

**Appendix C.4**

**Of the**

**Evaluation of Lifestyle Modification and Cardiac Rehabilitation in**

**Medicare Beneficiaries\***

**Systematic Review of Multifactorial Lifestyle Modification for**

**Coronary Heart Disease**

John Orwat, Ph.D, AM

Ann Collard, RN, MS, Ph.D

Sarita Bhalotra, MD, PhD

Donald S. Shepard, Ph.D

William B. Stason, MD, MSci

Jose Suaya, MD, PhD, MBA, MPH

Gail K. Strickler, PhD, MS

Schneider Institutes for Health Policy

Heller School, MS 035

Brandeis, University

Waltham, MA 02454-9110

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## **I. Introduction**

Several studies and comprehensive literature reviews document the value of modifying coronary artery disease (CAD) risk factors to prevent disease progression among individuals with established CAD. In some instances, reversal of actual disease is also possible. Modifiable risk factors include diet, exercise, tobacco use, stress, and social support. Several studies and literature reviews assess programs that offer interventions focused on modifying one or two risk factors, such as the comparison of dietary change programs. However, recommended guidelines for the treatment of CAD suggest that interventions should address the range of modifiable risk factors (Clark et al., 1999). Lifestyle modification programs are those that deliberately target multiple risk factors.

This literature review examines randomly controlled trials of lifestyle modification programs for individuals with known coronary artery disease. We define CAD as the overt expression of coronary artery disease including: recent (in prior 6 months) myocardial infarction (MI); persistent yet stable angina due to documented myocardial ischemia; and recent utilization of CAD related health care services such as angioplasty, stent or CABG. Diagnosis of CAD could be made by angiography or documented by noninvasive tests such as ETT, echocardiography, nuclear tests, or PET scans.

## **II. Methods**

### **A. Literature Search**

MEDLINE and Web of Science computerized searches were performed to identify relevant studies published between 1995 and 2005. In addition, bibliographies of qualifying published studies were examined to identify additional papers. Minimum inclusion criteria were checked by two researchers who reviewed titles and abstracts. Keywords included: (1) heart disease diagnosis including coronary artery disease, myocardial infarction, coronary events, and treatments including coronary artery bypass surgery, percutaneous transluminal coronary angioplasty, and heart surgery; (2) interventions including risk reduction, lifestyle modification, behavioral modification, risk modification, multifactorial program, lifestyle change; (3) outcomes including mortality, morbidity, recurrent non-fatal cardiac events, blood pressure, cholesterol, overweight or obesity, well-being, and quality of life; (4) types of intervention including stress management, diet changes, relaxation, and social support. The search was limited to articles on humans and those written in English. Only randomized controlled trials (RCTs) were considered.

### **B. Study Inclusion Criteria**

RCT titles and abstracts were checked by two researchers to ensure they met minimum inclusion criteria. For this review, we considered studies of both residential and outpatient interventions for coordinated lifestyle modification programs delivered by a variety of professionals. We intentionally excluded programs of cardiac rehabilitation since this intervention is reviewed elsewhere in this document. Lifestyle modification studies were chosen based on content, duration of intervention and follow-up, and intensity. Trials were included if they: (1) were randomly controlled trials; (2) included patients with our definition of CAD; (3)

reported having three of four of the following interventions: supervised exercise, diet, stress management, and social support; (4) staffed by one or more therapists with at least weekly contact; and (5) an intervention lasting at least 3 months plus a 1 year follow-up (selected because a shorter follow-up is inadequate to detect outcomes or study benefits.) Reviewed articles were published from 1995 to the present. Outcomes of interest included the impact of programs on risk reducing behavior of individuals (e.g., compliance with diet recommendations) and biological changes (e.g., LDL cholesterol). Symptom regression or occurrence/reoccurrence, utilization of health care services, and mortality were also considered, if reported by the study.

In all, seventy studies were considered, but ultimately only seven fully met our study criteria. Three studies were conducted by a group in Sweden (referred as the Scandinavian group in this document) (Hofman-Bang et al., 1999; Lisspers et al., 1999; Sundin et al., 2003), one examined an Ornish-type program (Gould et al., 1995), two involved the Women's Lifestyle Heart Trial (Toobert et al., 1998; Toobert et al., 2000), and one study was conducted by the Vestfold Heartcare Study Group in Norway (Vestford Heartcare Study Group, 2003).

### **C. Abstraction of Papers**

Each qualifying paper was abstracted by at least one medically-trained scientist according to a pre-determined abstraction protocol. A second reader reviewed abstractions, and corrections/additions were made with the agreement of the primary reviewer.

### **D. Report of Findings**

Associations between programs and risk reduction, such as behavior (e.g., compliance with diet recommendations) and physiological changes (e.g., LDL cholesterol) are derived from these RCTs. Conclusions are based on systematic review of the literature rather than quantitative evaluation.

## **III. Description of Study Characteristics**

### **A. The Ornish Program**

Although there are several evaluations of the Ornish program, only Gould et al. (Gould et al., 1995) met the inclusion criteria for this literature review. Subjects for this RCT (n=35) were diagnosed with coronary artery disease documented by recent arteriography. Subject recruitment procedures are unclear from the study description. The primary outcome measures were severity of perfusion abnormalities on rest-dipyridamole PET images and stenosis severity, as validated by arteriography at baseline and at 5 years. Other inclusion criteria included no recent myocardial infarction (MI) and a left ventricular ejection fraction greater than 25%. Subjects were ineligible if they were taking lipid-lowering drugs and if they did not reside in the greater San Francisco area. The control group received "usual care" by their regular physician.

Subjects were randomized into either an Ornish intervention group or control group after arteriography and informed consent, but prior to baseline measurement. Participants were predominately male, with 20 men in

the intervention group and 12 men and 3 women, for a total of 15, in the control group. Average age of the intervention group was 57 years and 68 years for the control group. The significance of this age difference is not known. Breakdown by diagnosis and minority status were also not reported. However, the authors reported that the “control and experimental groups were comparable.” Table 1 displays selected patient characteristics.

## **B. The Prime Time Intervention**

Two studies by Toobert et al. (Toobert et al., 1998; Toobert et al., 2000) also met our inclusion criteria. Both studies examined the physiologic and behavioral impact of the “Prime Time” intervention for postmenopausal women with documented coronary heart disease as defined in the Framingham Heart Study. These criteria included documented atherosclerosis, MI, PTCA, and/or CABG. Permission from the primary care physician or cardiologist was required for participation in the study. Subjects were excluded if they had other co-morbid life-threatening illnesses, an MI during the preceding six weeks, a history of receiving streptokinase or alteplase, or being scheduled for bypass surgery. The authors reported these exclusion criteria to be consistent with the 1990 Ornish study (Ornish et al., 1990a).

These two studies utilized several methods to recruit subjects, including presentations and mailings. Subjects were briefly assessed by project staff, attended an orientation, and, if selected, completed a baseline assessment. Subjects were stratified by diabetes, smoking, and total/HDL cholesterol ratios, and then randomized into two groups. It is unclear from the article if the 98 women who originally responded to recruitment materials differed from the women eventually randomized into the study. With the exception of co-morbid conditions, intervention and control groups did not differ on other measures, such as age, years since initial diagnosis of CHD, ethnicity, BMI, blood pressure, and lipids.

In the first Toobert study (Toobert et al., 1998), behavioral changes and psychosocial outcomes were assessed at 4- and 12-month periods. Behavioral outcomes included adherence to the program (e.g., diet, smoking, stress-management, exercise, and group support), as well as the impact of stress management, distress, social support, and self-efficacy on psychosocial functioning. Controls had “no intervention beyond the usual care of their physician,” (Toobert et al., 1998). Table 1 displays selected patient characteristics.

Twenty-eight postmenopausal women participated in the study—16 women comprised the intervention group and 12 women were controls. Differences in cardiac diagnoses in each group were not significant. Nine subjects in the intervention group and eight subjects in the control group had a nonfatal MI or CABG; six subjects in the intervention group and three women in the control group had atherosclerosis; and one subject in each group had PTCA. Cumulatively, 94% of those in the treatment group had one or more co-morbid conditions while 100% of those in the control group had one or more co-morbid conditions. The average age for the intervention group was 64 (SD 9), and 62 (SD 11) for the control group ( $p=0.57$ ). There were also no significant differences with regard to medications, marital status, education, ethnic/racial background, and smoking status.

The second study (Toobert et al., 2000) evaluated adherence to the program, behavioral outcomes, medication changes, physiologic outcomes, and quality of life among postmenopausal women who participated in the intervention as compared to controls. Recruitment mechanisms were the same as the 1998 study. Again, the control group received no treatment beyond usual physician care. Selected patient characteristics are displayed in Table 1.

This study included 25 postmenopausal women, 14 in the intervention group and 11 in the control group. Once again, study participants varied on only one measure, co-morbidity. The average number of co-morbidities among the intervention group was 2.6 (SD 1.7) and 4.1 (1.9) among the control group. Groups did not differ by cardiac diagnoses- seven intervention subjects and eight controls had experienced a nonfatal MI, three women in the intervention group and four women in the control group had a CABG, and five women in the intervention group and four in the control group had PTCA. Once again, the cumulative significant difference of co-morbidity was that 94% of those in the treatment group had one or more co-morbid conditions while 100% of those in the control group had one or more co-morbid condition. The average age for the intervention group was 64 (SD 10) and 63 (SD 11) for the control group ( $p=0.80$ ). There were no significant differences with regard to medications, marital status, education, ethnic/racial background, and smoking status.

### **C. The Scandinavian Studies**

A third group of studies from Sweden met our study inclusion criteria. These studies examined the behavioral and physiologic impacts of a multifactorial cardiac rehabilitation program. Lisspers et al. (Lisspers et al., 1999) examined the 12-month behavioral effects of the program for a group of patients ( $n=87$ ) after a PTCA procedure. Utilizing the same sample, Hofman-Bang (Hofman-Bang et al., 1999) evaluated behavioral and physiological outcomes at 12 and 24 months. Sundin et al. (Sundin et al., 2003) compared three levels of intervention intensity with a control group to assess the impact of program intensity ( $n=132$ ).

The patient population utilized by the Lisspers et al. (Lisspers et al., 1999) and Hofman-Bang's (Hofman-Bang et al., 1999) studies were recruited from an outpatient clinic at Karolinska Hospital, Stockholm, Sweden. To be included in the study, subjects had to have one or more coronary artery stenoses requiring PTCA and one or more clinically insignificant atherosclerotic stenoses or plaques evaluated by quantitative computerized angiography. Subjects had to be younger than 65 years of age, employed, a minimum capacity of 70W on a bicycle ergometer test following the PTCA, and have no other co-morbid diseases "of importance to completion of the program," (Hofman-Bang et al., 1999). The control group experienced "standard care" which was referral to their family doctor following one post PTCA outpatient visit at the Department of Cardiology.

Of the 151 subjects initially identified between 1993 and 1995, 93 met the inclusion criteria. Six subjects (2 in intervention group and 4 in control group) left the study, leaving 87 subjects in the final sample (46 in the intervention group and 41 in the control group). Subjects did not differ significantly by gender (37 men and 9

women in the intervention group and 36 men and 5 women in the control group). The average age for each group was  $53 \pm 7$  (Table 1). Subjects did not differ significantly on smoking patterns, comorbid diagnoses, exercise tolerance, cholesterol, or triglycerides. Most medication usage was also not significantly different between the two groups. Two exceptions were that the control group had a higher percentage of subjects on betablockers (90% C vs. 70% I,  $p < 0.05$ ) and the intervention group had more subjects on lipid lowering drugs (41% I vs. 22% C,  $p = 0.06$ ). Although not significantly different, 43% of the intervention group and 32% of the control group had experienced a previous MI (Table 1).

Sundin et al. (Sundin et al., 2003) recruited male patients only who were being treated at the Thoracic Clinics at the Karolinska Hospital in Stockholm. Inclusion criteria included treatment for PTCA, CABG, or AMI; age 70 or younger; a minimum capacity of 70W on a bicycle ergometer test; ability to read and understand Swedish; no “somatic or psychiatric diseases of importance to completion of the program” and no addiction problems. A standard care group served as control, much as the above Swedish studies.

Of the 433 participants initially screened, 31 subjects did not meet inclusion criteria, 169 individuals did not respond, and 89 refused. Additionally, the study sample excluded 12 subjects who never started or withdrew early from the intervention. The final sample of 132 subjects were randomly assigned to one of four groups: residential multifactorial ( $n=33$ ), outpatient multifactorial ( $n=31$ ), outpatient stress focused intervention ( $n=32$ ), and standard care control group ( $n=36$ ). Selected subject characteristics were reported for the entire sample. The mean age was 58.8 years old, 5% had AMI, 50% CABG, and 46% PTCA. Subjects' characteristics did not vary significantly among the study groups. Groups did not differ in comorbid diagnoses, tobacco use patterns, or medications, except for use of lipid lowering drugs.

#### **D. Vestfold Heartcare Study**

The Vestfold Heartcare Study group (Norway) assessed the influence of a “comprehensive lifestyle intervention” on lifestyle measures and five-year coronary risk factors. Subjects were recruited from the Toensberg area and two neighboring cities, a sample the authors report is representative of Norway. From August 1996 to July 1997, consecutive patients younger than 67 years of age and admitted for AMI, unstable angina pectoris (UAP) or after a CABG were asked to participate in the study prior to leaving hospital, usually within 7-14 days of the event. Those with exercise-induced ischemia as indicated by an ergometer bicycle test were excluded. Those with ST-depression or chest pain were subjected to coronary angiography and were then only included if they had been successfully revascularized with PCI or CABG. Control group care consisted of standardized nurse-based information and care through a cardiologist.

A total of 197 individuals participated in the study, 98 in the intervention and 99 in the control. Demographic and medical data were not significantly different for the two groups. The mean age for the intervention group was 54 and the control 55 years of age. Eighty-one percent of the intervention group and 84% of the control were male (Table 1). Experimental and control groups did not significantly differ on blood pressure, BMI, and biochemistry (e.g., cholesterol). Subjects did not differ significantly on cardiac diagnoses: (AMI-intervention group –39%, control group-34%; CABG intervention group-24%, control group-26% and PCI: intervention group –19%; and control group-20% (Table 1).

## **IV. Characteristics of Program Interventions**

The following sections discuss specific characteristics of the various study interventions. Table 2 displays duration, content and intensity data on each program. Table 3 provides further data on program intensity for each program.

### **A. Ornish**

Gould et al. (Gould et al., 1995) examined the effectiveness of an Ornish intervention compared to a control group. The authors used descriptions of the program in the original 1990 study and supplemental descriptions (Ornish, 1992) to calculate hours of intensity (Table 3). The Ornish-type program consists of lifestyle related educational experiences and lectures which focus on a very low-fat vegetarian diet, moderate exercise, stress management, and group support. Phase I of the program is an intensive 1-week retreat, followed by Phase II consisting of two 4-hour and one 2-hour meetings per week for 12 weeks. These meetings included supervised exercise, stress management, a catered meal, and group support (1 hour each). The 2-hour meeting included supervised exercise and a lifestyle related lecture. Phase III consists of one 4-hour session weekly for 40 weeks, followed the same pattern as the 4-hour meetings in phase II. For each phase of the program, a physician, registered nurse, exercise physiologist, psychologist, registered dietician, and a stress management specialist conducted activities appropriate to their specialty (Table 2).

Twelve-month quantification of on-site hours and on-site sessions/days are displayed in Table 3. To calculate these numbers for this program, several assumptions were made. First, we assumed that the one week intensive workshop were full 7 hour days over 5 days, totaling 35 hours. This was summed with the 12 weeks of 10 hours of meetings per week (120 hours) followed by 40 weeks of 4-hour meetings (160 hours). Participants of the Ornish intervention might expect to spend a total of 315 hours over 81 sessions

### **B. Prime Time Intervention**

The Prime Time intervention for postmenopausal women with coronary artery disease studied by Toobert et al. (Toobert et al., 1998; Toobert et al., 2000), consisted of a program of a low-fat vegetarian diet, moderate exercise, stress-management training, group support, and smoking cessation. The first phase of the program was a 7 day retreat, which subjects attended free of charge and with their partner. The retreat consisted of a dietician guiding participants in understanding a low-fat vegetarian diet with daily cooking classes, monitored meals, and discussions about foods. A yoga instructor led the group in stress management training twice per day, which included instruction in stretching, relaxation, breathing, meditation, and imagery. Moderate exercise classes were led by an exercise physiologist who assessed the individual's intensity capacity, then led them in warm-up, walking or aerobics, and cool down. Group support was conducted during the evenings to share feelings with the goal of decreasing social isolation.

For 15 months post retreat, twice weekly 4-hour meetings were conducted, again including partners. These meetings included exercise, yoga/stress management, a meal, and group discussions. Participants were

also encouraged to independently engage in stress management and exercise. Stress management was encouraged for 1-hour per day and an audiocassette was available to assist this activity. One hour of exercise, three times per week was also encouraged. Finally, meetings were reduced to every other week for 6 months, then once per month for the final 3 months (Table 2).

Twelve month, on-site hours and days/sessions (Table 3) were calculated for the retreat (assumed 7 hour days for 7 days) and subsequent meetings. A total of 451.4 hours were spent participating in on-site programmatic activities over the 7-day retreat and 100.6 additional sessions (Table 3).

### **C. Scandinavian Group**

Lissper et al., Hofman-Bang et al. and Sundin et al. (Hofman-Bang et al., 1999; Lisspers et al., 1999; Sundin et al., 2003) each evaluated different aspects of an intervention to change behavior through health education sessions, skills training, and habit reversal. They focused on diet, relaxation, exercise, and smoking. Participants first met with a nurse who tailored the program to the specific needs of the individual, e.g. assessment, planning and goal setting, relapse prevention planning, etc.

The first phase of the program included a 4-week residential stay consisting of health education, and behavior change in the major lifestyle areas previously identified. Participants were served and instructed how to prepare standard, low fat diet per Swedish guidelines. Unspecified training in exercise was also conducted. Stress management was defined as "Type A behavioral drills and relaxation training." Finally, social support was provided but how this was accomplished was not specified. The second phase of the program lasted 11 months and consisted of regular contact with a nurse who reviewed participant self-observations and reporting of their behavior change. Nurses gave feedback, and assisted with problem solving and re-planning. The final phase of the program lasted for one year and consisted of individuals encouraged to exercise on their own (Table 2).

Lisspers et al. (Lisspers et al., 1999) quantified the hours of the 4-week residential program at 78 hours (Table 3). For the 11 month nursing contact period, it was assumed by reviewers to take three hours per week, based on usual practices. No on-site hours or telephone contact hours were identified for the final year of the program since subjects were on their own. Thus, the 12-month intervention totaled 222 on-site hours over the 28 day residential and 144 additional nurse contact hours following residential discharge (Table 3).

### **D. Vestfold Heartcare Group**

The Vestfold Heartcare Study group's intervention included health education, dietary modifications, exercise, stress management, and psychosocial support. The first phase of the program included 6 weeks of "heart school" conducted in a rehab center at the Hospital of Vestfold in Norway. This school included interventions provided by a multidisciplinary cardiac team including dietary counseling by a dietician, supervised exercise by a specially educated physiotherapist, lifestyle risk reduction, stress management, regular group meeting twice per week, and individual counseling. Following heart school, participants

engaged in a 9-week phase in which they exercised twice per week with an exercise physiologist at a local gym. They were also invited to group meetings every third month following the initial school (Table 2).

We calculated the hours spent in this program by first assuming the 6-week heart school which was 5 days per week and 7 hours per day (210 hours). The Vestfold group did report the length of the 9 weeks of physical exercise twice per week to be 55-minute classes, which we rounded to one hour (total of 18 hours). Finally, we assumed the group meetings every third month lasted for 2 hours per meeting and met quarterly after the first 6 weeks of heartcare school, for a total of 7 meetings. However, since we are only calculating initial 12-month hours, we included only 3 (total of 6 hours) of these meetings. Thus, total hours for the initial 12 months of this intervention were 234 and included the 30-day heartcare school and additional 21 sessions (Table 3).

## **V. Discussion of Outcomes**

Overall, both experimental cases and controls improved on most measures. In some cases these effects did not hold up over time and in several instances, effects actually reversed between the first and second year measurement. In the following section we consider discussion of behavioral and physiologic outcomes separately. Table 4 reports behavioral outcomes for the specific studies. These include measures of patient adherence, percentage of calories from saturated fat consumption, physical activity scores, stress management scores, physical activity frequency, a rating scale of Type A personality behaviors (Bortner Score), and frequency of relaxation sessions. Table 5 reports low density lipo-protein (LDL) levels for patients in the specific studies. Finally, Table 6 reports Body Mass Index (BMI) changes for study patients. In some instances, all measures were not available for every study.

### **A. Behavioral Outcomes**

Adherence to a specific program or treatment is often difficult and the stricter the program the greater difficulty in patient compliance. Surprisingly, Gould reported greater than a 50% improved adherence among experimental cases in their Ornish-type program compared to controls. This is particularly impressive in that the Ornish program is quite difficult to follow and the outcome measurement was performed at 5 years.

Regarding the measurement of percentage of calories consumed from saturated fat, Toobert (Toobert et al., 1998) reported greater than a 50 percentage point reduction among experimental cases compared to controls at 1 year follow-up. In their later study Toobert (Toobert et al., 2000) reported greater than a 40% reduction in saturated fat consumption at year 1 and this increased to over 50% at year 2 of follow-up. Similarly, the Vestfold HeartCare study (Vestfold Heartcare Study Group, 2003) also found a 27 percentage point difference between experimental cases and controls in the percentage of calories derived from saturated fat at 2-year follow-up.

In the 1998 study, Toobert reported a 14 percentage point increase among experimental cases compared to controls when asked about their exercise activity over the prior 7 days (1-year measure) (Toobert et al.,

1998). In the 2000 study, a physical activity score was calculated and while cases improved more than controls by 9 percentage points at the 1-year follow-up, controls eclipsed this difference and improved 22 percentage points more than experimental cases at the 2-year follow-up. Similarly, in the earlier 1998 study, experimental cases scored 78 percentage points better on a stress management score than did controls at 1-year follow-up. However, in the later study (2000), while experimental cases scored greater than 50 percentage points better than controls on the stress management score at year 1, this effect did not persist into year-2 follow-up when controls improved more than experimental cases by 7 percentage points.

Comparisons of outcomes between the Sundin (Sundin et al., 2003) residential treatment study arm versus the outpatient treatment study arm are interesting. Experimental subjects demonstrated improvement of greater than 19 percentage points on dietary habits compared to controls and greater than 41 percentage point improvement on exercise frequency at 1-year follow-up. However, controls scored more favorably on the Bortner scores, a measure of Type-A personality characteristics. In the outpatient study arm of this research study, experimental cases improved more than controls by 23 percentage points on both dietary habits and exercise frequency measured at 1-year follow-up. Greater improvement in the Bortner score was also observed in experimental cases.

In the Hofman-Bang, et al. residential study (1999) experimental cases scored greater than 16 percentage points higher than controls on the dietary index measure at 1-year follow-up, but this difference dropped substantially at 2-years. The improvement in exercise frequency was significantly greater among experimental cases (67 percentage points) at 1-year follow-up than among control patients; and while somewhat lower at the 2-year measure, experimental cases still demonstrated a 57 percentage point difference compared to controls at 2-year follow-up. While the frequency of relaxation sessions increased in both patient groups from baseline to 1-year follow-up (higher in experimental cases), the differences were not statistically significant. At 2-year follow-up, the frequency was higher among the intervention group, but not statistically significant.

Finally, in the Lisspers study (Lisspers et al., 1999), experimental cases had an increase of 67 percentage points regarding weekly exercise sessions compared to controls at 1-year follow-up.

## **B. Physiologic Outcomes**

Results for LDL levels are displayed in Table 5 and results for BMI are displayed in Table 6.

Regarding the low density lipo-protein levels (LDL), both experimental cases and controls in each study showed reduction in LDL levels at both 1-year and 2-year follow-up. In most cases, the experimental group experienced greater reduction than the control group, but differences were not significant. The only exception to this is the original Ornish study (Ornish et al., 1990b) which measured LDL levels at 12 months and found a highly significant difference between experimental cases and controls. This significant difference was not found in the study by Gould et al. (Gould et al., 1995) when LDL was measured at 5 years. In two instances, the outpatient arm of the Sundin et al. study (Sundin et al., 2003) and the Hoffman-Bang study (Hofman-Bang et al., 1999) controls experienced greater reduction in LDL than experimental cases at 1-year, and 2-year follow-up respectively, but these differences were not statistically significant.

While significant differences were not observed for reduction in LDL, significant reductions were observed in weight loss. Overall, all experimental patient groups in every study experienced greater overall weight loss (measured by the body mass index- BMI) than did controls and these differences were statistically significant. The one exception to this finding was the outpatient arm of the Sundin 2003 study (Sundin et al., 2003) in which both experimental cases and controls groups gained weight from the baseline to the 1-year follow-up measure. This weight gain, though slight, was statistically significant with experimental cases gaining less weight than controls. However, it should be noted that measurement of BMI as measures in these studies does not take into effect the fat/muscle ratio which may be a more useful measure than simple BMI alone.

## **VI. Conclusions**

### **A. Overall Benefits**

As previously stated, in almost all studies both experimental subjects and controls demonstrated some improvement in most measures. This may be due to the fact that all patients, regardless of group assignment, were motivated to make some changes in their lives. This motivation and willingness to make life style changes may be enhanced because all patients were diagnosed with coronary heart disease, and thus may have appreciated the importance of making healthy changes in their lives. Moreover, perhaps the Hawthorne effect of participating in a study may explain some of the improvements. Indeed high motivation among all patients may explain the lack of significant differences between experimental cases and controls. The magnitude of this improvement varied by study and duration. In some cases, improvements at 1 year reversed themselves at the 2 year follow-up.

### **B. Variations in Intensity**

Examining the intensity of programs provides a useful prism through which to evaluate patient outcomes and compare programs. However, for the purpose of this comparison, we examined only the first 12 months of each program, even though some programs lasted 2 years. Ranking programs by their intensity (Table 3), the Primetime program has the highest intensity at 451 hours of professional contact provided over 108 sessions. The Ornish Program lags somewhat behind at 315 hours provided over 81 sessions. This represents a 30% hour reduction in professional hours delivered in twenty-five percent fewer sessions compared to the Primetime intervention. The Vestfold study ranks third in intensity at 234 hours of professional care delivered in 51 sessions. This program is roughly half as intensive as the Primetime program (52% fewer hours delivered in 47% fewer sessions). The residential arm of the Scandinavian Program ranked fourth in intensity at 222 hours of professional contact. The outpatient arm of this study was the least intensive study, 51 hours of professional contact delivered over 17 sessions. This represents approximately one-tenth the intensity of the highest intensity Primetime program, seventeen percent of the Ornish program intensity, and approximately twenty percent of the intensity of the Scandinavian residential study arm and the Vestfold Heartcare program.

### **C. Relation of Intensity to Outcome**

As more intensive programs make greater demands on participant time and likely use more health care resources, their incremental impact is a critical question. The Ornish Program (Gould et al., 1995) demonstrated excellent adherence rates based on the adherence score, as well as the best LDL and BMI outcomes. The experimental group's adherence scores were greater than 51 percentage points better than controls. This was the second most intensive program.

The most intensive program, the Primetime program, showed that compared to controls, experimental cases had greater improvement in the percentage of calories consumed from fat, physical activity, and stress management activities. For physical activity these gains disappeared during the second year for the experimental group, whose members, at the end of year two, scored worse than at baseline, compared to controls who improved. The authors contend this attenuation is due to less group support at the end of the program (Toobert et al., 2000). In the earlier Primetime study (Toobert et al., 1998) effects were even more dramatic at 12 months (51 percentage point greater reduction in calories from saturated fat in experimental subjects compared to control subjects, and 113 percentage points better than controls on stress management, where experimental subjects improved substantially while control subjects worsened.) This program utilized a 12-month follow-up design. This dampening of study effect at 2 years was also seen in the Hoffman-Bang residential program, where positive diet and exercise outcomes were reduced in year 2 and relaxation remained the same. Since effects seem to diminish over the second year, new models may be needed to achieve more long-term impacts. One option to explore would be telephone-based approaches, which have proved effective in other types of behavioral interventions (McKay et al., 2005). Another promising option is an approach emphasizing home-based activities that strengthen self-reliance, as discussed in the chapter on cardiac rehabilitation

Comparing outcomes for residential and outpatient study groups in the Sundin et al., (Sundin et al., 2003) study, one observes similar outcomes for both diet and exercise at 12 months. Interestingly, the Bortner score (Type A personality measure) was better in the outpatient group than in the residential program when experimental cases were compared to controls. Given the presumed higher cost of residential programs, one might question the value of expending additional resources when similar outcomes are achieved in less costly outpatient settings. Perhaps outpatient settings strengthen self-reliance and initiate behaviors that are easier for the client to maintain over the long run.

The most dramatic outcome effect was observed in the fourth most intensive intervention, Lisspers et al (1999) (Lisspers et al., 1999) and Hofman-Bang (Hofman-Bang et al., 1999). This residential study reported a 67 percentage point increase in exercise frequency in the experimental group at 1 year follow-up compared to the increase in control group. This advantage subsequently decreased to 57 percentage points at year 2.

While some impressive results were observed in behavioral outcomes across programs, less dramatic results were observed in physiologic measures of LDL (Table 5) and BMI (Table 6). Experimental cases were lower than controls in five of the seven studies (in two studies controls were lower than experimental

cases), and these differences were not significant in follow-up at year 1, year 2, and year 5. Thus, improved effects were not seen in the higher intensity programs.

However, in the four studies reporting BMI, all experimental cases experienced significant reductions in BMI compared to controls. However, the most intensive program, (Toobert et al., 2000) reported reductions in BMI only slightly above the mean (mean is 5.4; range is 0.73 to 11.42 percentage points). The Ornish type program (second most intensive program) reported the greatest reduction in BMI, 11 percentage points. This finding is not surprising given the extreme restrictions of the Ornish diet. The least intensive outpatient intervention (outpatient arm of the 2003 Sundin et al. study (Sundin et al., 2003) reported the least BMI reduction, although the difference was statistically significant.

While the lack of significant differences between experimental subjects and controls may be disappointing given the comprehensiveness of many of the programs studied here, it may be that usual care alone appears to have great potential in providing positive outcomes among the motivated subjects who joined these randomized trials. Thus, depending on the target population, it may be more efficacious to augment usual care with some specific strategy such as stress management versus developing a multi-factorial program that may not be cost-effective.

#### **D. Limitations of Studies**

Although, some programs demonstrated greater improvements than others, generalization from these studies is problematic for several reasons. First, there are only a few multifactorial studies. Second, studies varied by methods of outcome measurement, particularly measures of behavioral changes. Third, the small number of subjects in these studies may have been insufficient to detect significant differences in outcomes, and such differences might have been more apparent in a larger sample size. Fourth, gender is another variable that should be considered. Some studies enrolled only men (Sundin et al., 2003) and Toobert et al. (1998; 2000) (Toobert et al., 1998; Toobert et al., 2000) enrolled only women. Thus, results from these studies may not be generalizable to the opposite gender. In the other four studies, females represented fewer than twenty percent of the study population. Future studies should strive to balance study populations between both men and women. Fifth, the reliance on patient self-reporting and recall for accurate representation of behaviors may be inaccurate and bias the findings. Finally, regarding study design, while all of these reported studies employed some type of randomized assignment, they may have limited external validity. These study patients may have been extremely motivated and thus not necessarily representative of the general population.

Finally, the randomization procedure used by Ornish may have introduced a significant problem of self-selection into his study. In his study randomization of patients took place before enrollment, a design he argues was necessary because patients' expectations may not be met if they agreed to participate in the study and then were randomized into the control group. This argument can be debated, as the same rationale used could exist for virtually any study in which patients may end up in a control group and all the other studies used conventional randomization. In fact, only about half of the patients randomized to the treatment arm consented to be in the study. The data in Appendix B suggests, indeed, that experimental

subjects may have been more motivated, as their baseline LDL was substantially lower (152 mg/dl) than control subjects (167 mg/dl). The difference (about 10 percent) is in fact comparable to the improvements obtained in many of these studies. Thus, while the intervention by Ornish appears to be one of the most effective, its success may be due as much to motivated, self-selected participants as to the effectiveness of the intervention. In general, results of the studies reported in this literature review should be evaluated in the context of these identified design weaknesses.

**Table 1. Selected Characteristics of Controlled Clinical Trials of Multifactorial Interventions for Patients with Coronary Heart Disease**

Lead Author, Year, and Group	N	Mean Age (years)	% Female	Cardiac Diagnoses			
				% MI	% Stable Angina	% CABG	% PCTA
Gould et al. (1995)	35	59	9%	NR	NR	NR	NR
Toobert et al. (2000)	25	63.4	100%	7%	NR	3%	5%
Toobert et al. (1998) <sup>1</sup>	28	63.1	100%	9%	NR	9%	1%
Sundin et al. (2003), RM	69	57.6	0%	4%	NR	50%	46%
Sundin et al. (2003), OM	67	57.0	0%	3%	NR	48%	49%
Hofman-Bang et al. (1999)	87	53.0	16%	89%	NR	NR	NR
Lisspers et al. (1999)	87	53.0	16%	86%	NR	NR	NR
Vestfold Heartcare Group (2003)	197	54.4	18%	37%	2%	25%	20%

Notation: RM denotes residential multifactorial; OM denotes outpatient multifactorial; MI denotes myocardial infarction; CABG denotes coronary artery bypass graft; PCTA denotes percutaneous transluminal coronary angioplasty; NR denotes not reported.

See Appendix A for study descriptions.

<sup>1</sup> Toobert et al. (1998) reported the combined percentage of patients with MI or CABG; this combined percentage is shown in both of these columns.

**Table 2. Description of Multifactorial Interventions for Patients with Coronary Heart Disease**

Intervention	Lead Author, Year	Phase I Intervention			Phase II Intervention			Phase III, Treatment
		Duration	Content	Intensity	Duration	Content	Intensity	
Ornish Program <sup>1</sup>	Gould et al. (1995)	1) 1 week retreat 2) 12 weeks	1) a,b,c,d,e 2) a,b,c,d a,b,d	2) two four-hour sessions/ week except one two-hour session/ week for (c)	40 weeks	a,b,c,d	4 hours/ week	Self-directed, self-pay, lifestyle using self-help principles, such as case management by Ornish Program for those who desire more supervision.
Primetime program	Toobert et al. (2000); Toobert et al. (1998)	7 day residential retreat with partner	a,b,d,e,f c (yoga)	daily 2 times/day	65 weeks	a,b,c,d	two 4-hour sessions /week with partner	6 months: One 4-hr meeting bi-weekly. 3 months: One 4-hr meeting/ month.
Scandinavian program (residential)	Hofman-Bang et al. (1999); Lisspers et al. (1999); Sundin et al. (2003)	4 week residential	a,b c f	18 hours each 20 hours 6 hours	48 weeks, 3 hours per week <sup>2</sup>	g		
Scandinavian program (outpatient)	Sundin et al. (2003)	52 weeks	a,b,c	17 three hour sessions 1 - 6 = weekly 7 - 12 = bi-weekly 13 - 17 = monthly				
Vestfold heartcare program	Vestfold Heartcare Group (2003)	6 week	a,d,e,g	2 hours, 2 times/week	9 weeks	a  d, e	2 times/week for 55 minutes session every three months	Exercise on own at home, either on own or with group.

<sup>1</sup> Gould et al., 1995 do not describe the Ornish program but instead reference Ornish et al., 1990, which is used here.

<sup>2</sup> Assumed by reviewers take 3 hours per week based on usual practices.

a = supervised exercise

b = diet/meal support

c = stress management

d = group support/meetings

e = informational lectures

f = smoking cessation

g = individual counseling

**Table 3. Intensity of duration of Multifactorial Interventions in Coronary Heart Disease**

Intervention	Lead Author, Year	Intensity (12 month) <sup>3</sup>		Duration Program Duration (months)
		Professional <sup>2</sup> Contact Hours, Initial 12 Months (Hours)	Professional <sup>2</sup> Contact Sessions, Initial 12 Months (Sessions) <sup>2</sup>	
Ornish Program <sup>1</sup>	Gould et al. (1995)	315	96	12
Primetime residential program	Toobert et al. (2000); Toobert et al. (1998)	451	108	24
Scandinavian residential program	Hofman-Bang et al. (1999); Lisspers et al. (1999); Sundin et al. (2003)	222	172	12
Scandinavian outpatient program	Sundin et al. (2003)	51	17	12
Vestfold (heartcare) outpatient program	Vestfold Heartcare Group (2003)	234	51	24

<sup>1</sup> Gould et al. (1995) does not describe the Ornish program, instead references Ornish et al. (1990), which is used here.

<sup>2</sup> Professional contact denotes physician, exercise, physiologist/physical therapist, dietician, nurse, yoga instructor, counselor.

<sup>3</sup> The 12-month interval always begins with Phase I but may also contain Phase II or III, depending on the duration of the phases.

**Table 4. Behavioral Outcomes in Controlled Studies of Multifactorial Interventions in Coronary Heart Disease**

Study	Intervention	N	During Follow Up (yrs.)	Endpoint (measure)	Baseline		Change (%)			Experimental Superior*	p value
					Experi-mental	Control	Experi-mental	Control	Diff.		
Gould et al. (1995)	Ornish Program	35	5	Adherence score (score) <sup>1</sup>	0.67	0.60	70.15	18.33	51.82	+	<0.001
Toobert et al. (2000)	Primetime program.	25	1	% calories from saturated fat (%)	7.80	9.50	-52.56	-8.42	-44.14	+	<0.000
			2	% calories from saturated fat (%)	7.80	9.50	-60.26	-8.42	-51.84	+	<0.000
			1	Physical activity (score) <sup>2</sup>	3.90	2.30	17.95	8.70	9.25	+	0.01
			2	Physical activity (score) <sup>2</sup>	3.90	2.30	-5.13	17.39	-22.52	-	0.01
			1	Stress management (score) <sup>3</sup>	1.50	1.40	140.00	85.71	54.29	+	0.04
Toobert et al. (1998)	Primetime program.	28	1	% calories from saturated fat (%)	8.80	9.50	-59.09	-8.42	-50.67	+	0.00
			1	Physical activity: # days exercised/ last 7 days (# days)	3.80	2.40	18.42	4.17	14.25	+	0.05
			1	Stress management (score) <sup>3</sup>	1.40	1.40	164.29	85.71	78.57	+	0.00

**Table 4. Behavioral Outcomes in Controlled Studies of Multifactorial Interventions in Coronary Heart Disease - Continued**

Study	Intervention	N	During Follow Up (yrs.)	Endpoint (measure)	Baseline		Change (%)			Experimental Superior*	p value
					Experi- mental	Control	Experi- mental	Control	Diff.		
Sundin et al. (2003)	Scandinavian program, residential arm	69	1	Diet habits (score) <sup>4</sup>	11.40	10.62	20.18	1.04	19.14	+	<.002
			1	Exercise frequency/wk (weekly frequency)	3.00	3.60	24.67	-16.67	41.33	+	ns
			1	Bortner score (score) <sup>5</sup>	4.83	5.45	-7.87	-8.99	1.12	-	<.001
Sundin et al. (2003)	Scandinavian program, outpatient arm	67	1	Diet habits (score) <sup>4</sup>	10.04	10.62	24.90	1.04	23.86	+	<.002
			1	Exercise frequency/wk (wkly freq)	3.24	3.60	6.79	-16.67	23.46	+	ns
			1	Bortner score (score) <sup>5</sup>	5.19	5.45	-9.25	-8.99	-0.26	+	<.001

**Table 4. Behavioral Outcomes in Controlled Studies of Multifactorial Interventions in Coronary Heart Disease - Continued**

Study	Intervention	N	During Follow Up (yrs.)	Endpoint (measure)	Baseline		Change (%)			Experimental Superior*	p value
					Experi- mental	Control	Experi- mental	Control	Diff.		
Hofman- Bang et al. (1999)	Scandinavian program, residential arm	87	1	Diet index (score) <sup>4</sup>	10.50	10.10	22.86	5.94	16.92	+	<.05
			2	Diet index (score) <sup>4</sup>	10.50	10.10	18.10	16.83	1.26	+	<.05
			1	Frequency of exercise sessions/wk (wkly freq)	2.50	3.10	80.00	12.90	67.10	+	<.05
			2	Frequency of exercise sessions/wk (wkly freq)	2.50	3.10	76.00	19.35	56.65	+	<.05
			1	Frequency of relaxation sessions/wk (wkly freq)	4.50	3.00	66.67	100.00	-33.33	-	ns
			2	Frequency of relaxation sessions/wk (wkly freq)	4.50	3.00	73.08	60.00	13.08	+	ns

**Table 4. Behavioral Outcomes in Controlled Studies of Multifactorial Interventions in Coronary Heart Disease - Continued**

Study	Intervention	N	During Follow Up (yrs.)	Endpoint (measure)	Baseline		Change (%)		Diff.	Experimental Superior*	p value
					Experimental	Control	Experimental	Control			
Lisspers et al. (1999)	Scandinavian program, residential arm	87	1	frequency of exercise/wk (wkly freq)	2.60	3.10	76.92	9.68	67.25	+	<.025
Vestfold Heartcare Group (2003)	Vestfold heartcare program	197	2	Saturated fat	34.00	35.00	-37.35	-10.29	-27.07	+	<0.001

\* '+' indicates that, for this measurement over time, the experimental group had greater improvement over the control group.

'-' indicates that, for this measurement over time, the control group had greater improvement over the experimental group.

a = Significance of change, experimental vs. control group.

b = Significance of between group differences was calculated across three follow-up periods combined.

c = Group x time effect.

<sup>1</sup> = Adherence score is a measure of adherence to exercise, diet, and stress management program; details are not clear from publication.

<sup>2</sup> = Summary of Self-Care Activities Questionnaire, composite self care score for physical activity; details are unclear from text.

<sup>3</sup> = Summary of Self-Care Activities Questionnaire, composite self care score for stress management activities; details are unclear from text.

<sup>4</sup> = Diet measured using a 1-week daily food intake diary.

<sup>5</sup> = Bortner Type A rating scale assessed Type A behavior, including hostility, anger, pressured drive, and dominance.

Notation: Diff denotes difference (experiment minus controls); wkly freq denotes weekly frequency

**Table 5. Physiological Outcomes in Controlled Studies of Multifactorial Interventions in Coronary Heart Disease: LDL**

Study	Intervention	Duration of Follow Up (years)	N	Baseline (mg/dL)		Change (%)			Experimental Superior**	p value
				Experi-mental	Control	Experi-mental	Control	Differ-ence		
Ornish et al. (1990)	Ornish Program*	1	40	151.6	167.1	-37.2	-5.8	-31.5	+	0.007
Gould et al. (1995)	Ornish Program*	5	35	143.1	168.2	-28.4	-12.6	-15.7	+	ns
Toobert et al. (2000)	Primetime program.	1	25	156.0	138.0	-12.2	-8.0	-4.2	+	ns
Toobert et al. (2001)	Primetime program.	2	25	156.0	138.0	-12.2	-5.1	-7.1	+	ns
Sundin et al. (2003)	Stockholm program, RM	1	69	125.7	126.8	-11.2	-6.6	-4.6	+	ns
Sundin et al. (2003)	Stockholm program, OM	1	67	127.2	126.8	-4.3	-5.2	0.9	-	ns
Hoffman-Bang (1999)	Stockholm program, RM	2	87	139.0	143.0	-5.6	-10.8	5.2	-	ns

\*Total/ High density lipoprotein (HDL) cholesterol ratio

\*\* '+' indicates that, for this measurement over time, the experimental group had greater improvement over the control group.

'-' indicates, for this measurement over time, the control group had greater improvement over the experimental group.

Notation: mg/dL denotes milligram per deciliter; LDL denotes low-density lipoprotein cholesterol; RM denotes residential multifactorial; OM denotes outpatient multifactorial; ns denotes not significant.

**Table 6. Body Mass Index (BMI)**

Author	Baseline		Change (%)			Experi- mental superior	p value
	Experi- mental	Control	Experi- mental	Con- trol	Differ- ence		
Gould et al. (1995)**	29.71	25.39	-8.78	2.64	-11.42	+	<.001
Sundin et al. (2003), RM	27.20	27.10	-1.10	2.21	-3.32	+	<.03
Sundin et al. (2003), OM	27.00	27.10	1.48	2.21	-0.73	+	<.03
Toobert et al. (2000)	32.00	32.00	-6.25	0.00	-6.25	+	<.05

\*BMI (kg/m-squared); data not reported for Vestfold (2003)

\*\*Gould et al. (1995) reported average subject weight (kg). BMI calculated using an average height for men (1.75 meters) and women (1.63 meters), weighted for sample characteristics.

Notation: RM denotes residential multifactorial intervention; OM denotes outpatient multifactorial intervention.

## Appendix A.

### Table A.1 Characteristics of Subjects of Controlled Clinical Trials of Multifactorial Interventions for Patients with Coronary Heart Disease

Appendix A: Characteristics of Subjects of Controlled Clinical Trials of Multifactorial Interventions for Patients with Coronary Heart Disease

Lead Author, Year	Subjects	N	Mean Age (sd) or (min,max)	% F	Diagnoses			
					% MI	% Stable Angina	% CABG	% PTCA
Gould et al., 1995;	CAD documented by arteriography, no recent MI or lipid-lowering drugs, left ventricular ejection fraction greater than 25%, reside in San Francisco.	35	59.0	9%	NR	NR	NR	NR
Toobert et al., 2000;	Post menopausal women with documented atherosclerosis, MI, PTCA, and/or CABG.	25	63.4	100%	7%	NR	3%	5%
Toobert et al., 1998;	Post menopausal women with documented atherosclerosis, MI, PTCA, and/or CABG.	28	63.1	100%	9% (%MI or CABG)	NR		1%
Sundin et al., 2003;	Males, <70, treated with PCTA, CABG, or had AMI, after tx: able to perform a bicycle ergometer test with min. capacity of 70W, no other somatic or psychiatric diseases, understand Swedish, no addiction problems.	69	57.6	0%	4%	NR	50%	46%
Sundin et al., 2003;	Males, <70, treated with PCTA, CABG, or had AMI, after tx: able to perform a bicycle ergometer test with min. capacity of 70W, no other somatic or psychiatric diseases, understand Swedish, no addiction problems.	67	57.0	0%	3%	NR	48%	49%
Hofman-Bang et al., 1999;	> 1 significant coronary stenosis suitable for PTCA and at least one additional clinically insignificant coronary atherosclerotic lesion evaluated by quantitative computerized angiography; < 65; employed; able to perform a bicycle ergometer test with a min. capacity of 70 W following PTCA; no other diseases of importance for completion of the program	87	53.0	0.1601	0.8851	NR	NR	NR
Lisspers et al., 1999	> 1 significant coronary stenosis suitable for PTCA and at least one additional clinically insignificant coronary atherosclerotic lesion that could be evaluated by quantitative computerized angiography; < age 65; employed; able to perform a bicycle ergometer test with a min. capacity of 70 W following the PTCA; no other diseases of importance for completion of the program	87	53.0	0.16	0.862	NR	NR	NR
Vestfold Heartcare Group, 2003;	Consecutive patients < 67 admitted for AMI, UAP or after CABG. Exercise induced ischaemia excluded (as indicated by an ergometer bicycle test), ST-depression or chest pain were subjected to coronary angiography and the only included provided they had been successfully revascularized with PCI or CABG.	197	54.4	18%	37%	2%	25%	20%

\*See table 4 for description of program. NR = not reported.

## Appendix B.

**Table B.1. Characteristics of Intervention of Controlled Clinical Trials of Multifactorial Interventions for Patients with Coronary Heart Disease**

**Appendix B: Characteristics of Intervention of Controlled Clinical Trials of Multifactorial Interventions for Patients with Coronary Heart Disease**

Lead Author, Year	Experimental Group(s)*	Control Group	Duration Rx (months)	Duration F/U (years)	Study Endpoints
Gould et al., 1995;	Ornish Program.	Usual care	12	5	Size and severity of myocardial perfusion abnormalities. Behavioral and physiological outcomes
Toobert et al., 2000;	Primetime program.	Usual care	24	2	Behavioral and physiological outcomes
Toobert et al., 1998;	Primetime program.	Usual care	24	1	Behavioral outcomes
Sundin et al., 2003;	Stockholm program, residential arm	"Standard rehabilitation control group"	12	1	Behavioral and physiological outcomes
Sundin et al., 2003	Stockholm program, outpatient arm	"Standard rehabilitation control group"	12	1	Behavioral and physiological outcomes
Hofman-Bang et al., 1999;	Stockholm program	usual care: 1 outpatient visit at clinic after PTCA; family physician for further 2ndary prevention efforts.	12	2	Behavioral and physiological outcomes
Lisspers et al., 1999	Stockholm program	usual care: 1 outpatient visit at clinic after PTCA; family physician for further secondary prevention efforts.	12	1	Behavioral outcomes
Vestfold Heartcare Group, 2003	Vestfold heartcare program	Usual care: nurse-based information on CHD and lifestyle measures; routine outpatient cardiologist.	24	2	Behavioral and physiological outcomes

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