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

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Abstract

Purpose. 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.

Methods. This study employs a nonexperimental (prospective time series) design to investigate changes in cardiovascular disease in 2974 men and women from 24 socioeconomically diverse sites who participated in an intensive cardiac rehabilitation program at baseline, 12 weeks, and 1 year. Paired t-tests were used to assess differences by comparing baseline values to those after 12 weeks, baseline values to those after 1 year, and values after 12 weeks to those after 1 year.

Results. Eighty-eight percent 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 body mass index (BMI), triglycerides, low density lipoprotein cholesterol, total cholesterol, hemoglobin A1c, systolic blood pressure, diastolic blood pressure, depression, hostility, exercise, and functional capacity. These differences also remained significant after 1 year. There was additional significant improvement between 12 weeks and 1 year only in BMI, high density lipoprotein cholesterol, functional capacity, and hostility, 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 HDL, which was unchanged) ($p < .005$).

Conclusions. This intensive cardiac rehabilitation program was feasible and sustainable for most patients who enrolled and was associated with 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. (Am J Health Promot 2010;24[4]:260–266.)

Key Words: Intensive Cardiac Rehabilitation, Cardiovascular Disease, Lifestyle Change, Prevention Research. Manuscript format: research; Research purpose: program evaluation; Study design: nonexperimental (prospective time series); Outcome measure: behavioral, clinical, psychological; Setting: clinical/health care; Health focus: medical self-care, nutrition, physical activity, stress management, weight control; Strategy: behavior change, policy; Target population age: seniors, adults

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INTRODUCTION

Coronary heart disease (CHD) is the leading cause of death among women and men in the United States, claiming 445,700 lives in 2005.[1] It is estimated that CHD health expenditures will reach $165.4 billion in 2009.[1] Risk factors for CHD include lifestyle behaviors such as poor nutrition and sedentary behavior and psychosocial factors such as stress, depression, and hostility.[2,3]

Since 1977, we have developed and studied the effects of an intensive cardiac rehabilitation program in a series of randomized controlled trials and demonstration projects. Results showed clinically significant and statistically significant improvements in risk factors and biomarkers of cardiovascular disease as well as improvements in frequency of angina, exercise capacity, exercise radionuclide ventriculography, coronary atherosclerosis, myocardial perfusion, and cardiac events.[4–14] In a demonstration project with Mutual of Omaha, 77% of patients who were eligible for revascularization were able to safely avoid it by going through this intensive cardiac rehabilitation program instead.[15]

Purpose

To determine if this program was efficacious and effective in larger groups of patients as administered by clinical staff at community sites in various parts of the country, Highmark Inc began offering this program to patients in 24 diverse settings in four different states. This provided an opportunity to study the efficacy and effectiveness of an intensive cardiac rehabilitation program in "real-world"

Table 1
Intensive Cardiac Rehabilitation Sites

Hospital Site	City, State	No. of Participants
Alegent Health (Bergan and Alegent-Immanuel sites)	Omaha, Nebraska	52
Allegheny General Hospital	Pittsburgh, Pennsylvania	196
Charleston Area Medical Center	Charleston, West Virginia	186
The Wellness Center at City Hospital	Martinsburg, West Virginia	41
Dubois Regional Hospital	Dubois, Pennsylvania	44
Excela Health (Frick and Westmoreland sites)	Greensburg, Pennsylvania	139
Good Samaritan Health System	Kearney, Nebraska	11
Hamot Medical Center	Erie, Pennsylvania	247
Highmark Inc*	Pittsburgh, Pennsylvania	472
Jameson Health System	New Castle, Pennsylvania	154
Jefferson Regional Medical Center	Pittsburgh, Pennsylvania	178
Lehigh Valley Hospital	Lehigh, Pennsylvania	49
Monongahela Valley Hospital	Monongahela, Pennsylvania	105
Ohio Valley Medical Center	Wheeling, West Virginia	16
Princeton Community Hospital Association, Inc	Princeton, West Virginia	41
St Joseph's/Camden Clark Memorial Hospital	Parkersburg, West Virginia	23
St Mary's Hospital	Huntington, West Virginia	136
Swedish American Health System	Rockford, Illinois	206
United Hospital Center	Clarksburg, West Virginia	169
West Virginia University Hospitals, Inc	Morgantown, West Virginia	136
Wheeling Hospital	Wheeling, West Virginia	34
Windber Medical Center	Windber, Pennsylvania	339
Total		2974

* Highmark provided the intensive cardiac rehabilitation program as well as reimbursing its costs.

settings at relatively low cost, but it also illustrates some of the challenges in conducting multisite studies in which outcomes data are collected primarily for clinical management of patients. It was hypothesized that participation in the program would result in healthier behaviors and thus improved health outcomes as demonstrated by improvements in lipids, blood pressure, hemoglobin A1c, weight/body mass index (BMI), psychological symptoms, and increased functional capacity.

METHODS

Design

This study employs a nonexperimental (prospective time series) design to examine the efficacy and effectiveness of an intensive lifestyle change program on risk factors related to cardiovascular disease at baseline, 12 weeks, and 1 year.

Sample

2974 men and women (ranging in age from 21 to 89 at baseline) participated in this intensive cardiac rehabilitation program at 24 health care sites in Nebraska, West Virginia, Pennsylvania, and Illinois between 1998 and 2009. A complete list of program sites can be found in Table 1. The full program inclusion/exclusion criteria have been previously reported.[12–14] In brief, participants were eligible for the program if they had diagnosed CHD or significant risk factors for CHD, including type 2 diabetes; were medically stable; and did not have a history of substance abuse.

Demographic information for all study participants is presented in Table 2. Most participants had health insurance that covered program costs, and the remainder of the sample paid for the program out of pocket. Prior to enrollment in the program, participants were screened for eligibility and informed consent was obtained. Participants were recruited using a range of mechanisms including mass mailings, local media coverage, health fairs, health care providers, and general promotion of the program.

Measures

Data were collected from study participants using a combination of methods including fasting blood draw, self-report questionnaires, exercise stress test, and clinical measurement. A more detailed description of assessment procedures has been provided in previous publications.[12–14] The following variables were self-reported: exercise (min/wk), dietary cholesterol intake (mg/d), dietary fat intake (percentage of total calories), and psychosocial measures. Objective measures included functional capacity measured on a treadmill (Metabolic Equivalent of Task [MET]), total cholesterol (mg/dL), hemoglobin A1c (analyzed only in those who presented with a diagnosis of diabetes at baseline), low density lipoprotein cholesterol (LDL; mg/dL), high density lipoprotein cholesterol (HDL; mg/dL), BMI, systolic and diastolic blood pressure, triglycerides (mg/dL), depression, and hostility. Dietary intake (fat and cholesterol) was assessed using a 3-day diet diary, and exercise was recorded in a weekly log.

Depressive symptoms were assessed using the Center for Epidemiology Studies–Depression scale (CES-D).[16] This 20-item measure asks respondents to indicate how often they experienced specific depressive symptoms during the past week (e.g., "I was bothered by things that don't usually bother me") using a four-point Likert scale (None, Some, Much, or All of the Time). Total scores range from 0 to 60, with higher scores indicating more symptoms of depression. Scores above 23 suggest the presence of clinical depression. Internal consistency of the CES-D is high ($\alpha > .90$) and the tool's construct validity is supported by significant correlations with clinician ratings of depression.

Hostility was evaluated using a modified 27-item version of the Cook-Medley Hostility Scale[17] that is answered in a true/false format (e.g., "It makes me impatient to have people ask for my advice or otherwise interrupt me when I am working on something important"). Total scores range from 0 to 27, and higher scores reflect greater hostility.

Intervention

The intensive cardiac rehabilitation program included four components:

healthy diet, moderate physical activity, psychosocial group support, and stress management techniques. A detailed description of this program has been provided in previous publications.[4–15,18] In brief, participants were instructed to eat a low-fat, whole-foods, plant-based diet (fruits, vegetables, whole grains, legumes, soy products) low in refined carbohydrates, exercise for a minimum of 3 h/wk (e.g., walking), attend group support meetings, and practice stress management techniques such as restorative yoga and meditation for 1 h/d. Patients were encouraged to continue following these guidelines for at least 1 year.

Patients were asked to attend an 8-hour orientation as well as 4-hour sessions held twice a week for 12 weeks that included group support, didactic lectures, cooking demonstrations, supervised exercise, guided stress management sessions, case management, and a group meal. After 12 weeks, participants were stratified based on clinical profiles into groups that received ongoing stress management and group support for 2 hours once a week for up to 40 additional weeks, depending on level of risk. All participants were encouraged to meet weekly in a self-directed community for the remainder of the year in which they continued these 2-hour sessions on their own, and also received monthly case management calls from a nurse for the remainder of the year.

Program staff at each site included a medical director, a registered dietitian, an exercise physiologist, a stress management specialist, a nurse case manager, and a licensed mental health professional. All staff took part in a 3- to 5-day training session that was led by professional staff at the nonprofit Preventive Medicine Research Institute and/or Highmark Inc to learn how to deliver this intervention. Administration of the program was standardized across all sites.

Analysis

We analyzed the data in two different ways. The primary approach was to analyze only data from patients for whom complete data were available in each parameter at baseline, 12 weeks, and 1 year (Table 3). As a secondary approach, we analyzed all available data from all patients, even though there were data for more patients at baseline than at 12 weeks or 1 year (Table 4). This helped to counter the possibility that there was a selection bias in those who completed testing at 12 weeks or 1 year—i.e., the possibility that patients at baseline who were more or less sick did not complete subsequent testing. It also provided information on the effects from baseline to 12 weeks and baseline to 1 year in a larger sample.

We used *t*-tests (two-tailed) to assess differences by comparing baseline values to those after 12 weeks and baseline values to those after 1 year. We also used *t*-tests to compare values between 12 weeks and 1 year. These analyses were also repeated in the subset of this sample that was over the age of 65 at baseline because of the implications for Medicare coverage of intensive cardiac rehabilitation. As a secondary analysis, we used *t*-tests to analyze all available data from all patients, even though there were data for more patients at baseline than at 12 weeks or 1 year.

RESULTS

At 12 weeks, we obtained complete data from 90.9% of participants who enrolled in the program and near-complete data from 94.9% of baseline respondents. At 1 year, we obtained complete data from less than 50% of participants who enrolled in the program and near-complete data from 62.7% of baseline respondents. As noted earlier, 88.8% of patients remained enrolled in the program after 12 weeks and 78.1% remained enrolled in the program after 1 year.

In Table 3, we analyzed data from patients for whom complete data were available at all three time points in each variable. Significant differences were observed in the expected direction (improvements) for all observed variables except HDL between baseline and 12 weeks ($p < .005$ in all measures) and also between baseline and 1-year follow-up ($p < .005$; Table 3). Similar results were found for the subset of this sample that was ≥ 65 years of age between baseline and 12 weeks and baseline and 1 year (detailed analysis available upon request).

In Table 4, we analyzed all available data from all patients, even though there were data for more patients at baseline than at 12 weeks or 1 year. Again, significant differences were observed in the expected direction (improvements) for all observed variables between baseline and 12 weeks ($p < .005$ in all measures) and also between baseline and 1-year follow-up ($p < .005$; Table 4).

HDL decreased between baseline and 12 weeks, although less than LDL, but not significantly between 12 weeks and 1 year. HDL rose significantly between 12 weeks and 1 year (Table 3). As previously described, reductions in HDL in response to healthy lifestyle changes have a different prognostic significance than low HDL levels in those consuming a typical American diet, as we measured regression of coronary atherosclerosis in earlier randomized controlled trials even though HDL declined somewhat.[5,7,18,19]

There was additional significant improvement between 12 weeks and 1 year only in BMI, HDL, functional capacity, and hostility, and significant recidivism between 12 weeks and 1 year in all other measures (except triglycerides, depression, and dietary cholesterol), yet improvements from baseline to 1 year remained significant in all measures despite the recidivism.

DISCUSSION

We have reported the health outcomes of an intensive cardiac rehabilitation program in 2974 participants administered by 24 hospital sites in four states between 1998 and 2009. The data include significant improvements in clinical, behavioral, and psychological outcomes at 12 weeks that were somewhat less but still statistically significant and clinically significant after 1 year. These include improvements in risk factors associated with CHD (i.e., triglycerides, LDL, total cholesterol, blood pressure, BMI) as well as improved psychological health (i.e., reduced depression and hostility). Participant retention for this program was high.

Table 2
Participant Demographics

	Baseline	12 wk	1 y
Participation, No.			
Total enrolled	2974	2658	1380
Age, y			
Average age	58.7	58.0	59.4
Range	21–89	22–89	30–89
Gender, %			
Male	47.6	47.9	52.4
Female	52.4	52.1	47.6
Employment status, %			
Employed	54.5	54.9	48.9
Unemployed	6.1	5.8	5.7
Disabled	4.5	4.1	3.4
Retired	26.9	27.0	31.7
Unknown	8.0	8.3	10.3
Marital status, %			
Married	74.4	75.5	78.6
Widowed	6.4	6.5	6.3
Divorced	8.8	8.7	6.9
Never married	3.3	3.2	2.6
Committed relationship	1.4	1.2	0.6
Separated	5.1	4.7	5.0
Unknown	0.5	0.2	0.1
Diagnosed conditions, %			
Coronary heart disease	48.6	49.1	53.3
Diabetes	34.2	33.1	29.4
Hyperlipidemia	78.8	20.0	19.6
Hypertension	74.3	19.7	19.0
Obesity	68.1	16.7	15.5
Ethnic origin, %			
Asian	0.6	0.6	0.3
Black, not of Hispanic origin	3.2	3.0	2.0
Filipino	0.0	0.0	0.1
Hispanic of Mexican, Puerto Rican, Cuban, Central American, or South American descent	0.2	0.2	0.1
Indian subcontinent	0.6	0.6	0.8
Middle Eastern	0.1	0.1	0.2
Native American	0.8	0.8	0.7
Native Hawaiian	0.0	0.0	0.1
Other	0.2	0.2	0.3
Unknown	2.1	1.6	0.6
White, not of Hispanic origin	92.2	92.9	94.9
Highest level of education completed			
Less than 7th grade	0.2	0.2	0.2
Junior high school	0.8	0.8	1.0
Partial high school (10th or 11th grade)	1.9	1.9	1.8
High school graduate	26.6	25.9	27.5
Partial college or specialized training	19.1	19.0	15.7
College graduate	26.0	26.6	29.1
Graduate degree	20.3	20.6	20.8
Unknown	5.0	4.6	4.0

These results suggest that an intensive cardiac rehabilitation program can improve numerous health outcomes, enhance quality of life, and potentially lead to long-term decreases in health expenditures. Previous randomized trials established the efficacy of this intervention in controlled research settings; this study goes a step further by demonstrating the effectiveness of the program in clinical/community sites in various parts of the country in larger groups of patients.

These findings are important, as it is a common and often self-fulfilling misconception that few, if any, patients are able to make and sustain intensive lifestyle changes to this degree. We hope that our findings may encourage other health professionals to offer intensive lifestyle changes to their patients.

We recognize that not all patients with CHD are interested in making intensive lifestyle changes to this degree, but for those who are, given the proper support of intensive cardiac rehabilitation programs such as this, the data reviewed above show that they do remarkably well as indicated by a wide variety of clinical metrics. The rather low attrition rates of 11.2% at 12 weeks and an additional 10.7% at 1 year indicate that this intensive cardiac rehabilitation program is sustainable for most patients who enroll. (Many patients continued to participate in the intensive cardiac rehabilitation program who did not provide data at 12 months for reasons described below.)

Of note is that recent studies of this intensive cardiac rehabilitation program showed that it beneficially affected gene expression[20] as well as telomerase levels,[21] thereby providing insight into some of the mechanisms by which intensive lifestyle changes may show beneficial effects in only 12 weeks.

Although this study has considerable strengths, including a large, socioeconomically diverse sample, a few limitations must be noted. There was no control group or comparison sample and this was not a randomized clinical trial, so caution must be exercised when attributing demonstrated changes to the intervention. Because not all patients who completed the program

Table 2
Continued

	Baseline	12 wk	1 y
Income, %			
$7500 or less	1.1	1.1	1.0
$7501–$15,000	3.1	3.0	2.8
$15,001–$25,000	8.9	8.8	9.1
$25,001–$35,000	10.8	10.9	11.2
$35,001–$50,000	14.9	15.3	14.8
$50,001–$75,000	15.8	15.8	15.0
$75,001–$100,000	9.3	9.3	7.7
$100,001 or over	7.1	6.7	5.3
Unknown	29.0	28.9	33.1

provided data, it is possible that there was a selection bias, but, as indicated earlier, the main reason was a change in insurance coverage in which clinical tests were no longer covered, and this was unrelated to disease severity or adherence. Medication data was not available for all patients, but all patients were instructed not to make changes in their medications during the intervention unless advised to do so by their physician. Some of these data were self-reported and therefore may be subject to bias. This sample is not as diverse with respect to ethnicity as would be optimal, although it was socioeconomically diverse. Finally, all

Table 3
Intervention Outcomes at 12 Weeks and 1 Year for All Participants†

	Baseline vs. 12 wk				Baseline vs. 1 y				12 wk vs. 1 y			
	Baseline Mean (SD)	12 wk Mean (SD)	No.	% change	Baseline Mean (SD)	1 y Mean (SD)	No.	% Change	12 wk Mean (SD)	1 y Mean (SD)	No.	% Change
Triglycerides, mg/dL	179.1 (125.7)	160.2 (87.8)	1322	−10.6*	179.1 (125.7)	160.3 (104.5)	1322	−10.5*	160.2 (87.8)	160.3 (104.5)	1322	+0.1
BMI	32.0 (7.1)	29.9 (6.3)	1328	−6.6*	32.0 (7.1)	29.5 (6.3)	1328	−7.8*	29.9 (6.3)	29.5 (6.3)	1328	−1.3*
LDL, mg/dL	107.9 (37.3)	88.9 (32.3)	1229	−17.6*	107.9 (37.3)	99.8 (34.9)	1229	−7.5*	88.9 (32.3)	99.8 (34.9)	1229	+12.3*
HDL, mg/dL	45.1 (13.0)	39.3 (10.9)	1317	−12.9*	45.1 (13.0)	44.6 (12.9)	1317	−1.1	39.3 (10.9)	44.6 (12.9)	1317	+13.5*
Systolic BP, mm Hg	132.7 (17.4)	121.1 (14.7)	1332	−8.7*	132.7 (17.4)	126.4 (16.6)	1332	−4.7*	121.1 (14.7)	126.4 (16.6)	1332	+4.4*
Diastolic BP, mm Hg	79.0 (10.3)	72.3 (8.7)	1331	−8.5*	79.0 (10.3)	75.2 (9.8)	1331	−4.8*	72.3 (8.7)	75.2 (9.8)	1331	+4.0*
Total cholesterol, mg/dL	188.8 (45.7)	158.9 (40.5)	1323	−14.9*	188.8 (45.7)	175.3 (43.4)	1323	−6.2*	158.9 (40.5)	175.3 (43.4)	1323	+10.3*
Dietary cholesterol, mg/dL	202.0 (185.7)	9.3 (26.1)	1064	−95.4*	202.0 (185.7)	22.7 (63.1)	1064	−88.8*	9.3 (26.1)	22.7 (63.1)	1064	+144.1*
Dietary fat, g/d	27.1 (10.9)	9.3 (2.6)	1092	−65.7*	27.1 (10.9)	11.1 (5.0)	1092	−59.0*	9.3 (2.6)	11.1 (5.0)	1092	+19.4*
Hemoglobin A1c, %	7.3 (1.5)	6.5 (1.0)	329	−11.0*	7.3 (1.5)	6.89 (1.4)	329	−5.6*	6.5 (1.0)	6.89 (1.4)	329	+6.0*
Exercise, min/wk	90.2 (112.8)	228.8 (90.1)	1294	+153.7*	90.2 (112.8)	197.4 (111.0)	1294	+118.8*	228.8 (90.1)	197.4 (111.0)	1294	−13.7*
Functional capacity, MET	9.0 (3.0)	11.0 (3.1)	1055	+22.2*	9.0 (3.0)	11.2 (3.2)	1055	+24.4*	11.0 (3.1)	11.2 (3.2)	1055	+1.8*
Cook-Medley hostility‡	7.8 (4.7)	6.3 (4.3)	1255	−19.2*	7.8 (4.7)	6.0 (4.2)	1255	−23.1*	6.3 (4.3)	6.0 (4.2)	1255*	−4.8**
CES-D depression§	11.4 (9.1)	6.0 (5.8)	1258	−47.4*	11.4 (9.1)	6.3 (6.4)	1258	−44.7*	6.0 (5.8)	6.3 (6.4)	1258	+5.0

† BMI indicates body mass index; LDL, low density lipoprotein cholesterol; HDL, high density lipoprotein cholesterol; BP, blood pressure; MET, Metabolic Equivalent of Task; CES-D, Center for Epidemiology Studies–Depression scale.
‡ Range of scores is 0 to 27.
§ Range of scores is 0 to 60.
* $p < 0.005$.
** $p < 0.05$.

Table 4
Intervention Outcomes at 12 Weeks and 1 Year for All Participants Using All Available Data†

	Baseline vs. 12 wk				Baseline vs. 1 y				12 wk vs. 1 y			
	Baseline Mean (SD)	12 wk Mean (SD)	No.	% Change	Baseline Mean (SD)	1 y Mean (SD)	No.	% Change	12 wk Mean (SD)	1 y Mean (SD)	No.	% Change
Triglycerides, mg/dL	160.7 (131.7)	165.8 (94.2)	2631	−8.2*	179.1 (125.5)	160.6 (104.4)	1328	−10.3*	160.2 (87.8)	160.3 (104.5)	1322	+0.1
BMI	33.3 (7.5)	31.2 (6.8)	2653	−6.3*	32.0 (7.1)	29.5 (6.3)	1332	−7.8*	29.9 (6.3)	29.5 (6.3)	1333	−1.3*
LDL, mg/dL	108.5 (38.1)	90.6 (33.7)	2477	−16.5*	107.7 (37.2)	99.9 (34.9)	1255	−7.2*	88.9 (32.4)	99.7 (34.8)	1258	+12.1*
HDL, mg/dL	45.1 (12.8)	39.6 (11.0)	2619	−12.2*	45.1 (13.0)	44.6 (12.9)	1324	−1.1*	39.3 (10.9)	44.6 (12.9)	1319	+13.5*
Systolic BP, mm Hg	132.1 (16.9)	121.1 (14.3)	2677	−8.3*	132.7 (17.4)	126.4 (16.6)	1333	−4.7*	121.1 (14.7)	126.4 (16.6)	1333	+4.4*
Diastolic BP, mm Hg	78.9 (10.2)	72.8 (8.7)	2677	−7.7*	79.0 (10.3)	75.2 (9.8)	1331	−4.8*	72.3 (8.7)	75.3 (9.8)	1332	+4.1*
Total cholesterol, mg/dL	187.7 (46.8)	162.1 (42.1)	2634	−13.6*	186.8 (45.7)	175.4 (43.4)	1329	−6.1*	158.9 (40.5)	175.2 (43.4)	1325	+10.3*
Dietary cholesterol, mg/dL	209.4 (189.0)	10.6 (31.3)	2505	−94.9*	201.9 (186.4)	22.8 (63.0)	1078	−88.7*	9.2 (26.0)	22.8 (62.9)	1076	+147.8
Dietary fat, g/d	28.6 (10.9)	9.6 (3.3)	2515	−66.4*	27.1 (11.0)	11.1 (5.0)	1106	−59.0*	9.3 (2.6)	11.1 (5.0)	1107	+19.4*
Hemoglobin A1c, %	7.4 (1.6)	6.6 (1.1)	786	−10.8*	7.3 (1.5)	6.9 (1.4)	335	−5.5*	6.5 (1.0)	6.8 (1.4)	358	+4.6*
Exercise, min/wk	82.1 (112.0)	224.8 (91.2)	2644	+173.8*	90.1 (112.6)	194.1 (111.0)	1300	+115.4*	228.7 (90.1)	194.4 (111.1)	1302	−15.0*
Functional capacity, MET	8.5 (3.0)	10.4 (3.2)	2323	+22.4*	9.0 (3.0)	11.3 (3.2)	1086	+25.6*	11.0 (3.1)	11.2 (3.2)	1070	+1.8*
Cook-Medley hostility‡	7.9 (4.7)	6.5 (4.3)	2628	−17.7*	7.8 (4.7)	6.0 (4.2)	1259	−23.1*	6.3 (4.3)	6.0 (4.2)	1260	−4.8**
CES-D depression§	11.8 (9.1)	6.7 (6.5)	2630	−43.2*	11.4 (9.1)	6.3 (6.4)	1261	−44.7*	6.0 (5.8)	6.3 (6.4)	1264	+5.0

† BMI indicates body mass index; LDL, low density lipoprotein cholesterol; HDL, high density lipoprotein cholesterol; BP, blood pressure; MET, Metabolic Equivalent of Task; CES-D, Center for Epidemiology Studies–Depression scale.
‡ Range of scores is 0 to 27.
§ Range of scores is 0 to 60.
* $p < 0.005$.
** $p < 0.05$.

participants did not receive the same number of sessions after the first 12 weeks because of risk stratification, which may have affected 1-year outcomes, although all patients were instructed to follow the same intervention for 1 year.

Missing assessment data do not reflect program completion rates, as it was not possible to obtain data from all participants at 12 weeks and 1 year, primarily because of changes in patients' health benefit structures and/or life circumstances. For example, some patients had changes in their health insurance if they switched jobs and no longer received the same benefits that allowed for program-related hospital visits and laboratory tests. Also, several of the participating hospitals are community hospitals in which clinical care, not research, is the priority.

This experience illustrates some of the challenges in conducting multisite studies in which outcomes data are collected primarily for clinical management of patients, not for research purposes. The advantage is that these studies can be conducted at much lower cost. The disadvantage is that when patients lose insurance coverage, then they no longer have reimbursement for their program-related hospital visits and laboratory tests, which is why at 12 weeks, as noted earlier, we obtained complete data from 90.9% of participants who enrolled in the program and near-complete data from 94.9% of baseline respondents. However, at 1 year, we obtained complete data from less than 50% of participants who enrolled in the program and near-complete data from 62.7% of baseline respondents. We hope that our findings will generate interest in conducting large-scale studies of this type in which funding is sufficient to collect data on all outcome measures.

CONCLUSIONS

In summary, this intensive cardiac rehabilitation program was effective and efficacious, showing that it is feasible and sustainable for most patients who enrolled to remain in a large-scale real-world intervention over time. It demonstrates that the intervention works when it is administered by staff at multiple clinical/community

sites in four different states. Second, it shows the challenges of collecting complete data when the study cannot provide guaranteed funding for data collection and the need for future studies to do so. Third, the intervention of intensive cardiac rehabilitation is efficacious and was associated with numerous subjective and objective improvements in health status. These improvements were also seen in patients 65 years of age or older, indicating that Medicare coverage of intensive cardiac rehabilitation programs is warranted.

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References

1. American Heart Association. *Heart Disease and Stroke Statistics—2009 Update.* Dallas, Tex: American Heart Association; 2009.
2. Rozanski A, Blumenthal JA, Davidson KW, et al. The epidemiology, pathophysiology, and management of psychosocial risk factors in cardiac practice: the emerging field of behavioral cardiology. *J Am Coll Cardiol.* 2005;45:637–651.
3. Yusuf S, Hawken S, Ounpuu S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. *Lancet.* 2004;364:937–952.
4. Ornish DM, Scherwitz LW, Doody RS, et al. Effects of stress management training and dietary changes in treating ischemic heart disease. *JAMA.* 1983;249:54–59.
5. Ornish D, Brown SE, Scherwitz LW, et al. Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. *Lancet.* 1990;336:129–133.
6. Koertge J, Weidner G, Elliott-Eller M, et al. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration Project. *Am J Cardiol.* 2003;91:1316–1322.
7. Ornish D, Scherwitz LW, Billings JH, et al. Intensive lifestyle changes for reversal of coronary heart disease. *JAMA.* 1998;280:2001–2007.
8. Gould KL, Ornish D, Scherwitz L, et al. Changes in myocardial perfusion abnormalities by positron emission tomography after long-term, intense risk factor modification. *JAMA.* 1995;274:894–901.
9. Gould KL, Ornish D, Kirkeeide R, et al. Improved stenosis geometry by quantitative coronary arteriography after vigorous risk factor modification. *Am J Cardiol.* 1992;69:845–853.
10. Dod HS, Bhardwaj R, Sajja V, et al. Effect of intensive lifestyle changes on endothelial function and on inflammatory markers of atherosclerosis. *Am J Cardiol.* In press.
11. Pischke CR, Weidner G, Elliott-Eller M, et al. Comparison of coronary risk factors and quality of life in coronary artery disease patients with versus without diabetes mellitus. *Am J Cardiol.* 2006;97:1267–1273.
12. Daubenmier JJ, Weidner G, Sumner MD, et al. 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. *Ann Behav Med.* 2007;33:57–68.
13. Govil SR, Weidner G, Merritt-Worden T, Ornish D. Socioeconomic status and improvements in lifestyle, coronary risk factors, and quality of life: the Multisite Cardiac Lifestyle Intervention Program. *Am J Public Health.* 2009;99:1268–1270.
14. Frattaroli J, Weidner G, Merritt-Worden TA, et al. Angina pectoris and atherosclerotic risk factors in the multisite cardiac lifestyle intervention program. *Am J Cardiol.* 2008;101:911–918.
15. Ornish D. Avoiding revascularization with lifestyle changes: the Multicenter Lifestyle Demonstration Project. *Am J Cardiol.* 1998;82:72T–76T.
16. Radloff L. The CES-D Scale: a self-report depression scale for research in the general population. *Appl Psychol Meas.* 1977;1:385–401.
17. Barefoot JC, Dodge KA, Peterson BL, et al. The Cook-Medley hostility scale: item content and ability to predict survival. *Psychosom Med.* 1989;51:46–57.
18. Ornish D. *The Spectrum.* New York, NY: Ballantine Books; 2008.
19. Ornish D. Was Dr. Atkins right? *J Am Diet Assoc.* 2004;104:537–542.
20. Ornish D, Magbanua MJM, Weidner G, et al. Changes in prostate gene expression in men undergoing an intensive nutrition and lifestyle intervention. *Proc Natl Acad Sci U S A.* 2008;105:8369–8374.
21. Ornish D, Lin J, Daubenmier J, et al. Increased telomerase activity and comprehensive lifestyle changes: a pilot study. *Lancet Oncol.* 2008;9:1048–1057.