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A COMPARISON OF TRADITIONAL AND MODIFIED CARDIAC REHABILITATION PROTOCOLS ON COMPLIANCE TO EXERCISE, PATIENT SELF-EFFICACY, CARDIOVASCULAR OUTCOMES, AND PROGRAM COST

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ABSTRACT

A COMPARISON OF TRADITIONAL AND MODIFIED CARDIAC REHABILITATION PROTOCOLS ON COMPLIANCE TO EXERCISE, PATIENT SELF-EFFICACY, CARDIOVASCULAR OUTCOMES, AND PROGRAM COST

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Several problems have been identified with the traditional protocol (TP) for cardiac rehabilitation (CR) including low participation rates, poor facilitation of exercise beyond 3 months, and most recently, a decrease in insurance reimbursement. Additionally, even though continuous electrocardiogram monitoring (CECGM) is not required during exercise in low and moderate risk patients, it is commonly used despite the cost and the possibility its use may negatively impact patient self-efficacy (SE) towards independent exercise. To address these concerns, a reduced cost modified protocol (MP) designed to promote SE toward independent off-site exercise was developed. The study objectives were to compare the effectiveness of the MP to a TP and to evaluate differences in program cost over 6 months. Outcomes included exercise behavior, program participation, SE toward exercise, and cardiovascular (CV) health measures. Eighty low to moderate risk CR patients were randomized to a TP ($\underline{n}$=42) or a MP ($\underline{n}$=38). The first month patients followed identical regimens and included 3 CECGM exercise sessions/wk with encouragement to achieve a total of $\geq$ five 30 minute sessions/wk. Patients were also scheduled to attend a 3 part CV risk factor nutrition series. In Wk 5, the independent protocols were initiated. The TP patients were encouraged to continue a facility based program including 3 supervised exercise sessions/wk for 6 months and utilized CECGM during the initial 3 months. The MP emphasized an off-site exercise regimen which was facilitated via group educational support meetings, and telephone follow-up. The MP patients discontinued CECGM in Wk

5 and were gradually weaned from facility based exercise. Statistical significance was set at $p \leq .05$. The MP elicited superior rates of off-site exercise over 6 months and total exercise (sum of supervised & off-site) during the final 3 months. Program participation was significantly higher in the MP. Both protocols were effective in improving CV measures (body mass index, peak $\dot{V}O_2$, submaximal rate pressure product, heart rate and blood lipids); however, no between group differences were found. The only significant protocol differences in SE measures were found in the MP who had higher SE levels while exercising without CECGM. The cost analysis revealed the average MP patient cost of $1,619 was $738 less than the TP cost of $2,349 and was primarily a result of less CECGM. In conclusion, the reduced cost MP was found to be as effective as the TP in improving CV health outcomes and promoted superior levels of patient participation and independent exercise over 6 months. The MP has potential positive implications for hospitals utilizing managed care and cost capitation.

DEDICATION

To my parents, who have provided me with the foundation to persevere, achieve goals, and appreciate life.

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CHAPTER ONE

Introduction

The devastating impact of cardiovascular disease (CVD) in the United States is well documented. In 1993 nearly one million people died of CVD. However, the number of persons surviving with CVD is escalating and has nearly doubled in the past five years. This is partially due to advances in medical treatment, including comprehensive risk-factor modification, cardiac medications, and surgical procedures. The 1993 estimate of patients living with CVD is 13.5 million (American Heart Association [AHA], 1996). This includes persons who have survived a heart attack, undergone a cardiovascular (CV) procedure, or have documented CVD. Cardiovascular disease often results in a decreased quality of life, absenteeism from work, and high medical costs due to surgery and ongoing medical care (Ades, Huang, & Weaver, 1992; AHA, 1996; Levin, Perk, & Hedback, 1991; Oldridge et al., 1993). Additionally, spouses and significant others commonly experience disruption in their lives, including economic and psychological stress (Erling & Oldridge, 1985; McGhee, Graham, Newton & Horgan, 1994). Potentially, all persons with CVD could benefit from cardiac rehabilitation (CR) services which include exercise training and, more recently, comprehensive CV risk-factor education.

The relationship between physical activity and the development and management of cardiovascular disease is well established (Hedback, Perk, & Wodlin, 1993; Lavie, Milani, & Littman, 1993; Leon et al., 1990; Vermeulen, Lie & Durrer, 1983; Whaley & Blair, 1995). Exercise is a standard recommendation in the treatment for CVD and is commonly the foundation of cardiac rehabilitation programs and secondary prevention efforts. Exercise can result in improved cardiovascular function, increased anginal threshold, stabilization or regression of coronary atherosclerosis, and decreases in morbidity and mortality (Hedback et al., 1993; Ornish et al., 1990; Schuler et al., 1992; Sullivan, 1993; U.S. Department of Health and Human Resources [USDHHR], 1995). The positive influence that exercise has on atherosclerosis, morbidity and mortality is, in part, due to the ability of exercise to favorably affect established CV risk factors including hypertension, dyslipidemia, diabetes, thrombolytic activity, obesity, stress, depression and possibly smoking behavior efforts (Abraham, Pava, Shuster, & Rosenbaum, 1996; Balady et al., 1994; Fava).

Historical Basis and Format of Cardiac Rehabilitation (CR)

Since the 1970s many formalized CR programs have been implemented. These programs have been designed to help patients with CVD recover from CV events or procedures and improve functional capacity. The following includes a brief summary of traditional CR protocols. Readers desiring a more detailed description of CR should refer to Appendix A and/or the American Association for Cardiovascular and Pulmonary Rehabilitation (AACVPR) Guidelines for Cardiac Rehabilitation Programs, (1995). Traditionally, CR has been divided into four phases.

Phase I refers to inpatient care and includes initial ambulation of the patients' post-cardiac event. Patients also are provided guidelines regarding physical activity and CV risk-factor management to implement at home. Phase II refers to the first portion of outpatient CR and generally includes 36 supervised exercise sessions completed over a 3- to 4-month period in which patients are monitored with continuous electrocardiographic monitoring (CECGM). Additionally, patients receive education regarding CV risk factors and the management of their condition.

After completing Phase II, if patients are stable (based on the absence of anginal symptoms, ischemic episodes, and/or frequent threatening arrhythmias), they are encouraged to enter the maintenance phase of CR (Phases III/IV). During Phases III and IV, patients receive less supervision and discontinue CECGM during exercise. Phase III typically lasts 3 to 6 months, while Phase IV represents a long-term maintenance program which sometimes is offered in a different facility than Phases I, II, and III.

By the late 1970s, most major insurance companies covered the costs of Phases I and II. This included the costs of a maximal graded exercise test (GXT) at baseline and near the completion of the 36 exercise sessions, as well as the costs associated with CECGM. Reimbursement for the maintenance Phases (III/IV), however, is rare. Typically there is a fee which patients are required to pay.

Need for the Study

Research evaluating patients who are compliant to the traditional protocol (TP) of CR has clearly demonstrated the effectiveness of such procedures in improving multiple variables associated with CV health. Benefits include physiological and psychological improvements, reductions in morbidity and mortality, and cost savings (Balady et al., 1994; Hedback et al., 1993; Lavie et al., 1993; Levin et al., 1991; USDHHR, 1995; Whaley & Blair, 1995). However, the exercise-related benefits can be realized only if patients are compliant to a supervised or independent exercise long-term regimen. Unfortunately, overall participation and compliance to traditional CR and independent exercise programs are poor among CVD patients (Daltroy, 1985; Engblom et al., 1992; Oldridge, 1988, 1991; Radtke, 1992).

Participation data, obtained on individuals in the United States who meet the criteria indicating a need for CR services, suggest that less than 25% of such persons ever begin a formalized rehabilitation program (Oldridge, 1991). Furthermore, compliance among those who do begin traditional CR is poor beyond 3 months. Drop-out rates for supervised CR programs are typically 25% to 50% by 6 months and as high as 90% by one year (Balady et al., 1994; Daltroy, 1985; Oldridge, 1991). There is little research describing the exercise behavior of patients after they discontinue using CR services; however, available data suggests that less than 25% of those patients who do continue exercise, participate at levels sufficient to maintain cardiorespiratory benefits (Daltroy, 1985; Radtke, 1992).

A major concern facing CR programs, which could further reduce participation and compliance rates, is the decline in the number of insurance companies reimbursing for CR services. Of those which do reimburse, many no longer pay for 36 CECGM sessions as in the past, particularly if the patient is stable and is classified as low or moderate risk as defined in the Position Report on CR by the American College of Cardiology (ACC) (1986) and/or described by the AACVPR, Guidelines for Cardiac Rehabilitation Programs (1995). Also, some hospitals and insurance companies are working together to develop capitation plans and "bundling" of services to reduce costs (Froelicher, Herbert, Myers, & Ribisl, 1996; Lavie & Milani, 1995).

Due to the poor participation and compliance rates to the TP of CR, the reductions in insurance reimbursements, and the changing health care environment, there is a need for the development of cost-effective interventions. The AACVPR encourages CR outcome research that evaluates the effectiveness of interventions, including innovative methods which differ from the TP of CR. These interventions need to include ways which can increase participation by patients with coronary artery disease (CAD) population, improve long-term exercise compliance, and produce outcomes that are equal or superior to those of the traditional method of cardiac rehabilitation. Additionally, gaining knowledge on determinants of behavioral adoption and compliance to exercise in the cardiac population may help to determine how to modify programs to improve outcomes.

The number and type of sessions CR patients should attend has been an area of debate among authorities of cardiac rehabilitation for several years. At the forefront of this debate is the amount of costly CECGM and supervision that is required (AACVPR, 1995; ACC Position Report on CR, 1986; Byl, Reed, Franklin, & Gordon, 1988; Keteyian, Mellett, Fedel, McGowan, & Stein, 1995). According to AACVPR Clinical Practice Guidelines (1995), low- and moderate-risk patients are at minimal danger during exercise, and the expensive, staff-intensive CECGM sessions are only necessary for the high-risk cardiac patient (Byl et al., 1988; Greenland & Pomilla, 1989; Keteyian et al., 1995). Although low- and moderate-risk cardiac patients are not required to have CECGM, it is still a common practice. In part, this practice is driven by the revenue from insurance billing. Each of the Phase II sessions with CECGM costs from $50.00 to $120.00 per session, totaling from $1,800.00 to $4,300.00 for 36 sessions billed to the insurance company.

Third-party reimbursement for cardiac rehabilitation has clearly influenced the traditional format of CR since its inception in the 1970s. The reimbursement system may also be responsible for the resistance to change in some programs, given that the charges for CECGM are still the primary source of revenue for many programs. A program model for CR based on risk stratification was proposed by Oldridge in 1991; however, programs using a risk stratification system vary with their protocol. Additionally, several effective interventions have been evaluated which differ from the TP of CR and do not rely on on-site billing of CECGM for reimbursement (Debusk et al., 1994; Haskell et al., 1994). Cost-effective programs will likely fit better with capitative payment, particularly if they produce positive outcomes and demonstrate long-term efficacy.

For selected high-risk patients, it appears that the cost of 36 sessions with CECGM may be prudent and justifiable, given the greater risk these patients have of developing new or reoccurring CV complications. However, for low- and moderate-risk patients, the expensive CECGM sessions are difficult to justify. Continuous electrocardiographic monitoring does not appear to improve significantly patient safety (Keteyian et al., 1995), and, as previously described, the overall participation and long-term compliance rates to facility-based CR are poor. Additionally, due to the facility-centric nature of the traditional format of CR, it may not be helpful to patient confidence toward adopting and maintaining an independent exercise regimen after discontinuing formalized CR.

Both outcome expectancy and self-efficacy are predictors of behavioral compliance (Bandura, 1977, 1982). Outcome expectancy refers to one's judgment that certain behaviors will lead to desired outcomes. For instance, one might have different expectations as to the benefit of exercise one's health. Self-efficacy is defined as the belief or confidence that a person can effectively perform a desired behavior, such as the confidence to perform exercise behaviors. According to Bandura (1982, 1986), if people lack self-efficacy, they will probably behave ineffectually, even if they know what to do and how to do it. Performance accomplishments, vicarious experiences, verbal persuasion, and physiological state are all factors that influence one's self-efficacy. As described by Lemanski (1990) in reference to CR, self-efficacy beliefs are likely derived from a combination of factors: (a) improvements in exercise capacity, (b) observations of others following exercise recommendations, (c) internal physiological cues, and (d) encouragement from rehabilitation specialists and other patients.

Research on the relationship of self-efficacy to exercise strongly supports the position that self-efficacy operates as an important mechanism in exercise behavior (Allen, 1990; Gortner & Jenkins, 1990; Stewart, Mason & Kelemen, 1988). In fact, self-efficacy may be a superior determinant of exercise compliance compared to physical capability. Two related studies involving CR patients (Ewart, 1989; Ewart, Stewart, Gillian, & Kelemen, 1986) revealed patient's self-efficacy judgments predicted adherence to exercise prescriptions better than functional capacity.

The poor long-term compliance and adherence outcomes produced by traditional CR protocols may be reflective of patients not receiving the comprehensive education and support necessary to improve their expectancy outcome and self-efficacy toward exercise. For example, it is possible that patients who consistently exercise in a supervised setting with CECGM may not develop the efficacy expectations, thoughts, and behaviors needed to sustain an off-site exercise regimen. This is particularly a concern for patients in a program which does not emphasize developing a self-directed off-site exercise regimen. Patients following the traditional method of CR may become dependent on the CECGM and staff supervision while exercising and, therefore, be fearful and lack confidence when exercising without it.

Another potential weakness of the TP which may affect compliance is the conflicts many patients have with the program format. Given that numerous studies indicate high drop-out rates among patients who begin CR, administrators of such programs should consider why patients drop out, and why most ($\geq$ 75%) cardiovascular patients never begin a formalized rehabilitation program (Oldridge, 1991).

Consideration of patients' reasons for poor program compliance is important for the overall participation and success of cardiac rehabilitation interventions. For example, when prospective CR patients learn that program consists of attending three exercise sessions a week for 3 months (36 sessions), they may be overwhelmed, particularly if they are planning to return to work and/or live a great distance from the facility. There are several reasons for potential low participation and overall compliance that merit consideration. Attendance at the rehabilitation program may consistently conflict with other essential priorities the patient has, thus causing the following questions to arise: Is the facility inconveniently located, or is transportation a problem? Does the program meet the patient's expectations? Can the patient afford the program? Is the patient aware of exercise options more compatible to his/her lifestyle (Oldridge & Streiner, 1989)?

No program is going to meet the needs of all patients, yet it is essential to consider the importance of the patient perspective. Low- and moderate-risk CR patients should be offered a program that facilitates independence and long-term adherence to a self-directed exercise regimen and other CV risk-reducing behaviors so that prolonged benefits can be realized. In an effort to provide a form of CR that will be appealing to potential patients and insurance companies and will provide quality patient care, a modified method of CR has been proposed.

Purpose of Study

This research study was designed to evaluate the patient outcomes of a modified protocol (MP) of CR, compared to patients offered a TP of CR, over a 6-month period. It is important to note that this investigation was conducted as an effectiveness trial, not as an efficacy trial. Efficacy trials study treatments under ideal conditions so that participants are included only if they follow the treatments as specifically defined in the intervention protocol. However, effectiveness trials offer a treatment or program to patients and allow the patients to accept or reject the program as they might ordinarily do. This study fits the criteria of an effectiveness trial, given that, regardless of protocol adherence rates, as many participants as possible were included in both comparison groups during follow-up evaluations. No extra staff were hired for the implementation of either intervention. Dependent variables measured included (a) patient adherence, (b) outcome expectancy and self-efficacy to exercise, (c) physiological measures associated with cardiovascular health, and (d) program cost. The MP was developed based on principles believed to promote adherence to long-term exercise and CV risk-reducing behaviors. The MP is based on the theory of self-efficacy (Bandura, 1977, 1986) and, in addition, includes strategies used to enhance behavioral compliance to exercise such as regular follow-up evaluations of exercise goals, group meetings, and the encouragement of spousal/significant-other support (Debusk et al., 1994; Robison et al., 1992; Stofflemeyer et al., 1993).

Hypotheses

The following general hypothesis was subdivided into five categories for examination: Compared to the traditional protocol for cardiac rehabilitation, a modified protocol designed to promote self-efficacy to self-directed exercise will produce superior results during a 6-month study period in the following variables: (a) overall exercise and off-site personal exercise program (PEP) adherence, (b) self-efficacy levels toward overall exercise and an off-site PEP, (c) outcome expectancy toward exercise, (d) selected physiological and risk factor associated with cardiovascular health, and (e) program cost.

Exercise Adherence and Program Participation

Hypotheses 1(a) and 1(b). As compared to TP patients, MP patients will exhibit superior adherence over 6-month rates to: (a) an off-site PEP and (b) overall exercise (the combination of on-site exercise and off-site PEP).

Hypothesis 2. A greater number of patients in the TP group than in the MP group will discontinue facility-based exercise within the first 6 weeks and fail to return for their 6-month follow-up evaluation.

Self-efficacy Levels toward Exercise

Hypothesis 3. Among all patients, self-efficacy toward an off-site PEP will exhibit positive correlations with overall and off-site exercise compliance.

Hypotheses 4 (a) and 4 (b). Compared to that engendered in the TP patients, patient confidence while exercising without continuous ECG monitoring will improve more in the MP patients: (a) from baseline (zero weeks) to 6 weeks and (b) from baseline to 3 months.

Hypothesis 5. Compared to the TP participants, the MP participants will exhibit greater levels of self-efficacy related to an off-site PEP at the 3-month and 6-month evaluations.

Outcome Expectancy toward Exercise

Hypothesis 6. Among all patients, outcome expectancy toward exercise will exhibit positive correlations with overall and off-site exercise PEP compliance and with physiological outcomes.

Hypothesis 7. Compared to the TP participants, the MP participants will exhibit higher levels of outcome expectancy toward exercise at the 3-month and 6-month evaluations.

Cardiovascular Outcomes Associated with Cardiovascular Health

Hypothesis 8. Improvements in measures associated with cardiovascular health from baseline to 3 months will not be significantly different between the MP and TP comparison groups.

Hypothesis 9. Improvements in measures associated with cardiovascular health from baseline to 6 months will be greater in the MP than in the TP.

Program Cost

Hypothesis 10. Due to the MP design, which includes offering fewer CECGM sessions and total on-site exercise sessions compared to the TP, it is expected that the average billing cost per patient in the MP will be significantly less than the average cost per patient in the TP. The cost determination will be based on the average compliance rates of the participants in each treatment group.

Definitions and Abbreviations of Key Terms

Adherence and compliance. In the scientific literature on exercise, the terms "adherence" and "compliance" are often used interchangeably, although there are some exceptions. Compliance is commonly referred to as the degree of adherence to a protocol or treatment, while adherence refers to independently sustaining behavioral changes. For the purposes of this study, the terms will be used interchangeably and will represent the percentage of completion of recommended supervised and non-supervised exercise sessions. For example, a person who attends and completes 5 of 10 hospital-based exercise sessions would have an adherence or compliance rate of 50% to these sessions. The same principle will be used for calculating adherence to off-site, self-directed exercise sessions.

Anaerobic threshold (AT). The point during physical activity when anaerobic metabolism begins to significantly supplement aerobic metabolism to meet energy demands.

CAD. The abbreviation for coronary artery disease.

Continuous electrocardiographic monitoring (CECGM). The type of electrocardiogram monitoring used in most Phase II cardiac rehabilitation programs. A single lead monitor is affixed to patients during on-site exercise sessions. Typically, cardiac rehabilitation programs obtain an ECG rhythm strip at rest, during each mode of exercise, and following the patient's post-exercise cool-down.

CREASES. The acronym for Cardiac Rehabilitation Exercise Adherence Self-Efficacy Study.

CR. The abbreviation for cardiac rehabilitation.

CVD. The abbreviation for cardiovascular disease.

Dropout. Term based on two criteria: (1) patients who discontinued facility-based exercise within the first 6 weeks of starting CR, and (2) patients who did not return for follow-up testing without a documented physiological problem which limited their ability to exercise.

Graded Exercise Test (GXT). A procedure used to evaluate exercise capacity and also for diagnostic and prognostic purposes relative to coronary artery disease.

Maximal Oxygen Uptake ($\dot{V}O_{2max}$). The highest rate of oxygen consumption attained during exercise at sea level (usually expressed in liters per minute or milliliters per kilogram of body weight per minute). VO_{2max} represents the maximum rate of aerobic metabolism. Typically, one or more of the following criteria are used to determine if VO_{2max} has been achieved: (a) respiratory exchange ratio (RER) is $\geq$ to 1.05; (b) 85% of predicted maximal heart rate is achieved; (c) heart rate plateaus occurs in spite of increasing workloads; (d) oxygen consumption plateaus with increasing workloads; and (e) rating of perceived exertion (RPE) is 17 or greater, signifying "very hard" work.

Peak Oxygen Uptake ($\dot{V}O_{2peak}$). The greatest oxygen consumption achieved during a GXT when the patient reaches volitional fatigue and stops exercising. The criteria mentioned for VO_{2max} may or may not be met.

Personal Exercise Program (PEP). A self-directed exercise program based on the exercise prescription and follow-up provided by the patient's cardiac rehabilitation center. Options include one or a combination of the following: home-based program, corporate-based program, mall walking, or exercising at a health club.

Phases I, II, III, and IV Cardiac Rehabilitation. The four phases of cardiac rehabilitation. Phase I is the inpatient phase of rehabilitation. Phases II, III, and IV are all outpatient CR. During Phase II, patients typically exercise with CECGM and supervision by staff throughout the exercise period. Phases III and IV are considered maintenance phases. Patients do not wear CECGM and receive less staff supervision during the exercise sessions.

Polar™ Heart Rate Monitors. A heart rate monitor that operates using a transmitting sensor worn on the user's chest and a receiving recorder worn on the wrist. In this study, Polar™ monitors were provided to the MP participants for a 3-week period to help establish their off-site exercise training intensity.

Metabolic Equivalent Unit (MET). A unit of measurement used to estimate the metabolic cost of physical activity relative to resting metabolic rate. One MET = 3.5 milliliter of oxygen consumed per kilogram of body weight per minute; one MET = resting metabolic rate.

Rating of Perceived Exertion (RPE). Numerical ratings assigned to the perceived effort associated with performance of an exercise task; usually, either a 0-10 or a 6-20 rating scale is used. In this study a 6-20 scale was used, with 6 representing no effort (i.e., seated at rest) and 20 relating to a state of physical exhaustion (Borg, 1982).

Rate Pressure Product (RPP). The product of systolic blood pressure and heart rate. RPP provides an index of myocardial oxygen demand.

Respiratory Exchange Ratio (RER). The ratio of carbon dioxide produced to oxygen consumed during any given activity. RER is computed as Vco_2/Vo_2.

Self-efficacy (SE). The perception of one's ability or confidence to perform a behavior at a certain level.

Submaximal Rate Pressure Product (SRPP). The product of systolic blood pressure and heart rate at a submaximal workload. SRPP provides an index of oxygen demand.

Expectancy Outcome (EO). Pertains to one's judgment that certain behaviors will lead to desired outcomes.

TP (Traditional Protocol). The protocol used in this study which represents the standard or traditional CR program. The control group followed the TP.

MP (Modified Protocol). The experimental protocol used in this study which is a lower cost protocol compared to the TP designed to promote self-efficacy to independent exercise.

V-slope Method. A method used to detect anaerobic threshold (AT). The VCO_2 (vertical axis) is plotted breath by breath against the VO_2 (horizontal axis). The AT or ventilatory threshold is the point at which VCO_2 increases out of proportion to aerobic metabolism.

CHAPTER TWO

Review of the Literature

This chapter presents a review of the literature pertaining to outpatient cardiac rehabilitation with an emphasis on the independent interventions used in this study, as well as the dependent measures which include CV outcomes and self-efficacy toward exercise. The review is presented in three parts. First, the documented benefits of CR programs will be summarized. Secondly, a description of the concept of self-efficacy and outcome expectancy will be described which is supplemented with a review of several self-efficacy exercise studies. Lastly, a summary of CR interventions which rely on or emphasize off-site exercise regimens is presented.

Benefits of Cardiac Rehabilitation

The relationship between physical activity and the development and management of cardiovascular disease is well established (Leon et al., 1990; Whaley & Blair, 1995). Exercise is a standard recommendation in the treatment for CVD and is the foundation of CR programs and many CVD secondary prevention efforts (AACVPR, 1995). Exercise can result in improved CV function increased anginal threshold, and appears to play a role in halting and reversing atherosclerosis (Ornish et al., 1990; Schuler et al., 1992; Watts et al., 1992). Additionally, reductions in mortality have been documented (Hedback et al., 1993; Vermeulen et al., 1983; Whaley and Blair, 1995). The positive impact of exercise on overall health and atherosclerosis is in part due to its ability to effect psychological and physiological parameters which effect CV risk. These include: hypertension, dyslipidemia, diabetes, thrombolytic activity, obesity, stress, depression, and may be helpful in smoking cessation efforts (Balady et al., 1994; Fava et al., 1996).

Measures Associated with Cardiovascular Health

The following includes a summary of the dependent measures associated with CV health evaluated and discussed in this study. Each variable will be individually summarized with reference to how exercise affects the variable in relation to CV health.

Blood Pressure. With training, both systolic and diastolic blood pressure tend to decrease at rest and at given submaximal work rates in individuals who are hypertensive (systolic pressure $\geq$ 140 mm Hg, diastolic pressure $\geq$ 90 mm Hg). Changes are less likely to occur in patients who are normotensive (systolic pressure $\geq$ 120 mm Hg, diastolic pressure $\geq$ 80 mm Hg). In some instances the peak systolic blood pressure achieved may be increased while peak diastolic blood pressure may be reduced. Additionally, the rate at which blood pressure returns to pre-exercise levels during recovery increases and may even be reduced to lower than pre-exercise levels (ACSM, Resource Manual for Guidelines for Exercise Testing and Prescription, 1993). A meta-analysis of 25 longitudinal studies evaluating the effect of exercise training on blood pressure by Hagberg and Seals (1986) revealed that the average sample size weighted reductions in systolic and diastolic blood pressure were 10.8 mm and Hg 8.2 mm Hg, respectively.

Rate Pressure Product and Submaximal Rate Pressure Product. Rate pressure product (RPP) is the product of heart rate times systolic blood pressure. Measurement of RPP can be done at rest or during exercise. Submaximal RPP (SRPP) refers to an RPP measured at a level of work below maximal levels. RPP is used as an index of relative cardiac work and correlates to directly measured myocardial oxygen uptake and coronary blood flow over a wide range of exercise intensities (Clausen, 1977; Redwood, Rosing, & Epstein, 1972; Sim & Neill, 1974). After training, RPP tends to be reduced at rest and at submaximal work intensities as a result of a decrease in heart rate and/or blood pressure submaximal endurance is enhanced. This equates to the patient accruing the ability to exercise longer at the specified submaximal workload with less fatigue compared to baseline levels. Among patients with angina, it has been demonstrated that training led to the ability to achieve a higher RPP and, thus, more work, prior to the development of angina (Clausen, 1977; Sim & Neill, 1974). Additionally, several studies have shown that similar changes are also accompanied with a decrease in ECG changes that are suggestive of myocardial ischemia (Ehsani, Biello, Schultz, Sobel, & Holloszy, 1986).

Functional Capacity. Exercise training can improve measured maximal and peak functional capacity through a variety of mechanisms including (a) hemodynamic and cardiac changes, (b) alterations in neurohumoral responses, and (c) peripheral changes in oxygen delivery and skeletal muscle. Reported improvements in cardiac patients typically range from 11% to 66% after 3 to 6 months of exercise training, with the greatest improvements among the most unfit (Thompson, 1988). Recently, Milani, Labie, & Spiva (1995) have demonstrated that many of these reported changes in functional capacity are likely a gross overestimation of true functional capacity. They reported that in CR patients, compared to directly measured METs, estimated METs overestimated the actual measured value by up to 38% at baseline tests, and up to 90% after 3 months. These overestimations of MET capacity could potentially have negative safety and psychological implications if patients are given exercise prescriptions based on these overestimations. For instance, patients with exercise-induced angina may increase their susceptibility of dangerous cardiac rhythm disturbances and ischemia, which potentially could lead to atrophy of viable myocardial tissue. Psychologically, patients could feel like failures and lose confidence to perform physical activities if they cannot comfortably perform the list of activities the rehabilitation professionals said they should be able to perform based on estimated METs.

Anaerobic Threshold (AT). Refers to the point when anaerobic metabolism begins to significantly supplement aerobic pathways to provide energy to sustain work. It also sometimes refers to ventilatory threshold given that the ventilatory rate tends to significantly increase at the onset of AT. The increase in ventilation is in part due to the respiratory buffering response to expel carbon dioxide due to increases in lactate production from anaerobic metabolism. Through training, the achievement of AT can be delayed, yielding an enhanced submaximal endurance capacity and improved ability to exercise longer, at a given work rate. From a practical perspective, increases in AT for many cardiac patients may equate to an improved ability to complete activities of daily living with less fatigue such as housework, shopping, walking stairs and conducting job related activities (McConnell, Clark, Conlin, & Hass, 1993; McConnell, Laubach & Clark, 1995).

Body composition: Weight, height and Body Mass Index (BMI). Exercise and physical activity play an important role in weight management efforts, including decreasing abdominal obesity which is positively correlated with dyslipidemia (Goldberg & Elliot, 1985), hypertension (Hagberg & Seals, 1986), glucose intolerance in diabetics (Defronzo & Ferranni, 1991), all of which increase the risk for CVD. Body mass index is an index of person's weight relative to his or her height and is calculated using the formula—weight in kilograms divided by height in meters squared. BMI can be used to classify obesity and is classified in three grades as described by Jaequier (1987): Grade 1 obesity (BMI of 25-29.9); Grade 2 obesity (BMI of 30-40); and Grade 3 obesity (morbid obesity) (BMI > 40). Obesity-related health risks including CVD begin in the range of 25-30 kg/m^2.

The number of CR interventions which have reported on weight change and body composition is limited. In the Cardiac Rehabilitation Clinical Practice Guidelines (USDHHR, 1995), 334 scientific papers involving CR and secondary prevention interventions were reviewed. Only 11 of the 334 were random trials addressing changes in body weight following CR which included exercise training. Eight of the studies showed favorable outcomes; however, only three showed significant differences in the experimental groups compared to the control groups for greater than one year (Kallio, Hamalainen, Hakkila, & Luurila, 1979; Ornish et al., 1990; Wilhelmsen et al., 1975). A possible reason so few of these studies exhibited significant weight reductions in patients is that all patients were included in the analyses regardless of their weight. It is likely that some patients used in the analyses were at ideal body weight or were underweight; therefore losing weight would not be a positive outcome. In fact, it is likely that selected underweight patients gained weight during the evaluation period. Thus, the preceding decreases the chances of achieving a mean decrease in body weight. It is more appropriate to evaluate weight loss as a benefit only in those patients who exhibited BMIs of 25 or greater. In contrast, among those patients with a BMI below 25, it is more appropriate to evaluate their success based on weight gain or weight stabilization.

Blood lipids. It is well established that exercise training can improve the plasma lipoprotein profile and lower risk for initial and repeat CV complications. Reductions in blood lipids have been associated with decreases in morbidity and mortality in a number of randomized prospective clinical trials (Superko & Krauss, 1994). In exercise-based CR programs, when weight reduction is controlled for, total cholesterol and low density lipoprotein (LDL) either decrease modestly or do not change significantly, while high density lipoprotein (HDL) has been reported to increase 5%-16% (Bittner & Oberman, 1993; Goldberg & Elliot, 1985). The expected effect of exercise on triglycerides is a decrease; however, the degree of change reported in the literature is variable which is in part dependent on dietary composition (Superko & Krauss, 1994). If weight loss occurs as a result of exercise and diet, improvements in all lipid parameters is typically enhanced (Goldberg & Elliot, 1985).

Comprehensive interventions which include multifactorial CV risk reduction interventions (exercise, diet, behavioral counseling, stress management) can produce significantly greater improvements in blood lipids than exercise-based interventions alone. The data from three comprehensive interventions which included exercise, nutrition, and behavioral management and did not utilize lipid lowering agents were pooled together (Superko & Krauss, 1994). The analysis revealed a 10%-24% reduction in total cholesterol and a 9% to 37% average reduction in LDL. Triglycerides exhibited increases up to 22% (Ornish et al., 1990), and decreases up to 24% (Schuler et al., 1992). The changes in HDL ranged from a 3% decrease to a 2% increase. Of these three trials, the Lifestyle Heart Trial (Ornish et al., 1990) produced the greatest reductions in the total and LDL cholesterol, at the same time, however, producing negative outcomes in triglycerides and the HDL profile. The undesirable changes found in HDL and triglycerides are likely due to the high levels of carbohydrate (~70%) and low levels of total fat (~10%) utilized in the Ornish diet. The Heidelberg trial (Schuler et al., 1992) and the Saint Thomas Angiographic Regression Trial (Watts et al., 1992) produced positive outcomes in all lipid parameters. An exciting finding with these three trials is the study in which participants exhibited significantly more cases of stabilization and regression of atherosclerotic plaques when compared to both the experimental groups using lipid lowering therapy and the control groups (Superko & Krauss).

Interventions which also include lipid lowering medications on the average can produce greater improvements in lipid parameters which are also associated with outcomes related to atherosclerotic regression (Superko & Krauss, 1994) and improvements in coronary artery blood flow (Quinn, Alderman, McMillan, & Haskell, 1994). However, as previously noted, even though the total improvements in the lipid profile is typically superior in the pharmacological interventions compared to the non-pharmacological lifestyle trials, their rates of regression and stabilization of atherosclerotic plaques is inferior (Superko & Krauss, 1994). These findings suggests that the patients utilizing lipid lowering therapy may not have been as compliant to exercise and nutrition interventions which comprehensively affect CV risk factors and positively effect coronary artery disease independent of improvements in the lipid profile.

Type A behavior and negative stress. It is well established that hostility and despair are two components associated with negative stress and type-A behavior which increase the predisposition toward CAD. A recent study (Everson, Kaplan, Goldberg, Salonen, & Salonen, 1997) evaluating the effect of despair on atherosclerosis reported people who expressed high levels of despair had a 20% greater increase in atherosclerosis over 4 years than those who had low levels of despair. Hopelessness and depression are often feelings which accompany feelings of despair. Two different prospective studies which evaluated adults with a depressed affect revealed that depression was associated with an increased relative risk of 1.5 for fatal ischemic heart disease (Anda et al., 1993) and a 2.2 relative risk increase for fatal and nonfatal coronary heart disease (Ford, Mead, Chang, Levine, & Klag, 1994). Among individuals who have already experienced a heart attack, depression appears to be one of the most powerful risk factors for predicting a repeat CV event within 18 months post event (Frasure-Smith, Lesperance, & Talajic, 1995).

There is some evidence that exercise training can help reduce anxiety levels and enhance the overall mood state (Blumenthal & Wei, 1993; Dishman, 1985); however, little has been reported on the role of exercise in decreasing levels of hostility and despair.

Cardiovascular morbidity and mortality. It has not been determined if CR reduces the rates of repeat myocardial infarctions; however, reductions in morbidity and mortality have been established (Hedback et al., 1993; Vermeulen et al., 1983). According to the Executive Summary Report contained in the Clinical Practice Guidelines for Cardiac Rehabilitation (USDHHR, 1995), exercise-based cardiac rehabilitation interventions typically result in a 15% reduction in mortality, while multifactorial CR and secondary prevention interventions have been shown to decrease mortality rates by 26%. The specific mechanism(s) for decreases in CV mortality are difficult to quantify due to the multiple risk factors and unknown factors influencing the disease process. Exercise can positively affect CV health and the prognosis of the cardiac patient by improving functional capacity, blood pressure, dyslipidemia, obesity, diabetes, blood clotting factors, stress and depression. Specifically in relation to blood lipids, the changes necessary to achieve decreases in CV morbidity and mortality have been established based on over 20 years of clinical trials. It appears that a 10% lowering of total and LDL cholesterol with variable increases in HDL will produce reductions in CV morbidity and mortality (Superko & Krauss, 1994). It is possible that the decreases in mortality may be a result of increased medical surveillance of participants in CR. It is not uncommon for CR professionals to identify patients who exhibit a new onset negative change during rehabilitation sessions. The CR professional then notifies the patient's primary physician of the problem which often leads to further evaluation and/or a change in the patient's pharmacological regimen. For example, during CR exercise sessions, a patient may exhibit a significant negative response in blood pressure, a dangerous arrhythmia, or a non-symptomatic ischemia which would otherwise not be identified. Additionally, it is possible that cardiac patients in CR programs have higher treatment and compliance rates to cardiac medications (beta blockers, calcium channel blockers, ace inhibitors, aspirin, lipid lowering agents), all of which have demonstrated efficacy relative to decreasing CV morbidity and mortality.

Economic Benefits of Cardiac Rehabilitation

A recent comprehensive review on the cost effectiveness of CR was published by Ades, Pashkow, and Nestor (1997). They calculated the dollars per year of life saved ($/YLS) by combining the results of over 20 randomized trials of CR on mortality, morbidity, and studies of patient charges for rehabilitation and medical expenses for hospitalizations after rehabilitation. Their results revealed the $/YLS was $4,950 projected for 1995 for patients utilizing CR services compared to those who did not. It was concluded that compared with other post-myocardial infarction treatment interventions, CR is more cost-effective than CABG, thrombolytic therapy, and cholesterol-lowering drugs, but not as cost effective as smoking cessation programs.

Self-Efficacy, Outcome Expectancy, Exercise and Cardiac Rehabilitation

Self-efficacy is defined as the belief or confidence that a person can effectively perform a desired behavior. The self-efficacy theory is derived from social learning theory and hypothesizes a relationship between perceived self-efficacy and behavioral changes (Bandura, 1977). According to Bandura (1982, 1986), if people lack self-efficacy, they will probably behave ineffectually, even if they know what to do and how to do it. Furthermore, an individual's self-efficacy will determine the level of effort and perseverance that will be expended despite possible barriers. Bandura (1977) distinguishes between two types of expectations: (a) efficacy expectancy or self-efficacy (SE) as defined above, and outcome expectancy (OE) which is defined as a person's belief that a certain behavior will produce a particular outcome. Making the distinction between these terms is important because it is possible for a person to believe that a certain behavior will lead to a particular result (OE), but if he or she does not have the confidence to perform the behavior, the outcome expectancy information likely will not affect his or her actions.

Research on exercise and other health behaviors strongly supports the position that self-efficacy operates as an important mechanism in behavior (Allen, 1990; Ewart, 1989; Ewart et al., 1986, 1983; Gortner & Jenkins, 1990; O'Leary, 1985). In fact, research applying Bandura's theory to exercise indicates that self-efficacy is a more important determinant of exercise compliance than physical capability as exemplified in two related studies by Ewart (1989) and Ewart et al. (1986). Ewart and colleagues found that self-efficacy judgments in CR patients predicted adherence to exercise prescriptions better than functional capacity evaluations.

When comparing the role of OE and SE, Bandura's (1977) theory of self-efficacy suggests that SE is a more central determinant of adherence than OE. Studies which have compared SE and OE in predicting exercise and other health behavior have supported Bandura's theory indicating that SE is a better predictor of exercise and other health behaviors than OE (Desharnais et al., 1986). However, behavior change is most likely to occur when expectations of SE and outcomes are altered simultaneously (Lee, 1984).

Factors which influence self-efficacy include (a) enactive experience/performance accomplishments, (b) vicarious experiences, (c) verbal persuasion, and (d) physiological states. *Enactive experience* refers to behaviors that have been accomplished in the past. For example, a cardiac patient, who was previously successful with a walking program conducted on a treadmill, would likely be more confident conducting his or her first session in a CR program that utilizes a treadmill, compared to a patient who had never walked on a treadmill. *Vicarious experiences* refers to observing another person perform the desired behavior successfully. An example which is sometimes used in CR programs to make incoming patients more comfortable includes having them observe experienced CR participants perform their exercise during their orientation to the program. This is often followed up with a success story told by the CR professional or a previously successful patient. The verbalization of the success story provides an example of another source of efficacy information called *verbal persuasion.* Verbal persuasion refers to verbally making the patient or participant believe he or she can perform the suggested behavior successfully. It is important that the practitioner or facilitator does not verbalize a behavior that is unrealistic or unattainable. Lastly, *physiological states* is the SE information source which refers to how the participant may be responding to performing the behavior. For instance, a new patient who becomes very nervous and excited at the first exercise session may have more problems performing the suggested behaviors than a patient who is relaxed.

Figure 1 illustrates a self-efficacy compliance model as it relates to a CR program using exercise and nutrition interventions. The figure is adapted from a CR self-efficacy model by Allen (1988). It exhibits the interrelationship between the responsibility of the rehabilitation educator and the efficacy perceptions of the patient which can support the self-efficacy level needed for the patient, and the rehabilitation program to achieve their goals. It suggests the rehabilitation educator should utilize efficacy information to help patients develop their self-efficacy through the four sources of efficacy information: (a) enactive experiences, (b) verbal persuasion, (c) vicarious experiences, (d) internal feedback, and (e) physiological states. Following Figure 1, is a summary of several studies in CR which evaluated the role of self-efficacy in exercise behavior is included.

Ewart et al. (1983) examined the effect of self-efficacy on compliance with exercise regimens in men with clinically uncomplicated myocardial infarctions. They demonstrated that self-efficacy expectation scores following treadmill exercise testing predicted both the duration and the intensity of subsequent off-site exercise and treadmill exercise tests. Jenkins (1987) also studied patients recovering from myocardial infarction and showed that higher self-efficacy expectation levels toward walking predicted increased behaviors in these areas during the first month post-myocardial infarction.

Allen et al. (1990) evaluated patients following coronary artery bypass (CABG) surgery and found that self-efficacy expectations predicted activities of daily living and physical, social, and leisure functional status in the periods 1 month and 6 months after surgery. Gortner and Jenkins (1990) worked with post-CABG patients also. Jenkins conducted an experimental intervention evaluating self-efficacy and activity level following CABG. He evaluated if inpatient education and telephone monitoring during convalescence enhanced perceptions of cardiac efficacy and reported efficacy. Significant differences were found for experimental patients in self-efficacy expectations for walking between 4 and 8 weeks and between 8 and 24 weeks following CABG. Experimental patients also reported higher levels of general activity at 4 and 8 weeks and higher levels of walking at 8 weeks. At 12 weeks, the only significant treatment differences remaining for experimental patients were the higher general activity levels. Self-efficacy scores summed for all physical activities at Week 8 were significant predictors of self-reported activity at 12 and

Cardiac Rehabilitation Program Exercise Goals

Self-Efficacy:

1. Patient believes he/she can comply to exercise and nutrition goals
2. Patient accomplishes behavior according to recommendations
3. Behaviors create improved CV outcomes
4. Patient develops self-efficacy to independently maintain behaviors which support improvements in CV health long-term.

Rehabilitation Educator ⟷ Rehabilitation Patient

Responsibilities:

1. Obtain knowledge of relevant efficacy information sources
2. Obtain knowledge of patient condition, capabilities and barriers
3. Strive to enhance compliance to exercise and nutrition recommendations through enhancing patient self-efficacy by:

   (a) Verbal persuasion; individual & group education, audiovisuals & phone contact.

   (b) Vicarious experiences; modeling desired behaviors during exercise sessions, group educational/ support meetings, audio-visuals & heart healthy nutrition classes.

   (c) Performance accomplishments; assessing the patients' past success with exercise and nutrition & determining comfort levels toward program recommendations.

   (d) Physiologic states; increasing the patients awareness of what they should expect to feel during exercise including techniques to identify normal & abnormal responses to exercise/physical activity.

Perceptions:

1. Efficacy Expectation (self-efficacy) —confidence in ability to perform the recommended exercise and nutrition behaviors.
2. Outcome Expectation (outcome expectancy)—belief that exercise and nutrition recommendations are beneficial to one's health).

Figure 1. Self-Efficacy Compliance Model for Exercise and Nutrition Recommendations in a Cardiac Rehabilitation Program. Note: Adapted from Allen (1988), Self-efficacy in health and behavior research and practice, Cardiovascular Nursing, 24 (6), 37.

24 weeks. Gortner and Jenkins concluded that self-efficacy expectations in the recovering CABG patient can be influenced by inpatient education and outpatient telephone coaching.

Ewart et al. (1986) showed that self-efficacy mediates strength gains during circuit weight training in 40 males with CAD. They showed that pre-training self-efficacy levels toward circuit weight training predicted post-test strength gains even after controlling for frequency of exercise participation, type of training, and baseline strength. Two years later, Stewart et al. (1988) reported on 25 patients who had been compliant to the circuit weight training for 3 years and showed the levels of self-efficacy increased directly with strength gains.

In regard to measurement of SE, Courneya and McAuley (1994) emphasize the importance of measuring self-efficacy levels in all components provided in an exercise prescription which include (a) intensity, (b) frequency, (c) duration, and (e) mode. They point out if self-efficacy is measured with respect to a single statement combining frequency, duration and intensity, it will be impossible to determine which component of self-efficacy a patient may lack.

In summary, studies which have evaluated the relationship of self-efficacy to exercise and physical activity support Bandura's (1977) theory of SE. Furthermore, the studies suggest that self-efficacy expectancies can be positively affected by using techniques that alter the four factors which influence self-efficacy (performance accomplishments, vicarious experiences, verbal persuasion, and physiological state). As suggested by Courneya and McAuley (1994), multifaceted measurement of self-efficacy is essential to determine the specific area of self-efficacy that is limiting. Therefore, measurement tools should encompass all parameters typically addressed in a traditional exercise prescription.

A Summary of Cardiac Rehabilitation Interventions

A number of studies have been conducted to evaluate methods of CR which include exercise which are different from the traditional facility-based cardiac rehabilitation. These programs often emphasize methods which promote a home-based or self-directed off-site exercise program for patients, and often include behavioral interventions for other behaviors including diet, and commonly include some form of case management. The majority of studies which emphasize a home exercise program component used stable low- and moderate-risk cardiac patients. An excellent review of these studies, and all major studies evaluating CR completed from the 1970s until 1995, are included in two sources: the Cardiac Rehabilitation Clinical Practice Guidelines (USDHHR, 1995), and the Resource Manual for Guidelines for Exercise Testing and Prescription (ACSM, 1993). The following discusses the effect of these interventions on functional capacity and, in selected studies, blood lipid outcomes.

From 1979 to 1991, seven studies compared off-site exercise interventions to supervised exercise-based CR interventions. Only one of these studies (Heath, Maloney, & Fure, 1987) showed a significant between-group difference in functional capacity. The between-group difference reported was in favor of the supervised exercise intervention. In this study, it is noteworthy that patients in both groups' mean baseline mean capacity was less than 5 METs. The between-group differences were revealed at a 12-week assessment—the supervised exercise group mean METs increased from 4.4 to 8.8, and the unsupervised exercise group mean METs 4.9 increased to 7.6. The six studies which did not find between-group differences did all produce significant improvements individually from baseline to exit testing. Evaluations were conducted anywhere from 8 to 26 weeks post-initiation of the intervention. All patients' baseline mean MET capacities were 6 or greater. The average MET capacity increases were modest and ranged from 1.4 to 3.0 METs (Debusk et al., 1985; Debusk, Houston, Haskell, Fry, & Parker, 1979; Hands et al., 1987; Miller, Haskell, Berra & Debusk, 1984; Oldridge et al., 1991; Stevens & Hanson, 1984; Taylor, Houston-Miller, Ahn, Haskell & Debusk, 1986).

Debusk et al. (1979) reported on 70 patients which were randomized to one of three groups: 28 patients to gymnasium exercise training, 12 patients to home exercise training, and 30 patients to no training controls. The exercise intervention included cycle ergometry for 30 mins, seven days per week. After 11 weeks, both of the exercise interventions showed significant improvements in functional capacity ($p < .01$) compared to the controls; however, no significant between-group differences were found.

Six years later Debusk et al. (1985) reported on a similar study which included 100 patients. Thirty patients were in a facility-based program, 33 patients were in a home program using transtelephonic ECG monitoring for home exercise five times per week for 30 mins, and 37 non-exercising patients were used as controls. As in his 1979 study, Debusk found that both of the exercise interventions showed significant improvements in functional capacity ($p < .05$) compared to the controls; however, no significant between-group differences were found in the exercise interventions.

A multifactorial study in Canada included exercise and behavioral counseling for the patient and spouse (Oldridge et al., 1991). The exercise intervention included 99 patients who were encouraged to conduct facility-based exercise two times per week for 50 mins for 8 weeks, with encouragement to exercise off-site three times per week. Compared to 102 usual care controls, the experimental group showed significant improvements in exercise tolerance ($p < .05$); however, at 12 months, there were no significant differences between the groups, suggesting that the intervention was not effective in promoting long-term exercise behavior.

In 1994, Debusk et al. again reported on an intervention which included transtelephonic ECG monitoring for home exercise five times per week for 30 mins. However, in this study the intervention was made multifactorial by including extensive behavioral, diet, and exercise counseling and follow-up with case managers. Additionally, lipid lowering medications were used in patients with hyperlipidemia. They found significant increases in functional capacity ($p \leq .001$) among 293 patients randomized to the intervention, compared to 292 usual care participants. However, in the analysis of functional capacity, only 5% of the usual care were included. These individuals were the patients who attended a supervised facility-based CR program. Changes in lipid parameters were significantly superior in the experimental group in total cholesterol and LDL cholesterol ($p < .001$). The mean percent decrease in total cholesterol and LDL cholesterol, respectively, were 11% and 23.5%. No significant improvements were found between the groups in HDL and triglycerides.

Another comprehensive trial which included exercise and nutrition was conducted in Germany (Schuler et al., 1992). The intervention included facility-based and home exercise and intensive dietary instruction (emphasizing a 20% fat diet) with behavioral counseling and follow-up. The exercise intervention included 60 mins of facility-(metabolic ward) based exercise per day for the first three weeks. Thereafter, 30 mins of exercise was encouraged per day which was supplemented with two one-hour group training sessions per week. After one year, the 45 experimental patients showed significant increases in oxygen consumption ($p < .05$) compared to the 43 patients in the control group who received usual care. Additionally, the experimental group showed significant between-group differences in reducing total and LDL cholesterol ($p < .001$). The mean decreases in total cholesterol and LDL in the experimental group were 9.7% and 8.9%, respectively. There was no significant between-group differences in HDL and triglycerides; however, the experimental group lowered its triglycerides 21%. A unique characteristic of this trial was that cardiac catheterizations were conducted at baseline and at 1 year, and revealed that the experimental group experienced significantly more regression and stabilization of atherosclerotic lesions in the coronary vessels.

An additional multifactorial intervention, The Stanford Coronary Risk Intervention Project (SCRIP) (Haskell et al., 1994) included home-based exercise with transtelephonic ECG monitoring five times per week for 30 mins, diet and behavioral management, and the use of lipid lowering medications as needed. After four years, compared to 145 medically-treated usual care patients, the 155 experimental patients significantly increased their functional capacity ($p < .001$). Significant between-group differences were also reported in the following lipid parameters: (a) total cholesterol, (b) LDL cholesterol, (c) HDL cholesterol, and (d) triglycerides ($p \leq .002$). The mean percentage improvements in lipids in the experimental group were as follows: (a) total cholesterol (16.8%), (b) LDL cholesterol (18%), (c) HDL cholesterol (11.7%), and (d) triglycerides (19%). Follow-up testing in the SCRIP trial also included evaluation of complications and evaluation of atherosclerotic lesions. The intervention group had no serious CV complications during exercise training and a significantly higher number of patients showing improvements or stabilization in atherosclerotic lesions compared to the control group.

The preceding summary suggests that with appropriate instruction and follow-up, CR interventions for low- and moderate-risk patients which rely on a significant off-site exercise component can produce similar improvements in functional capacity compared to traditional rehabilitation-based exercise interventions. Additionally, the multifactorial studies by Debusk et al. (1994), Haskell et al. (1994), and Schuler et al. (1992) show promising results in relation to methods which can produce superior results in functional capacity and lipid management compared to traditional interventions. The studies by Haskell et al. (1994) and Schuler et al. (1992) also showed positive outcomes in relation to atherosclerosis. A characteristic of the multifactorial interventions which may be responsible for their success is the behaviorally-based education and frequent follow-up regarding exercise and nutrition behaviors. With the exception of the SCRIP trial (4-year follow-up), the long-term impact of these interventions is not known, given that their follow-up evaluations were conducted 1 year or less from initiation.

CHAPTER THREE

Methods

Design and Participants

The 6-month randomized effectiveness trial was initiated following approval from the Human Subjects Research Committees at Michigan State University and Blodgett Memorial Medical Center in Grand Rapids, Michigan. Additionally, permission was obtained from area cardiologists and physicians who refer patients to Blodgett Memorial Medical Center's Cardiac Rehabilitation Program. This study fits the criteria of an *effectiveness* trial because patients were randomized into one of two interventions and encouraged to follow the suggested protocol. In *efficacy* trials, researchers study the treatments under ideal conditions, meaning that patients are only included if they follow the treatment as specifically defined in the intervention protocol. Effectiveness is established by offering a treatment or program to patients and allowing them to accept or reject it as they might ordinarily do. Regardless of adherence, patients were encouraged to return for follow-up evaluations. Additionally, no extra staff were hired for the implementation of either intervention. This study employed 2x2 and 2x3 (group x time) repeated-measures designs for the major dependent variables. The dependent measures were (a) exercise adherence, (b) outcome expectancy of exercise, (c) self-efficacy to exercise behaviors, and (d) selected physiological variables associated with cardiovascular health. The majority of dependent variables were measured at three time periods: baseline, 3 months, and 6 months. Self-efficacy, outcome expectancy, and exercise adherence were also assessed at 1.5 months, while blood lipids and demographic characteristics were only measured at baseline and 6 months. Participants were randomly assigned to a traditional or modified CR protocol which included exercise. Table 1 contains a chronological overview of the study, and Table 2 summarizes the dependent measures evaluated during the 6-month evaluation period.

Table 1

Chronological Summary of Methodology, Participant Protocols

Overview
Participants followed the same protocol for the first four weeks, including a three-session group CV risk factor/nutrition session. In Week 5 individual protocols were initiated. During exercise sessions, patients received CV risk factor education and feedback on evaluations and assessments. Educational video viewing was encouraged.

Week 1
Potential participants offered three outpatient exercise sessions with CECGM per week. Encouragement provided to exercise $\geq$ 5 sessions per week for $\geq$ 30 mins per session. Exercise logs were provided to document off-site exercise. Medical history obtained. Lipid profile, GXT and group education scheduled. Nutrition logs provided.

Weeks 2 - 3	Week 4
Three CECGM rehab exercise sessions per week. Informed consent provided. Participants randomized to traditional or modified protocol. Protocol schedule reviewed	Three CECGM rehab exercise sessions per week. GXT exercise prescription reviewed. Protocol schedule reinforced. Feedback on nutrition logs provided. Viewing of selected videos encouraged.

Week 5
Individual Protocols Initiated

Traditional Protocol (TP)	Modified Protocol (MP)
Weeks 5 - 12 Three rehab exercise sessions per week with CECGM continue through Week 12. Patients receive education on CV risk factors and medications.	Week 5 Three rehab exercise sessions, CECGM discontinued; Polar™ heart rate monitors provided to patients to use on and off-site for 3 weeks.
Weeks 13-24 Three exercise sessions per week without CECGM. Staff supervision and education is reduced.	Weeks 6-10 On-site exercise reduced to two sessions per week. Weekly education/support group initiated to facilitate independent exercise and nutrition behaviors.
Weeks 25-26 Patients offered two rehab exercise sessions per week.	Weeks 11-16 Patients are encouraged to attend one exercise session education/support group per week.
	Weeks 17-26 One rehab exercise session and education/ support group every two weeks.

Table 2

Assessments and Data Collection During the 6-Month Study Period

Weekly, 1.5, 3, and 6 months	• Rehabilitation Exercise Compliance • Off-Site Exercise Compliance • Total Exercise Compliance	
Baseline and 6 months	• Graded Exercise Test • Cardiovascular Risk Factors • Lipid Profile • Nutritional Assessment • Exercise Behavior • Peer Learning & Support	• Demographics • Self-Efficacy • Outcome Expectancy • Social Support • Perceptions of Health • Stress
1.5 months	• Self-Efficacy • Social Support • Peer Learning & Support	• Outcome Expectancy • Stress • Perceptions of Health
3 months	• Graded Exercise Test • Self-Efficacy • Social Support • Peer Learning & Support	• Cardiovascular Risk Factors • Outcome Expectancy • Stress • Perceptions of Health

Participants were obtained from cardiac patients who were referred to the Blodgett Hospital's Department of Preventive Cardiology and Rehabilitation. Patients are referred to CR following a cardiovascular event or procedure, or if they have documented coronary artery disease. Patients approached for this study were literate men and women between 35 and 75 years of age, who were low or moderate risk as defined by the ACC (1986) and described by the AACVPR (1995), as summarized in Appendix B, and were in CR for the first time. Additionally, patients had the ability to walk on a treadmill, and had a body mass index (BMI) of less than 40 (Jaequier, 1987). Patients were excluded if they lived more than 30 miles from the facility, had a documented history of chronic psychological disorders, or had obvious substance abuse problems other than nicotine and caffeine. Determinations for the preceding conditions were based on medical records, a graded exercise test, and information obtained via questioning during initial rehabilitation sessions.

Randomization Procedures

Within two weeks of entering the cardiac rehabilitation program, patients were identified as potential participants based on the aforementioned inclusion criteria. Potential participants were asked if they were receptive to participating in a research project evaluating the effectiveness of cardiac rehabilitation. Receptive patients received a verbal summary of the project and an informed consent form which they were asked to read and sign (Appendix C). Of 106 patients approached who appeared to fit the study inclusion criteria, 16 did not participate due to the following reasons: Seven patients stated they were going to leave the area for greater than one month during the 6-month evaluation period. Four patients lived greater than 30 miles from the rehabilitation facility. Two patients had jobs which required frequent travel. Two were already involved in exercise regimens which included follow-up testing at their work place. One patient provided no specific explanation.

Patients were recruited over a 6.5-month period. Ninety patients agreed to sign the informed consent and were given a code number. Of these, 10 patients were not included for various reasons. Four patients were excluded due to their high risk status (Appendix B), while six patients were excluded from the analysis due to uncontrollable events prior to their 3-month evaluation which affected their ability to exercise. Of these six patients, two patients became symptomatic and required bypass surgery within one month of initiating cardiac rehabilitation, three patients developed unstable angina making them high risk, and two patients had musculoskeletal injuries which limited their ability to exercise. Patients requiring angioplasties and stents during the 6-month evaluation period were kept in the study sample if this did not interrupt their ability to exercise for more than one week. The specific number of patients discontinuing contact with the rehabilitation facility for no apparent physiological reason and not returning for their 3- and/or 6-month evaluations was documented, as included in Hypothesis 2.

Each time five or more patients were recruited and agreed to sign the informed consent, their code numbers were placed in an envelope and drawn blindly from the envelope and randomly assigned to either the TP or MP. Of the 80 viable patients, 35 men and 7 women (mean age 58.9, range 37 to 73 years old) were randomly assigned to the TP, and 31 men and 7 women (mean age 58.8, range 40 to 75 years old) were randomly assigned to the MP. Participants were provided with individual guidelines for their assigned protocol, including a timeline of the questionnaires and physiological evaluations. All patients were informed that they were expected to return for their follow-up testing even if they were unable to follow their suggested education and exercise protocol at the rehabilitation facility. Patients were also informed that their insurance company would be billed for services typically covered by insurance (baseline and 3-month GXT, baseline blood lipid profile, and CECG monitored exercise sessions). Patients without insurance or those who were not fully reimbursed for the preceding billing fees were not charged during the first 3 months. However, all patients were responsible for a $4.00 charge for each on-site exercise session during the final 13 weeks of the program. The patients were not billed for the 6-month physiological testing (GXT and blood lipid profile). These costs were covered by research funding, given that insurance typically only covers an entry and a 3-month GXT.

Dependent Measures

The physiological dependent measures were assessed at baseline (within 2 to 3 weeks of starting outpatient cardiac rehabilitation), at 3 months, and at 6 months. Blood lipids and demographic characteristics were only assessed at baseline and 6 months. The subjective measures, self-efficacy and outcome expectancy measures, were assessed at four intervals: baseline, 1.5 months, 3 months, and 6 months while exercise adherence was also quantified at these times (Table 2).

Exercise Adherence / Frequency Rates

Exercise adherence was documented for 6 months for off-site/PEP, on-site facility-based exercise, and total exercise in weekly increments. Total exercise was obtained from the sum of on-site and off-site exercise. The patient's suggested weekly exercise compliance goal was five sessions of aerobic activity per week for 30 mins or longer. Intensity was based on guidelines of exercise prescriptions given to patients following their GXT. On-site exercise was documented in the patient's medical record by cardiac rehabilitation staff. Patients were instructed to document their PEP on an exercise log which included the intensity, duration, and type of activity completed. Patients were encouraged to include a variety of activities and were given credit for non-standard exercise activities if the activity fit the intensity and duration parameters of their exercise prescription. Logs were assessed by staff on a weekly basis and reviewed with each patient. If patients did not bring in their logs, a staff person would ask them open-ended questions about their PEP and document the information in the medical charts. Patients not present at the facility for 2 or more consecutive weeks were contacted by a staff person within 3 weeks to be questioned about their PEP for documentation. For evaluation purposes, 30 or more mins of aerobic activity per day was counted as a session. The exercise adherence data for both on- and off-site exercise and for the total number of sessions was quantified and compared in the following increments—baseline to Week 6, Week 7 through Week 12, and Week 13 to Week 26. A 100% compliance standard for exercise frequency was predetermined for each of the preceding time increments for both facility-based exercise, and total exercise as follows.

On-site exercise compliance standards. Compliance was defined as the number of sessions offered to the patients in their respective protocols (TP or MP). The TP offered patients a total of 72 sessions over 6 months; 36 the first 3 months with CECGM, and 36 the final 3 months of the evaluation period without CECGM (Table 3a.).

MP patients were encouraged to attend a minimum of 36 sessions (17 sessions, entry through 6 weeks; 10 sessions, Weeks 7 through 12; and 9 sessions the last 3 months) if they felt completing the majority of exercise off-site was more convenient and desirable to them. However, MP patients had the option to exercise on-site for up to 53 on-site sessions over 6 months by attending two on-site exercise sessions per week from Weeks 7 to 26 (Table 3b).

Total exercise compliance standards. The compliance standard was five exercise sessions per week for 30 mins or greater for both protocols for each evaluation increment throughout the 6-month evaluation period. The total number of sessions was calculated by summing both the on- and off-site exercise for each evaluation increment and during the 6-month period (Table 3c).

Table 3a: TP On-Site Exercise Compliance Standards

Time period	Entry - 6 weeks	7 -12 weeks	13 - 26 weeks	6 month total
# of sessions	18	18	36	72

Table 3b: MP On-Site Exercise Maximum Compliance Options

Time period	Entry - 6 weeks	7 - 12 weeks	13 - 26 weeks	6 month total
# of sessions	17	12	26	53

Table 3c: TP & MP Total (On- and Off-Site) Exercise Compliance Standards

Time period	Entry - 6 weeks	7 - 12 weeks	13 - 26 weeks	6-month total
# of sessions	≥ 30	≥ 30	≥ 65	≥ 130

Off-site exercise compliance standards. No valid off-site compliance standard could be set because the amount of off-site exercise completed was in part dependent on the amount of on-site exercise participants completed each week. While off-site exercise is not reported relative to a compliance standard, the absolute amounts quantified are addressed relative to Hypothesis 1(b).

Demographics and Subjective Dependent Measures

Demographics

Thirty-nine questions addressed patient demographic variables and characteristics. Twenty of these questions and characteristics were previously shown to be correlated with exercise compliance (Friis & Armstrong, 1986; Harlan et al., 1995; Kulik & Mahler, 1992; Mirotznik et al., 1995; Oldridge & Spencer, 1985; Oldridge & Streiner, 1989). The questions were asked at baseline and 6 months and addressed age, gender, employment status, occupation, social support, peer support, annual income, travel distance to the rehabilitation facility, and transportation barriers. Additionally other factors were quantified at baseline to assess the homogeneity of the two study groups. These included diabetes, family CV history, smoking status, and medications (Appendix I).

Subjective Dependent Measures

A questionnaire (Appendix D) to assess outcome expectancy, self-efficacy, perceptions of health, social support, and stress as it relates to anxiety, despair, and demographics was piloted on a group of eight cardiac rehabilitation patients of varying ages and educational backgrounds to assess the readability and comprehension of the questions. Patients were given their initial questionnaire during the second or third week of entering outpatient cardiac rehabilitation. The questionnaire was repeated at 1.5 months, 3 months and 6 months, respectively. Each question type was preceded by written instructions. Prior to completing the baseline questionnaire, verbal instructions were provided on each question type with specific examples for the more involved questions (i.e., self-efficacy questions). For subsequent questionnaires, participants were encouraged to ask questions if there were items they did not understand. Apparent illogical responses on questions were reviewed with participants to assure comprehension.

Self-efficacy and outcome expectancy to exercise. Individualized, program-specific measures of self-efficacy and outcome expectancy were constructed based on principles and guidelines described by Bandura (1977), Courneya and McAuley (1994), and Feltz (1988). The rationale for tracking self-efficacy and outcome expectancy levels over time was two-fold: (a) to determine the relationship between outcome expectancy and self-efficacy to exercise behavior, and (b) to evaluate if there are differences in self-efficacy and outcome expectancy that change over time within and between the two protocols. For instance, do the modified protocol patients exhibit more improvement in their self-efficacy toward exercise when compared to the traditional protocol patients?

Self-efficacy. Nine questions were used to assess self-efficacy related to exercise behavior. Specifically, the questions were designed to address patient confidence toward exercise frequency, duration, intensity, confidence regarding exercising without CECGM, and confidence to facility-based supervised exercise and off-site exercise.

Five questions were used to assess patients' confidence in completing on-site, off-site, and total aerobic exercise for 30 mins or longer per session. Two questions used a five-point Likert format with responses ranging from no confidence to excellent confidence in regard to on-site and off-site exercise. Three questions using an 11-increment probability scale ranging from 0% to 100% in 10% increments (0% equals no confidence, 100% equals complete confidence) were used to assess on-site, off-site and total exercise. For on-site exercise, the 11-point exercise confidence probability scale was applied from one to 3 days per week. For off-site exercise and total exercise, the 11-point exercise confidence probability scale was applied from 1 to 7 days per week. These questions were analyzed by multiplying the percent confidence rating by the number of days the patients predicted they would exercise, and summing the total score for each question type.

To assess patients' confidence level while exercising without CECGM, a five-point Likert format question was used. Responses ranged from very uncomfortable (1) to very comfortable (5). The question was asked two ways: (a) comfort level while exercising at the cardiac rehabilitation facility, and (b) comfort level exercising outside the cardiac rehabilitation facility.

To measure the patient's confidence toward exercising at a specific intensity, patients answered one question using the Borg scale (Borg, 1982). Using the 15-increment Borg scale, ranging from 6-20 (7 = very, very light; 19 = very, very, hard), the patients were asked at what rating of perceived exertion (RPE) they were capable of exercising at for 30 mins or more.

One self-efficacy question was designed to address the patient's confidence toward exercising a specific duration at an RPE of 12 to 13. The question involved in a seven-point Likert format ranging from 15 mins to 105 mins or more.

Two questions assessed the patients' perceptions toward their fitness and health and were categorized with the self-efficacy questions. Both questions incorporated a six-point Likert type question ranging from strongly disagree to strongly agree. One question addressed the patients' ability to complete daily and leisure activities, and the other question addressed the patients' feeling toward their physical condition (Appendix D, questions 22 and 23).

<u>Outcome expectancy</u>. One question was devoted to measuring the outcome expectancy to the exercise regimen suggested by the cardiac rehabilitation staff in playing a role in maintaining and improving health status (Appendix D, question 26). The question utilized an 11-point Likert type format ranging from no confidence to complete confidence.

Variables Associated with Cardiovascular Health

Physiological variables and levels of stress in relation to levels of anxiety and despair were measured to evaluate changes among participants within each protocol and evaluate potential outcome differences between the two interventions. These variables were chosen based on years of research which have established risk factors associated with CV health (Balady et al., 1994). Additionally the physiological outcomes were used to help validate expected changes resulting from reported exercise compliance. The variables measured included: functional capacity, heart rate, blood pressure, rate pressure product, respiratory exchange ratio, anaerobic threshold, weight, height, body mass index, blood lipids, and perceptions of stress and the frequency of feelings of hostility despair.

Functional capacity. Functional capacity was measured based on oxygen uptake (VO_2) during maximal graded exercise tests (GXTs) on a treadmill. The same continuous ramped treadmill protocol was used for each patient during each of his or her evaluation. The protocol selection involved individually choosing workloads believed to maximally stress the patient's cardiorespiratory system in 8 to 12 min. Gas analysis was obtained using a Sensor Medics 2900. Respiratory gasses were collected using a 30-secs rolling average. Prior to each test, patients were encouraged to exercise as long as possible, and were instructed to inform the testers if they experienced any unordinary signs or symptoms including chest pain, light-headedness, dizziness, joint or leg discomfort, or unusual shortness of breath. Patients were instructed on how to use the Borg RPE Scale ranging from 6 to 20. RPE ratings were obtained every 2 to 3 mins throughout the GXTs. The testers (a physician and an exercise physiologist) monitored the ECG, blood pressure, and gas analysis, and followed the ACSM Guidelines for Exercise Testing (1992). If patients were asymptotic and physiological parameters were within normal limits as defined by the ACSM, the GXT was continued until criteria indicating a maximum $\dot{V}0_2$ was achieved or the patient exercised to volitional fatigue. Criteria for defining a maximum $\dot{V}0_2$ included a respiratory quotient (RQ) of 1.05 or greater, achievement of greater than 85% predicted maximal heart rate, a leveling off of $\dot{V}O_2$ or heart rate with increasing workloads, and an RPE of 17 or greater.

Anaerobic threshold (AT). AT was determined using the V-Slope method as described in the definitions included in Chapter 1. Two exercise physiologists trained to evaluate the AT by the V-slope method were blind to each other and selected the AT. If their selection differed by 3% or more, a third trained investigator also selected the AT. If any two of the three investigators matched within 3%, the lower of the two numbers was used as the AT. Patients with indistinguishable anaerobic thresholds were not included in the analysis.

Respiratory exchange ratio (RER). RER, which is determined by computing the ratio of CO_2 to O_2, was obtained throughout all GXTs and was used for determination if a peak test had been achieved.

Hemodynamic measures. Heart rate and blood pressure were measured at rest, at submaximal workloads and at peak exercise. Heart rate was measured via a 12-lead electrocardiogram. Blood pressure was measured at rest, at a selected submaximal exercise, and at peak exercise via auscultation. Hypertension was classified as a resting blood pressure with the systolic reading of 140 or greater, and/or a diastolic reading of 90 or greater. Rate pressure product (RPP) was determined at rest and during a submaximal workload. RPP was determined by the formula: heart rate multiplied by systolic blood pressure.

Body composition: Weight, height and Body Mass Index (BMI). Weight and height were determined using a calibrated balanced healtho-meter scale. Baseline weight and height were documented during the first week of the program. Subsequent weight measurements were documented at the time of their 3-month and 6-month graded exercise test evaluations. BMI was determined using the formula, weight in kilograms divided by the square height in meters. Obesity was classified in three grades as described by Jaequier (1987): Grade 1 obesity (BMI of 25-29.9); Grade 2 obesity (BMI of 30-40) and Grade 3 obesity (morbid obesity) (BMI > 40.)

Blood lipids. Parameters included total cholesterol, low density lipoprotein, high density lipoprotein, triglycerides, and the ratio of total cholesterol to high density lipoprotein. Measurements were based on venous blood samples drawn and analyzed at the Blodgett Memorial Medical Center Blood Laboratory. Patients who were referred to cardiac rehabilitation following open heart surgery or a myocardial infarction were required to wait 6 weeks from their event or procedure date prior to their baseline blood assessment. This minimized the possibility of falsely depressed levels which are common following major physiological trauma such as open heart surgery or a myocardial infarction (National Cholesterol Education Program Guidelines Expert Panel Report, 1993). Patients who were referred following angioplasty, stent placements, rotoblation, or documented CVD had their blood samples drawn and analyzed within 3 weeks of initiating CR. Patients were instructed to (a) fast, (b) abstain from vigorous exercise for 12 or more hours, and (c) avoid alcohol for a minimum of 72 hours. Patients were provided the identical instructions for their 6-month assessment and instructed to repeat the blood draw at the same time of day as their first draw.

Stress responses negatively associated with cardiovascular health. Two questions were devoted to rating stress levels and feelings inversely associated with cardiovascular health. Both questions utilized the Likert format. One question rated perceptions of levels of negative stress on a 6-point scale ranging from none to very high. The other question assessed the frequency of feelings of hostility and despair and used a five-point scale ranging from never to very often.

Program Cost

Program cost was reported based on the program costs multiplied by the mean average participation rates of patients in each protocol over the 6-month evaluation period. The program cost calculation included the cost of the procedures typically billed to insurance companies and the out-of-pocket fees billed to patients for maintenance exercise sessions. This included the number of on-site sessions with and without CECGM during the 6-month period. Additionally, two blood profiles and two GXTs were included in the program cost. The formula to calculate the cost of each protocol is presented below. The unknowns are noted with the ("X") marks and are dependent on the number and type of on-site sessions attended by each protocol as defined in the results.

The TP and MP average cost per patient will be calculated based on the following:

Mean number of on-site sessions conducted with CECGM (X) x $ 72 =	$X.00
Mean number of "quick look" ECG strips session (X) x 30.00 =	$X.00
Mean number of on-site sessions conducted without CECGM (X) x $4 =	$X.00
Two blood lipid profiles ($30 each) x 2 =	$60.00
Two metabolic GXTs ($272 each) x 2 =	$544.00
Total Cost =	$X.00

Program Interventions

Patient Care Prior to Entering Outpatient Cardiac Rehabilitation

Patients in this study received a referral for outpatient cardiac rehabilitation while they were inpatients in the Blodgett Memorial Medical Center cardiovascular unit. During their inpatient stay, patients were ambulated under the direction of an exercise physiologist or registered nurse with exercise training. Patients were taught the basic exercise skills including stretching techniques and intensity monitoring skills (RPE and pulse taking skills). Prior to discharge, patients were scheduled for their initial visit to outpatient cardiac rehabilitation and given guidelines for implementing a progressive walking protocol and other physical activities they could safely perform based on their condition. The walking protocol was conservative, recommending that patients not elevate their heart rate greater than 20-30 beats above their resting heart rate (10-15 beats if they were on a beta blocking agent), and not to exceed an RPE of 12-13. The walking protocol encouraged patients to work up to at least 20 consecutive minutes of walking daily by their first visit to outpatient cardiac rehabilitation. Most patients initiated outpatient cardiac rehabilitation within 3 weeks after discharge from the hospital.

<u>Care Prior to Initiation of Individual Protocols: Entry to Week 4</u>

For a chronological overview of the project including the differences between the protocols, see Table 1. A summary of the physiological and subjective testing schedule is included in Table 2.

The initial 4 weeks of care offered to patients were identical for both groups and were characteristic of the first 4 weeks of most Phase II cardiac rehabilitation programs in the United States (AACVPR, 1995). This included an orientation session, a maximal GXT, and three supervised exercise sessions per week with CECGM.

During the orientation session and the first week of rehabilitation sessions, patients completed questionnaires and provided information pertaining to (a) medical history, (b) exercise and nutrition behaviors, and (c) CV risk factors. Detailed medical histories were obtained from the patient's medical record (released by the patient's physician with consent from the patient). By the second or third week, patients completed their initial physiological testing and subjective questionnaires including questions on self-efficacy and outcome expectancy to exercise.

Hospital-based exercise sessions included a warm-up, 30-40 mins of aerobic exercise with CECGM, and a cool-down. Blood pressure was taken upon entry, during exercise, and after exercise. Each session, patients' exercise information and relevant clinical events were documented in their medical records. Prior to completion of their baseline GXT, patients were informed to exercise at a conservative intensity as a safety precaution. The guidelines for conservative intensity included a heart rate no greater than 20-30 beats above resting levels (10-15 beats above resting levels for patients taking beta blocking agent) and/or a rating of perceived exertion (RPE) no greater than 13. Following the entry GXT, patients received individual follow-up on the results and guidelines for both on-site exercise and PEP sessions (Appendix E). Patients were taught how to regulate their exercise intensity based on one or more of the following methods: (a) training heart rate range, (b) the talk test, and (c) RPE (Borg, 1982). All patients were encouraged to achieve a total of five or more aerobic exercise sessions per week (combination of on- and off-site exercise) for 30 mins or longer. Logs were provided to each patient to document their off-site exercise.

Results of the GXT were used for determination of risk classification and for developing an exercise prescription. Patients were also given a demonstration of guidelines for strength training utilizing free weights at the rehabilitation facility. Patients who had not experienced a myocardial infarction or open heart surgery were given strength training guidelines during the first month. Patients who were post-open heart surgery or post-myocardial infarction typically were provided the guidelines 4 to 6 weeks following the event or procedure. Patients were asked to bring in their PEP log weekly for documentation of their exercise/activity duration, intensity, and frequency. Staff documented the PEP information in each patient's chart. Those patients not bringing their logs in were asked about the frequency, duration, and intensity of their off-site exercise for the week. Those patients not attending the rehabilitation facility for two consecutive weeks were called and interviewed about their off-site exercise program within 3 weeks of their last contact with a staff member.

Patient education was provided in three forms: (a) before, during and after exercise sessions, (b) group classes, and (c) via selected video tapes. The education patients received before and during exercise sessions included the following areas: (a) basis for medications, (b) principles of exercise training, (c) CV risk factors, (d) monitoring exercise intensity, (e) signs and symptoms meriting professional intervention, (f) target values for blood lipids, and (g) a review of nutrition principles. Once patients verbally demonstrated comprehension of these areas, they were checked off on a Service Documentation Form (Appendix G).

Patients were scheduled to attend the group education classes within the first two months of care. The three-session nutrition/CV risk factor education series was designed to improve the patient's awareness of cardiovascular risk factors and to emphasize the role of nutrition in preventing and managing atherosclerosis. Guidelines were based on current research including the results of recent clinical trials shown to elicit positive results in preventing the progression of atherosclerosis in cardiac patients (Ornish et al., 1990; Schuler et al., 1992; Sullivan, 1993). Nutrition guidelines emphasized improving nutrient density by increasing dietary fiber containing foods and limiting saturated fats and cholesterol. Calorie intakes were suggested to achieve or maintain ideal body weight. Fat intake goals included no greater than 22-25 grams of total fat per 1000 calories with less than 7% of calories from saturated fat, and less than 150 milligrams of cholesterol. (Note: Diabetics were encouraged to consume 30-33 grams of fat per 1000 calories.) Dietary fiber goals were 20 or more grams of dietary fiber per 1000 calories. Patients were educated on these guidelines via the food pyramid, sample menus, a computerized dietary analysis (Nutritionist IV, 1994), and in group classes. Patients also had the opportunity to attend a "hands on" heart healthy cooking program. A summary of the nutrition/CV education program is included in Appendix H. In an effort to supplement individual and group education and to meet individual needs, patients were scheduled to view selected videotapes before or after their scheduled exercise sessions throughout the program. In the fifth week, the patients' interventions changed according to the protocol to which they were randomly assigned. The methodologies of the two protocols (traditional and modified protocols) are described below.

The Traditional Protocol (TP)

Traditional Protocol: Weeks 5 to 12

Patients randomly assigned to the TP continued to follow a Phase II format characteristic of most CR programs in the United States. The regimen included three CECGM hospital-based exercise sessions per week, with encouragement to exercise independently, to achieve a total of five or more sessions per week. Patients who had not finished the three-part group education were encouraged to do so. Additionally, during exercise sessions, patients continued to receive education on cardiovascular risk factors with emphasis placed on those putting the patient at the greatest risk. Once a patient demonstrated verbal competency of a topic, it was documented on the Service Documentation Form (Appendix G). Additionally patients were encouraged to view selected videos before or after their exercise sessions to reinforce individual and group education. During the first 12 weeks, if a patient was absent for more than a week, he or she was contacted by phone. Off-site PEP was documented on a weekly basis among patients who continued to attend on a weekly basis. Patients absent for more than one week were asked about their PEP via the telephone. The Phase II period continued until patients completed 12 weeks or 36 sessions.

Traditional Protocol: Weeks 13 to 26

After 12 weeks or 36 sessions, TP patients were encouraged to attend the Phase III maintenance regimen for 3 months. The Phase III regimen was similar to the Phase II program in that it consisted of three sessions per week; however, exercise sessions were without CECGM and patients received less staff supervision. Phase III monitoring consisted of a resting and post-exercise blood pressure and a ECG strip. Patients were taught how to document their workloads and duration of activities during their Phase III sessions. Those patients not choosing to follow the Phase III regimen were encouraged to follow a PEP of their choice. Also, they were given the option to re-enroll in the on-site exercise program at any time and were scheduled for their 6-month evaluation.

The Modified Care Protocol (MP)

Modified Protocol: Weeks 5 to 10

Participants randomly assigned to the modified protocol followed a protocol designed to provide a method of cardiac rehabilitation for low- and moderate-risk patients that would facilitate improved long-term independent control of exercise and other health behaviors at a reduced cost compared to the traditional protocol. The modified protocol (see Table 1 and Appendix F) was based on Bandura's (1977) theory of self-efficacy as it applies to exercise behavior. Emphasis was placed on the importance of establishing an off-site exercise program and utilized principles from models previously shown to be effective in promoting good adherence in primary and secondary prevention settings (Debusk et al., 1994; Robison et al., 1992; Stofflemeyer et al., 1993).

The MP had three primary differences from the TP: (a) The number of on-site exercise sessions with continuous ECG monitoring was reduced, (b) the overall number of rehabilitation exercise sessions offered were decreased, and (c) patients were offered an ongoing weekly CV education/support group in addition to the standard group educational series offered to the TP. The reduction of CECGM exercise sessions and overall exercise sessions was achieved by discontinuing CECGM after 12 on-site exercise sessions (or 1 month after starting the program). Patients instead received a "quick" ECG strip and a blood pressure assessment before and after their on-site exercise sessions. Additionally, patients were given a Polar™ Heart Rate Monitor for 2 to 3 weeks to monitor both their on and off-site exercise regimen. Patients were instructed to utilize the monitor for practicing their pulse monitoring skills and to learn to correlate their rating of perceived exertion (RPE) with their training heart rate range. After their sixth week, MP patients' sessions were reduced to two per week. The ECG "quick" strips were completed before and after exercise one time per week through Week 12. At this time, weekly educational/support group meetings called the "heart health forum" for patients and their spouses were held every Thursday at 8:00 A.M. or 3:00 P.M. Patients were encouraged to exercise before or after the meeting to avoid extra travel to and from the facility. The meetings were designed to provide supplemental education and support for patients' adherence to their exercise program and other cardiovascular risk reducing behaviors. During meetings, patients were given the opportunity to ask individual questions and discuss issues amongst themselves. Patients unable to attend meetings were given a copy of educational materials covered. An ongoing theme in the meetings was the importance of independent long-term off-site exercise compliance. The meetings were facilitated by CR staff. The first 5 to 10 mins of each meeting included round table introductions which were followed by a brief discussion regarding off-site exercise compliance. Patients were encouraged to share their successes and barriers regarding their exercise and nutrition program. Also, patients were asked to bring in their exercise logs to each meeting so staff could review and provide written feedback. The final 50 mins were devoted to education and discussions regarding exercise, nutrition, and other topics associated with CV health. Patients were encouraged to offer ideas on health-related topics they would like discussed. A summary of the format and topics covered are included in Appendix J.

Modified Protocol: Weeks 11 to 26

At the onset of Week 11 through Week 17, MP participants were encouraged to attend only one on-site exercise session per week if they were comfortable with their PEP; however, patients desiring to exercise at the facility two times per week were allowed to do so. From Week 17 through Week 26, or 6 months, patients were encouraged to reduce their on-site exercise sessions and educational group meetings to one session every

2 weeks; however, if desired, patients had the option to exercise on-site up to two times per week.

CHAPTER FOUR

Results and Discussion

Chapter Four is organized in the following way: Initially the preliminary data analysis of baseline measures including the patient demographics and attendance to the group educational sessions are presented. The remainder of the chapter is devoted to describing the results of 10 experimental hypotheses. Complete data sets were not obtained for all dependent measures at all assessment periods for the 80 patients in this study. Therefore, to maximize the sample size, any participant who had completed the testing necessary to answer the individual hypotheses were included in the analyses.

Preliminary Data Analyses

Baseline Analyses

Of the 80 patients who met the inclusion criteria at baseline, the following summarizes how many patients' data were collected through the 6-month evaluation. Exercise frequency data were completed by 78 participants, and subjective questionnaires were completed by 65 participants during the 6-month period. In some cases, patients failed to answer all questions. Physiological data were documented on 67 patients during the 6-month period. Among physiological variables, reasons for missing data included the following: (a) inability to determine an anaerobic threshold using the V-slope method, and (b) submaximal rate pressure product (SRPP) could not be documented at the 3-month or 6-month GXT if blood pressure was not obtained at the same treadmill grade and speed as during their baseline GXT.

To determine if the two groups were homogenous, an analysis was conducted on 103 baseline variables and characteristics. Continuous variables were evaluated using correlations, while chi-square analyses were conducted on the dichotomous variables. Results of the analysis of 39 demographic and subjective responses revealed only one question that was significantly different between groups. The question was one of six questions pertaining to social support and asked: "Do you have someone who is close to you who understands the importance of a regular exercise program?" (See Appendix D, question 13) Participants responded with either a "yes" or a "no." The TP had significantly more "no" responses ($p < .05$). Five of 41 participants answered "no" to the question, while none of the 38 patients in the MP answered "no" to the question. None of the five other social support questions were significantly different between the groups, including two questions which specifically assessed significant-other support toward exercise behavior.

Among physiological variables, t tests indicated no significant differences between baseline variables, with the exception of resting blood pressure. The mean baseline resting systolic blood pressure of 137 mm Hg $\pm$ 17 for the TP group was significantly higher (p = .001) than the systolic blood pressure of 123 mm Hg $\pm$ 18 for the MP group. Diastolic blood pressure in the TP group (84 mm Hg $\pm$ 7) was significantly higher (p = .01) than in the MP group (79 mm Hg $\pm$ 9). A comparison of blood pressure responses during exercise, including SRPP, were not significantly different between the two groups during baseline GXT testing. Moreover, the parameter Peak VO_2 , expressed as METs, approached being statistically higher in the MP at baseline testing (p = .06). Both groups' mean peak VO_2 was greater than 6.0 METs at baseline, classifying them as low-risk cardiac patients based on functional capacity.

Group Education Interventions Participation

Nutrition/CV Education Series. Both study groups were encouraged to attend three educational sessions on cardiovascular risk factors and nutrition. The attendance rates were similar, as illustrated in Table 4. Seventy percent of the TP participants attended all three classes, and 79% of the MP patients attended all three classes. It was noted patients who had exercise classes which were not directly before or after the education meeting were less likely to attend.

Table 4: Patient Attendance to the 3-Session Nutrition/Cardiovascular Education Classes

No. of Classes Attended:	0	1	2	3
TP n = 42 % of total n	3 (7 %)	3 (7 %)	7 (16%)	29 (70 %)
MP n = 38 % of total n	2 (5 %)	1 (3%)	5 (13%)	30 (79%)

Heart health forum /support group attendance. The heart health forum was part of the MP independent intervention and was only offered to the MP participants. The number of sessions attended by the MP participants was quantified based on frequency of attendance. Eighty-seven percent of participants (n = 33) attended three or more sessions, while 58% (n = 22) attended five or more of the forum sessions. Four participants (11%) did not attend any forum meetings, while one participant attended one meeting. Table 5 summarizes the attendance in these group meetings. The format and content of the forums are included in Appendix J. Reasons stated for non-participation to the forum meetings included transportation barriers, work conflicts, family obligations, and lack of interest.

Table 5: MP Patient Attendance to the Heart Health Forum

MP forums attended	0	1-2	3-4	5-6	7-8	9-10	11-12	13-14	$\geq$15
# of patients total n = 38	4	1	11	5	5	5	3	2	2
% of total n	10.5	2.6	28.8	13.2	13.2	13.2	7.9	5.3	5.3

Experimental Hypotheses

Exercise Adherence and Program Participation

Hypotheses 1(a) and 1(b). The two parts of this hypothesis involve two questions: Compared to TP patients, the MP patients will exhibit superior adherence frequency rates to (a) an off-site personal exercise program (PEP) and (b) overall exercise (combination of on-site and PEP) compared to TP patients over 6 months.

To evaluate Hypothesis 1, exercise frequency was summed within three time increments: baseline through 6 weeks, Weeks 7 to 12, and Weeks 13 to 26. The exercise frequency was also summed over the 6-month study period. The preceding was completed for off-site exercise (PEP), on-site exercise, and total exercise (the sum of PEP and on-site exercise). While on-site exercise was not specifically included as a hypothesis, it was quantified and incorporated in the evaluation because it contributes to the total exercise frequency. It also has implications in regard to program compliance standards and costs which will be addressed in Hypothesis 10. A summary of the mean exercise frequency by protocol is included in Table 6. Exercise frequency data were analyzed using three separate 2x3 (Protocol x Time) ANOVAs for PEP, on-site, and total exercise frequency. Lastly, while not specifically stated in Hypothesis 1, the total exercise is described in relation to the overall recommended compliance standard of five times per week.

Hypothesis 1(a): PEP frequency. The results for the off-site personal exercise program ANOVA indicated a significant main effect for protocols, $F(1, 74) = 4.38$, $p = .05$, with the MP demonstrating a higher off-site exercise compliance than the TP, thus supporting hypothesis 1(a). A significant times effect was also revealed, $F(2, 73) = 4.03$, $p = .02$. The interaction (protocol by time) was not statistically different; $F(2, 148) = 2.07$, $p = .08$. Because the results showed a main effect for group, a main effect for time, a post-hoc analysis of the individual time increments (Table 7) was conducted to clarify the findings (Table 6).

Table 6: A Comparison of TP and MP Mean Exercise Frequency (± SD) Over 6 Months

Exercise Type	Group/n	Weeks 1-6	Weeks 7-12	Weeks 13-26	6-Month Total
On-site	TP/40	13.3±3.7	11.1±6.5	4.3±6.7	28.8±13.0
Exercise	MP/38	13.5±2.7	8.5±4.3	6.9±7.6	29.2±10.7
PEP	TP/39	15.3±7.1	15.5±7.8	39.8±21.2	69.5±33.6
Exercise	MP/37	16.5±7.5	20.8±6.9	49.3±15.2	83.5±25.6
Total (PEP+ on	TP/39	27.6±7.7	26.2±8.2	44.1±21.1	98.1±33.4
site) Exercise	MP/37	29.4±7.7	28.5±8.6	54.1±25.6	111.8±29.1

Table 7: Mean (± SD) Overall Exercise Frequency Per Week Compared to the Exercise Compliance Standard of Five or More Exercise Sessions Per Week

Time period ->	Entry - 6 weeks	7 - 12 weeks	13 - 26 weeks	6-month total
TP, n=39	4.6±1.3	4.4±1.4	3.4±1.6	3.8±1.3
(%) of standard	(95%)	(87%)	(68%)	(76%)
MP, n=37	4.9±1.3	4.8±1.4	4.2±1.5	4.3±1.2
(%) of standard	(98%)	(95%)	(83%)	(86%)

Post-hoc tests revealed that during the first 6 weeks, the PEP frequencies among protocols was similar. However, the modified protocol PEP frequency rates were superior to TP rates during Weeks 7 to 12, $F(1,77) = 8.24$, $p = .005$. During Weeks 13-26, the frequency rates appear higher in the MP, but the difference were not statistically significant, $F(1, 74) = 2.82$, $p = .097$.

The higher levels of PEP in the MP group during Weeks 7 to 12 are partially due to the protocol designs, given that the TP group was offered and received more on-site exercise sessions during Weeks 7 through 12. However, during Weeks 13 through 26, protocol design cannot explain the lower PEP rates by the TP participants, who were offered significantly more on-site sessions during this period, but on the average, they attended fewer sessions than the MP participants.

Another potential reason the MP group exhibited superior rates of PEP exercise is the attendance at the heart health forum meetings (Appendix J). During the meetings, participants were encouraged to discuss their successes and barriers to achieving their overall goal of five or more sessions per week. Patients were expected to turn in their exercise logs, which were returned with written feedback. The peer and facilitator support and education that the patients received in the meetings may also have helped the MP patients establish and adhere to a PEP, as well as provided a reason to periodically exercise on-site. Additionally, given that one facilitator conducted most of the meetings, the patients were able to develop a good personal rapport with him and receive continuity in their education and feedback. Patients who stated they could not attend the meetings due to scheduling conflicts were mailed the educational information and encouraged to drop off their logs at the facility for feedback. In contrast, TP patients were provided education while they exercised on-site, often by different rehabilitation staff. The focus of the education in the TP group emphasized knowledge rather than behavior (see Service Documentation Form, Appendix G). Minimal time was devoted to assessing PEP behavior and reinforcing the goal of five exercise sessions per week. It is often difficult for staff to educate patients while exercising in a traditional CR setting, given that a significant portion of the staff time is devoted to taking blood pressures and ECG strips before, during, and after the exercise sessions. Additionally, when exercise classes are full with new participants who require more supervision, little time is available to educate and follow-up with patients. In many cases, little time was available to provide consistent feedback in regard to their PEP and overall exercise goals.

Hypothesis 1 (b): Total exercise frequency. The results of the ANOVA evaluating total exercise (sum of PEP and on-site) indicated no statistically significant main effect between protocols during the 6-month period to support the hypothesis. However, a trend was noted in favor of the MP, $F(1, 73) = 2.93$, $p = .09$. Subject time effect did not reveal a statistical difference, $F(2, 72) = 1.24$, $p = .29$. This can be viewed as a positive finding for both groups in the context that baseline to 6 months, the overall exercise frequency did not appear to decline significantly. The interaction (protocol x time) also did not reveal a statistically significant difference, $F(2, 146) = 1.48$, $p = .23$.

In regard to the total exercise compliance standards as described in Methods (Chapter Three), participants in both protocols were encouraged to exercise five or more times per week for 30 mins or longer per session. Table 7 summarizes the total exercise frequency in relation to compliance standards by protocol. Overall, neither group achieved the compliance standard for any of the time increments measured, and both groups' compliance rates declined over time. However, as described in Hypotheses 1(a) and 1(b) and illustrated in Table 7, the MP maintained a higher level of exercise frequency over time. Analysis of the exercise frequency to determine the percentage of patients by protocol achieving the compliance standard revealed that during the first 3 months, 42% of the MP participants and 36% of the TP participants achieved the compliance standard. During the final 3 months, 30% of the MP participants and 18% of the TP participants achieved the standard. The actual rate of exercise compliance during Weeks 13-26 was 15% higher in the MP, which was statistically different between groups, $F(1, 74) = 11.4$, ($p = .034$). For the 6-month period, the MP group achieved 86% of the compliance standard which was 10% higher than in the TP, but the differences were not statistically significant, $F(1, 73) = 2.93$, ($p = .09$).

Potential reasons the MP demonstrated higher compliance rates during the final 3 months of the program may include the potential benefits associated with its behavioral emphasis, which included facilitator and group support; that is, patients were given specific tips to identify and overcome exercise barriers, and were consistently asked how they were doing in relation to the overall exercise compliance standard of five exercise sessions per week.

In summary, Hypothesis 1(a) was supported, given that the PEP exercise frequency was superior in the MP during the 6-month evaluation compared to the TP, based on the main effect found in favor of the MP. Hypothesis 1(b) was not supported, given that the total exercise frequency over time (sum of PEP and on-site) did not show a statistically significant main effect. In relation to the total exercise compliance standard of five sessions per week or more, neither group achieved the standard. However, a greater percentage of the MP participants achieved the compliance standard and maintained higher compliance rates from Weeks 7 through 26 of the evaluation period compared to the TP participants. During the final 13 weeks, the MP group achieved 83% of the compliance standard, which was 15% higher than in the TP group. This compliance rate was statistically different and suggests that the MP performed significantly more exercise during the final 3 months of the evaluation period.

Hypothesis 2. This hypothesis stated that a greater number of patients in the TP will discontinue facility-based exercise and overall contact with the cardiac rehabilitation facility compared to the MP during the 6-month evaluation period. The criteria to answer this hypothesis included individuals who discontinued on-site exercise sessions within 6 weeks from starting, and did not return for their 3-month and 6-month physiological testing with no apparent physiological reason which limited their ability to exercise. Hypothesis 2 was supported based on the results of a chi-square analysis: X^2 (1, N = 80) = 3.91, p = .05. Statistical significance was demonstrated based on the likelihood ratio in favor of the MP. These results are summarized in Table 8 and reveal that 23.8% of the TP participants compared to 7.9% of the MP participants discontinued regular on-site exercise sessions within 6 weeks of starting and did not return for follow-up evaluations.

Table 8: Participation Rates by Protocol Over the 6-Month Evaluation Period

	Total/n	# who discontinued contact/dropped (%)	# who continued contact/stayed (%)
Traditional Protocol	42	10, (23.8%)	32, (76.2%)
Modified Protocol	38	3, (7.9%)	35, (92.1%)

Potential reasons for the significantly superior participation rates in the MP group may include the fact that the time commitment suggested for the MP was significantly less than for the TP group. The TP protocol participants may have found it more difficult to arrange travel and/or work commitments to accommodate three sessions per week into their schedule. Also the thought of attending three on-site exercise sessions per week for 3 months may have been overwhelming to those TP patients who discontinued participation. In contrast, MP patients were told by Week 4 that they would be reduced to two sessions per week in Week 6, and by Week 11 they could be decreased to one on-site session per week. Finally, the heart health forum meetings may have influenced MP patients' participation. It is possible that the education, consistent reinforcement of exercise goals, peer support, and the rapport with the group facilitators may have positively influenced the patients' commitment to follow their suggested protocol.

Self-efficacy Levels toward Independent Exercise

Hypothesis 3. Hypothesis 3 stated that among all patients, self-efficacy toward a PEP will exhibit positive correlations with overall and off-site exercise compliance. To evaluate this, Pearson Correlations were conducted.

The relationship between self-efficacy and a PEP, and self-efficacy and overall exercise were evaluated based on two self-efficacy questions (see Appendix D, questions 30 and 33). The first self-efficacy question stated: "What is your level of confidence regarding following a PEP three sessions per week?" The second self-efficacy question had patients rate their confidence in the number of days that they felt they could complete a PEP on their own (without cardiac rehabilitation) over the next 3 months. The correlations are listed in Table 9 and reveal that both questions significantly correlated with the PEP and overall exercise behavior during the three time increments. The only time increment where a significant correlation was not shown occurred when the two self-efficacy questions were asked at 1.5 months, which did not significantly correlate with PEP and overall exercise behavior during Weeks 7-12. The strongest correlations for both self-efficacy questions were revealed when relating self-efficacy to exercise behavior over the final 3 months.

The correlations found with PEP self-efficacy and PEP and overall exercise behavior provide support for Hypothesis 4. In general, these results are similar to other findings in the exercise adherence literature showing a correlation with exercise self-efficacy and exercise behavior. However, it is important to distinguish between the studies which involved healthy populations and those which involved patients with chronic disease, given their potential differences in motivation and perception of barriers (Harlan et al., 1995). Also, caution needs to be taken when comparing these results with other

Table 9: Correlations of Exercise Self-efficacy to PEP and Overall Exercise Behavior[1]

Variables	Initial SE Exercise Weeks 1-6	1.5-month SE Exercise Weeks 7-12	3-month SE Exercise Weeks 13-26	3-month SE Exercise total Weeks 1-26
		PEP Exercise Behavior		
3 day PEP Self-efficacy	.26 *	.36 **	.45 **	.48 **
Total PEP Frequency SE	.40 **	.20	.47 **	.54 **
		Overall Exercise Behavior		
3 day PEP Self-efficacy	.25 *	.27 *	.45 **	.45 **
Total PEP Frequency SE	.36 **	.12	.47 **	.51 **

* $p < .05$, ** $p < .01$

[1]Note: Initial and 1.5-month scores are based on $n = 68$ for both questions; 3-month scores were based on $n = 66$ for the 3-day PEP self-efficacy question, and $n = 65$ for total PEP frequency self-efficacy question.

studies. The self-efficacy questions used in this study were specifically developed to have relevance to the patients and to the independent interventions employed. Additionally, the majority of self-efficacy studies conducted specifically on CR patients focus on facility-based exercise sessions, not self-efficacy levels toward off-site PEP sessions, as was done to evaluate this hypothesis (Corneaya & McAuley, 1994; Lemanski, 1990).

Hypotheses 4 (a) and (b). Hypothesis 4 stated that compared to the TP participants, participant confidence while exercising without continuous ECG monitoring will improve more in the MP participants: (a) from baseline (zero weeks) to 6 weeks, and (b) from baseline to 3-months. To examine these hypotheses, two questions were used which evaluated patient confidence while exercising without the ECG monitor, both in and out of the rehabilitation facility (see Appendix D, questions 24 and 25). A 2x2 repeated measures ANOVA was conducted for each question with protocol as between-groups measurement and time (baseline to 1.5 months, and baseline to 3 months). Table 10 summarizes the mean scores by protocol for the three measurement periods.

Hypothesis 4 (a). As compared to the TP participants, the MP participants were expected to demonstrate greater change in confidence while exercising without the CECGM at the 1.5-month evaluation. The basis for this hypothesis was that a week before the MP participants were given their 1.5-month questionnaire, they were weaned from their CECGM and given reinforcement that it was safe to exercise without the CECGM. In contrast, the TP participants were required to use the CECGM for on-site exercise sessions. The analysis of patient confidence from baseline to 1.5 months found no support for Hypothesis 4(a), given that it showed no significant main effects while exercising without CECGM both out of the supervised program, $F(1, 62) = .76$, $p = .386$, and while exercising in the facility, $F(1, 61) = 1.11$ $p = .297$. A major effect for time was shown for confidence improving from baseline to 1.5 months only when exercising without CECGM

Table 10: Mean Patient (± SD) Confidence Scores While Exercising Without CECGM On-Site and Off-Site

	Confidence Exercising On-Site		
Protocol & Sample Size	Baseline score	1.5-month score	3-month score
Traditional Protocol n = 33	3.10±1.3	4.06±.76	4.00±.76
Modified Protocol n n = 32	3.44±1.1	4.28±.89	4.41±.94
	Confidence Exercising Off-Site		
	Baseline score	1.5-month score	3-month score
Traditional Protocol n = 33	3.59±1.1	4.09±.82	4.00±1.0
Modified Protocol n = 32	3.87±.90	4.13±.98	4.41±.98

out of the facility, $F(1, 62) = 6.45$, $p = .014$. No statistically significant interaction was revealed for either question.

Hypothesis 4(b). Support was found for Hypothesis 4(b) given the baseline to 3-month ANOVA revealed a significance between protocol difference in patient confidence while exercising without CECGM, both out of the facility, $F(1, 62) = 5.15$, $p =.027$, and in the facility, $F(1, 61) = 4.5$, $p = .038$. The MP had higher confidence levels than the TP for both settings. A significant time effect was also revealed while exercising out of the facility without CECGM, $F(1, 62) = 7.66$, $p < .007$, and in the facility, $F(1, 61) = 28.14$, $p < .001$. Observation of the mean scores reveals that they progressively increased in the MP group from baseline to 1.5 months and from 1.5 months to 3 months, while in the TP group confidence levels essentially remained unchanged from 1.5 to 3 months. No statistically significant interaction was revealed for either question.

The lower confidence levels found at 3 months among the TP may have been influenced by the differences in the independent interventions. The TP participants were required to have CECGM while exercising on-site for the first 3 months. This may have made them feel a medical need to be using the monitor, thus making them feel less comfortable exercising without CECGM. In contrast, the MP participants were weaned off the CECGM in the fifth week and given a Polar™ heart rate monitor that they could use while exercising both on-site and off-site. Additionally, in the sixth week they were told that they only need to come to on-site exercise sessions two times per week. The combination of being told that they no longer needed CECGM while also being encouraged to focus on their PEP may have improved the MP participants' self-efficacy while exercising without CECGM. Additionally, based on the theory of self-efficacy (Bandura, 1977), higher confidence levels at 3 months in the MP group may have contributed to their superior PEP and overall exercise behavior during the final 3 months of the evaluation period. On the other hand, even though the scores from baseline to 3 months were statistically significant in favor of the MP, it could be argued that the scores may not be clinically important in influencing exercise behavior. The basis for this is exemplified when applying the mean scores to the actual questionnaire. For example, does the 3-month TP participants' mean score of 4.0, which equates with "comfortable" while exercising in and out of the facility without CECGM, differ from the MP mean 3-month score of 4.41 (5 is "very comfortable") in relation to affecting exercise behavior?

To determine the practical clinical relevance of these differences, post-hoc analyses were conducted. Frequency of responses were evaluated at the 3-month evaluation between the two protocols. The frequencies revealed that the percentage of MP participants selecting 5 ("very comfortable") while exercising without CECGM in and out of the facility was significantly higher in the MP group for both conditions. Specifically, while exercising *in* the facility without CECGM, 56% of the MP participants (18 of 32) answered "very comfortable," while only 30% (10 of 33) of the TP patients answered "very comfortable." When addressing the patient comfort levels without CECGM while exercising *out* of the facility, 63% (20 of 32) of MP answered "very comfortable" while only 33% (11 of 33) of the TP patients answered "very comfortable." Additionally, a post-hoc analysis was conducted to evaluate how the responses to these questions correlated with exercise behavior during the final 3 months of the program. The analysis revealed that the confidence at 3 months toward exercising in and out of the facility without CECGM significantly correlated with PEP behavior during weeks 13-26 ($p < .01$). The post-hoc analyses provide at least partial support for the clinical relevance of the significantly higher confidence levels in the MP group and may explain its higher exercise frequency during the final 3-months of the evaluation.

In summary, no support was found for Hypothesis 4(a), given that the baseline to 1.5 month ANOVA showed no statistical differences between the two protocols. Hypothesis 4(b) was supported, given that the baseline to 3-month ANOVA revealed a significant between-protocol effect on patient confidence while exercising without CECGM favored the MP. From the perspective of establishing long-term exercise behavior, it is noteworthy that the patient 3-month confidence level was higher than the 1.5-month confidence level.

Hypothesis 5. Hypothesis 5 stated that compared to the TP participants, the MP participants will exhibit greater levels of self-efficacy related to a PEP at 3-month and 6-month evaluations. To evaluate this, 2x3 (protocol x time) ANOVAs were conducted on each of six questions addressing self-efficacy to a PEP. The questions are listed in Appendix D (see questions 29, 30, 32, 33, 35, and 36).

The summary of the ANOVAs are included in Table 11. The sample size, means, and standard deviations on each question by protocol are summarized in Table 12. No statistically significant main group effects or interactions were revealed for any of the self-efficacy questions evaluated, thus no support was found for Hypothesis 5.

The ANOVAs did indicate time effects in four of the six questions which included: self-efficacy of doing daily and leisure activities, self-efficacy in physical condition, self-efficacy to exercise frequency, and self-efficacy toward exercise duration. The questions evaluating self-efficacy toward PEP frequency, and self-efficacy toward exercise intensity did not exhibit statistically significant time effects. Individual post-hoc analyses on the four questions which exhibited significant time effects are described following Table 11 and Table 12. Post-hoc analysis, based on significant time effects, assessed changes in the four questions which addressed patient confidence toward (a) performing daily and leisure activities, (b) their perception of their physical condition, (c) exercise duration, and (d) frequency of total exercise. A summary of mean scores on the confidence scales and their possible implications are presented below.

Table 11: ANOVA Summary Comparing TP and MP Self-efficacy Level to Exercise Completed at Baseline, 3 Months and 6 Months

Self-Efficacy (SE) Questions	df	F	p
Daily & Leisure Activities SE			
Protocol	1, 52	1.89	.18
Time	2, 104	9.65	.001**
Interaction	2, 104	.67	.513
Physical Condition SE			
Protocol	1, 51	.41	.53
Time	2, 102	22.44	.001**
Interaction	2, 102	.07	.93
Total Exercise Frequency SE			
Protocol	1, 50	.65	.43
Time	2, 100	5.78	.004**
Interaction	2, 100	.16	.85
PEP Frequency SE			
Protocol	1, 50	.87	.36
Time	2, 100	.47	.63
Interaction	2, 100	.34	.72
Exercise Intensity SE			
Protocol	1, 51	1.25	.27
Time	2, 102	2.19	.12
Interaction	2, 102	1.11	.34
Exercise Duration SE			
Protocol	1, 49	.77	.39
Time	2, 98	4.21	.02*
Interaction	2, 98	.38	.69

* $p \leq .05$, ** $p \leq .005$

Table 12: TP and MP Mean Scores (± SD) On Self-efficacy Questions Related to Exercise

Self-efficacy Question Protocol/ Sample size	Baseline	3-month	6-month
Daily & Leisure Activities SE			
TP / 24	3.43±99	4.09±67	4.00±1.17
MP / 31	3.81±98	4.16±98	4.32±.70
Physical Condition SE			
TP / 24	3.17±1.03	3.65±.83	3.83±.78
MP / 30	3.30±.92	3.83±.83	3.93±.91
Total Exercise Frequency SE			
TP / 24	559±136	505±167	509±134
MP / 28	534±104	490±138	475±115
PEP Frequency SE			
TP / 24	507±145	502±171	503±125
MP / 28	492±126	482±134	456±125
Exercise Intensity SE			
TP / 23	12.74±1.10	12.74±1.01	13.09±1.62
MP / 30	12.63±1.03	13.07±1.17	14.83±1.78
Exercise Duration SE			
TP / 24	2.68±.95	2.91±1.06	3.05±1.00
MP / 30	2.79±.94	3.24±1.02	3.17±.80

Viewing the responses on self-efficacy levels toward performing daily and leisure activities in relation to the specific question scale, the baseline scores of both groups were between "slightly agree" and "agree." At 6, months both groups' mean scores increased to "agree" or slightly above "agree." Similarly, the participants' self-efficacy levels toward their physical condition revealed that the baseline scores of both groups were closest to "slightly agree." At 6 months, both groups' mean scores approached "agree," revealing that participants in both protocols felt more confident about their physical condition.

Based on the findings of these two questions, it is possible that these specific confidence improvements may support increased future overall activity levels in these patients, based on the self-efficacy theory (Bandura, 1977). Specifically, self-efficacy and physical activity work by Allen et al. (1990) revealed that self-efficacy expectancy levels in post-CABG patients predicted activities of daily living and physical, social, and leisure functional status at one month and 6 months after surgery. Similarly, Ewart et al. (1986) demonstrated that patients' perceptions to perform specific physical activities (i.e., walking, stair climbing) were predictive of future exercise behaviors.

Viewing the responses on self-efficacy levels toward exercise duration reveals that at baseline, both protocols were confident toward conducting aerobic exercise between the 30 and 45 mins. At 6 months, mean scores indicated that participants in both protocols were confident toward exercising for 45 mins, as they improved their confidence regarding how long they could do aerobic exercise. Self-efficacy and exercise research conducted by Ewart et al. (1983) examined the effect of self-efficacy on compliance with exercise regimens in men with clinically uncomplicated myocardial infarction (MI). It was demonstrated that self-efficacy expectation scores following treadmill exercise testing predicted both the duration and the intensity of subsequent treadmill exercise tests and off-site exercise. The higher the participants' perceived physical efficacy, the greater the self-reported duration and intensity of home exercise. While the self-efficacy questions used in this study were not used by Ewart et al. (1983), the present findings also provide support that confidence toward exercise duration can lead to future exercise performance.

The question which addressed the patients' confidence toward overall exercise frequency (combination of on-site and PEP) exhibited significant decreases in both protocols. When viewing the specific question scale, both groups' baseline scores indicated that they were confident of completing 5.6 (TP) and 5.3 (MP) days per week. At 3 months, the self-efficacy scores decreased to 5.1 days per week in the TP and 4.9 in the MP. The 6-month scores essentially remained the same in the TP; however, in the MP, the confidence toward exercising dropped to 4.7 days per week. Based on this, both groups appeared to have inflated initial levels of confidence toward the number of days per week they would exercise. Interestingly, when viewing these self-efficacy levels towards total exercise in relation to total exercise frequency data (Tables 6 and 7), they appear to show a similar trend. Exercise frequency in both groups tended to decrease over time, thus providing support for the role of self-efficacy toward exercise frequency in predicting actual exercise frequency. However, these results should be interpreted with caution, given that the sample size for the exercise frequency data and the self-efficacy questionnaires are different.

In summary, Hypothesis 5 was not supported, given that no significant main effects or interactions were found between the groups for any of the six self-efficacy questions related to exercise. Four of the self-efficacy questions showed significant time effects. The post-hoc analysis of these questions indicated that three of the four questions showed improvements (SE toward leisure and daily activities, self-efficacy toward physical condition, and self-efficacy toward exercise duration). The question of self-efficacy toward total exercise frequency showed that both protocols scores decreased, suggesting that both groups may have been overly confident upon starting their outpatient cardiac rehabilitation program.

Outcome Expectancy toward Exercise

Hypothesis 6. Hypothesis 6 stated that among all patients, outcome expectancy toward exercise will exhibit positive correlations with overall and off-site exercise PEP compliance. This was based on question 26 (Appendix D) which asked: "If you follow the exercise program suggested by the cardiac rehabilitation staff, what is your level of confidence it will play a role in improving and maintaining your health status?" The correlations revealed one significant relationship between the initial outcome expectancy level and baseline to 1.5 month behaviors. A summary of the correlations are included in Table 13. No other significant correlations were found with PEP and overall exercise behavior over the 6-month period.

In summary, no substantial support for Hypothesis 6 was found, given that only one of four time increments showed a significant correlation of outcome expectancy with PEP and overall exercise behavior. It is worth noting that the majority of outcome expectancy and exercise studies have been conducted in individuals without documented CVD. These studies have shown that outcome expectancy is not as good a predictor for exercise behavior as is self-efficacy (Desharnais et al., 1986). Thus, the findings in this study are similar to previous studies with non-cardiac patients examining the relationship of outcome expectancy and exercise. However, given the limited research available on cardiac patients, generalizations should not be made about the relationship of outcome expectancy to exercise behavior until additional studies are conducted using the same or similar assessment tools.

Hypothesis 7. Hypothesis 7 stated that compared to the TP participants, the MP participants will exhibit higher levels of outcome expectancy toward exercise at the 3-month and 6-month evaluations. Hypothesis 7 was evaluated using a 2x3 ANOVA (protocol x time) and was based on one question which had patients rate their confidence on the role of the exercise program suggested by the rehabilitation staff in improving and maintaining their health (see Appendix D, question 26). Table 14 summarizes the mean scores by each protocol.

Table 13: Outcome Expectancy Correlations with PEP Behavior and Overall Exercise Behavior

Variables	Initial OE Exercise Weeks 1-6	1.5-month OE Exercise Weeks 7-12	3-month OE Exercise Weeks 13-26	6-month OE Exercise total Weeks 1-26
		PEP Exercise Behavior		
OE of Exercise	.28 *	.18	.12	.10
		Overall Exercise Behavior		
OE of Exercise	.27 *	.19	.14	.08

* = significance LE .05 (2-tailed)

Table 14: TP and MP Mean (+/- SD) Outcome Expectancy (OE) Scores to Exercise

	Baseline	3 Month	6 Month
Traditional Protocol	8.63±1.0	8.54±1.2	8.58±1.0
Modified Protocol	8.71±0.9	8.68±1.3	8.58±1.2

No support was found for Hypothesis 7, given that no statistically significant differences were observed: main effect $F(1, 53) = .07$, $p = .787$; time effect $F(2, 106) = .20$, $p = .819$; or interaction $(2, 106) = .83$, $p = .879$. The scores at the three time periods measured were essentially unchanged. At baseline and during subsequent evaluations, patients in both protocols exhibited high levels of outcome expectancy toward exercise. Based on the 11 increment question (0 = no confidence and 10 = complete confidence), both protocols rated their outcome expectancy toward exercise between good confidence (a score of 8) and complete confidence (a score of 10) throughout the 6-month period. Given that the baseline scores were near the top end of the measurement scale, the likelihood of scores improving is less likely than if the groups had lower initial scores.

In summary, no support for Hypothesis 7 was found given that there were no between-group differences in outcome expectancy. From a practical perspective, both groups of patients entered the program with a good outcome expectancy toward the role of exercise in maintaining and improving health. This high level of outcome expectancy was maintained throughout the program.

Outcomes Associated with Cardiovascular Health (Hypotheses 8 and 9)

Overview, Hypothesis 8 and 9. Both hypotheses address outcomes associated with CV health. Hypothesis 8 involves the baseline to 3-month outcomes between the protocols, and Hypothesis 9 addresses the baseline to 6-month outcomes between the protocols. The CV measures used to evaluate the protocols performance were selected based on a well-established body of research identifying risk factors associated with CV health commonly evaluated in clinical research (Balady et al., 1994). Ten measures associated with CV health are evaluated in both hypotheses. Hypothesis 9 also includes an evaluation of five blood lipid parameters.

To answer Hypotheses 8 and 9, it was necessary to determine the between-group differences. The initial intention was to conduct MANOVAs on the self-efficacy variables.

Due to missing data, individual 2x2 repeated measures ANOVAs were conducted on all dependent variables to determine if either protocol created significantly different results. Before presenting the ANOVA results, a summary of the data is presented to give background on the variables and to illustrate if the individual protocols' outcomes showed improvements. Percent improvements in outcomes for each protocol are presented individually. To specifically answer Hypotheses 8 and 9, the results of the 2x2 ANOVAs (protocol x time) are presented to illustrate if the changes in the groups are statistically different.

Hypothesis 8 stated that improvements in measures associated with CV health from baseline to 3 months will not be significantly different between the MP and TP comparison groups. It was expected that the improvements in the groups would be similar at 3 months. This was based on previous research indicating that both compliance and CV improvements in CR programs during the first 3 months are reasonably good. Seventy to 80% of patients who initiate traditional CR typically complete the first 3-months and typically show significant improvements in functional capacity and measures associated with CV health (Balady et al., 1994; Daltroy, 1985; Oldridge, 1991). Even though the MP patients were offered significantly fewer on-site sessions than the TP patients, it was expected that the MP intervention would also produce significant improvements from baseline to 3-months. It was believed the techniques used in the MP to facilitate increased self-efficacy and support to an off-site PEP regimen would facilitate the exercise behaviors needed to produce similar CV improvements.

The mean outcome scores with standard deviations from baseline to 3 months and the percent change in the individual protocols are included in Table 15. The only variables

Table 15: TP and MP Baseline and 3-Month CV Measures, Means, and Standard Deviations[1]

CV Physiological Variables	Protocol/N	Baseline	3-month	% Change[1]
Weight (pounds)	TP/31	189.9±30.1	186.1±30.2	-2.0
	MP/33	196.1±44.8	192.6±43.4	-1.8
Body Mass Index	TP/31	28.3±3.4	27.7±3.5	-2.0
(wt. kgs/ht. meters^2)	MP/33	28.3±4.9	27.7±4.7	-1.
Functional Capacity (METs)	TP/30	6.1±1.5	6.5±1.8	6.6
	MP/33	6.8±1.6	7.2±1.5	5.9
Anaerobic threshold	TP/26	4.4±1.0	4.6±1.3	4.5
(METs)	MP/29	4.9±1.0	5.3±0.8	8.2
Resting Heart rate	TP/31	76.5±24.4	71.4±13.2	-6.7
(beats/minute)	MP/35	73.7±16.6	69.7±13.0	-5.4
Resting Systolic BP	TP/31	138.7±17.7	130.8±13.4	-5.7
(mm Hg)	MP/35	123.6±17.7	127.9±17.9	3.4
Resting Diastolic BP	TP/31	84.1±7.5	81.8±7.8	-2.3
(mm Hg)	MP/35	79.5±8.7	80.7±9.3	1.5
Sub-maximal RPP	TP/23	158.6±55.5	149.7±48.2	-5.6
(beats/minute x mm Hg x 10^{-2})	MP/29	173.7±55.4	161.3±46.4	-7.1
Stress Level	TP/32	2.5±1.3	2.3±1.3	-8.0
	MP/32	2.5±0.9	2.5±1.0	0.0
Despair/Hostility Frequency	TP/32	1.6±0.9	1.4+1.0	-12.5
	MP/32	1.6±0.6	1.4+0.7	-12.5

[1] Percent change refers to within group baseline to 3-month change

not showing a trend toward improvement in the individual protocols were resting systolic and diastolic blood pressures and stress levels in the MP. Among both protocols, baseline measures evaluating levels of stress indicated that these were between "very low" and "low." The frequency of situations which created feelings of despair or hostility were between "very seldom" and "sometimes"; thus, the likelihood of reporting significant improvements in these measures was low. Most of the other variables appeared to demonstrate similar relative improvements from baseline to 3-months according to the percent changes.

To answer Hypothesis 8, the 2x2 ANOVAs were conducted to determine if the changes in the two groups were statistically different (Table 16). The analysis provided support for Hypothesis 8, given the lack of significant differences between the two groups. Only 2 of 10 dependent measures (one in each protocol) revealed a significant main effect; anaerobic threshold ($p = .027$) in favor of the MP, and resting systolic blood pressure ($p = .008$) in favor of the TP. The resting systolic blood pressure also exhibited the only significant interaction ($p = .018$). Six of 10 measures showed significant time effects [body weight and BMI ($p < .000$), functional capacity ($p =. 001$), anaerobic threshold ($p = .001$), heart rate ($p = .026$), and submaximal rate pressure product ($p = .043$)], suggesting that when combined, participants in both protocols had significant improvements in these variables.

The main effect and interaction found in the analysis of resting systolic blood pressure was due to the combined effect of a reduction in blood pressure in the TP and a slight increase in resting systolic blood pressure in the MP (Table 15). It is noteworthy that the resting systolic blood pressure was the only physiological variable at baseline which was found to be significantly different between the protocols. Because the TP baseline resting systolic blood pressure was significantly higher (139 mm Hg) than that in the MP (124 mm Hg), the likelihood for the TP resting systolic blood pressure decreasing was

Table 16: ANOVA Summary Comparing Baseline and 3-Month Outcomes Associated with CV Health

Variables	df	F	p
Body Weight			
Protocol Effect	1, 64	.46	.500
Time Effect	1, 64	21.91	.000**
Protocol x Time	1, 64	.02	.897
Body Mass Index			
Protocol Effect	1, 62	.00	.985
Time Effect	1, 62	21.68	.000**
Protocol x Time	1, 62	.01	.950
Peak MET Capacity			
Protocol Effect	1, 61	3.45	.068
Time Effect	1, 61	11.94	.001**
Protocol x Time	1, 61	.03	.855
Anaerobic Threshold (MET)			
Protocol Effect	1, 53	5.17	.027*
Time Effect	1, 53	11.73	.001**
Protocol x Time	1, 53	.82	.369
Resting Heart Rate			
Protocol Effect	1, 64	.37	.547
Time Effect	1, 64	5.18	.026*
Protocol x Time	1, 64	.09	.761
Resting Diastolic BP			
Protocol Effect	1, 64	2.58	.113
Time Effect	1, 64	.27	.606
Protocol x Time	1, 64	2.64	.109
Resting Systolic BP			
Protocol Effect	1, 64	7.41	.008**
Time Effect	1, 64	.53	.471
Protocol x Time	1, 64	5.90	.018*
Submaximal RPP			
Protocol Effect	1, 50	.78	.382
Time Effect	1, 50	4.32	.043*
Protocol x Time	1, 50	.01	.935
Stress Levels			
Protocol Effect	1, 62	.19	.667
Time Effect	1, 62	1.58	.214
Protocol x Time	1, 62	.64	.427
Despair/Hostility Frequency			
Protocol Effect	1, 62	.03	.868
Time Effect	1, 62	3.19	.079
Protocol x Time	1, 62	.13	.722

* $p \leq .05$, ** $p \leq .01$

greater. The superior increase in anaerobic threshold found in the MP could be due to several factors, including differences in the level of exercise intensity, the overall level of activity performed, and differences in compliance and participation rates or a combination of thereof.

In summary, Hypothesis 8 was accepted due to the lack of significant differences between the protocols based on 2x2 ANOVAs of 10 dependent variables. Only one variable in each protocol showed a main effect or interaction. Resting systolic blood pressure showed a significant between-group change for the TP, and anaerobic threshold exhibited a significant main effect in favor of the MP which provides support for a superior training effect in MP participants. Overall, both protocols appeared to be effective in promoting CV outcomes during the first 3 months, as supported by significant time effects showing improvements in their weight, BMI, functional capacity, anaerobic threshold, resting heart rate, and submaximal rate pressure product. Resting diastolic blood pressure and the frequency of despair or hostility remained unchanged in both groups. Stress levels also did not change in the MP but exhibited small change in the TP (2.5 to 2.3).

Hypothesis 9 stated the improvements in measures associated with CV health from baseline to 6-months will be greater in the MP than in the TP. The basis for this hypothesis was the high rates of noncompliance (up to 50% by 6 months) which typically occur between 3 and 6 months among patients following the TP for CR (Balady et al., 1994; Daltroy, 1985; Oldridge, 1991). Even though the MP offered significantly fewer on-site exercise sessions, it was expected that a larger percentage of the MP patients would conduct more PEP sessions and overall exercise, which would promote superior outcomes compared to the TP.

To answer Hypothesis 9, the identical analysis procedures were used as in answering Hypothesis 8. For background, a summary of the mean data, standard deviations are presented, as well as a summary of the within-group percent change for each variable to illustrate if improvements had occurred. To answer the hypothesis, the between-group differences based on the 2x2 ANOVA are presented. In addition to the 10 variables measured in Hypothesis 8, five lipid variables are included.

The mean outcome scores with standard deviations, and the percent change in the individual protocols, are included in Table 17(a) (10 CV measures) and Table 17(b) (5 lipid measures). The only variables not showing a trend toward improvement in the individual protocols included: (a) resting systolic and diastolic blood pressure and (b) despair/hostility levels in the TP. In the TP the change in resting systolic blood pressure was less than 1%, and the change in weight, BMI and resting blood pressure was less than 2%. In the MP both blood pressure variables increased slightly. As mentioned in Hypothesis 8, among both protocols the baseline measures evaluating levels of stress and the frequency of feelings of despair were low; thus, the likelihood of realizing significant improvements in these measures was low.

The baseline and 3-month lipid values based on percent change indicate all variables improved in both protocols. The MP exhibited higher levels of percent change in all lipid variables, with the exception of the improvement in HDL, which was 2% higher in the TP.

To answer Hypothesis 9, the 2x2 ANOVAs were conducted to determine if the changes in the two groups were statistically different. The results of the ANOVAs conducted on the CV outcome measures and blood lipid measures are included in Table 18(a) and 18(b), respectively. The analysis did not support Hypothesis 9 due to the lack of significant differences found between the two groups. Only 1 of 15 dependent measures revealed a significant main effect—the resting systolic blood pressure ($p = .008$) is in favor of the TP. However, the main effect shown was not a result of an improvement, but rather was due to the significant difference from baseline, which did not change significantly at 6 months as illustrated in Table 17(a). Ten of 15 measures (five of the CV outcome measures, and all five lipid measures) showed significant time effects revealing overall

Table 17(a): TP and MP Baseline and 6-Month CV Measures, Means, and Standard Deviations[1]

CV Outcome Variables	Protocol/N	Baseline	6-Month	% change[1]
Weight (pounds)	TP/32	192.2±27.7	188.8±30.1	-1.8
	MP/35	193.2±44.8	189.0±45.5	-2.2
Body mass index	TP/32	28.4±3.0	27.9±3.6	-1.8
(wt. kgs/ht. meters^2)	MP/35	28.1±4.9	27.5±4.8	-2.2
Functional Capacity (METs)	TP/29	6.4 ±1.7	6.8±1.7	6.3
	MP/34	6.9 ±1.6	7.4±1.5	7.2
Anaerobic threshold (METs)	TP/25	4.6±1.1	4.7±1.3	2.2
	MP/31	4.9±1.0	5.3±1.1	8.2
Resting Heart rate	TP/32	76.6±23.1	68.0±12.1	-11.0
(beats/minute)	MP/35	73.5±16.5	68.5±12.6	-6.8
Resting Systolic BP	TP/32	136.9±17.2	137.4±16.4	0.3
(mm Hg)	MP/35	123.0±18.1	124.9±17.8	1.5
Resting Diastolic BP	TP/32	83.4±6.7	82.3±8.4	-1.1
(mm Hg)	MP/35	79.3±8.7	81.4±9.9	2.6
Sub-maximal RPP (beats/minute	TP/26	169.1±51.1	146.3±39.1	-13.4
x mm Hg x 10^{-2})	MP/29	173.7±57.4	153.1±45.6	-11.9
Stress Level	TP/27	2.5±1.3	2.3±1.3	-8.0
	MP/32	2.5±0.9	2.4±1.0	-4.0
Despair/Hostility Frequency	TP/27	1.7 ±0.9	1.7±1.0	0.0
	MP/32	1.5 ±0.6	1.3 ±0.7	-13.3

[1] Percent change refers to within group baseline to 3 month change

Note: The changes in resting systolic and diastolic blood pressure in the MP are increases.

Table 17(b): Blood Lipids Values: TP and MP Baseline and 6-Month Means and Standard Deviations[1]

	Protocol/n	Baseline	6-Month	% Change[1]
Total Cholesterol	TP/28	190.7±36.8	181.1±32.0	-5.0
(mg/dl)	MP/34	200.8±40.9	179.7±29.9.	-10.5
Low Density	TP/27	123.3±33.2	111.± 23.3	-9.3
Lipoprotein (mg/dl)	MP/30	132.4±38.6	114.5±26.1	-13.5
High Density	TP/28	35.0±9.4	38.0±10.1	8.6
Lipoprotein (mg/dl)	MP/32	35.2±9.1	37.5±7.7	6.5
Triglycerides (mg/dl)	TP/27	162.2±75.2	144.2±67.1	-18.0
	MP/34	179.9±115	140.2±76.0	-22.1
Total Cholesterol:HDL	TP/28	5.6±1.2	5.0±1.3	-10.7
	MP/34	6.0±1.8	5.0±1.5	-16.7

[1] Percent change refers to within group baseline to 6-month changes

Table 18(a): ANOVA Summary Comparing Baseline and 6-Month Variables Associated with CV Health

Variables	df	F	p
Body Weight			
Protocol Effect	1, 65	.00	.948
Time Effect	1, 65	10.10	.002**
Protocol x Time	1, 65	.11	.740
Body mass index			
Protocol Effect	1, 65	.14	.711
Time Effect	1, 65	10.58	.002**
Protocol x Time	1, 65	.11	.738
Functional Capacity in (METs)			
Protocol Effect	1, 61	3.29	.075
Time Effect	1, 61	4.36	.041*
Protocol x Time	1, 61	.38	.541
Anaerobic Threshold (METs)			
Protocol Effect	1, 54	2.60	.113
Time Effect	1, 54	2.65	.110
Protocol x Time	1, 54	.72	.401
Resting Heart Rate (Beats/min)			
Protocol Effect	1, 65	.13	.721
Time Effect	1, 65	10.93	.002**
Protocol x Time	1, 65	.78	.379
Resting Diastolic BP (mm Hg)			
Protocol Effect	1, 65	2.22	.141
Time Effect	1, 65	.15	.702
Protocol x Time	1, 65	1.87	.176
Resting Systolic BP (mm Hg)			
Protocol Effect	1, 65	2.58	.000**
Time Effect	1, 65	.26	.611
Protocol x Time	1, 65	.08	.780
Submaximal RPP			
Protocol Effect	1, 53	.22	.642
Time Effect	1, 53	19.57	.000**
Protocol x Time	1, 53	.05	.820
Stress Levels			
Protocol Effect	1, 62	.00	.979
Time Effect	1, 62	.24	.623
Protocol x Time	1, 62	.00	.967
Despair/Hostility Frequency			
Protocol Effect	1, 57	.03	.139
Time Effect	1, 57	1.52	.223
Protocol x Time	1, 57	2.75	.102

* $p \leq .05$, ** $p \leq .01$

Table 18(b): ANOVA Summary Comparing TP and MP Baseline and 6-Month Blood Lipids

Variables	df	F	p
Total Cholesterol	1, 60	.30	.583
Protocol Effect	1, 60	12.48	.001**
Time Effect	1, 60	1.73	.194
Protocol x Time			
Low Density Lipoprotein			
Protocol Effect	1, 55	.71	.403
Time Effect	1, 55	11.69	.001**
Protocol x Time	1, 55	.55	.461
High Density Lipoprotein			
Protocol Effect	1, 58	.00	.945
Time Effect	1, 58	15.36	.000**
Protocol x Time	1, 58	.21	.647
Triglycerides			
Protocol Effect	1, 59	.13	.724
Time Effect	1, 59	6.71	.012*
Protocol x Time	1, 59	.95	.334
Total Cholesterol:HDL			
Protocol Effect	1, 58	.32	.574
Time Effect	1, 58	24.50	.000**
Protocol x Time	1, 58	.90	.346

* $p \leq .05$, ** $p \leq .01$

improvements by the participants in the following measures: body weight and BMI (p = .002), peak MET capacity (p = .041), resting heart rate (p = .002), and submaximal rate pressure product (p < .0001), total cholesterol (p = .001), LDL (p = .001), triglycerides (p = .012), HDL (p < .0001) and total cholesterol/HDL (p < .0001).

In summary, the analysis did not support Hypothesis 9, given the lack of significant differences found between the two groups based on the 2x2 ANOVAs. The single main effect found in resting systolic blood pressure was not related to an improvement, but rather to a significantly higher baseline blood pressure which remained elevated at the 6-month evaluation. The significant time effects found in 10 of 15 measures (five of the CV measures and five lipid measures) suggests that both protocols promoted significant improvements in CV health in the following measures: body weight and BMI, functional capacity, resting heart rate, submaximal rate pressure product, total cholesterol, low density lipoprotein, high density lipoprotein, triglycerides, and the total cholesterol to high density lipoprotein ratio. Because both protocols appeared to elicit improvements in the majority of the parameters it was less likely for between-group differences to occur.

Discussion Related to Hypotheses 8 and 9

In evaluating these data from an overall programmatic effectiveness perspective, it is important to note that these CV outcome data reflect only patients in matched pairs at baseline to 3 months and from baseline to 6 months. Obviously, these data do not include those patients who failed to return for their evaluations, so the overall impact of each of these protocols in relation to protocol effectiveness should not be based only on the CV outcomes presented here. It was revealed in Hypotheses 2 that significantly more patients dropped out of the TP compared to the MP. Among both protocols, it is very probable that patients not returning for their follow-up testing were the patients who were less compliant, both on and off-site exercise.

Weight and BMI. The mean change in both groups indicated a significant weight loss. However, the loss in each group averaged only about four pounds. Gauging success on weight loss assumes that everyone in the study needed to lose weight. This assumption is not correct for all patients in this study. An increased risk for CVD has been associated with BMIs of 25 or greater. From observing the patients' mean scores and standard deviations and the original raw data, it is clear that some patients had BMIs which were at 25 or less. The patients with BMIs below 25 potentially could benefit from weight gain. It was noted that several patients from both protocols included weight gain as a goal. Therefore, in the future, to properly evaluate weight loss as a benefit, only those patients who exhibited BMIs of 25 or greater should be used in the weight loss analysis. In contrast, among those patients with a BMI of 25 or less, it is more appropriate to evaluate their success based on weight gain or weight stabilization. This method of analysis would be more valid and would show significantly greater reductions in weight loss in the two protocols.

Functional capacity related measures. Compared to other studies evaluating CR, the MET capacity changes based on measured peak $\dot{V}O_2$ translated in this study were lower than commonly reported in the literature. After 3 to 6 months of exercise training, increases in maximal $\dot{V}O_2$ reported in post-myocardial infarction patients ranges from 11% to 56%, and among post-bypass patients the range is typically 14%-66% (Balady et al., 1994; Thompson, 1988). In this study, we found only a 6.5% and 6% increase in peak VO_2 by the TP and MP groups, respectively, at 3 months. The 6-month peak $\dot{V}O_2$ revealed that patients maintained or had slight increases in their peak $\dot{V}O_2$ during the final 3 months of the study. Possible explanations why the MET capacities reported in this study were significantly lower than usually reported include the delay in conducting the baseline GXTs. Also, it may be due to the high baseline functional capacity in these study patients, or the fact that past studies often reported on predicted functional capacities, which typically overestimate functional capacity. Lastly, the previously reported improvements are predominantly based on efficacy trials, not effectiveness trials. Each of these points is addressed below in more detail.

The mean baseline MET capacity of participants in this study exceeded 6 METs in both groups, which classifies them as low-risk cardiac patients based on functional capacity (AACVPR, 1995). Studies in the literature evaluating CR patients often include patients with lower functional capacities (patients with MET levels less than 5) in their analyses. Highly deconditioned patients typically produce more significant improvements in their MET capacities than patients with higher functional capacities. For example, if a patient has a baseline MET capacity of 3.5 and he or she improves 1 to 4.5 METs, the patient will exhibit a 29% increase in functional capacity. However, a low-risk patient who also improves by 1 MET (i.e., 6 to 7 METs) exhibits only a 15% improvement.

Another factor to consider is that many earlier studies did not use gas analysis and often included estimations of MET capacity based on the total test time and the treadmill speed and grade. Myers, Buchanan and Smith (1992) showed that test time changes are not valid methods of estimating functional capacity in cardiac patients. Using treadmill duration can overestimate actual levels of functional capacity by up to 40%. This is particularly true if holding on to the treadmill hand rails during the tests is permitted. It is possible for patients to achieve apparent significant MET improvements, based on treadmill speed and grade, without exhibiting actual increases in MET capacity based on oxygen consumption. Lastly, the majority of CR interventions which report changes in functional capacity are usually facility-based efficacy trials. It is not uncommon that the patients analyzed are selected based on a preset level of adherence to the facility-based regimen; thus, higher levels of change would be expected compared to trials not requiring a minimum participation standard.

In regard to anaerobic threshold, the greater increases found in the MP baseline to 3 months could be due to a number of possibilities, including differences in the level of exercise intensity and the overall level of activity performed by these patients. Additionally, this was likely due to the higher percentage of patients in the MP showing improvements compared to the TP as supported by a post-hoc analysis. The baseline to 6-month evaluation of anaerobic threshold showed a 2.2 % mean increase in the TP and 8.2% increase in the MP; however, the increases between groups were not significantly different. Additionally, no time effects were shown at the baseline to 6-month evaluation which suggests that the overall intensity of exercise during the final 3 months of the study may have been too low to promote further improvements. From a practical perspective, the mean anaerobic thresholds of participants in both protocols was achieved above 4.5 METs. This is at or above the intensity of effort needed to independently perform most activities of daily living (e.g., personal hygienic care, most house and yard work, driving, climbing stairs, walking up to three miles per hour) and many leisure activities (e.g., golf, fishing, bicycling, croquet, dancing and some competitive games) if conducted at a low intensity.

Another variable, rate pressure product (RPP) is associated with functional capacity. RPP is the product of systolic blood pressure and heart rate, and is an index of relative cardiac work. It is highly related to directly measured myocardial oxygen uptake and coronary blood flow over a wide range of exercise intensities (Clausen, 1977; Sim & Neill, 1974). It is well documented that a lowering of heart rate and systolic blood pressure at the same given workload represents a reduced cardiac demand. In this study, the submaximal RPP was measured at the same work level (speed and grade) at the different test periods. The time effects shown, $p = .043$ at 3 months, and $p < .0001$ at 6 months, indicate that the patients in both protocols had reductions in heart rate and/or systolic blood pressure efficient while exercising at the same given work load over time. Individually, no statistically significant between-group differences were shown. However, it was encouraging that the individual submaximal RPP improvements for both groups at the 6-month evaluation exceeded 11% and was approximately 5% higher than the improvements reported at the 3-month evaluation.

Resting blood pressure and heart rate changes. With training, it is expected that resting blood pressure and heart rate will decrease in patients with abnormally elevated levels (hypertensives). The baseline blood pressure in the MP was within normal limits, and the levels did not change significantly at the 3-month and 6-month evaluations. In the TP, as previously reported, resting blood pressure was significantly higher than for the MP at baseline. The TP realized a significant lowering of their resting systolic blood pressure at the 3-month evaluation; however, at 6 months, the blood pressure appeared to increase near baseline levels. This change may be associated with the gradual decline in exercise frequency during the final 3 months and/or changes in medications. Interestingly, most of the other physiological variables evaluated exhibited changes which commonly accompany decreases in blood pressure. For instance, individually, the TP participants had an 11% decrease in heart rate from baseline to 6 months. Overall, the significant time effects shown for heart rate at both the 3-month and 6-month evaluations suggests that both groups exhibited significant decreases in resting heart rate.

Stress and despair/hostility measures. No significant changes in these scores were noted. As previously stated, due to the apparently low levels of stress and despair/hostility responses which were reported at baseline, the likelihood of seeing significant improvements in these measures was low. It is possible that the patients may have had significantly higher levels of stress and/or despair/hostility prior to their CV event and immediately post event. However, by the time they entered outpatient CR and answered the baseline questionnaire, their levels of stress may have normalized as they did not appear to negatively influence their CV risk status.

Blood lipid parameters. Based on the ANOVAs, no significant between-group differences were found between the protocols. However, both groups demonstrated improvements in their lipid profiles based on the significant time effect and the relative changes which were noted (Tables 17b and 18b). When contrasting the lipid results of this study, with lipid outcomes of other secondary prevention studies (Haskell et al., 1994; Schuler et al., 1992; Superko & Krauss, 1994) which have included similar interventions, it appears that some patients in the present study may have the potential for realizing improvements in coronary blood flow. Ultimately, such changes contribute to decreases in morbidity, and mortality.

For instance, Superko and Krauss (1995) reported that from an epidemiological standpoint for secondary prevention, a minimum of a 10% absolute lowering of total and LDL cholesterol is needed to elicit reductions in morbidity and mortality. In this study, the TP did not achieve this standard for total cholesterol (5% decrease); however, their 9% decrease in LDL approached the 10% standard. The MP achieved the standard for both values; total cholesterol and LDL cholesterol decreased 10.6% and 13.5%, respectively.

Schuler et al. (1992) evaluated the impact of a comprehensive intervention in patients with coronary artery disease. The intervention included facility-based and home exercise and intensive dietary instruction (20% fat diet) with behavioral counseling and follow-up. No lipid lowering agents were used in this trial. After one year, mean decreases in total cholesterol and LDL in the experimental group were 9.7% and 8.9%, respectively. Moreover, triglycerides decreased 21%. A unique characteristic of this trial was that the patients underwent cardiac catheterization at baseline and at one year, and a significant number of those in the intervention group demonstrated regression or stabilization of atherosclerotic lesions in the coronary vessels.

Another secondary prevention trial, The Stanford Coronary Risk Intervention Project (SCRIP) (Haskell et al., 1994), included home-based exercise with transtelephonic monitoring five times per week for 30 mins, diet and behavioral management, and the use of lipid lowering medications as needed. After four years, the mean percentage of improvements in lipids in the experimental group were as follows: total cholesterol (-16.8%), LDL cholesterol (-18%), HDL cholesterol (+11.7%), and triglycerides (-19%). Baseline and follow-up testing in SCRIP included evaluation of changes in coronary atherosclerotic lesions. The intervention group had a significant number of participants who showed significant improvements in atherosclerosis as compared with the control group.

The work summarized above conducted by Haskell et al. (1994), Schuler et al. (1992) and Superko and Krauss (1995) provides support for potential outcomes which may be realized among the patients in this study based on improvements in their lipid profiles. When contrasting the changes with the lipid results of this study (see Table 17b), the probability for these improvements to occur based on the percent changes appears to be greatest in the MP participants. The higher percent changes in the MP may have been a result of the reinforcement and review of dietary principles which occurred in the heart health forum meetings. Additionally the higher overall patient compliance rates during the final 3 months may have led to the greater percent change observed in lipid levels.

Program Cost

Hypothesis 10. Hypothesis 10 stated that due to the MP protocol design, which included offering fewer CECGM sessions and total on-site exercise sessions, it was expected the average billing cost per patient in the MP group would be significantly less than the average cost per patient in the TP. The unknown in this hypothesis was the compliance to the number and type (with or without CECGM) of on-site sessions.

The average cost per patient was calculated based on a mean exercise frequency of the type of exercise session, metabolic treadmill tests, and lipid profiles for the 6-month program. The different costs and price of each protocol, based on 100% compliance, are listed in Table 19 (TP) and Table 20 (MP).

The cost difference based on 100% compliance is $1,453.00 less per patient in the MP. This difference was calculated based on the difference from the TP cost based on $3,340.00 (Table 19), and the MP cost ($1,87.00) based on 100% compliance (Table 20).

To determine the actual costs to answer the hypothesis, it was necessary to evaluate the on-site compliance in each protocol and to determine the number and type of sessions attended by patients. A summary of patient compliance on-site is listed by protocol in Table 21. When viewing the compliance standards, the higher levels noted by the MP can be explained because they were offered fewer on-site sessions, particularly during weeks 7-26.

The TP was expected to conduct more on-site exercise during the 6-month study, given that they were offered significantly more on-site sessions. Interestingly, an 2x3 (proto x time) ANOVA analysis revealed no statistical difference between protocols (main effect), $F(1, 75) = .23$, $p = .63$.

It was not surprising that the average on-site exercise frequency was nearly identical over the first 6 weeks, given that TP and MP participants were each offered 18 and 16 sessions, respectively. During Weeks 7-12, TP patients were offered 18 sessions and the MP patients were offered a maximum of 12, but encouraged to attend only 10 if they were comfortable with their PEP. The final 3-month on-site exercise frequency data revealed a large decrease in exercise compliance at the rehabilitation facility, particularly among the TP participants. Even though they were encouraged to attend three sessions per week, the average patient only attended four sessions during the final 3 months of the study. The MP participants were encouraged to attend a minimum of 9 and a maximum of 26 exercise sessions during the final 3 months. The average patient only attended seven sessions. The

Table 19: TP Cost Per Patient Based On 100% Compliance

Mean # of on-site sessions with CECGM (36) x $72.00/session	=	$2,592.00
Mean # of on-site sessions without CECGM (36) x $4.00/session	=	$144.00
Two blood lipid profiles x $ 30.00/profile	=	$60.00
Two metabolic GXTs x $272.00	=	$544.00
Total Cost of TP based on 100% compliance	=	$3,340.00

Table 20: Cost of MP Based On 100% Compliance

Mean # of sessions with CECGM (9.2) x $ 72.00/session	=	$662.40
Mean # of sessions with "quick look" ECG strips(13) x $25.00/session	=	$325.00
Mean 3 of sessions without CECGM (6.9) x $ 4.00/session	=	$ 27.60
Two blood lipid profiles x $ 30.00/profile	=	$60.00
Two metabolic GXTs x $272.00	=	$544.00
Total Cost of MP based on 100% compliance	=	$1,887.00

Table 21: TP and MP Mean (± SD) On-Site Exercise Compliance Standards in Relation to the Suggested Protocol

Time period ->	Entry - 6 weeks	7 - 13 weeks	14 - 26 weeks	6-month total
TP Sessions Recommended	18	18	36	72
Sessions TP completed	13±4	11±7	4±7	29±13
% of total	74%	62%	12%	40%
MP sessions Recommended	17	12	26	53
Sessions MP completed	14±3	9±4	7±8	29±11
% of total	80%	71%	27%	55%

poor compliance to the on-site sessions during the final 3 months of the program may in part be due to a $4.00 out-of-pocket charge patients received for these sessions. Other reasons for poor patient attendance included returning to work, transportation problems, or time conflicts.

Based on the mean on-site exercise compliance rates, the actual costs for the protocols were calculated and are included in Tables 22 (TP), and 23 (MP).

Hypothesis 10 was supported, given that the actual average billed cost per patient was $730.28 less in the MP over the 6-month evaluation period. This difference was determined based on the average billed cost in the TP, which was $2,349.28 (Table 22), while the average billed cost in the MP was $1,619.00 (Table 23). The majority of the savings was due to the reduced number of sessions using the CECGM and the overall number of on-site sessions the first 3 months. Given that the patients were low and moderate risk as defined by AACVPR (1995), the discontinuation of CECGM was justified.

The cost savings shown in this study has positive implications, given that the MP patients overall showed equal or greater improvement as compared with the TP. In fact, MP participants had higher levels of program participation (Hypothesis 2) and PEP behavior, and demonstrated similar outcomes to the TP. They additionally exhibited higher levels of confidence while exercising without the CECGM at the 3-month evaluation. The MP, or a similar program design, may be especially appealing to hospitals which are served by insurance companies using managed care and which have cost capitation of their services. If the $730.28 savings among the patients in the MP is applied to 30 patients, the amount exceeds $20,000 which is typically billed to insurance companies. Although not quantified, the reduction in the number of highly supervised exercise sessions with CECGM attended by the MP also reduced staff needs. The maintenance exercise sessions that the MP attended on Tuesdays and Thursdays were typically staffed by one CR

Table 22: Traditional Protocol Program Cost Per Patient Based on Mean Participation Rates

Mean # of on-site sessions with CECGM (24.0) x $72/session	=	$1,728.00
Mean # of on-site sessions without CECGM (4.3)x $4/session	=	$17.20
Two blood lipid profiles x $ 30/profile	=	$60.00
Two metabolic GXTs x $272	=	$544.00
Total TP average cost per patient	=	$2,349.28

Table 23: Modified Protocol Program Cost Per Patient Based on Mean Participation Rates

Mean # of sessions with CECGM (9.2) x $ 72.00/session	=	$662.40
Mean # of sessions with "quick look" ECG strips(13) x $25/session	=	$325.00
Mean # of sessions without CECGM (6.9) x $ 4/session	=	$ 27.60
Two blood lipid profiles x $ 30/profile	=	$60.00
Two metabolic GXTs x $272.00	=	$544.00
Total MP average actual cost per patient	=	$1,619.00

professional and one undergraduate exercise physiology intern. While not specifically quantified, such modifications will lead to an additional cost savings.

In summary, Hypothesis 10 was supported, given that the actual average billed cost per patient was $730.28 less in the MP over 6 months. This difference was determined based on the average cost in TP of $2,349.28, and the average cost in the MP of $1,619.00. The average cost per patient was calculated on the mean exercise frequency of the type of exercise session, metabolic treadmill tests and lipid profiles for the 6-month program. The cost savings, and the higher confidence levels the MP patients exhibited toward exercising independently without CECGM, provides support for discontinuing the use of the costly CECGM once it is determined that the patient is stable.

CHAPTER FIVE

Summary and Recommendations

Study Summary

The purpose of this prospective randomized clinical study was to compare the effectiveness of a modified protocol and a traditional protocol for outpatient cardiac rehabilitation. Comparison of the two protocols was based on testing in five areas: (a) exercise adherence, (b) self-efficacy levels to exercise, (c) outcome expectancy toward exercise, (d) selected physiological and risk factor outcomes associated with cardiovascular health and (e) program cost. Eighty participants were used in the evaluation. Inclusion criteria included low- and moderate-risk cardiac patients as defined by AACVPR who were between 35-75 years of age. Two treatments were implemented: a MP served as the experimental intervention and the TP served as the control. Thirty-eight patients (31 men and 7 women, mean age 59) were randomized to the MP, and 42 patients (35 men and 7 women, mean age 59) were randomized to the TP.

Both protocols followed the same regimen for the first four weeks which included three on-site exercise sessions with CECGM. Participants were also scheduled to attend a three-session nutrition CV risk factor education series during the first month. All participants were given a total exercise goal of five or more aerobic sessions per week for 30 mins or longer. The TP was modeled after an exercise-based method of CR commonly used in CR facilities in the United States. The protocol included offering patients three CECGM exercise sessions per week for the initial 12 weeks, totaling 36 sessions. During the final 3 months, patients were also offered 36 sessions; however, the CECGM was discontinued. The majority of the education given to the TP participants was directed toward increasing knowledge of CV risk factors and was provided during the exercise sessions. The MP was in part based on Bandura's theory of self-efficacy (1977). The protocol was designed to promote self-efficacy to independent exercise behavior in hopes of facilitating exercise long term to maintain CV risk reduction benefits and to reduce the high dropout rates which typically occur in traditional CR by 6 months. To improve confidence levels while exercising without CECGM and ultimately to promote their PEP confidence, MP patients were removed from the CECGM in the fifth week. Additionally, from Week 6 and beyond, patients were weaned from their on-site exercise sessions to a maximum of two times per week. They were also encouraged to attend heart health forum meetings weekly until the 16th week. Thereafter, the MP patients was encouraged to attend the heart health forum meetings and on-site exercise session once every two weeks until the end of the 6-month period. The heart health forum meetings were designed to provide support and behaviorally-based education directed toward increasing patients' independent exercise programs and other behaviors associated with CV health.

Testing and collection of the dependent measures were conducted throughout the 6-month period. Exercise frequency data were collected weekly for both on- and off-site exercise and were quantified into three increments: (a) baseline to Week 6, (b) Weeks 7-12, and (c) Weeks 13-26. Demographic data and characteristics previously correlated with exercise adherence (Friis & Armstrong, 1986; Harlan et al., 1995; Mirotznik et al., 1995; Oldridge & Spencer, 1985; Oldridge & Streiner, 1989; Orth-Gomer et al., 1993) were collected at baseline and after 6 months. Subjective questionnaires, which included questions on self-efficacy and outcome expectancy, were completed at four time periods (baseline, 1.5 months, 3 months, and 6 months). Physiological measures including metabolic GXTs were obtained at baseline, 3 months and 6 months. Blood lipids (total cholesterol, low density lipoprotein, triglycerides, and high density lipoprotein) were measured at baseline and 6 months.

Baseline data were analyzed using correlations and chi-square analyses to evaluate if the groups differed at baseline. Between-group differences evaluated over the 6-month time period were measured using 2x2 and 2x3 (groups x time) repeated measures ANOVA.

The ANOVA allowed for the evaluation of the main effects, time effects and interaction. Each protocol's physiological outcomes were evaluated individually to determine how participants in each protocol responded individually and to compare it with previous research in CR.

Results Summary

The evaluation of the two protocols was based on the general hypothesis: Compared to the traditional protocol for cardiac rehabilitation, a modified protocol designed to promote self-efficacy to exercise will produce superior changes during the 6-month study period in the following five areas: (a) exercise adherence, (b) self-efficacy levels to exercise, (c) outcome expectancy toward exercise, (d) selected physiological and risk factor outcomes associated with CV health, and (e) program cost. The general hypothesis was evaluated using 10 specific hypotheses, three of which had two parts. The following is a brief summary of the findings of the hypotheses in the five areas tested.

Exercise Adherence and Program Participation (Hypotheses 1a, 1b, and 2)

Exercise adherence was addressed with Hypotheses 1(a) and 1(b) which stated that compared to TP patients, the MP patients would exhibit superior adherence rates over 6-months to: an off-site PEP (Hypothesis 1a) and overall exercise (Hypothesis 1b). Hypothesis 1(a) was accepted given that the MP patients exhibited superior rates of PEP exercise behavior during the 6-month evaluation compared to the TP patients. Hypothesis 1(b) was not supported, given that both protocols had similar rates of total exercise (sum of on-site and PEP) during the 6-month period. While not addressed as a specific hypothesis, an evaluation of the patients' exercise behavior in relation to the program compliance standard of five exercise sessions per week for 30 mins or longer was conducted. The compliance evaluation revealed that the MP patients had a significantly greater percentage of patients achieving the compliance standard (five or more exercise sessions per week), and also maintained higher exercise compliance rates from Week 7 through 6 months. The differences were most pronounced during the final 3 months of the program. In regard to on-site exercise, overall there were no significant differences between the protocols in the number of on-site exercise sessions conducted, even though the TP patients were offered 19 more on-site visits during the 6-month study period.

Program participation was addressed in Hypothesis 2 and stated that a greater number of patients in the TP, compared to the MP, will discontinue facility-based exercise within the first 6 weeks and fail to return for their 6-month follow-up evaluation. Hypothesis 2 was supported based on the significantly higher number of TP patients discontinuing exercise at the CR facility within the first 6 weeks and not returning for their 6-month evaluation.

Self-efficacy to Exercise (Hypotheses 3, 4a , 4b and 5)

The relationship of self-efficacy toward exercise with exercise behavior was addressed in Hypothesis 3, which stated that among all patients, self-efficacy toward a PEP will exhibit positive correlations with overall exercise and PEP compliance. This relationship was found to be true; thus, Hypothesis 3 was accepted.

Patient confidence between the protocols while exercising without CECGM, both on-site and during a PEP, was assessed in Hypotheses 4(a) and 4(b). Hypothesis 4(a) stated that the confidence levels would be superior in the MP from baseline to 1.5 months; Hypothesis 4(b) stated that the confidence levels would be superior in the MP from baseline to 3 months. Hypothesis 4(a) was not supported, given that there were no significant differences between the groups; however, Hypothesis 4(b) was accepted given that the MP confidence levels were superior toward exercising without CECGM both on-site and during a PEP compared to the TP confidence levels.

Hypothesis 5 assessed self-efficacy toward exercise between the two protocols based on six different questions measured at baseline, 3 months, and 6 months. The questions evaluated the patients' confidence in performing daily and leisure activities and their confidence in their physical condition. Additionally, the questions assessed the patients' confidence toward exercise frequency, duration, and intensity. Hypothesis 5 was not supported, given that none of the six self-efficacy questions revealed significant differences between protocols. Post-hoc analysis, based on significant time effects, assessed the changes in four questions which addressed patient confidence toward (a) performing daily and leisure activities, (b) perception of their physical condition, (c) exercise duration, and (d) frequency to total exercise. The analysis of these questions indicated that three of the four questions showed improvements (SE toward leisure and daily activities, self-efficacy toward physical condition, and self-efficacy toward exercise duration). The question on self-efficacy toward total exercise frequency showed both protocols scores decreased similarly suggesting they may have been overly confident upon starting their outpatient CR program. Interestingly, this decrease in confidence appears to correlate with the trends showing a decrease in exercise behavior.

Outcome Expectancy to Exercise (Hypotheses 6 and 7)

Neither of the hypotheses addressing outcome expectancy were supported; however, it is noteworthy that both groups exhibited high levels of outcome expectancy toward exercise at baseline which was maintained throughout the program.

Hypothesis 6 stated that among all patients, outcome expectancy toward exercise would exhibit positive correlations with overall and PEP adherence rates. Hypothesis 6 was not accepted, given that among all participants outcome expectancy was not found to exhibit a statistically significant positive correlation with off-site and overall exercise behavior.

Hypothesis 7 stated that compared to the TP patients, MP patients would exhibit higher levels in outcome expectancy toward exercise at 3-month and 6-month evaluations. Given that no significant between-group differences were found in outcome expectancy between the TP and the MP, Hypothesis 7 was not supported.

Outcomes Associated with CV Health (Hypotheses 8 and 9)

Hypothesis 8 stated that improvements in measures associated with CV health from baseline to 3 months would not be significantly different between the MP and TP comparison groups. The evaluation supported Hypothesis 8 based on 2x2 ANOVAs revealing the lack of between-group difference found among the 10 parameters measured. Only one variable in each protocol showed a main effect or interaction. Resting systolic blood pressure showed a significant between-group difference in the TP, and anaerobic threshold exhibited a significant main effect in favor of the MP, which provides support for a superior training effect in MP participants. Overall, both protocols appeared to be effective in promoting outcomes associated with CV health as supported by significant time effects showing improvements in their weight, BMI, functional capacity, anaerobic threshold, resting heart rate, and submaximal rate pressure product. Resting diastolic blood pressure and levels of stress and despair remained unchanged in both groups.

Hypothesis 9 stated that improvements in measures associated with CV health from baseline to 6-months will be greater in the MP group than in the TP group. To answer this hypothesis, 15 dependent measures were analyzed using 2x2 ANOVA. These included the same 10 measures used to answer Hypothesis 8, as well as five blood lipid parameters. The analysis did not support Hypothesis 9, given the lack of significant differences found between the two groups. Upon viewing the blood pressure values, it was concluded that the main effect found in resting systolic blood pressure was not related to an improvement, but rather to a significantly higher baseline blood pressure (was significantly different at baseline) which remained elevated at the 6-month evaluation. The significant time effects found in 11 of 15 measures (6 of 10 of the CV outcome measures and all 5 lipid measures) suggests that both protocols promoted significant improvements in CV health in the following measures: body weight and BMI, functional capacity, resting heart rate, submaximal rate pressure product, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, and the total cholesterol-to-HDL ratio. Given that both protocols elicited participant improvements in the majority of the variables, it was less likely for between-group differences to occur.

Program Cost (Hypothesis 10)

Hypothesis 10 stated that the mean cost per patient would be lower in the MP over the 6-month period than in the TP. This hypothesis was accepted based on the actual cost billed to the average patient in each protocol. The average billed cost in TP was $2,349.28, while the average billed cost in the MP was $1,619.00, a savings of $730.28 per patient in the MP over the 6-month period. This difference was determined based on The average cost per patient was calculated based on the mean exercise frequency of the type of exercise session, metabolic treadmill tests, and lipid profiles for the 6-month program. The majority of the savings was due to the reduced number of sessions using the CECGM and the overall number of on-site sessions the first 3 months. While not quantified, the number of staff-to-patient contact hours necessary to conduct the MP was lower than the TP. This was due to the fact that the MP patients initiated maintenance exercise sessions without CECGM in Week 6 (which required less staff supervision), and the patients were reduced to a maximum of two on-site sessions per week. The cost savings demonstrated by the MP, along with the positive outcomes that the protocol produced, has potential positive implications for hospitals and insurance companies using managed care and cost capitation.

Study Limitations and Considerations

1. Even though each patient was randomly assigned to one of the two protocols, it was not possible to fully blind either the participants or the CR staff, given that patients followed their specific on-site protocols in the same facility. For the first four weeks, all participants followed the same protocol, which included exercising on Mondays, Wednesdays and Fridays. From the sixth week on, patients in each protocol exercised on different days. At this time, the MP patients were weaned to two sessions per week, which

were offered on Tuesdays and Thursdays. The TP patients continued to exercise on Mondays, Wednesdays, and Fridays.

2. Given that the off-site exercise was self-reported, there is the possibility of spurious reporting by patients.

3. No standardized physical activity questionnaire was used to quantify the patients' non-exercise physical activity (i.e., leisure, work) which potentially could affect cardiorespiratory fitness and other physiological variables measured in this study.

4. Factors such as the timing (i.e., morning or afternoon) of the administration of physiological tests and subjective questionnaires, as well as the presence of different testers while testing, may have influenced individual responses during repeated evaluations.

5. Given that most of the patients in this study were taking one or more cardiac medications, there is the potential that physiological responses were effected during different tests due to level of activity of the medication, patient compliance to medications, or changes in the pharmacological regimen. To control for this, medications and prescription changes were documented during the course of this study to subjectively assess any potential effects of differences in pharmacological therapy. No significant differences were found between the groups.

6. Viewing the baseline functional capacity data of the study participants indicates that these patients were, on the average, low-risk healthy cardiac patients. It is possible that the baseline GXT was not conducted early enough to ensure quantification of the full training effect which occurred after each patient underwent his or her CV event of procedure. The primary reason for this is that all apparent low-and moderate-risk inpatients are sent home from the hospital with a specific training program to be initiated prior to starting outpatient CR. Typically, patients do not initiate outpatient CR for 2-3 weeks after leaving the hospital. Furthermore, the actual baseline GXT is not completed until 2 to 3 weeks after formal outpatient CR is initiated. Therefore, it is likely a significant training

effect occurred prior to baseline testing. Finally, given that all of the patients in this study were classified as low- and moderate-risk patients based on their functional capacities, their likelihood for improvement was not as that which might be expected to occur in highly deconditioned patients.

7. Each protocol was multifaceted (i.e., format and the content and amount of education) which makes it is difficult to identify specific protocol components with outcomes, particularly since the level of participation and comprehension by participants is variable.

8. Given that the ethnic composition of the study participants was virtually all Caucasian (> 95%) special consideration for potential cultural differences should be considered when applying these methods to different ethnic groups.

9. Previous work by Oldridge (1991) identified a number of factors which can affect program participation and exercise compliance including smoking status, social support, socioeconomic status, age, gender, educational level, and obesity. These factors should be considered when evaluating compliance data. In the present study, these factors were not thoroughly evaluated; however, the mean baseline levels in the two groups were not statistically different.

Study Attributes/Strengths

1. The fact that this study was an effectiveness trial conducted under ordinary circumstances enhances its external validity and makes it more applicable for facilities considering modifying their cardiac rehabilitation program. No special equipment or staff were required to implement either protocol. Additionally, many studies that are reported in the CR literature often only include those patients who state they can comply to the specific regimen during the study period and therefore are reporting on the efficacy of the intervention. Participants in this study were randomized to one of two interventions and

were encouraged to follow a recommended protocol for CR but were not informed that they had to maintain a certain level of attendance to be involved with the project.

2. The data collection period for this study encompassed an entire year for both protocols. This time span limited the bias for varying environmental conditions which may affect exercise behavior; i.e., winter weather compared to summer. Patients in both protocols were recruited and started the study over a 6.5-month period. Patients were then followed for 6 months.

3. A sedentary control was not used in this study. The MP group was compared to an intervention which has well-established benefits for improving physiological parameters that are conducive to CV health and decreasing morbidity and mortality (Hedback et al., 1993; Lavie et al., 1993; Leon et al., 1990; Vermeulen et al., 1983; Whaley & Blair, 1995). Therefore, given that the MP was less expensive and required less staff supervision, from an economic and clinical standpoint, the MP can be viewed as a success as long as it elicits participant outcomes equal to those produced by the TP.

4. Overall, both protocols produced significant improvements in parameters associated with CV health. When these improvements are contrasted to previous research on patients with coronary heart disease which have elicited increases in coronary blood flow and reduced CV morbidity and mortality (Balady et al., 1994; Haskell et al., 1994; Schuler et al., 1992; Superko & Krauss, 1994), it is possible that patients from this study have realized these benefits.

Potential Attributes of the TP Intervention

Potential Increase in Patient Safety as a Result of Frequent ECG Monitoring

Given patients in the TP for CR received CECGM during exercise for the first 3 months, the frequency of visits and the intensity of the monitoring has a greater potential for identifying latent abnormalities such as heart rhythm disturbances and myocardial ischemia. For instance, among post-angioplasty patients, given the high rate of restenosis during the first 3-months, it is possible that the CECGM could identify new onset ischemia (i.e., significant electrocardiogram ST-segment depression) related to restenosis.

Improvements in Physiological Outcomes

It is possible that the patients who exercise on-site more frequently could realize greater benefits associated with CV health as a result of exercising at a higher intensity compared to individuals exercising off-site. Reasons why patients may exercise at a higher intensity on-site include the variety of equipment, staff facilitation to meet suggested workloads, peer support, and the increased comfort associated with exercising at a higher intensity in a monitored, medically-supervised environment.

One-on-one Exercise Support and Frequency of Facility Contact

Some patients who are fearful or lack confidence and motivation to exercise independently might discontinue exercise if they get weaned to two sessions per week with less staff supervision 6 weeks after starting. These patients may benefit from the one-on-one support from rehabilitation staff three time per week. Without it, such patients may not achieve the skills and physiological improvements which may augment their confidence to succeed independently.

Simple Program Implementation and Reduced Staff Training Requirements

Given that the TP presents a preset standard for staff and patients to follow, it simplifies the diversity of staff training necessary and makes the implementation easy. In addition to the standard skills required to conduct traditional cardiac rehabilitation (ECG interpretation, basic exercise physiology as it relates to cardiac patients, basic life support), staff in the MP need to develop skills in working with patients in the group setting and in obtaining skills to facilitate health behavior change.

Economics

The traditional protocol of cardiac rehabilitation provides a simple method for generating program revenue if reimbursement is provided by insurance companies for the

CECGM and GXTs. This may also be true if the program is in an area where the mean patients' income allows for payment of CR services without insurance reimbursement.

Potential Attributes of the MP Intervention

The Heart Health Forum Meetings

The heart health forum meetings provided an increased opportunity for social support from other patients, significant others (spouse, family member, or friend), and staff in regard to education and pursuing specific goals. The benefit of group support for health behavior change is well established (Friis & Armstrong, 1986; McGee et al., 1994; Orth-Gomer et al., 1993). Education and support can also produce improvements in self-efficacy. The patient value of support and educational aspects of the meetings was revealed by several patients who attended the meeting regularly, but discontinued use of the CR exercise facility. These patients stated they were comfortable doing their exercise off-site, but liked to attend the meetings to learn more information and to gain support to continue with their exercise and other lifestyle goals. Another benefit of these meetings was that they provided an avenue which promoted a comprehensive lifestyle approach to CV risk factor reduction rather than the traditional exercise-based form of CR.

Total Patient Participation

Based on the results of Hypothesis 2, the modified protocol maintained a larger percentage of patients who remained in contact with the CR facility. This permitted a greater likelihood of identifying medical problems through regular contact and increased the potential of facilitating CV risk reduction in these patients. The reasons for the greater level of overall participation by the MP patients may have been that the MP regimen offered more flexibility, and the suggested level of visits required a reduced time commitment. For example, starting in the sixth week, the MP participants were allowed to exercise at the time of their choice between 7:00 A.M. and 5:30 P.M. on Tuesdays and Thursdays. In contrast, TP patients were required to select a specific time that they were encouraged to attend on Mondays, Wednesdays, and Fridays. The TP participants time commitment and associated lack of flexibility may have been responsible for a greater percentage of the TP discontinuing regular contact with the facility. This is particularly likely among patients who returned to jobs. It is possible that if more flexible programs with a decreased time commitment were offered, the participation and compliance rates to cardiac rehabilitation could be improved nationally.

Patient Confidence and Responsibility Towards Independence

The MP emphasized the importance of developing a PEP. Given that the MP participants were encouraged to shape and model a PEP they could perform long-term may increase their potential for success for independent exercise in the long term. During the first 6 weeks and throughout the program, MP participants were encouraged to evaluate their off-site exercise options and to identify barriers to success. In contrast, the majority of the staff contact with the TP participants was facility-centric, given that the focus was devoted to teaching patients to exercise in the on-site program which they were encouraged to do three times per week. The TP patients were not spending as much time, nor were they receiving as much consistent facilitation to model an independent regimen off-site. It is possible that the TP patients who were compliant to the on-site regimen had difficulty continuing an off-site regimen, particularly after the first 3 months of insurance-reimbursed sessions were over. This may be attributed to several reasons. The TP patients may have become dependent of the staff and equipment and may have failed to develop the confidence and skills necessary to adhere to an off-site regimen. Another attribute to developing a PEP is that if patients have developed the skills and confidence to conduct an exercise program without supervision, they may have a greater likelihood of independently returning to exercise if they relapse. Finally, the TP patients may feel that they require a facility and supervision to conduct a proper exercise program.

Decreased Program Cost and Decreased Staff Needs

The MP may appeal to hospitals served by insurance companies using managed care and cost capitation or both. Based on the compliance levels of the average patient in each protocol, a $730.28 savings per patient was realized over the 6-month period. If this figure is applied to 30 patients from each group in this study, the MP reduces costs typically billed to insurance companies by nearly $22,000 compared to the costs billed in the TP. In addition, the reduced number of the supervised exercise sessions with CECGM attended by the MP reduced staff needs. Furthermore, the maintenance exercise sessions that the MP attended on Tuesdays and Thursdays were typically staffed by one CR professional. A potential low-cost adjunct to the MP would be for insurance companies and hospitals involved in managed care to consider reimbursing costs for home exercise equipment and/or memberships at selected health clubs and recreation facilities. Patients could exercise at home or at selected facilities on a regular basis, but would periodically visit the CR facility for education, physiological monitoring, and assessments.

Potential for Merging Primary and Secondary CV Prevention Efforts

The space availability and staff time provide an excellent opportunity for hospitals with CR programs to include a primary prevention component. This could be a way to generate additional revenue and potentially decrease first-event CV morbidity and mortality rates. Patients at risk for CVD could easily be merged into a program with low- and moderate-risk patients following a MP or similar protocol. The low- and moderate-risk cardiac patients and the at risk patients could also attend the group educational support classes together. Separate times would be allocated for the high-risk cardiac patients who require CECGM.

Increased Potential for Long-term Follow-up

Given that the MP staggers the visits over a 6-month period, it provides an excellent template for promoting longer-term follow-up of the CR patient. Traditionally, CR patients complete their follow-up testing 3 months after baseline testing, not at 6 months. Post-3-months is a point in the TP for CR where contact with the facility tends to diminish significantly (Balady et al., 1994; Daltroy, 1985; Oldridge, 1991). This was substantiated in the present study. Even though patients in the TP were offered up to 3-sessions per week, the average patient only attended 4 sessions during the final 3 months of the program. The exercise frequency data revealed that 45% (19 of 42) of the TP patients attended at least one session during the final 3 months. Among the MP participants, 76% (29 of 38) of the patients attended at least one on-site exercise session during the final 3 months. Additionally, numerous MP participants attended the heart health forum meetings, but did not exercise at the facility.

<u>Future Data Evaluation and Research on CREASES</u>

1. Evaluate the correlation of self-efficacy measures with physiological outcomes. For example, do the patients who had greater confidence in performing exercise and physical activity produce greater improvements in their functional capacity than patients with lower self-efficacy levels?

2. Limited research has focused on off-site exercise adherence in the CR patient; therefore, additional analyses may involve isolating factors in this study that correlated with PEP success (socio-economic status, social support, educational level, smoking status, and/or age).

3. Based on the factors which appeared to be most predictive of success, develop a questionnaire with fewer questions for potential use in CR facilities. If further validation of the questionnaire can be established, the questionnaire could be used by CR professionals to specifically determine the most important factors which need to be addressed in each patient to enhance the likelihood for compliance and success both on and off-site. Such a questionnaire might be able to determine when the patient can be weaned from the facility-based exercise program and be successful off-site.

4. Minimal self-efficacy research in the cardiac population has involved women. Given that the participation and compliance by women in CR is lower than in males, assess the subjective questionnaires including the self-efficacy data in the 14 women in this study to evaluate if they are significantly different from the men.

5. Evaluate variables collected in CREASES which were not included in the original hypotheses. These variables include (a) nutrition behavior and nutrition SE levels, (b) smoking, (c) the roles peer learning and support have on behavioral compliance, and (d) demographic characteristics (i.e., social support, economic status, age) .

6. Conduct a 3-year follow-up evaluation on TP and MP patients. The evaluation variables will include an assessment of all variables measured at baseline as well as an assessment of subsequent morbidity and mortality.

Summary Recommendations

Interventions involving low- and moderate-risk cardiac rehabilitation patients should offer flexibility and variety and involve the patient in designing the intervention which will allow the patient to achieve and maintain his or her long-term goals. Educational efforts should emphasize helping patients independently perform behaviors conducive to cardiovascular health, rather than focusing on knowledge gains. The cardiac rehabilitation clinician should become knowledgeable of determinants of behavior change, including the role of self-efficacy in health behavior. Success should not be based on how long or the number of times patients exercise at a rehabilitation facility. It is probably more important to direct patient counseling to enhance success off-site, given that most patients will not remain with a facility-based program for more than 6 months. Success should be based on favorably modifying all behaviors that are associated with improving and maintaining cardiovascular health long-term. The MP evaluated in this study demonstrated an effective reduced cost cardiac rehabiliation intervention which promoted patient independence and has potential for hospitals utilizing managed care and cost capitation.

APPENDICES

APPENDIX A

Summary of Traditional Cardiac Rehabilitation

Appendix A

Summary of Traditional Cardiac Rehabilitation (AACVPR, 1995)

Phase I cardiac rehabilitation refers to the initial program phase and occurs while the patient is in the hospital. The purpose is to provide basic patient education regarding the patient's condition and to reduce deconditioning that normally accompanies bed rest. The patient is provided with range of motion activities, intermittent sitting or standing, and walking.

Phase II cardiac rehabilitation refers to outpatient exercise therapy for low-risk, moderate-risk, or high-risk patients as determined from medical history, graded exercise test results, and documentation of arrhythmias, left ventricular function, or concurrent disease. Risk factor education and psychological and vocational needs are met as ordered, with desired outcomes specified by the physician and the cardiac rehabilitation staff. This period generally consists of three exercise sessions per week for 3 months in duration or until 36 sessions are completed.

Phase III and IV interventions refer to the extended outpatient and exercise maintenance phases of cardiac rehabilitation. Patients are generally moved into these stages when stabilized cardiovascular and physiological responses to exercise have been obtained and either the desired outcome from exercise therapy has been achieved or no additional progress is evident. Some programs distinguish between the Phase III and IV phases, while others simply have a maintenance program and make no distinction. Duration for the Phase III program commonly varies from 3 months to 1 year, while Phase IV is designed to be available indefinitely.

APPENDIX B

Guidelines for Risk Stratification of Cardiac Rehabilitation Patients

Appendix B

Guidelines for Risk Stratification of Cardiac Rehabilitation Patients (AACVPR, 1995)

Low Risk

- Uncomplicated myocardial infarction, coronary artery bypass grafting, angioplasty, or artheroectomy.
- Functional capacity $\geq$ 6 METs 3 or more weeks after clinical event.
- No resting or exercise induced myocardial ischemia manifested as angina and/or ST segment displacement.
- No resting or exercise induced complex arrhythmias.
- No significant left ventricular dysfunction (ejection fraction $\geq$ 50%).

Moderate Risk

- Functional capacity < 5-6 METs 3 or more weeks after clinical event.
- Mild to moderately depressed left ventricular function (ejection fraction 31 to 49%).
- Failure to comply with exercise prescription.
- Exercise induced ST- segment depression of 1-2 mm or reversible ischemic defects (echocardiography or nuclear radiography).

High Risk

- Severely depressed left ventricular function (ejection fraction $\leq$ 30%).
- Complex ventricular arrhythmias at resting or appearing or increasing with exercise.
- Decrease in systolic blood pressure of > 15 mm Hg during exercise or failure to rise consistent with exercise workloads.
- Myocardial infarction complicated by congestive heart failure, cardiogenic shock, and/or complex ventricular arrhythmias.
- Patients with severe CAD and marked (>2 mm) exercise induced ST-segment depression.
- Survivor of cardiac arrest.

APPENDIX C

Participant Informed Consent

Appendix C

Participant Informed Consent

Purpose of the Research Study. The study is designed to evaluate factors among low- and moderate-risk cardiac rehabilitation patients which may predict exercise compliance to rehabilitation sessions and self-directed exercise regimens. Low- and moderate-risk determination will be based on guidelines described by the American College of Cardiology. Nutritional habits (as they relate to cardiovascular health) will also be evaluated. Additionally, the study will determine if a modified program methodology that provides fewer on-site exercise sessions and is supplemented with group educational/ support sessions is an effective method of improving exercise compliance, patient outcomes, and program costs.

Duration of Participant Involvement. The final evaluation will take place at the end of six months, though the majority of participant involvement will occur during the initial three months of cardiac rehabilitation.

Description of Procedures. The procedures include comparing cardiac rehabilitation patients following a modified protocol to patients following a traditional care protocol over a six-month period. The usual care protocol involves 12 weeks of Phase II cardiac rehabilitation consisting of three sessions per week. After 12 weeks, participants can exercise on their own or continue with a Phase III program. The modified protocol is identical to the original protocol for the first six-weeks; however, the number of on-site exercise sessions will gradually be reduced. During Week 7 through Week 10, the number of exercise sessions will be decreased to two times per week, and participants will be asked to attend a group educational session one time per week. During Weeks 11-16, there will be one rehabilitation session per week and one education/exercise support meeting per week. During Weeks 17-24 there will be one rehabilitation session and one exercise support group every two weeks.

Experimental Procedures. The experimental procedures involve answering questionnaires and the usual physiological testing that accompanies participation in a cardiac rehabilitation program. The questionnaires will ask questions regarding participants' exercise and health habits, including nutrition and stress. Participants will be asked to answer these questionnaires during the first month of the program and again at the end of 6 months. Also, there will be a few questions that will be answered on a monthly basis. Participants will be encouraged to document their non-rehabilitation sessions using a log provided by the rehabilitation center.

Physiological testing will take place during the first two weeks of the program, after three months, and at the end of six months. The testing includes an evaluation of exercise capacity using a graded treadmill exercise test and a blood analysis of total cholesterol, low density lipoprotein cholesterol (LDL), high density lipoprotein cholesterol (HDL), and triglycerides. At the end of six months, participants will be asked to complete an additional treadmill exercise test and a blood lipid analysis. There will be no additional costs for these or any tests associated with this research.

Risks of Study to Patients or Others. There is a standard risk with any cardiac rehabilitation program. There exists the possibility of certain dangers occurring during exercise sessions and testing. These include abnormal blood pressure, fainting, disorder of heartbeat, and in rare instances heart attack or death.

Procedures Used to Minimize Patient Risk. An individualized exercise prescription will be devised for each patient based on a maximal graded exercise test with oxygen analysis. This will provide information on the exercise intensity, duration, and suggested frequency that the patient should follow for a safe and effective exercise program. Patients will be educated on their exercise prescription and guidelines to decrease risks associated with exercise. This will include contraindications to exercise and procedures to follow if symptoms develop.

Benefits of Study to Patients or Others. The results of this study will be used to improve the quality of the present cardiac rehabilitation protocol. Also, in a published form the information from this study can be used by other researchers and cardiac rehabilitation programs to improve the care and outcomes for cardiac rehabilitation patients.

The potential benefits which may be obtained from this research may include the following: (a) a method which enhances the patient's knowledge and skills related to exercise and nutrition that help to reduce morbidity and mortality; (b) a method which enhances the patient's self-efficacy (confidence) and long-term compliance to exercise and nutrition recommendations; (c) a method of cardiac rehabilitation which will serve a greater number of patients due to a reduction in cost, increased program flexibility, and a reduction in on-site exercise sessions; (d) a program which reduces program costs for patients, insurance companies, and hospitals utilizing a prospective payment system; (e) a template which is devised for long term follow-up and tracking of patients; and (f) a tool that is to be used in conjunction with physiological outcomes to determine the ideal time to initiate a self-directed regimen.

Alternate Procedures of Treatment. Participants will not receive any alternate procedures of treatment; however, patients randomized to the modified protocol will follow a program which includes some modifications beginning in the seventh week of the program. At this time, participants in the modified protocol will have their on-site exercise sessions reduced to two times per week and will begin attending weekly educational support sessions focused on developing and maintaining a self-directed exercise regimen, and providing comprehensive lifestyle education related to cardiovascular health.

Compensation and Medical Treatment Available if Injury Occurs. No compensation for injury resulting from your participation in the protocol will be provided. Emergency equipment and trained personnel, including a physician, are available to deal with unusual situations which may arise. If problems or injuries resulting from the study occur, you may contact Preventive Cardiology and Rehabilitation at the following number: (616) 774-7936. Additionally, if you have any questions related to this research, feel free to contact Joe Carlson at the same number.

The information contained in the records of this study will be maintained in confidentiality, except that the FDA may inspect the records. Data relating to your participation may appear in any papers published as a result of the study, but your identity will remain confidential.

Your participation in this study is voluntary. You are free to withdraw from the study at any time. If you refuse to participate, you will not be penalized nor will you lose any benefits to which you are otherwise entitled.

I have thoroughly read the above information, and give my consent to be a subject in this study.

______________________________ Signature of Patient

____________________ Date

______________________________ Signature of Investigator

____________________ Date

APPENDIX D

Demographic, Social Support, Outcome Expectancy and Self-efficacy Questionnaire

Appendix D

Demographic, Social Support, Outcome Expectancy and Self-efficacy Questionnaire

Instructions: All information obtained from these questions will remain confidential. Please select the best answer or write in the information requested.

1. What is your date of birth ? ____/____/____
mth / day / yr

2. What is your gender? (1) male (2) female

3. What is your present marital status?
   (a) Single (never been married)
   (b) Married
   (c) Divorced
   (d) Spouse is no longer living

4. Ethnic background
   (1) Caucasian (white)
   (2) African American
   (3) Hispanic
   (4) Asian
   (5) Native American
   (6) Other: ________________

5. Educational level:
   1) 8th grade or less
   2) Some high school
   3) High school graduate
   4) Some college
   5) College graduate
   6) Masters Degree
   7) Ph.D.
   8) Other, please describe:
   ____

6. Approximately how many miles do you live from the cardiac rehabilitation facility?
   _______ miles

7. Does transportation to and from the cardiac rehabilitation facility make it difficult for you to attend cardiac rehabilitation sessions ?

(1) Never is a problem

(2) Very seldom is a problem

(3) Occasionally is a problem

(4) Commonly a problem

8. If you are presently working, does your job make it difficult for you to attend cardiac rehabilitation sessions ?

(1) Never is a problem

(2) Very Seldom is a problem

(3) Occasionally is a problem

(4) Commonly a problem

9. What is your present employment status?

(1) Employed. List approximate hours worked per week ______

(2) Retired. What was your last year of employment? ______

(3) On Disability. What was your last year of employment? ______

(4) Unemployed. What was your last year of employment? ______

10. Please write in your occupation. Note: if you are retired, unemployed, or on disability please list your last occupation.

____

11. Select your annual yearly income from 1-7 below. If you have a combined income, please include your total household income. If you are retired, unemployed, or on disability please select the income you made during the last year you worked.

(1) Less than $10,000 per year

(2) $10,000-$20,000 per year

(3) $20,000-$30,000 per year

(4) $30,000-$50,000 per year

(5) $50,000-$75,000 per year

(6) $75,000-$100,000 per year

(7) $100,000 or greater per year

SSQ

Instructions: Select the response that best describes how you feel about the following statements and questions. ***Note:*** Do not consider fellow cardiac rehabilitation participants as a close person unless you were friends with them before joining cardiac rehabilitation.

12. How often do you feel lonely or socially isolated?

(0) never *(1) very seldom* *(2) sometimes* *(3) often* *(4) very often*

13. Do you have someone who is close to you who understands the importance of a regular exercise program to improve your cardiovascular health?

(0) Yes *(1) No*

1) Yes *2) No*

14. Do you have someone who is close to you who provides positive feedback when you follow the exercise recommendations provided to you by cardiac rehabilitation?

(0) never *(1) very seldom* *(2) sometimes* *(3) often* *(4) very often*

15. Do you have someone who is close to you to exercise with during non-rehabilitation exercise sessions?

(0) never *(1) very seldom* *(2) sometimes* *(3) often* *(4) very often*

16. If there is a person that exercises with you during non-rehabilitation sessions please identify this person from the following choices:

(0) spouse *(1) significant other* *(2) family member* *(3) friend* *(4) other*

If you selected "other" please describe this person ____________________________

17. Do you have a person close to you who provides you support (or would) if you are having a difficult time following your suggested exercise regimen?

(0) never *(1) very seldom* *(2) sometimes* *(3) often* *(4) very often*

PS&L

18. How important do you feel fellow rehabilitation participants are in helping you follow the exercise regimen suggested by your cardiac rehabilitation staff (on-site and personal exercise sessions)? ***Note*:** This could include tips, support, or knowledge gained from interacting with other cardiac rehabilitation patients.

(0) no importance *(1) slightly important* *(2) important* *(3) very important* *(4) extremely important*

19. How important do you feel fellow rehabilitation participants have been in helping you make nutritional changes as suggested by your cardiac rehabilitation staff ? ***Note*:** this could include tips, support, knowledge gained from interacting with other cardiac rehabilitation patients.

(0) no importance *(1) slightly important* *(2) important* *(3) very important* *(4) extremely important*

TASQ

Instructions: Select the response that best describes how you feel about the following statements and questions

20. Based on the definitions of stress listed below[a] how would you rate your overall level of negative stress or distressors?

(0) none *(1) very low* *(2) moderate* *(3) high* *(4) very high*

a Stress Definitions:

Definition No. 1: The sum of the physical and emotional reactions to any stimulus that disturbs a person's homeostasis (physical and emotional balance).

Definition No. 2: The nonspecific response a person has to any demand ("stressors"), positive or negative. Stressors may be any event, condition, or situation that produces a physical or emotional response. Some examples include (a) a change such as moving or starting a new job; (b) overworking; (c) arguing; (d) worrying; (e) losing a family member or friend; (f) coping with a sickness or disease; (g) lack of sleep.

21. How often do circumstances in your life create feelings of hostility or despair?

(0) never *(1) very seldom* *(2) sometimes* *(3) often* *(4) very often*

PF&H

Instructions: Select the response (1-5) that best describes how you feel about the following statements and questions:

22. In my present physical condition, I can do the daily and leisure activities I desire:

(0) Strongly agree *(1) Disagree* *(2) Slightly agree* *(3) Agree* *(4) Strongly agree*

23. I believe I am in good physical condition:

(0) Strongly agree *(1) Disagree* *(2) Slightly agree* *(3) Agree* *(4) Strongly agree*

24. How comfortable would you be (or are you) exercising in the cardiac rehabilitation facility without an ECG heart monitor?

(0) very uncomfortable *(1) slightly uncomfortable* *(2) fairly comfortable* *(3) comfortable* *(4) very comfortable*

25. How comfortable are you exercising outside the cardiac rehabilitation facility without an ECG heart monitor?

(0) very uncomfortable *(1) slightly uncomfortable* *(2) fairly comfortable* *(3) comfortable* *(4) very comfortable*

EoO

Instructions: Select the response (1-10) that best describes how you feel about the following statements and questions

26. If you follow the exercise program suggested by the cardiac rehabilitation staff, what is your level of confidence it will play a role in improving and maintaining your health status?

No Confidence			Poor Confidence		Moderate Confidence		Good Confidence			Complete Confidence
0	1	2	3	4	5	6	7	8	9	10

27. If you follow the heart healthy nutrition recommendations suggested to you by the cardiac rehabilitation program staff, what is your confidence it will play a role in improving your health status?

No Confidence			Poor Confidence		Moderate Confidence		Good Confidence			Complete Confidence
0	1	2	3	4	5	6	7	8	9	10

28. If you follow other health and lifestyle recommendations (e.g., stress management, smoking cessation) suggested to you by the cardiac rehabilitation program staff, what is your confidence they will play a role in improving and maintaining your health status?

No Confidence			Poor Confidence		Moderate Confidence		Good Confidence			Complete Confidence
0	1	2	3	4	5	6	7	8	9	10

SETE

Select the response that best describes your level of confidences based on the following statements and questions.

Part A

29. What is your level of confidence regarding attending and completing **three supervised cardiac rehabilitation sessions** per week?

(1) None (2) Very Poor (3) Poor (4) Fair (5) Good (6) Very good (7) Excellent

30. What is your level of confidence regarding following a **personal exercise program (PEP) three sessions per week? Note**: A PEP consists of you choosing where and when you exercise and could include one or more of the following: (a) a home-based program where you would exercise in or near your home; (b) a health club or other exercise facility; or (c) mall walking, etc.

(1) None *(2) Very Poor* *(3) Poor* *(4) Fair* *(5) Good* *(6) Very Good* *(7) Excellent*

31. Rate your confidence regarding **how many days per week over the next 3 months** you could complete **cardiac rehabilitation exercise sessions.** These sessions involve at least 30 minutes of aerobic exercise at a rating of perceived exertion of 12-13 ("somewhat hard"). **Note**: A copy of the Rating of Perceived Exertion is attached

Percent Confidence of Completing Weekly Exercise Rehabilitation Sessions

No. of Days	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
One											
Two											
Three											

Please list any reasons that may make it difficult for you to attend and complete cardiac rehabilitation sessions over the next three months.

32. Rate your confidence regarding **how many days per week you will exercise** during the next 3 months. Each session should consist of 30 or more continuous minutes of aerobic exercise per day at an RPE intensity of 12-13. The total number days should include a combination of the number of hospital-based rehabilitation sessions and exercise sessions you feel you will do on your own.

Your Confidence of the Number of Days Per Week You Will Exercise

No. of Days	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
One											
Two											
Three											
Four											
Five											
Six											
Seven											

Please list any factors which you feel would consistently make it difficult for you to exercise.

33. Rate your confidence regarding completing a **personal exercise program (PEP) on your own** (without cardiac rehabilitation) over the next 3 months. Each session should consist of 30 or more continuous minutes of aerobic exercise at an RPE intensity of 12-13. **Note:** The place and time you choose to exercise is up to you and may include one or more of the following examples: (a) exercising in or near your home (biking, walking, swimming); (b) a health club or other exercise facility; (c) mall walking.

No. of Days	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
One											
Two											
Three											
Four											
Five											
Six											
Seven											

Please comment on any concerns or factors you feel may make it difficult for you to follow a PEP program. Examples may include:

34. How many **months** do you think you can follow an exercise program of 5 days per week for 30 minutes each session.

<u>Number of Months You Will Exercise Five Days Per Week</u>

- ❑ Less than 1 month
- ❑ 1 month
- ❑ 2 months
- ❑ 3 months
- ❑ 4 months
- ❑ 5 months
- ❑ 6 months
- ❑ 7 months
- ❑ 8 months
- ❑ 9 months
- ❑ 10 months
- ❑ 11 months
- ❑ 12 months

35. At what **intensity/Borg Rating of Perceived Exertion (RPE)** are you capable of being physically active for 30 continuous minutes? (circle one number)

6	
7	very, very light
8	
9	very light
10	
11	fairly light
12	
13	somewhat hard
14	
15	hard
16	
17	very hard
18	
19	very, very hard
20	

36. **How many minutes** are you capable of exercising at an RPE intensity of 12-13 ?

(1) 15 mins *(2) 30 mins* *(3) 45 mins* *(4) 60 mins*

(5) 75 mins *(6) 90 mins* *(7) 105 mins or more*

APPENDIX E

Personal Exercise Program (PEP) Guidelines

APPENDIX E

Personal Exercise Program (PEP) Guidelines

Blodgett Preventive Cardiology & Rehabilitation

___________________________, each session of your PEP should consist of 3 components: (a) the warm-up; (b) the training or exercise period; and (c) the cool down. (*Turn over for more tips and guidelines regarding your PEP!!!)

"PEP" TIPS	*YOUR GOALS*
1. THE WARM-UP—Why do it?? The warm-up is important for preparing your body for exercise and reducing your chance of injury. This involves gradually increasing your heart rate and blood pressure, increasing the blood flow to muscles, and loosening your joints. *HOW to do it??* First. do your suggested stretches, second, begin your first activity at a slower speed or lower intensity	• Before starting check your pulse. • Warm-up time ~ 5 mins.
2. AEROBIC TRAINING OR EXERCISE PERIOD. The purpose of the aerobic training period is to improve the functioning of the heart and lungs, and improve your energy level. Aerobic exercise examples include walking, jogging, biking & swimming. The word aerobic refers to oxygen dependent activities involving large muscle groups which can be done for long periods of time. Additional benefits of the training period include improving muscle tone and body composition, increasing high density lipoprotein (HDL), and decreasing triglycerides.	Aerobic Training Options 1. 2. 3. • Check your pulse half-way through your exercise period
How Hard or Intense Should I Be Exercising? A general guide to insure you are doing aerobic activity is the "talk test" meaning you should be able to carry on a conversation while exercising . Additionally use the training heart rate range determined for you based on your exercise test , and the Rating of Perceived Exertion Scale (RPE) for safely regulating your intensity.	Your Training HR Range _______beats/min. _______ beats/10 sec. Your RPE__________
How Many Times Per Week Should I Exercise? At minimum you should complete 3 sessions per week, however strive for five or more sessions per week, especially if you desire to become leaner, improve your lipids, and enhance your level of conditioning.	Exercise Frequency ________ sessions/wk
How Long Should I Exercise For Each Session? A goal to work toward is 30- 40 minutes however benefits can be achieved from less. Every little bit helps!	______ min. per session
3. COOL DOWN... Why Do It?? The cool-down is basically the opposite of the warm-up and is important for avoiding blood pooling and reducing the heart rate and blood pressure to pre-exercise levels. Simply reduce the intensity of the final activity or take a slow walk. Lastly, stretch and relax.	• Cool down time ~ 5 minutes, • When finished check your pulse.

WORK & LEISURE ACTIVITY GOALS... Decide work and leisure activities you would like to begin or resume. Examples may include job activities, dancing, golfing, hunting, hiking, biking, housework, gardening; some of these activities may count as a PEP session. If you begin a new activity inform a PCR staff member.	1. 2. 3. Return to Work (Y/N) __________________

Medication Guidelines

It is important you follow the recommendations provided by your physician when taking your medications. Strive to be consistent in the timing of your medication schedule. Some medications have a significant impact your heart rate and blood pressure response, before during and after exercise. If you change your medication, or forget to take your medication, please inform a staff member.

Symptoms to Be Aware of During Exercise

If you are exercising and experience any symptoms out of the ordinary, or any of those listed below, decrease the intensity of your exercise. If symptoms persist stop the activity. After stopping, if symptoms still do not subside, contact your physicians office.

- Undue shortness of breath
- Dizziness/lightheadedness
- Uncommon irregular heartbeats or palpitations
- Nausea and/or vomiting
- Any unusual muscle or joint discomfort
- Excessive fatigue
- Abnormal heart rate response
- Abnormal blood pressure response
- Angina (referring to discomfort, pressure, numbness, or tightness of the chest, back, arm(s), shoulder)

YOU *CAN* ACHIEVE MANY BENEFITS FROM ADHERING TO YOUR EXERCISE PROGRAM!!!! However, the benefits you achieve will be lost quickly unless you continue your program. Identifying a significant other to support you in your exercise/leisure activities and other health-related goals can be beneficial to your adherence. Let them know why and what you plan to accomplish and that their support is appreciated. Also, it is suggested you keep a record of your exercise sessions using the form provided by PCR or using a system you are already comfortable with. PCR Staff will be checking your activity logs on Mondays.

If you have any questions or concerns about maintaining your PEP program please feel free to contact PCR staff member. Happy Exercising!!!!

Participant signature____________________________ Date____________

Exercise Goal Support Person _________________________________ Date____________

Exercise Physiologist/ Nurse ___________________________________ Date____________

APPENDIX F

Modified Protocol Program and Testing Schedule

BLODGETT PREVENTIVE CARDIOLOGY AND REHABILITATION

Hospital Based Exercise, Education and Testing Schedule For:

____

Note: a staff person will remind you of appointments and schedule changes. Speak with Joe Carlson if you have any questions about your schedule. If necessary, schedule modifications can be made. Remember, we suggest you exercise a total of 5 times per week or more for 30 minutes or longer each session.

<u>Weeks 1- 5</u>
Exercise - Three rehabilitation exercise sessions per week. During weeks 1 to 4 ECG heart monitor will be worn. During week 5 or 6 you will discontinue using the ECG heart monitor and begin using a heart rate monitor on your wrist.

<u>Weeks 6 - 11</u>
Two rehabilitation exercise sessions are suggested per week (Tuesday and Thursday) with a group educational meeting before or after your Thursday exercise session. A "Polar" heart rate wrist monitor will be worn for these sessions. Before and after each session a staff member will obtain your blood pressure and an ECG strip. On Tuesday, exercise anytime from 7:00 A.M. to 4:30 P.M. (start by 4:30). On Thursday, in addition to your exercise session, there is a group meeting which will include a meeting at 8:00 A.M. <u>or</u> 3:00 P.M. (choose one). The purpose of these meetings are to provide education and answer any questions you have about exercise, nutrition, and cardiovascular risk factors. Also, your exercise log will be reviewed. It is suggested you exercise before or after the group meeting you attend. For example if you attend the 8:00 group meeting, exercise at 7:00 or 9:00 A.M.. Or if you choose to attend the 3:00 group meeting, exercise before or after the 3:00 meeting.

<u>Weeks 12 - 16 (4th month) -</u> **At minimum, you are encouraged to attend one rehabilitation exercise session and group meeting per week on Thursdays.** If desired, you have the option to also use the exercise facility on Tuesdays. A staff member will take your blood pressure and obtain an ECG strip before and after each session. You will be given a folder to keep record of your hospital based exercise sessions (blood pressure, heart rate and exercise type, duration and intensity). Staff will assist you in starting this process.

<u>Months 5-6 (weeks 17 - 26) -</u> **At minimum you are encouraged to attend one exercise session and group meeting every two weeks on Thursday.** If desired, you can exercise at the rehabilitation facility every Tuesday and Thursday.

<u>SUMMARY of EVALUATIONS & TESTING</u> (treadmill tests, blood tests & questionairres)

During the <u>first three weeks</u> of your program the following will be completed:
1) A treadmill test which directly measures oxygen consumption (using a mouthpiece)
2) A blood test to evaluate your total cholesterol, LDL, HDL and triglycerides
3) A paper and pencil questionnaire (takes ~10-15 minutes to complete)

<u>1.5-Months (6th week)</u> - Questionnaire (will take ~10 minutes).
<u>3-Months (12th week)</u> - Treadmill test and repeat questionnaire
<u>5.5 to 6 months (24-26 weeks)</u> - Final Testing; Treadmill test, blood test to measure cholesterol, LDL, HDL, and triglycerides, final questionnaire.

* We appreciate you keeping record of your off-site exercise program during this project. Thanks for your involvement!!!

APPENDIX G

Service Documentation Forms

APPENDIX G

Blodgett Preventive Cardiology & Rehabilitation
Education and Behavior Service Documentation Form

Patient's Stated Goals: ______________________________

Education Goals
- Return to Work—Type and Date ______________________
- Smoker: ❑ Yes ❑ No No Smoking Cessation Date Completed ________

	Key	Date/Signature	
	Competent	Reviewed	Completed
• Awareness of controllable risk factors			
• Verbalizes benefits of exercise program			
• Verbalizes and understands TTR			
• Verbalizes understanding of medications			
• Ability to monitor pulse			
• Ability to correlate RPE and HR			
• Nitro procedure (if applicable)			
• Review entry GXT results & exercise prescription			
• Review exit GXT restuls & exercise prescription			
• Lipid profile review			
• Dietary evaluation			

PEP Log (Date and initial; if verifying verbally date here and then document in notes.)

________________ ________________ ________________
________________ ________________ ________________
________________ ________________ ________________
________________ ________________ ________________

Orientation Date ________________
Entry GXT Date ________________
Exit GXT Date ________________
Lipid Profile Drawn ________________
Diet Classes #1 ________________
#2 ________________
#3 ________________
Phase III Home Program ________________
Subject of handouts given ________________
Comments ________________

KEY
V: verbalized understanding
NR: needs review
NA: not applicable

Phase II # of weeks ________________
Name ________________

Procedural Checklist For CREASES Participants

Instructions for Documention- For those procedures that are scheduled to be done please date the scheduled time *in pencil.* Once a procedure or behavior is completed please document the completion date in the box *with a pen* and also highlight the box with a highlighter. The boxes with //// indicates a period which has no scheduled procedure and should be left blank. **Patients randomized to the traditional protocol** will attend 36 ECG monitored exercise sessions and also attend the 3 group nutrition sessions. These patients <u>are not</u> to the attend the non- nutrition education support group classes. **Patients randomized to the modified protocol** will follow the protocol shown in Table 1 which includes both the three nutrition classes, and the ongoing nutrition support group classes.

	Entry	1 Mth	1.5 Mth	3 Mth	4 Mth	5 Mth	6 Mth
Informed consent signed, given to pt.		////	////	////	////	////	////
GXTs completed		////	////		////	////	
Laboratory blood work		////	////		////	////	
Questionairres		////			////	////	
Activity History		////	////	////	////	////	////
Social Support		////			////	////	
Peer support and learning		////			////	////	
Stress, dispair hostility questions		////			////	////	
Perceived fitness and health		////			////	////	
Expectancy outcome to exercise		////			////	////	
Expectancy outcome to nutrition		////			////	////	
Three Day Dietary Food Logs		////	////	////	////	////	
Self efficacy to exercise		////			////	////	
Self efficacy to nutrition		////			////	////	
Medical care usage summary	////	////	////	////	////	////	////
CV/Nutrition Education Classes	////	////	////	////	////	////	////
Session # 1 Please Date>>>>				////	////	////	////
Session # 2 Please Date>>>>				////	////	////	////
Session # 3 Please Date>>>>				////	////	////	////
Culinary Program (*optional*)							
Exercise Documentation	Wk#	Wk#	Wk#	Wk#	Wk#	Wk#	Wk#
On-site exercise tally / week	1	2	3	4	5	6	7
" " " " " "	8	9	10	11	12	13	14
" " " " " "	15	16	17	18	19	20	21
" " " " " "	22	23	24	25	26	27	28
PEP exercise tally/ week	1	2	3	4	5	6	7
" " " " "	8	9	10	11	12	13	14
" " " " "	15	16	17	18	19	20	21
" " " " "	22	23	24	25	26	27	28
Heart Health Forum Attendence	1	2	3	4	6	7	8
(Enter date)	9	10	11	12	13	14	15
	16	17	18	19	20	21	22

APPENDIX H

Summary of Cardiovascular Nutrition Protocol

APPENDIX H

Summary of Cardiovascular Nutrition Protocol

I. Program overview and general objectives

A. Participants will attend three group educational sessions designed to:

1. increase participant on the role of nutrition in the prevention and treatment of CVD.

2. provide dietary guidelines based on current research and professional organizations designed to halt the progression of atherosclerosis.

3. provide opportunity for preparing and tasting dishes with high nutrient density and low fat (particularly saturated fat) and cholesterol content.

B. Participants will be encouraged to complete a 3-day dietary food record. A Registered Dietitian will review and return the logs with feedback and recommendations.

C. The patients will be encouraged to bring a spouse or significant other.

II. Program Content

A. Three 75-minute group sessions: one hour of interactive presentation followed by optional discussion/question answer period or 15 minutes.

1. Session 1: The Role of Nutrition with CV Risk Factors.

a. Current facts and statistics relating to CVD.

b. The relationship between nutritional habits, atherosclerosis, and CVD risk factors.

c. An overview of basic nutrition principles and heart healthy nutrition guidelines.

2. Session 2: Implementation of the Heart Healthy Guidelines

a. Utilization of the food pyramid and labels to achieve a reduced-fat, nutrient-dense diet believed to halt the progression of atherosclerosis.

b. Obtain specific guidelines on grams of total fat, saturated fat and cholesterol to ensure patients do not exceed 25% of the calories from fat unless they are diabetic.

c. Learn how to obtain 20-25 grams of dietary fiber/1000 Kcals by selecting adequate amounts of legumes, whole grains, fruits, vegetables and small amounts of nuts and seeds

3. Session 3: Feedback on Dietary Logs, Tips on Dining Out and Question/Answer

   a. Review principles from session 2.

   b. Provide feedback on dietary logs and field questions.

   c. Provides tips for dining out.

   d. Miscellaneous question/answer period.

   4. Session 4 (optional 3 hour program): Hands on Heart Healthy Cooking

   a. A hands-on cooking class for patients and spouses at the Grand Rapids Culinary School.

   b. The program includes a 45-minutes classroom presentation by a Registered Dietitian and a chef on the basis of heart healthy eating and how to practically do it

   c. Participants are broken into groups of 3-5 participants and will prepare one to two dishes high in fiber and nutrients and low in total fat but particularly low in saturated fat and cholesterol.

   d. During the final 30-45 minutes, participants share a potluck style meal.

APPENDIX I

Health History/Risk Factor Questionnaire

Blodgett
MEMORIAL MEDICAL CENTER

PREVENTIVE CARDIOLOGY AND REHABILITATION

(616) 774-7936

MEDICAL HISTORY FORM

Date ____________________ Personal Physician ____________________

Participant's Name ____________________ Cardiologist ____________________

Birthdate __________ Age __________ Employer ____________________

Home Address ____________________ Occupation ____________________

City/State/Zip ____________________ Work Phone ____________________

Home Phone ____________________ Work Address ____________________

Person to Contact
In Case Of Emergency ____________________

CURRENT MEDICAL HISTORY

1. Please describe the medical problem that brought you to the hospital.

2. List all surgeries and procedures related to present medical problem.

Date/Hospital	Reason	Procedure

3. Please provide the following information about **ALL** medications you take on a regular basis.

Name	Dose(mg)	Frequency	Reason for Taking

4. Do you have any allergies? (i.e. drugs, food, pollen) No ☐ Yes ☐

   Explain: ____________________

PAST MEDICAL HISTORY

5. If you have had any of the following illnesses or surgeries please check the appropriate box below. Include the year it was diagnosed and other pertinent details such as hospitalizations, etc.

☐ Arthritis	☐ Diabetes	☐ Gout	☐ Liver Disease
☐ Asthma	☐ Emphysema	☐ Hiatal Hernia	☐ Rheumatic Fever
☐ Back Injury	☐ Epilepsy	☐ Kidney Disease	☐ Orthopedic Injuries/Limitations
☐ Chronic Bronchitis			

Additional Information: ____________________

D52-127-104

Have you ever had any of the following symptoms? Especially list those of a persistent, recurrent or severe nature.

6. **Fainting, convulsions or dizzy spells?** No ☐ Yes ☐
   Explain: ______
7. **Pain, stiffness or swelling of any joint or pain in the lower back?** No ☐ Yes ☐
   Explain: ______
8. **Pain, cramping, weakness or numbness in the legs, feet or arms?** No ☐ Yes ☐
   Explain: ______
9. **Please list all hospitalizations and surgeries** ______

PULMONARY (LUNG) HISTORY

10. Do you ever experience shortness of breath? No ☐ Yes ☐
    Check the boxes that apply.
    ☐ Walking
    ☐ Climbing 1 flight of stairs
    ☐ Interferes with usual work
    ☐ Awakens you from sleep
    ☐ Occurs while sitting still
    ☐ Other
    Describe: ______
11. Does your breathing affect your usual activities of daily living? No ☐ Yes ☐
    If so, how? ______
12. Do you have to sleep with more than one pillow? No ☐ Yes ☐
    If so, how many? ______
13. Are you currently smoking? No ☐ Yes ☐
14. Have you ever smoked in the past? No ☐ Yes ☐
15. If either question 13 or 14 is yes, how many per day:
    Cigarettes ______ Packs
    Cigars ______
    Pipe ______
    How many years have/did you smoke? ______
    If you no longer smoke, when did you quit? ______

CARDIAC HISTORY

16. **Have you ever been aware of any of the following:**
    Heart often "skips " a beat or "jumps" in your chest, or beats very fast? No ☐ Yes ☐
    Describe: ______
17. **Have you ever been told that you have a:**

Heart murmur	No ☐	Yes ☐
Enlarged Heart	No ☐	Yes ☐
Heart failure	No ☐	Yes ☐
Abnormal ECG	No ☐	Yes ☐
Other	No ☐	Yes ☐

Describe: ______

18. Have you ever experienced any pain or discomfort in your chest, jaw, arm or back? No ☐ Yes ☐

    If yes, please describe this feeling, what seems to bring on the discomfort and what relieves the symptoms.

    ____

    ____

    ____

    On the average, how many nitroglycerin tablets do you take a week? ____________

19. Have you ever been told that your blood pressure is:

High	No ☐	Yes ☐
Controlled with medication	No ☐	Yes ☐
Borderline high	No ☐	Yes ☐
Low	No ☐	Yes ☐

OCCUPATIONAL HISTORY

20. What is your occupation? ______________________________

21. Briefly describe your job responsibilities: ______________________________

    ____

22. How many years have you been in your present position? ____________

23. What is your current job status?

☐ Full-time	Hours per week ____________
☐ Part-time	Hours per week ____________
☐ Medical Leave	Estimated date of return ____________

24. If you anticipate returning to work, is your job likely to entail lifting, pushing, pulling or carrying heavy objects? No ☐ Yes ☐

PHYSICAL ACTIVITY HISTORY

25. Describe any physical activity which you do on a regular (2 times a week or more) basis; i.e. jogging, walking, bicycling, swimming, racquet games, golf, bowling or other recreational activities.

Type of Activity	Times/Week	Length of Session	Heart Rate

NUTRITIONAL HISTORY

26. How tall are you? ____________

27. Record your weight in pounds:

Present	6 Months Ago ____________
Age 25 ____________	What would you like to weigh? ____________

28. Are you currently following a special diet? No ☐ Yes ☐

    If so, list the type of diet and the number of calories. ____________

    ____

SOCIAL INFORMATION

29. What is your marital status? ______________________________

30. Do you have children? If so list their ages: ____________________

____

31. How has your family (spouse, children) dealt with your medical diagnosis?

____

____

32. Is your family supportive of your involvement in this program? No ☐ Yes ☐

33. Please fill in your family history as completely as possible. Identify family members that have or have had heart disease, high blood pressure, stroke, diabetes, obesity or died suddenly.

Relationship	Age Living	Age at Death	Cause of Death
Father			
Mother			
Brother(s)			
Sister(s)			

STRESS HISTORY

34. Classify your stress level. (circle one) High Medium Low

35. Are you able to identify the source of your stress?
Job, co-workers, boss, health, finances, marital, family relationship - parents, children - alcohol, drugs, other ____________________. (circle all that apply)

36. How do you usually cope with stress?
Ex: eat more, lose appetite, smoke, drink more, take tranquilizers, withdraw, lash out at source of stress, lash out at others not involved in stressful situation, talk it out, seek counseling, exercise, use relaxation exercise, other ____________________. (circle all that apply)

APPENDIX J

Modified Protocol Heart Health Forum Purpose, Format, and Content

APPENDIX J

Preventive Cardiology and Rehabilitation Heart Health Forum Meetings

Purpose: To provide education and support for safe and effective implementation of your personal exercise program (PEP) and heart healthy nutrition goals.

Format: One-hour meetings (come and go as you please). The first 15 minutes will be devoted to discussing questions, you have my have about the implementation of your off-site (PEP) regimen and eating behaviors. This will be followed by a 30-minute interactive presentation (see upcoming meetings below). The final 15 minutes will be devoted to a open discussion. Feel free to suggest any topics you would like presented. Spouses/ significant others are welcome.

Time and Place: Thursday at 8:00 A.M. or 4:00 P.M. (choose one). We suggest you exercise before or after the class.

Thursday, April 11: Weight Management: The causes of obesity and methods for achieving and maintaining a weight you are comfortable with.

Thursday, April 18: Exercise and heart disease: The benefits and identification of the amount of calories you should try to expend per week in an effort to halt the growth of atherosclerosis (fatty build in your blood vessels).

Thursday, April 25: "Stress"—What is it? How does it relate to heart disease? How can it be managed?

Thursday, May 2: Goal setting—Methods for properly setting, implementing and achieving lifestyle goals to lower CV risk.

Thursday, May 9: Feedback on computerized nutrition evaluations. Learn how your diet ranks with recommendations believed to manage and possibly reduce atherosclerosis (clogging of blood vessels).

Thursday, April 16: Topic to be determined by group (your ideas are appreciated).

Thursday, April 23: Overcoming difficult behavior chains—Techniques for identifying and overcoming barriers to achieving your behavioral goals.

Thursday, April 30: No meeting. The schedule for June-August will be posted mid-May.

Note: Please bring in your exercise logs to meetings so I can comment on your progress. If you can't make a meeting let me know and I can mail you the information.

Feel free to see or call me if you have any questions (774-7936 or 774-7197).

Happy exercising and dining,

Joe Carlson

P.S. Water, juice, & decaf coffee will be served.

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