

Appendix A.5

Of the

Evaluation of Lifestyle Modification and Cardiac Rehabilitation

in Medicare Beneficiaries

**Effectiveness of Lifestyle Modification Programs in Changing Behaviors of
Elders**

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Abstract

Introduction: This study compared the effectiveness of the Lifestyle Modification Program Demonstration (LMPD), traditional cardiac rehabilitation (CR), and no active intervention (No CR) on lifestyle behaviors and outcomes.

Methods: The study is based on a survey of Medicare beneficiaries aged 65 and over in LMPD, CR and No CR. The survey obtained information on participants' health status, clinical problems, family history, lifestyle behaviors (diet, exercise, medications, and knowledge about health and cardiac conditions), satisfaction with care, self-efficacy, social support, perceived stress, hostility, and living arrangements. The survey was administered at baseline and subsequently for up to two years. Controls were identified using a clinical algorithm and Medicare claims data. Potential selection bias was controlled by the use of matching process and key determinants of selection. Survey results were obtained from 1,001 individuals including 349 participants in the LMPD, 360 CR recipients, and 292 who received no CR.

Results: Several potentially important differences were found in baseline characteristics between the study groups. LMPD participants were more highly educated, more likely to have a family history of heart disease, were less likely to have been smokers, and were more likely to be living with spouses or partners and to own homes. These are characteristics that may well have affected lifestyle behaviors. Second, univariate analyses indicated more favorable improvements in process and outcome measures in the LMPD group. For example, the LMPD group was more likely to have attempted dietary changes and steps to relieve stress and improve socio-psychological health. They also experienced greater improvements in intermediate measures of health and socio-psychological well-being. Effects of the LMPD are highly statistically significant for process measures as well as all four outcome variables ($p < 0.001$). For example LMPD participants reduced scores on the limited activities scale by over 10.32 units in males and by 20.49 units in females compared to those in the No CR group. Regression estimates for other socio-psychological health showed significant differences between LMPD program participants and No CR participants.

Conclusions: Although part of the apparent superiority of the LMPD may be due to selection bias and differences in motivation and other patient characteristic, this analysis suggests that the LMPD program showed advantages over traditional CR in reported behaviors ranging from 11% to 39% after controlling for selection effects. Overall health benefits of lifestyle modification will depend both on the magnitude and the duration of change.

1. Introduction

Coronary heart disease (CHD) is the leading cause of death in the United States and worldwide and is also a major driver of medical care and economic loss from death and disability. CHD led to 7.2 million deaths worldwide in 2002, and 0.48 million deaths in the US in 2003.¹⁻² Americans 65 years or age or older account for 86% of CHD deaths.³ Lifestyle modification programs address this problem through secondary prevention to slow, prevent, or possibly reverse the progression of CHD. While meta-analyses and systematic reviews have found that both traditional cardiac rehabilitation (CR) programs and more intensive lifestyle modification programs appear effective, there has been little analysis on their comparative benefits. As the cost per participant to the Medicare program of Lifestyle modification programs is about four times that of traditional CR, such comparative effectiveness data are important to policy makers.⁴ As the time demands of lifestyle modification are also much greater than those of traditional CR, the data is important to patients and their families as well. This paper addresses that need through a survey-based comparison of health practices among Medicare beneficiaries with CHD choosing different options. After adjusting for selection effects, as described in a companion paper, we found that that more intensive lifestyle programs led to larger behavioral changes. However, the improvement in behaviors was much smaller than the difference in program costs, suggesting that traditional cardiac rehab may be a higher priority for the Medicare program.

2. Methods

A process and outcome evaluation of the Medicare Lifestyle Modification Program Demonstration (LMPD) for feasibility and cost effectiveness was assessed through an experimental design. Demonstration sites provide either the Dr. Dean Ornish Program for Reversing Heart Disease® or the Mind/Body Medical Institute program. Feasibility evaluation will include examining implementation processes to identify barriers, challenges, and successes. Cost-effectiveness evaluation will include clinical effectiveness, quality, and utilization of health services. In a broader perspective the evaluation study uses a multi-method data analytical model including data from case studies, participant and control surveys, claims, and medical records.

This report assesses the effectiveness of lifestyle modification programs in changing behaviors of elders. It employs univariate analyses followed by a series of cross-sectional multivariate regression models to assess and compare the impact of alternative programs. The comparative effectiveness of LMPD against regular CR programs and absence of any rehabilitation effort was examined for changes in both physical and socio-psychological health indicators. A series of regression models were designed in order to compare the effectiveness of the programs on both

process measures and outcomes between Lifestyle participants and two control groups who did and did not utilize CR. Using multivariate analyses improvement in both process measures and final outcomes were examined. Process and outcome measures as dependent variables in multivariate models were chosen from physical health as well as socio-psychological health indicators in order to provide a comprehensive picture of comparative effectiveness of programs.

Since the observations of control subjects for the baseline stage were not available plus the subjects were not assigned to programs thru a random process, we needed an alternative study design. Thus, our study design used the follow-up observations of treatment (LMPD patients) against two separate control groups (with and without CR). However in order to address the selection bias in this design, two major steps were undertaken. Firstly the matching processes mitigated the threat of selection bias to the fullest extent possible. Secondly each and every model was controlled for key determinants of selection where those selection explanatory variables were carefully determined according to the results of the earlier work of the team on analysis of self-selection processes and criteria. In order to further increase the internal validity of the model and address the history and maturity issues we found one outcome variable that had the value of baseline (last year weight and hence last year BMI) according to recollection of participants. This last variable allowed us to virtually construct a dif-in-dif model despite the fact that the original design did not collect data for baseline period for control subjects.

2.1 Population Studied

The LMPD survey collects beneficiary characteristics regarding health, clinical status, family history, lifestyle including diet, exercise, medications, knowledge about health and cardiac conditions, satisfaction with care, self-efficacy, social support, perceived stress, hostility, living arrangements and so forth. It was administered at baseline, and two follow-ups: Years One and Two. Controls were identified through a clinical algorithm from claims data and were only surveyed at Years One and Two. Controls were stratified according to their utilization of cardiac rehabilitation (CR).

Survey results for the first year follow up were obtained from 349 Lifestyle participants and 652 controls including 360 participants with CR and 292 participants without CR. The cross-section dataset for the regression estimations was prepared based on the survey results for the first year follow up. From the total 1,001 observations used for uni-variate analyses, 996 had no unresolved missing value in none of the covariates and were used for the regression estimates. See Appendix A for discussion of non-response bias.

3. Results

The focus of this report is on the comparative impact of Lifestyle modification program on major physical and socio-psychological health indicators. The report compares health indicators of participants from Lifestyle group and two control groups who did and did not utilize CR. Uni-variate estimates provide some initial results about how various programs might change the lifestyle and hence the health of participants. These estimates, also known as unconditional results, deemed to include some selection bias due to non-randomized assignment of participants in three groups. In other words there is a reasonable doubt that some participants might self-select themselves or being assigned in a non-randomized basis into a specific program. Their preference in choosing between no CR at all, regular programs, or most extensive Lifestyle programs is not random rather is determined according to their family history, own risk profile, socio-economic status and so forth.

The multivariate regression models can tease out the program effects more precisely, because they control for effects of the explanatory variables affecting the outcome variables. These estimates are known as conditional estimates and are believed to be less prone to the selection biases.

3.1 Uni-variate analysis

Table 3.1 shows the result of univariate analysis for some of the categorical variables. A Chi-squared (for two-by-two categories an Exact Fisher test) was conducted separately between each two groups.

From the 349 Lifestyle intervention participants 65.6% were male, 95.4% were non-Hispanic Whites, average age was 72.7 years. There was no significant difference in terms of key demographic variables indicating that three groups were more or less similar in terms of age, gender and race distribution. Lifestyle and CR utilizers were significantly more likely to own their home (86%, 88%) as compared to No CR subjects (79.8%). In examining the smoking history we observed that Lifestyle participants were significantly more likely to be never smoker (44.3%) compared to the No CR group (31.8%) and there was also a notable gap between the percentage of current smokers: 1.2% for Lifestyle compared to 10.5% for No CR subjects ($p < 0.001$). With respect to living arrangement, again the difference is significant: 74.2% of the Lifestyle participants enjoyed living with a spouse or partner, compared to No CR group with 66.8% ($p < 0.05$).

Two aspects of effectiveness of programs are investigated: process improvement and the outcome change. An example for process improvement is comparison of the percentage of patients that see their heart doctor or a cardiologist regularly. The result showed significant differences between groups: 88.2% for Lifestyle versus 84.6% for With CR and 78.3% for No CR groups. One outcome measure was the self reported health status where only 14.9% of the Lifestyle participant self assessed themselves as “poor to fair” compared to 27.9% for With CR ($p<0.001$) and 31.5% for No CR ($p<0.001$). Also when participants were asked “How much has health or emotional problems interfered with your social activities,” 70.4% of Lifestyle participants answered “none of the time” versus 52.8% of With CR ($p<0.001$) and 54.4% of No CR ($p<0.001$).

Table 3.1. Uni-variate statistics for selected categorical variables ^a

Characteristics	Lifestyle (<i>n</i> =349)	Control		Lifestyle Vs. WithCR	Lifestyle Vs. NoCR	WithC R Vs. NoCR
		WithCR (<i>n</i> =360)	No CR (<i>n</i> =292)			
Demographic Variables						
Gender						
Male	65.6	69.1	66.1	NS	NS	NS
Race						
Non-Hispanic white	95.4	92.8	92.5			
Non-Hispanic black	2.3	3.5	2.9	NS	NS	NS
Hispanic or Latino	1.2	1.7	1.4			
Other non-Hispanic	1.2	2.0	3.2			
Social Variables						
Live with spouse						
Yes	74.2	76.4	66.8	NS	*	**
Smoking						
Never smoked	44.3	35.2	31.8			
Previously smoked	54.5	62.2	57.7	*	***	***
Current smoker	1.2	2.6	10.5			
Home ownership						
Owner	86.0	88.0	79.8	NS	*	**
Process Measures						
Sees heart specialist/cardiolog.						
Yes	88.2	84.6	78.3	NS	***	*

Characteristics	Lifestyle (n=349)	Control		Lifestyle Vs. WithCR	Lifestyle Vs. NoCR	WithC R Vs. NoCR
		WithCR (n=360)	No CR (n=292)			
Outcome Variables						
Rating of health status						
Poor to fair	14.9	27.9	31.5	***	***	NS
4 weeks had chest pain						
Yes	14.4	20.4	23.9	*	**	NS
Accomplished less in past month?						
Did not have any problem	64.3	49.4	44.7	***	***	NS
Rating of support from family and friends						
Poor to fair	2.6	4.8	6.0	NS	*	NS
How much has health or emotional problems interfered with social activities?						
none of the time	70.3	52.8	54.4	***	***	NS

^a All the values are in percentage. For each pair-wise comparison Chi-Sqr (Fisher Exact for 2x2 tables) test results are reported, statistical significance of each pairwise comparison: * indicates P<.05, ** indicates P<.01, *** indicates P<.001, and NS indicates the difference is not statistically significant.

Notation: CR denotes cardiac rehabilitation

The uni-variate analysis was also conducted for some of the continuous variables. Variables and results of t-tests are reported in Table 3.2.

Table 3.2. Uni-variate statistics for selected continuous variables ^a

Characteristics	Mean			T-Test		
	Lifestyle	Control W/CR	Control NoCR	Lifestyle- WithCR	Lifestyle- NoCR	WithCR- NoCR
Physical Variables						
Age	72.70	73.36	72.90	NS	NS	NS
BMI a year ago (Baseline)	28.03	27.98	28.33	NS	NS	NS

Characteristics	Mean			T-Test		
	Lifestyle	Control W/CR	Control NoCR	Lifestyle- WithCR	Lifestyle- NoCR	WithCR- NoCR
Number of Risk Factors i.e. Blood Pressure, Cholesterol and Triglycerides (0 to 3)	2.02	1.86	1.99	*	NS	NS
Social Variables						
Years of education (6 to 18 years)	14.11	13.60	12.68	*	***	***
Number relative died of heart disease all ages plus others under 65 years	1.23	1.09	0.99	NS	*	NS
Process Measures						
Number of approaches tried for lifestyle change (0 to 21)	6.48	4.56	3.37	***	***	***
Number of activities done to relieve stress (0 to 9)	4.00	2.86	2.58	***	***	*
How often followed special diet/meal plan (0 to 4)	3.27	2.86	2.76	***	***	NS
Hours a week followed moderate recreation activities (scale 0=0 to 4=10 hours)	1.72	1.35	1.06	***	***	**
Hours a week followed heavy recreation activities (scale 0=0 to 4=10 hours)	0.74	0.41	0.28	***	***	*
Outcome Variables						
BMI after (1 st year follow up)	26.71	27.68	28.06	**	**	NS
Was bothered by symptoms (scaled 0 to 100)	13.31	17.99	19.93	***	***	NS
Had limited activities as of heart symptoms (scaled 0 to 100)	21.33	32.61	37.42	***	***	*
Were worried or anxious about heart symptoms (0 to 4)	0.54	0.70	0.69	**	*	NS
Total score of how Dr.	3.15	3.04	2.61	NS	*	*

Characteristics	Mean			T-Test		
	Lifestyle	Control W/CR	Control NoCR	Lifestyle- WithCR	Lifestyle- NoCR	WithCR- NoCR
helped in last 6 months (0 to 8)						
Cardiac self-efficacy scale (0 to 20)	14.88	14.55	13.70	NS	***	**
Social support scale (0 to 20)	17.19	16.41	16.23	*	**	NS
Strife scale (0 to 12)	1.32	1.77	1.90	**	***	NS
Perceived stress scale (0 to 40)	8.78	10.56	10.66	***	***	NS
Hostility scale base on Cook Medley hostility scale (0 to 12)	2.97	3.83	3.91	***	***	NS
Number of correct answers to questions of common beliefs about heart disease (0 to 7)	5.48	5.25	5.17	*	**	NS

^a Mean values are reported, statistical significance of each pairwise comparison: * indicates P<.05,

** indicates P<.01, *** indicates P<.001, and NS indicates the difference is not statistically significant.

Notation: CR denotes cardiac rehabilitation; BMI denotes body mass index

Uni-variate comparison for the average years of education for each group using a t-test showed that intervention group on average had a higher level of education compared to both With CR (p<0.05) and No CR groups (p<0.001). To investigate the effect of family history we have counted all immediate family members regardless of their age and added them with those relatives who have died younger than age 65 due to heart disease to make a continuous variable. Although the Lifestyle group had a higher death rate in their family compared to both control groups, the result of t-test suggests that only difference between Lifestyle and No CR group was statistically significant (p<0.05).

We also made a composite index to measure some of the risk factors that were supposed to be affected by a CR program and hence were important motivating factors. The index was made of the answers to series of the questions about the history of blood pressure, cholesterol, and

triglycerides. The index ranges from lowest score of 0 (all three factors were always in normal range) to highest 3 (all three factors were at least once out of normal range). The t-test showed that compared to other two groups, the Lifestyle participants with 2.02 score of risk factors had a worse history while the difference was significant only between Lifestyle and With CR group with 1.86 score ($p < 0.05$).

One of the question related to process improvement asked about the number of approaches were tried for lifestyle change by participants. Approaches include healthy diet, losing weight, stress reduction, stop smoking, regular exercise, reducing cholesterol, and controlling high blood pressure. The total score for number of approaches varies from lowest 0, for no personal and program recommended effort at all, to highest 21, indicating a full range of approaches resulting from combined efforts covered in part by CR and further strengthened by participants self conducted efforts. The Lifestyle group with average of 6.48 was the highest compared to With CR (4.56, $p < 0.001$) and No CR group (3.37, $p < 0.001$).

Another process measure of interest deals with stress relief efforts. An index was made to reflect these efforts. This index includes following activities aiming at stress relief: exercise or recreational activities (like gardening, walking, tennis), avoiding stressful situations, trying to manage stressful situations, meditation or yoga, taking personal time to relax and reflect, taking medications to help controlling stress, taking a bath, getting extra sleep, and any other significant personal effort. The index for number of activities done to relieve stress varies from lowest 0 to maximum 9 indicating all efforts mentioned above. The t-test showed the advantage of Lifestyle group over other two groups, concerning process measure of stress relief.

One outcome variable of interest is BMI. No significant difference was observed when the BMI a year ago (body mass index in the baseline) across three groups was compared. However over time the pace of change differed in the three groups. The average BMI of participants at the first follow up year appeared to be significantly different. It dropped more among Lifestyle participants and at the first follow up year the difference was significant ($p < 0.01$) between the Lifestyle (26.71) and both groups of With CR (27.68) and No CR (28.06).

For other outcome variables we observed a lower rate for anxiety, lower strife scale, higher cardiac self-efficacy scale, lower perceived stress scale, and lower hostility scale in favor of Lifestyle participants and the differences were always highly significant particularly when they were compared against No CR group.

3.2 Multivariate Analysis

We discussed some of the differences between Lifestyle and two control groups in previous sections. The univariate analysis suggests that as the result of the LMPD, the Lifestyle group overall enjoyed a better health status, both physically and emotionally. By using a series of multivariate analysis while controlling for all motivating factors for the sake of selection bias reduction, we can examine the effectiveness of LMPD on Lifestyle group against two With CR and No CR groups. Once we have dealt with the selection bias through controlling for important independent variables, any observed significant difference is probably a benefit of Lifestyle modification program, rather than an artifact of self-selection or program-selection.

In the multivariate regression analysis for observing the comparative effectiveness of programs, two different groups of process and outcome variables will be studied as dependent variables. The process and outcome measures are chosen from two domains: physical health and socio-psychological health. The change in diet, BMI gain, or heart related symptoms are examples of physical health indicators. From physical health domain six key variables are chosen where two of them are process change indicators, and other four variables are outcomes. We will then examine the impact of program on socio-psychological health indicators where we look at the comparative improvement, between Lifestyle and other two groups, in both process changes (relief stress efforts) and outcome variables (perceived stress or hostility scale).

3.3 Impact of program on health indicators

The impacts of LMPD on six dependent variables are assessed. To construct the regression models for comparison we entered two group dummy variables, one for Lifestyle participants (Lifestyle), and the other for With CR participants (WithCR). As a matter of fact these dummy variables are the policy impact variables where the reference category with which these two groups are being compared is the No CR group.

Outcome and process indicators were explained in uni-variate section. One additional outcome variable of interest is a composite index that adds up all limitations in physical activities due to heart symptoms. The index includes all sorts of limitation in vigorous activities, such as running, lifting heavy objects, participating in strenuous sports, moderate activities like dancing and golf, and light ones like walking one block. We call this dependent variable "limited activity scale". The scale varies from no limitation (zero) to the maximum possible limitations (100) due to heart symptoms.

For all regression models we have used the following independent covariates: two dummy policy impact variables indicating Lifestyle participants and With CR participants where the No CR group was the reference category, gender and two dummy variables indicating interaction effects between gender and membership in either Lifestyle or With CR groups, age, years of education (from 6 years for 8th grade or less to maximum 18 years for some postgraduate education), smoking history (1 for whom that reported as current or previously smokers), the BMI dummy variable that indicates whether body mass index according to the last year's participant weight was over 25 (over 25=1 less than 25=0), the total number of risk factors reported in the past history of participant which encompasses three items of blood pressure, cholesterol and triglycerides and ranges from 0=previously had no risk factor (very low risk) to 3=previously had all three risk factors (very high risk), a dummy variable for home ownership (1 = home owner), a dummy variable for living arrangement (1=living with spouse or partner), a dummy variable for family death history which is equal to 1 for participants who had either at least one case of immediate family member death from heart disease in any age, or other relatives only if they died younger than age 65 years, the race variable which is equal to 1 for all Non-Whites participants (Non-Hispanic White is the reference category), and a dummy variable for insurance coverage with value 1 if respondent had a full or partial insurance plan for prescription drugs.

Table 3.3 shows the result of regression estimates with dependent variables on columns and explanatory variables in rows. Each cell indicates the coefficient estimate followed by the legend of significance level.

Table 3.3. Regression results for impact of various cardiac rehab programs on selected outcome variables; (n = 996) ^a

Independent Variable	Process Measures			Final Outcomes						
	No. Approaches Tried	No. Diets or Spec. Meals Followed	No. Diets or Spec. Meals Followed	Limited Activities Scale	Symptoms Scale	Self Reported Health Status	BMI Change			
Intercept	2.37	1.79	***	3.76	22.30	***	2.22	***	3.40	***
Lifestyle group	2.97	*** 0.45	***	-10.32	*** -5.19	***	0.33	***	-1.37	***
WithCR group	1.28	*** 0.20	*	0.59	-1.36		0.09		-0.35	
Female	0.18	0.16		16.92	*** 5.29	**	-0.07		-0.59	*
Female in Lifestyle	0.21	0.03		-10.17	* -1.25		0.00		0.87	**
Female in W/CR	-0.05	-0.02		-8.90	* 1.57		-0.09		1.11	***
Years of education	0.08	* 0.00		-0.89	** -0.57	***	0.02	*	0.00	
Age	-0.02	0.00		0.48	*** 0.04		0.00		-0.03	**
Ever smoked	0.25	0.00		0.74	0.41		-0.08		0.03	
BMI over 25 (at baseline)	0.71	*** 0.00		6.80	*** 1.27		-0.13	*	-0.87	***

Independent Variable	Process Measures		Final Outcomes			
	No. Approaches Tried	No. Diets or Spec. Meals Followed	Limited Activities Scale	Symptoms Scale	Self Reported Health Status	BMI Change
Num. of risk factors (BP, Chol, Trig)	0.52	*** 0.04	2.64	** 0.55	-0.09	*** -0.12
Home ownership	-0.64	** 0.07	-6.81	** -2.66	* 0.16	* -0.30
Live with spouse	0.41	-0.03	-3.46	-1.49	0.03	-0.04
Key death history	0.22	-0.02	0.22	0.86	-0.07	-0.13
NonWhite	0.09	-0.12	1.99	0.63	-0.14	-0.32
Insurance for medications	0.00	0.08	0.33	0.30	-0.05	0.09

^a Statistical significance: * indicates p<.05, ** indicates p<.01, *** indicates p<.001.

For the outcome variable Limited Activities Scale (varying from 0 to 100) the estimated coefficients for nine covariates of Lifestyle group, female, female in Lifestyle, female in W/CR, years of education, age, baseline BMI over 25, number of risk factors, and home ownership are statistically significant. The program impact variable is the dummy variable of Lifestyle group. The coefficient of the impact variable is negative and highly significant indicating that participation in lifestyle modification program on average reduces the limited activities scale by 10.32 units for male and by 20.49 ($=10.32+10.17$) units for female participants compared to their counterparts in the reference category of No CR. In contrast women both complained more of their limitation in activities (16.92 $p<0.001$) and as we just mentioned gained more from Lifestyle program. The estimate for the impact variable in a regression model that does not take gender differences into account (not reported) was -13.58 ($p<0.001$). It indicates that participation in lifestyle modification program on average reduces the limited activities scale by 13.58 units.

Interestingly the coefficient of group dummy variable for patients in With CR group is not significant which indicates that there is no significant difference between two control groups (with CR vs. No CR). In the model the years of education was a supportive factor for reducing the limitation scale (-0.89, $p<0.01$) also as we expected age of the patient was a factor that intensified the limitations to the extent that one year increase in age increased the limitation scale by 0.48 unit ($p<0.001$). Again as we expected the overweight patients with BMI greater than 25 had a limitation scale 6.80 units higher than those with BMI under 25 ($p<0.001$). Risk factors like blood pressure, cholesterol and triglyceride were also important factors for increasing limitation in activities due to heart symptoms. Each factor was estimated to increase the limitation scale by 2.64 units ($p<0.01$).

The only variable that can be considered as a proxy for economic situation of patient is the home ownership which appears to be significant: ownership leads to lowering the scale by 6.81 units ($p<0.01$). We did not observe any significant racial difference in the outcome measures or other lifestyle variables in any one of the regression models for physical health indicators but as we will see in next section there are some racial differences in socio-psychological health indicators like stress and hostility. We have to mention that we just had a few number of patients from each racial minority and about 94% of our respondents were Non-Hispanic White. Living arrangement used to be a significant variable (-3.04, $p<0.05$) in absence of variable Age and in a negative relation with the limitation scale. However in the model with Age variable the coefficient of living arrangement variable appeared not to be significant (-3.46, $p=0.09$) probably due to co-linearity but it still tends to be a supportive variable to reduce the limitations in activities. In absence of covariate age, we also compared the effect of living with spouse on limitations in activities, between women and men and interestingly we found that women who were living with their

spouse were far better than male participants who had their spouse in home. In that setting of regression model (not reported) the estimate of interaction term which showed the gender difference in impact of living with spouse was reasonably big and significant (-8.04, $p < 0.05$).

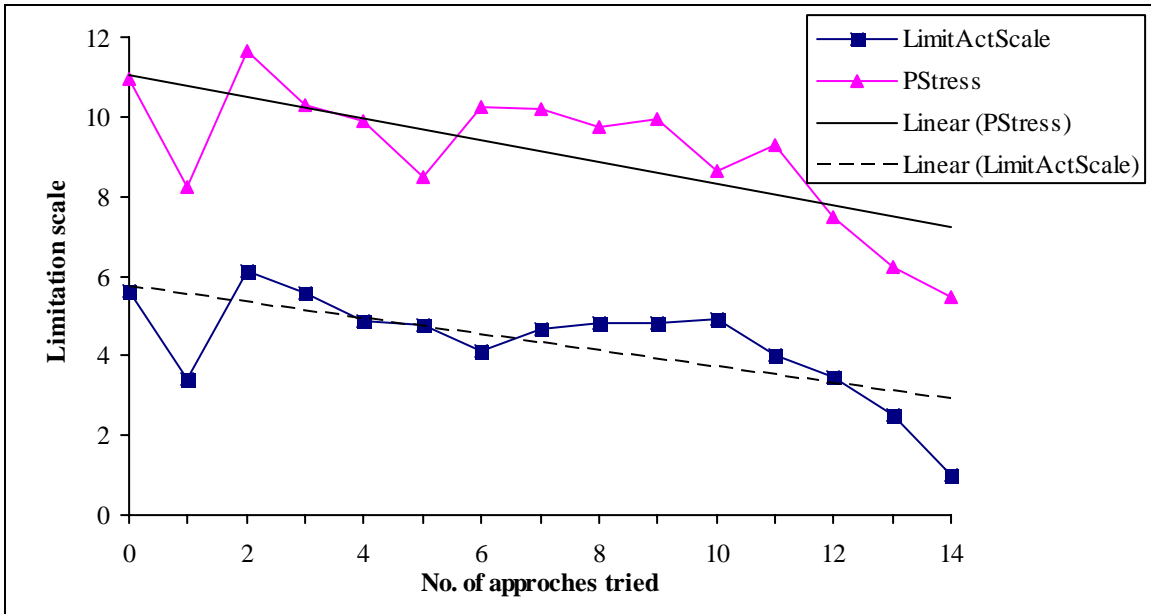
As we stated earlier we did not have access to the baseline characteristics of control subjects. The only variable that we had chance to examine its trend from the baseline for both Lifestyle and control groups was the BMI and the reason for this exception was that in addition to the current weight we had asked all participants the weight one year ago besides we could assume that their height remained unchanged from baseline to the first year follow up. The regression estimates for BMI gain is reported in the last column in table 3 indicating the important fact that Lifestyle group significantly did a better job in terms of BMI reduction (-1.37, $p < 0.001$). Again this is the male estimate and the female BMI reduction is about 0.5. In terms of BMI reduction the Control with CR group once again did not show any significant achievement since baseline, in comparison with reference group of Control No CR. We have entered the dummy variable of BMIOver25 in baseline and the negative sign of estimated coefficient (-0.87, $p < 0.001$) indicates that the more over weight the patients were in baseline the higher attainment in BMI reduction they had over the one-year follow up period. The construct and results of this last regression model are quite comparable with the study designs in which dif-in-dif estimates are used to evaluate the program impacts while mitigating the threats to internal validity due to history and maturity.

We discussed how the Lifestyle modification program improved some of the outcome variables. However these set of ultimate goals are supposedly attained through improvement in some of the intermediate outcomes which we know as process measures. Examination of the so-called mediating effect through regression of the outcomes on the process changes is necessary for assessment of the indirect causal relation between program and the outcomes. A set of regressions models showed that there is a significant relation between the major process measure of "Number of Approaches Tried toward Lifestyle Change" and the outcome measures. As an example the coefficient of independent variable "Number of Approaches Tried" is estimated to be negative and highly significant in regression model with dependent variable of Limited Activities Scale (-0.90, $p < 0.001$). This estimate indicates that each additional approach toward lifestyle change decreases the limitation scale by 0.9 unit (regression not reported).

In order to illustrate the relation between process measures and final outcomes, for each level of the process measure we calculated the mean value of two outcome variables and graphed them in Figure 3.1. The relation between the mean values of two outcome variables "Limited Activity Scale" and "Perceived Stress" with the process measure "Number of Approaches Tried" are

shown and the two downward sloping trend lines show how the outcome measures are declining (a decline means health improvement) by increasing the approaches toward lifestyle change.

Figure 3.1. Correlation between mean value of two outcome variables “Limited Activity Scale” and “Perceived Stress” and the process measure “Number Approaches Tried toward Lifestyle Change”



We repeated the same regression (details not reported) for other outcome variables as well. Results were quite consistent: coefficient of independent variable “Number of Approaches Tried” was estimated to be negative and significant for outcome variable “Symptoms Scale” (-0.37, $p < 0.01$), negative and significant for outcome “BMI Change” (-0.11, $p < 0.001$), and positive and significant for outcome “Self Reported Health Status” (0.02, $p < 0.01$). They all indicate that the more approaches tried toward life style change, the less symptoms observed, the higher loss in BMI, and the better self reported health status.

3.4 Impact of program on socio-psychological health indicators

We have conducted a series of regressions in order to find the impact of LMPD on some of the socio-psychological variables as we did previously for physical health indicators. We have examined three indicators: one for lifestyle change in such way that participants try to cope with their stress where we used number of approaches that patient chose to relief stress, the second variable was a measure of perceived stress, and the third one a scale for hostility. Regression estimates are shown in Table 4. The results of all three regression models supported the

comparative effectiveness of Lifestyle modification program over other alternatives of with and without CR.

Table 3.4. Regression results for impact of cardiac rehab programs on selected socio-psychological outcome variables; (n = 996)^a

Independent Variable	Process Measure		Final Outcomes			
	No. Approaches to Relief Stress		Perceived Stress		Hostility Scale	
Intercept	3.10	***	13.54	***	8.22	***
Lifestyle group	1.23	***	-1.83	**	-0.52	*
WithCR group	0.33	*	-0.17		0.09	
Female	0.24		1.82	*	-0.47	
Female in Lifestyle	0.39		0.25		-0.52	
Female in W/CR	-0.14		0.85		-0.07	
Years of education	0.05	**	-0.03		-0.15	***
Age	-0.02		-0.05		-0.03	*
Ever smoked	-0.08		0.16		-0.10	
BMI over 25 (at baseline)	-0.11		0.39		0.46	**
Num. of risk factors (BP, Chol, Trig)	0.10		0.11		-0.05	
Home ownership	-0.12		-0.37		-0.05	
Live with spouse	-0.15		-0.09		-0.25	
Key death history	0.06		0.33		0.25	
NonWhite	0.33		1.83	*	0.56	
Insurance for medications	0.02		-0.17		-0.36	*

^a Statistical significance: * indicates $p < .05$, ** indicates $p < .01$, *** indicates $p < .001$.

The coefficient of the policy impact variable (Lifestyle) for the regression of number approaches tried to relief stress was estimated to be positive and highly significant (1.23, $p < 0.001$). It indicates that Lifestyle participants tried a higher number of approaches to cope with their stress. When we assessed the result of these efforts again we found that the Lifestyle participants did a better job as their perceived stress was also 1.83 units lower compared to No CR group (-1.83, $p < 0.01$). They also showed a lower scale of hostility and the difference with No CR patients was -0.52 ($p < 0.05$). When we combine the results of first two regressions for number of approaches to relief stress and its effect on perceived stress (first two columns of result table) we see that even though the coefficient of dummy variable for membership in Control with CR group is estimated

to be positive and significant (0.33, $p < 0.05$) nevertheless we do not observe any effect from higher number of approaches toward stress relief on the perceived stress in the second regression as we saw for Lifestyle patients (the coefficient of WithCR variable is not significant in perceived stress regression model). Also we did not observe any significant difference between With CR and No CR groups with respect to hostility scale whereas there was a significant difference between Lifestyle and No CR groups. We observed a few interesting findings when we compared women and men. On average women reported a higher level of perceived stress compared to men (1.82, $p < 0.05$).

We were also interested to assess the effect of education on socio-psychological variables. The regression estimates suggest that the participant with higher level of education had more tendency to do something for stress relief (0.05, $p < 0.01$) and also showed a smaller degree of hostility (-0.15, $p < 0.001$). We also found that the older the participants they were the less degree of hostility they revealed. Getting older one year decreases the hostility scale by 0.03 unit ($p < 0.05$). As we mentioned earlier we did not find any racial difference in the physical health indicators but the new series of regression models for socio-psychological indicators show some evidences. As we see the Non-White participants have perceived higher amount of stress (1.83, $p < 0.05$). Interestingly the more overweight the patients were the higher scale of hostility they showed as the difference between hostility scale for two groups with BMI above and below the level of 25 was 0.46 ($p < 0.01$).

The outcome variables are not always directly improved by programs rather their change occur through intermediate outcomes also known as process measures. To examine such relation we conducted a series of regression model where we looked at the effect of the process measure of "Number of Approaches Tried" on the outcome variables. We found consistent results: the estimate for coefficient of independent variable "Number of Approaches Tried" was negative and significant for two major dependent outcome variables "Perceived Stress" (-0.20, $p < 0.01$) and "Hostility Scale" (-0.05, $p < 0.05$). In Figure 1 we observe the negative relation between the process measure and perceived stress: downward sloping line indicates that the higher the number of approaches tried toward lifestyle change the lower the level of perceived stress.

3.5 Magnitude of the impacts across all three groups

The cost per participant to the Medicare program of Lifestyle modification programs is about four times that of traditional CR; thus, the extent of impact differences are key to third party payers and policy makers.⁴ Likewise the time needed for a full course of lifestyle modification is much greater than those of traditional CR. Therefore the analysis of comparative effectiveness is important to patients as well. Our study suggests some comparative advantages for Lifestyle

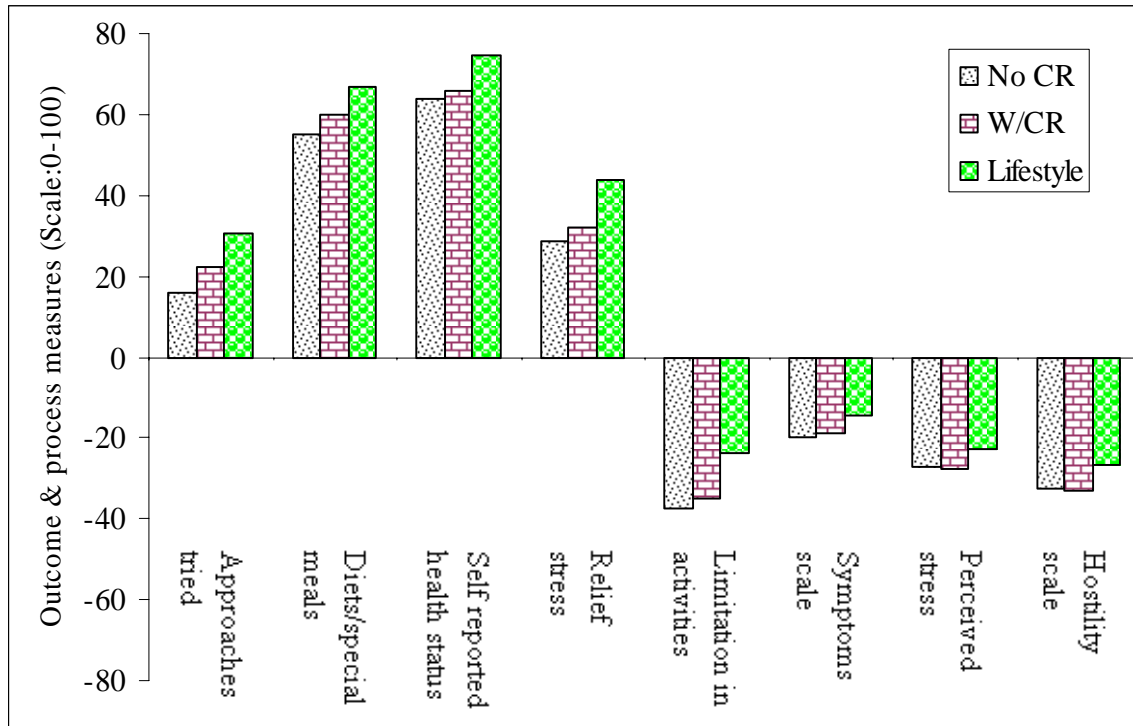
programs. The regression estimates provide us with conditional means of variables for each outcome variable or process measure across three categories of Lifestyle, with CR and no CR participants. The advantage of conditional means over unconditional means is that they contain much less of selection bias. The reason is that through regression models we control for effect of most of the important independent variables that supposedly impact outcome variables.

To provide an unbiased and real sense of difference between conditional and un-conditional means we discuss an example. The outcome variable symptom scale according to unconditional means estimates reported in Table 2 has the value of 19.93, 17.99, and 13.13 for No CR, With CR, and Lifestyle participants respectively. Once we have controlled the effects for influential independent variables using regression technique, the conditional mean values changed to 19.93, 19.06 and 14.32 for No CR, With CR, and Lifestyle participants, respectively. The No CR group is the reference group across all regression models and remains unchanged from the unconditional means. The pairwise gaps between groups were shorter in the conditional means compared to unconditional means, indicating that a portion of what appeared as superiority of Lifestyle program was the result of selection bias. In other words, if the Lifestyle participants were believed to be much better off compared to traditional CR participants, their superiority in health and socio-psychological status has come in part from their fundamental differences in terms of motivational factors and other abilities and not solely from Lifestyle program.

To assess the comparative effectiveness of more intensive programs, conditional means for eight process measures and outcome variables are chosen. The process measures are number of approaches tried toward lifestyle change, dieting and taking special meals, number of approaches tried to relieve stress. The outcome variables are self reported health status, limitation in activities due to heart problems, symptom scale, perceived stress, and hostility scale. Conditional means are depicted in Figure 2. To facilitate interpretation, the variables are divided into two favorable and unfavorable groups: for variables in favorable group, higher values indicate better results (like self reported health status); for variables in the unfavorable group, lower values are more desirable (e.g. hostility scale). Favorable variables are shown with positive values in upper half of graph and unfavorable variables are shown with negative values in the lower part of graph. Also for ease of comparison all variables are re-scaled based on their most extreme possible values to range between 0 and 100.

In general, the conditional means in Figure 3.2 suggest that the Lifestyle program was advantageous over both traditional CR programs and No CR cases. However in most of the cases the superiority is rather modest.

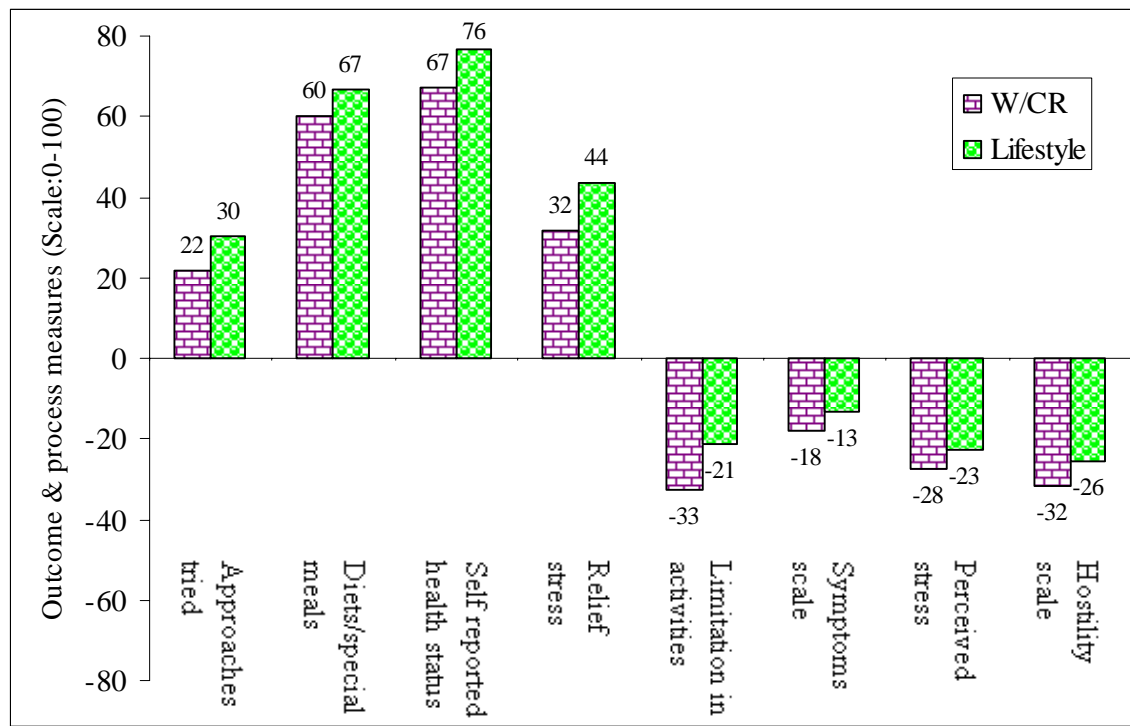
Figure 3.2. Three group comparison: conditional mean values in No CR, With CR and Lifestyle for selected variables



3.6 Comparative impacts between the two intensive groups

Policy makers and third party payers are increasingly interested in the comparative effectiveness among efficacious programs for decisions about coverage, recommendations, and reimbursement. To apply that concept here, we have focused on the two intensive programs, traditional CR programs versus more extensive Lifestyle modification programs. To address this critical question, we estimated a series of eight regression models to calculate conditional means for these two intensive programs. In this series of regression models, patients without CR were excluded from model and models were run based on pooled observations from traditional CR and Lifestyle groups. The process and outcome measures are the same as explained in Figure 3,2. Each model had 709 observations from first year follow up data consisting 360 traditional CR and 349 Lifestyle participants.

Figure 3. 3. Two group comparison: conditional mean values in With CR and Lifestyle groups for selected variables



In all eight regression models the differences between the two groups were significant ($p < 0.001$). To examine the magnitude of superiority of the more intensive program, in Figure 3.3 conditional means for Lifestyle programs are depicted according to the eight regression models. The advantage of Lifestyle over traditional CR varies from 11% for the diet/special meals scale (i.e., 67 vs. 60 scale units) to 36% for scale of approaches tried toward lifestyle change (i.e., 30 vs. 22 scale units).

4. Conclusions

In conclusion, this analysis suggests that the Lifestyle modification programs show some advantages over traditional CR in reported behaviors after controlling for selection effects. These ranged from 11% to 39% among the scales examined. On the other hand, a separate study found that the costs were about four times those of traditional CR.⁴ The added benefits of more intensive lifestyle modification do not seem commensurate with the substantially higher cost. The overall health benefits of lifestyle change depend on both the magnitude of change and the duration of change. Analyses of mortality benefits showed that some benefits persisted over five years, but attenuated over time.⁵ It is likely that the best value might be obtained from traditional

CR, which is increasingly recognized as comprehensive CR, combined with booster sessions to help participants continue their exercise and lifestyle changes over many years.

Appendix: Examination of Possible Non-response Bias

We investigated non-response to the survey by assessing whether the percentage of responders varied by categories of independent variables, such as age, within each of the study groups (i.e. Lifestyle, CR, Non-CR).

This is shown by the similarity of the percentage of response rates within each column in Table 1. In almost all cases, the small differences are not statistically significant. In the instances where they are statistically significant, the percentage differences are still only a few percentage points, suggesting that non-response bias has minimal, if any, impact.

Table A1. Variation in response rates by population characteristics

Groups		Lifestyle	With CR	No CR	Total
Overall population					
Total	Eligible (N)	440	847	835	2122
	Response Rate (%)	79.3%	42.4%	35.0%	47.1%
Breakdown by gender					
Male	Eligible (N)	284	550	544	1378
	Response Rate (%)	81.0%	45.1%	35.5%	48.7%
Female	Eligible (N)	156	297	291	744
	Response Rate (%)	76.3%	37.4%	34.0%	44.2%
Gender diff	p value	0.269	0.035	0.704	0.050
Breakdown by age					
Age <75	Eligible (N)	321	576	599	1496
	Response Rate (%)	79.1%	44.8%	37.1%	49.1%
Age 75 or older	Eligible (N)	119	271	236	626
	Response Rate (%)	79.8%	37.3%	29.7%	42.5%
Age diff	p value	1.000	0.044	0.044	0.006
Breakdown by qualifying event					
AMI	Eligible (N)	75	153	146	374
	Response Rate (%)	76.0%	47.1%	30.8%	46.5%
CABG	Eligible (N)	132	223	221	576
	Response Rate (%)	76.5%	41.3%	35.3%	47.0%
PCI	Eligible (N)	133	127	105	365
	Response Rate (%)	82.1%	43.5%	36.3%	49.1%
Stable Angina	Eligible (N)	71	179	179	429
	Response Rate (%)	81.7%	38.0%	35.8%	44.3%
Qualifying event diff	p value	0.543	0.384	0.706	0.452

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