate if within-group changes are statistically significant at the 0.05 level. Significance is indicated if the confidence interval does not cross zero.

BP indicates blood pressure; HDL, high-density lipoprotein; IMT, intima-media thickness; and LDL, low-density lipoprotein.

* $p < 0.05$.

† $p < 0.01$.

‡ $p < 0.001$.

## DISCUSSION

When compared with other lifestyle modification programs, the Dr. Dean Ornish Program for Reversing Heart Disease could be considered one of the most intense in terms of time commitment and dietary strictness. This comprehensive program attempts to simultaneously reduce an array of cardiovascular risk factors. The results reported here indicate that among patients with confirmed coronary artery disease, participation in the Ornish program appears to be associated with improved cardiovascular risk factors but no changes in carotid intima-media thickness. Patients who participated in traditional cardiac rehabilitation also experienced no changes in intima-media thickness.

Traditional cardiac rehabilitation is essentially a carefully monitored cardiovascular endurance exercise program. The primary focus of cardiac rehabilitation is aerobic conditioning and acquisition of a lifestyle that includes regular physical activity. The Ornish Program also includes a monitored exercise component. When the impact of physical activity and cardiovascular endurance on intima-media thickness has been evaluated in the past, the results have been mixed. Some have noted that physical activity participation appears to be related to a thinner intima-media thickness and a lower risk of future cardiovascular event[14,28]; however, in a 6-year clinical trial, Rauramaa et al.[13] demonstrated that aerobic physical exercise did not attenuate progression of atherosclerosis except in a subgroup of men not taking statins. A short-term study of middle-aged men also failed to support the hypothesis that aerobic exercise could prevent or reduce the age-associated increase in intima-media thickness in healthy men.[29] The current findings also suggest that regular aerobic exercise as offered through traditional cardiac rehabilitation or the Ornish Program is unable to change carotid intima-media thickness.

Comprehensive lifestyle change programs can impact several cardiovascular risk factors simultaneously. This is important because the presence of multiple risk factors can lead to acceleration of the atherosclerotic process.[30] Because the Ornish Program is a comprehensive lifestyle modification program, it has the capacity to improve glucose tolerance, cholesterol, triglycerides, body weight, and blood pressure and modify dietary intake by reducing saturated fats and increasing the number of whole foods that are abundant in phytochemicals. These risk factors and dietary modifications have been linked to reductions in carotid intima-media thickness.[11–20]

Using a variety of lifestyle change programs, several researchers have demonstrated that progression of atherosclerosis as measured by intima-media thickness can be reduced and overall regression can occur.[31–33] The Monitored Atherosclerosis Regression Study was a randomized, double-blind, placebo-controlled angiographic trial of lipid-lowering therapy in subjects with coronary artery disease.[31] Participants followed a low-fat, low-cholesterol diet. Regular exercise was not part of the intervention. Participants reduced the annual rate of carotid wall intima-media thickness progression by 0.13 mm/year, which was equivalent to the maximum rate of intima-media thickness progression observed in the Monitored Atherosclerosis Regression Study placebo group. A low-fat dietary lifestyle change was able to reduce the age-related progression in intima-media thickness, but absolute regression was not observed. Fields et al.[32] compared the effect of a conventional diet and exercise program and a control group with a group of men in a multimodality intervention involving dietary, exercise, herbal food supplement, and stress reduction approaches from Maharishi Vedic Medicine. After 1 year only the men who participated in the Maharishi Vedic Medicine group showed any signs of intima-media thickness regression. This lifestyle intervention was especially effective on participants with elevated health risks. Other lifestyle interventions also appear to be effective for those who have never smoked[15] and among postmenopausal women.[33]

Using a comprehensive lifestyle trial, Okada et al.[34] failed to correlate changes in total cholesterol with changes in intima-media thickness. Additional research is needed to ascertain if any single component of a comprehensive lifestyle change program is responsible for the reductions in intima-media thickness reported by others. It is also important to note that several trials using fluvastatin, lovastatin, and pravastatin alone and in conjunction with lifestyle change have also demonstrated intima-media thickness regression.[9,35,36] In general, these studies showed that lifestyle interventions that include cholesterol-lowering medications have an even greater influence on intima-media thickness than lifestyle interventions alone. Almost all of the participants in the present study were on statins, which may have enhanced the effect of both the cardiac rehabilitation and Ornish programs.

Perhaps the most common criticism of the Ornish Program is the rather aggressive dietary restrictions it encourages. When compared with the U.S. Department of Agriculture[37] recommendation to consume 30% of calories from fat, the Ornish Program recommendation to not exceed 10% of energy from fat could be considered extreme. Such a departure from both normal and recommended levels of dietary fat consumption raises questions about compliance and widespread adoption of the program. After 12 months Ornish participants in this study were still consuming 13% of calories from fat, while the rehabilitation group was closer to normal (26.2%). Compliance to this strict dietary recommendation was very good, suggesting that for individuals with advanced stages of cardiovascular disease, the program is realistic and compliance is achievable. Additional research is needed to determine what level of dietary fat may be therapeutic and still be widely accepted by the public, including those who are not motivated by the presence of cardiovascular disease. Because both groups were consuming relatively low amounts of dietary fat at baseline, it is possible that this limited the amount of intima-media thickness regression that could be obtained during the intervention.

In conclusion, these results suggest that the Ornish Program may be an effective way to improve cardiovascular risk factors but does not appear to impact the atherosclerotic process as measured by carotid artery intima-media thickness.

**SO WHAT? Implications for Practitioners and Researchers**

This study suggests that the Dr. Dean Ornish Program for Reversing Heart Disease can improve nutrition and reduce cardiovascular disease risks but may not affect intima-media thickness of the carotid artery. If this assertion holds true, practitioners should still promote healthy lifestyles to reduce risk. The effects of reduced risk on vascular tissue are still unclear.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