HEALTH OUTCOMES IN CARDIAC PATIENTS

By

AMY THERESA WALTERSCHEID

Bachelor of Science

Texas Woman's University

Denton, Texas

1993

Submitted to Faculty of the
Graduate College
Oklahoma State University
in partial fulfillment of
requirements for the
Degree of
MASTER OF SCIENCE
May, 1997

HEALTH OUTCOMES IN CARDIAC PATIENTS

Thesis Approved:

Thesis Advisor

Thomas C. Collins

Dean of Graduate College

ACKNOWLEDGMENTS

I wish to express sincere appreciation to my advisor and chair of my committee, Dr. Troy Adams, for his guidance, supervision, flexibility, friendliness, and most importantly his never ceasing encouragement and inspiration. I would also like to thank my committee members, Dr. Steven Edwards and Dr. Frank Kulling for their expertise and guidance. In addition, I would wish to express my appreciation to Dr. Pirzada Majid and his staff for their friendliness and assistance.

I would also like to express my love and appreciation to my parents, Sylvan and Theresa Mae for their positive role they have played in my education and my life!
I would like to thank Danny, Laurie, Greg and Julie for their encouragement, love and support in helping me obtain my goals.

Finally, I would like to give thanks and praise to the Lord, my God, through him all things are possible!

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER I

INTRODUCTION

Cardiovascular disease has accounted for 43% of all deaths since 1950, despite the declining mortality rate and the increase in technology and education (Cardiovascular Disease Statistics, 1996). Coronary heart disease is the leading cause of death for men over the age of 45 and for women over 65 years of age. Cardiovascular diseases account for $117 billion in health care costs and 736 years of potential years lost before the age of 65 (Burden of Chronic Disease & Infant Mortality, 1995). During 1993, the estimated number of hospital admissions for myocardial infarctions was 745,000 and for coronary artery bypass graph procedures was 485,000 (Monitoring Health Care in America, 1996). The estimated health care cost for coronary artery disease in 1994 was $56 billion and the loss of productivity was responsible for 14% of this cost (Cardiovascular Disease Statistics, 1996).

Since the mid 1970's cardiac rehabilitation programs have been implemented to help patients understand and cope with heart disease while enabling them to return to their

normal lifestyle through physical activity. However, even today, physical treatment and/or therapy for those who have undergone coronary artery bypass graph surgeries or have had a myocardial infarction often ends when the patient is discharged from the hospital. Cardiac rehabilitation programs serve as a link to bridge the gap between hospital discharge and resumption of daily activities.

The content of cardiac rehabilitation programs vary, but most include exercise training, educational counseling and risk factor modification with the purpose of improving functional capacity, relieving symptoms and enhancing quality of life (Thompson, 1995). Benefits of cardiac rehabilitation typically include: increased exercise tolerance, improvement in cardiac symptoms, improved blood lipid levels, decreased smoking, improved psychological well-being and reduced mortality (Guidelines for Cardiac Rehabilitation, 1995). Unfortunately, less than a third of heart patients who are candidates for cardiac rehabilitation take advantage of the potential benefits that a cardiac rehabilitation program has to offer (Cardiac Rehabilitation - Beneficial but Under-Used, 1995).

To identify the true benefits of the cardiac rehabilitation programs, as with many other treatments, outcome studies are useful and appropriate. Medical outcomes may include clinical end-points such as laboratory results, signs and symptoms, satisfaction of care ratings such as the quality of care, or well-being and/or functional status measures such as physical activity, mental health and limitations (Tarlov, et al., 1989). Self-reported measures from the patients are becoming increasingly important in measuring patient outcomes (McCarthy, et al., 1995). Often the physiological measurements do not

correlate with the functional capacity and well-being of the patients. By using and identifying self-reported well-being and physical functioning patient outcomes, the results can be useful and provide meaningful results for both the clinicians and the patients (Guyatt, et al., 1993). However, there is little evidence to date of cardiac rehabilitation studies that utilize comprehensive self-reported outcomes of well-being, physical functioning, social limitations, etc. Therefore, little documented information is available to determine how cardiac rehabilitation treatment impacts health-related patient outcomes.

In response to the changes in the health care system, outcome studies have been conducted and have become an important part of health care research (Ware and Sherbourne, 1992). The Medical Outcomes Study was one type of research project conducted with two main purposes which were: 1) To relate varying patient outcomes with differences in patient care, clinician speciality training, intensity of resources used, and clinical styles 2) To develop more practical instruments to use in monitoring patient outcomes (Tarlov, et al., 1989).

PURPOSE OF THE STUDY

The purpose of the present study is to compare the health related outcomes of heart patients who have and have not participated in a cardiac rehabilitation program.

HYPOTHESES

I. No significant difference will exist in physical functioning outcomes in the participants and the non-participants of cardiac rehabilitation.

II. No significant difference will exist in role limitations due to physical problems in the participants and the non-participants of cardiac rehabilitation.

III. No significant difference will exist in role limitations due to emotional problems outcomes in the participants and the non-participants of cardiac rehabilitation.

IV. No significant difference will exist in vitality outcomes in the participants and the non-participants of cardiac rehabilitation.

V. No significant difference will exist in social functioning outcomes in the participants and the non-participants of cardiac rehabilitation.

VI. No significant difference will exist in bodily pain outcomes in the participants and the non-participants of cardiac rehabilitation.

VII. No significant difference will exist in health perception outcomes in the participants and the non-participants of cardiac rehabilitation.

VIII. No significant difference will exist in mental health outcomes in the participants and the non-participants of cardiac rehabilitation.

OPERATIONAL DEFINITIONS

1) Cardiac Rehabilitation is the out-patient program by which heart patients, specifically those who have had a myocardial infarction or a coronary artery bypass graph surgery are restored to optimal health through exercise and educational programs.

2) Medical Outcomes Study was a large four-year study that researched the summary of care, styles of practice, speciality issues and outcome assessment.

3) Outcome is a measure of end-points indicating medical status, used to identify

effectiveness of treatment.

4) Quality of Life is the physical, mental, social status of a patient as it is related to health.

5) Treatment Group is the group of subjects that participated in the Oklahoma State University Wellness Center Cardiac Rehabilitation program.

6) Control Group is the group of subjects that did not participate in any cardiac rehabilitation program.

7) Myocardial Infarction is permanent damage or death to the heart muscle from lack of blood flow and oxygen due to one or more blocked coronary arteries.

8) Coronary Artery Bypass Graph (CABG) is a surgical procedure in which another artery or vein is used to re-route blood flow around a blockage in a coronary artery.

9) Cardiac or Heart Patient is a person with coronary artery disease.

EXTENT OF STUDY

Assumptions

1) The Medical Outcomes Study Short Form 36 Survey was valid and reliable with the sample used.

2) The subjects answered the questions to the survey accurately and honestly.

3) The subjects were representative of the cardiac patient population in general.

4) The subjects were similar in sociodemographic characteristics.

5) The physician and OSU Wellness Center records were accurate.

Delimitations

1) The study sample contained an unequal number of treatment group subjects (n=20), and comparison group subjects (n=47).
2) Subject selection was limited to men and women 55-75 years of age (prior to July 1, 1996).
3) Because of the small subject pool, there was no randomization on subjects.
4) Subjects were limited to those who had coronary artery bypass grafts and/or myocardial infarctions within the time limit of May 1994 to May 1996.

Limitations

1) There was no measure of baseline quality of life.
2) There was no criteria for the treatment group concerning attendance or completion of the cardiac rehabilitation program.
3) Only cardiac disease related histories were available, determination of other chronic diseases was not possible.
4) There was no control over participation in any other type of rehabilitation for the control group.

CHAPTER II

REVIEW OF LITERATURE

Prevalence of Coronary Artery Disease

In 1993, it was estimated that 60,340,000 Amercians had one or more forms of cardiovascular heart disease. Of those, 13,490,000 had coronary artery disease (CAD) (Cardiovascular Disease Statistics, 1996). Coronary artery disease caused 734,000 deaths in 1994 in the United States (Monitoring Health Care in America, 1996). As many as 13,490,000 people living today have had a heart attack and/or chest pain (Heart Attack and Angina Statistics, 1996). It is estimated that 1,500,000 people will have a heart attack within the period of one year. Cardiovascular diseases accounted for $117 billion in health care costs and 736 years of potential life lost before the age of sixty-five (Burden of Chronic Disease and Infant Mortality, 1995). Over 4 million cardiovascular surgeries where performed in 1993, including 485,000 coronary artery bypass grafts and over 1 million cardiac catherizations (Monitoring Health Care in America, 1996).

History of Cardiac Rehabilitation

As early as the 1700's, it was observed that activity was beneficial to the ill, specifically those with heart disease. An English physician observed that one of his heart disease patients who sawed wood for a half hour daily was nearly cured (Winslow, 1995). In the 1960's, inpatient rehabilitation was introduced to medical professionals when it was discovered that heart patients who participated in some type of movement activity recovered quicker than those who were on complete bed rest (Guidelines for Cardiac Rehabilitation Programs, 1995). Thus, the birth of the term "cardiac rehabilitation." Prior to this realization, the crude diagnostic techniques allowed only for diagnosis in the most severe disease state. Physicians believed that these patients could survive only with minimum stress on the heart, therefore they prescribed prolonged bed rest and inactivity. This bed rest led to physical de-conditioning, reduced work capacity, loss of strength, heart arrhythmias, lower blood volume, reduced lung functions and increased risk of thromboembolism (Leon, et al., 1990), all ofwhich created a greater need for cardiac rehabilitation (Froelicher, Herbert, Myers, & Ribisl, 1996).

It has been suggested that cardiac rehabilitation has "evolved into a medically efficacious, cost-effective intervention for patients" (Kelly & Donovan, 1995). Originally, cardiac rehabilitation began as a service solely for myocardial infarction patients, but has expanded the service to include other coronary artery disease patients (Guidelines for Cardiac Rehabilitation, 1995). With the growth of cardiac rehabilitation, diagnostic abilities, and both medical and surgical interventions in the past 20 years, cardiac rehabilitation has become an established standard of care for heart disease patients,

especially those who have had acute myocardial infarction, coronary artery bypass graft and /or angioplasty (Kelly & Donovan, 1995).

The Purpose of Cardiac Rehabilitation

The general goal of treating patients, that suffer from chronic diseases, including heart disease patients, is to restore daily functioning and well being (Stewart, et al., 1989). Specifically, the American Association of Cardiovascular Pulmonary Rehabilitation defines cardiac rehabilitation as "the process by which persons with cardiovascular disease are restored to and maintained at their optimal physiological, psychological, social, vocational and emotional status" (Guidelines for Cardiac Rehabilitation, 1995). Another expanded definition of cardiac rehabilitation is from the World Health Organization, which states "Cardiac rehabilitation is.....the sum of activities required to influence favorably the underlying cause of the disease, as well as to ensure the patients the best possible physical, mental and social conditions, so that they may, by their own efforts, preserve or resume when lost, as normal a place as possible in the life of the community" (World Health Organization, 1993). In relation to cardiac rehabilitation, the definition of rehabilitation is understood to include education, risk factor modification, such as smoking cessation, changing blood lipids, lowering hypertension and stress management counseling (Oldridge, 1991).

The ultimate goal of cardiac rehabilitation is to help patients with cardiac diseases return to active and productive live within their limitations. Basically, it means to restore physical, psychological and vocational status, slow or prevent the progression of the

disease, reduce the risk of sudden death, infarction and reduce anginal discomfort (Leon, et al., 1990). There is strong evidence that cardiac rehabilitation increases work capacity, lowers risk factors and decreases cardiac and overall mortality by 20% over a 3 year period (Ades, 1993). Other accepted benefits of cardiac rehabilitation include: higher return to work rates, improved left ventricular perfusion and function, improved psychological functions and reduced angina. There is evidence that when participating in cardiac rehabilitation for a minimum of 2-3 months, patients are able to reach their goal of cardiac rehabilitation which is returning to an active and productive life by increasing their functional capacity (Leon, et al., 1990).

Structure of Cardiac Rehabilitation

As the field cardiac rehabilitation developed, several phases or stages of cardiac rehabilitation were added. Phase I is the inpatient period from 1 to 14 days after surgery or event. Phase II takes place at some point after hospital discharge. The time until the start of rehabilitation and the length of the rehabilitation program varies for each patient's care. Basically, Phase II is the most closely monitored and supervised post-hospital discharge stage. Phase III and IV are called maintenance phases with less supervision and more independence (Guidelines for Cardiac Rehabilitation, 1995).

Annually, 1.5 million people have myocardial infarctions and nearly 468,000 coronary revascularization procedures are performed (Balady, et al., 1994). Patients, who are candidates for cardiac rehabilitation are those who have had myocardial infarction, coronary artery bypass graft, percutaneous transluminal angioplasty (PTCA), stable

angina, high risk CAD patients. Modified programs are available to those who have or have had a heart valve replacement, congenital heart defects and transplantations (Leon, et al., 1990).

Unfortunately, even though the Agency for Health Care Policy and Research (AHCPR) guideline panel found cardiac rehabilitation to be safe and beneficial, they have found the service to be greatly underused. Douglas B. Kamerow, AHCPR's director of Clinical Practice Guideline Development states "Less than a third of heart patients participate in cardiac rehabilitation programs, even though potentially all of them could benefit from the service" (Cardiac Rehabilitation - Beneficial But Under-used, 1995). In 1992 it was found that only 15% of eligible patients participate in cardiac rehabilitation programs (Thompson, 1995). According to Nanette K. Wengen, physicians are aware of cardiac rehabilitation programs, but do not refer patients to the service (Cardiac Rehabilitation - Beneficial But Under-used, 1995). The need for referrals by physicians compounds the problem of patient non-compliance and lack of knowledge (Oldridge, 1991).

Even though less than 15% of eligible cardiac rehabilitation patients participate in a cardiac rehabilitation programs, many drop out. At 3 months, the dropout rate is 2-25%, at 6-12 months it is 40-50% . When looking at long term changes, research shows that 12 months adherence to exercise programs and lifestyle change behaviors is about 50%. Certain populations in which participation is low are women, certain ethnic groups, the elderly, those who have difficulty with transportation, cardiac complications and those who are anxious and cautious (Thompson, 1995).

Cardiac rehabilitation programs vary in content. However, exercise is the main form of therapy for the patients (Leon, et al., 1990). Exercise is an effective means for improvements in both functional capacity and psychological well-being through reducing anxiety and depression while improving self esteem (Levine, 1988). There are two main types of programs, exercise only and exercise plus interventions which typically address risk factors (O'Conner, et al., 1989). The American Heart Association states that exercise therapy is not enough and "not synonymous with cardiac rehabilitation." The programs should be multidimensional in meeting patient needs (Balady, et al., 1994). Some researchers suggest that the exercise component is overemphasized and more attention should be paid to activity goals to enhance positive behavior (Bär, et al., 1992). The various components may include exercise, psychological issues, education and counseling of disease, medications, nutrition, and smoking, along with risk factor modifications, stress management and vocational guidance (Thompson, 1995). The goals of the education classes are to progress the patient to a healthy status, positive health behaviors, lower risk factors for the future, gain skills to cope with disease, improve physical skills, optimize health and choose optimal vocational and recreational activities (Guidelines for Cardiac Rehabilitation, 1995).

Cardiac rehabilitation has been beneficial in slowing of the CAD process by exercise and risk modification and a reduced mortality rate from myocardial infarctions (Kelly & Donovan, 1995). Many benefits across the domains of health can be found in cardiac rehabilitation. Benefits of a comprehensive cardiac rehabilitation program include increased exercise tolerance, improvement in symptoms (decrease angina, shortness of

breath and fatigue in heart failure patients) improved blood fat levels through nutrition and behavioral intervention counseling and exercise. Other noted benefits were decreased smoking, improved psychological well being, stress reduction and reduced mortality by 25% in patients after a heart attack (Cardiac Rehabilitation, Beneficial But Under-used, 1995).

Cost Effectiveness of Cardiac Rehabilitation

Patients suffering from chronic conditions, such as heart disease, are responsible for a majority of health care expenditures. As stated before, a goal of cardiac rehabilitation is to restore patients to maximum function, activities and well-being. Increased function and well-being may reduce the cost of health care (Stewart, et al., 1989). Cardiac rehabilitation cost effectiveness can be observed either through changing the atherosclerosis disease process or patient behavior (Ades, 1993). A study of cardiac rehabilitation cost by Ades, Huang and Weaver (1992) revealed that patients, who participated in a comprehensive cardiac rehabilitation program had lower rehospitalization cost in years following their events. There was $739 lower hospital admission cost in cardiac rehabilitation patients. A 1990 study found that there was a 62% reduction in hospital readmissions for the cardiac rehabilitation patients (Perk, Hedback & Engvall, 1990). Also, Balady et al., (1994) reported a decrease in use of cardiac medications, thus reducing additional medical costs.

The range of cost for patients participating in a 3 month cardiac rehabilitation program was $1,080-3,600 in 1991 (Ades, 1993). This is relatively inexpensive when

compared to the cost of undergoing coronary artery bypass graft surgery. One report indicated that a patient would have to participate in cardiac rehabilitation for 74 years to equal the cost of the coronary artery bypass graft surgery (Shephard, 1989).

Finally, cardiac rehabilitation significantly affects the return to work component of cardiac rehabilitation. For the coronary artery bypass graft patients, under the age of sixty-five, 60% return to work and 20% choose partial retirement which is a 5-10% increase over pre-operative figures (Ades, 1993). In the symptom free patient there was an increase in productivity and lower turnover rates that adds up to about $500 per worker year (Shephard, 1989).

Physiological Changes

One of the main goals of cardiac rehabilitation is to return patients to normal daily activities and functions (Bär et al., 1992). The role of physical activity in patient improvements has been connected to increased exercise tolerance and habits, and positive changes in risk factors such as lower blood lipids, lipoproteins, body weight, blood glucose and blood pressure (Cardiac Rehabilitation Guideline Panel, 1995).

It has been suggested that physiological adaptations to exercise are beneficial to cardiac rehabilitation patients. In the healthy population, exercise training increases VO2max (measurement of maximal oxygen consumption) as a result of changes in maximal stroke volume and arterio-venous oxygen [(a-v)O2] difference. Similar adaptations in VO2 occur in the cardiac patients mainly through a change in (a-v)O2 difference. Research has shown increases in VO2 from 11%-66% after 4-6 months for

coronary artery bypass graft patients. There is also a decrease in anginal pain because exercise training allows work at specific submaximal levels with a lower heart rate and therefore delaying the onset of pain from ischemia (Thompson, 1988).

Other physical responses related to exercise training are those related to reduction of risk factors for CAD. Changes that may occur in the body include weight loss, increased high density lipoproteins, lower blood pressure, and improvement in glucose-insulin management. Studies are inconclusive as to whether cardiac rehabilitation reduces the risk for a second myocardial infarction and death for heart attack patients, but trends indicate lower mortality rates in exercise groups compared to control groups (Leon, et al., 1990).

Safety of Cardiac Rehabilitation

The risk of sudden death in cardiac rehabilitation patients during exercise is a concern. There is a higher risk of death during exercise in cardiac rehabilitation patients compared to healthy individuals. Statistics show the risk of sudden cardiac death during vigorous exercise for a cardiac patient is estimated to be 1:60,000 to 1:65,000 person-hours of exercise, whereas in healthy individuals the rate is 1:565,000 person-hours of exercise. However, in low-moderate, supervised exercise cardiac rehabilitations programs the risk of cardiac arrest during exercise decreases approximately 50% when compared to vigorous exercise. The risk of cardiac arrest in low-moderate exercise as in rehabilitation programs is 1:111,966 person-hours of exercise for cardiac patients and the risk of sudden death is 1:783,972 person-hours of exercise (Balady, et al., 1994).

Psychological Changes

Exercise has also shown to have a significant direct relationship with improved psychological well-being and social adjustment and function (Cardiac Rehabilitation Guideline Panel, 1995), as well as personal, social, and physical aspects of quality of life (Deshotels, Planchock, Dech & Prevost, 1995). This is important because patients with cardiovascular disease may suffer from long term psychological distress and may have symptoms of depression, fatigue and/or reduced energy (Denollet, 1993). It is reported that 52% of patients who have had a myocardial infarction or coronary artery bypass graph experience psychological distress with symptoms such as anxiety, depression decreased self esteem and low levels of work and family functioning. All of these symptoms may continue for months and/or years (Murray, Munford & Munford, 1993).

Further, approximately 10-20% of myocardial infarction patients suffer from severe depression, and /or anxiety disorders, one-fourth of patients do not return to sexual activity and one-half decrease their sexual activity. Other psychosocial issues include family and marital problems, social isolation, and substance abuse (Taylor & Berra, 1993). Of those patients undergoing coronary artery bypass graft surgery, up to one-third of the patients endure some type of psychological impairment preventing them from returning to a productive lifestyle. Other specific issues exist for heart patients as well, such as anxiety about returning to activity due to concerns about recurring pain. In addition, those who actually experienced pain upon resumption of activity felt depressed and discouraged that the procedure was a failure (Murray & Beller, 1983). Such negative psychological issues influence a patients quality of life and possibly even affect morbidity

and mortality (Taylor & Berra, 1993).

Physical exercise affects the psychological well-being by reducing anxiety, muscular tension and depression, and promoting well-being (Leon et al., 1990). CAD patients are believed to experience similar benefits; reduced anxiety and depression, increased self esteem and more positive perception of their health (Thompson, 1988).

CAD patients who participate in education, counseling, psychotherapy and stress management programs have also shown improvements in quality of life (Balady, et al, 1994). Similarly, another study demonstrated that some direct intervention such as stress management counseling, may be more effective in reducing negative psychological issues in the CAD patient than exercise (Leon, et al., 1990).

With over half of myocardial infarction or coronary artery bypass graph patients experiencing some type of psychological distress, the need for psychological assessments and improvements has become an important issue. Pashkow, et al. (1995) suggested that psychological assessment is of great importance to initiate the long term well-being of cardiac patients. Taylor and Berra (1993) stated that in addition to assessment, there should be referral of patients for psychological help and monitoring the psychological status of the patient.

Social Changes

Along with the physical changes that cardiac patients endure, there are social changes and issues that must be addressed. For patients with cardiovascular disease, social contacts have a lowering effect on mortality rates due to cardiovascular

complications (Kaplan et al., 1982). When undergoing cardiovascular procedures and/or complications, patients under go social relationship, sexual functioning and vocational changes (Pashkow, et al., 1995). Social relationships have been found to be beneficial to the general health status due to the feeling of belonging and support that arise from social contacts (House, Robbins & Metzner, 1982). Social status, being married or widowed, has an effect on recovery. The married patients are more likely to recover quicker (Loose and Fernhall, 1995) and have a better chance of survival. Also, being male increases chances of speedier recovery (Pashkow et al., 1995). Men have a significant relationship between social contacts and reduced mortality. However, correlations between the two variables for women are high but not significant (House, et al., 1982).

Return to work rates are also found to be higher in men than in women (Deshotels, et al., 1995). A vocational outcomes study has indicated that cardiac rehabilitation patients return to work more frequently and incur reduced cost due to sick leave (Levin, Perk & Hedback, 1991). Berkman and Syme (1979), found that both formal and informal social contacts have a positive effect on lifestyle and reduced mortality rates. It has been observed that exercise therapy and positive changes that occur in the psychological realm of health also positively influence social affairs (Murray & Beller, 1983) thus re-enforcing the role of social relationships in the cardiac rehabilitation process.

Cardiac Rehabilitation as it Relates to Health and Outcomes

Health as defined by the World Health Organization is "a state of complete

physical, mental, and social well-being and not just the absence of disease and infirmity." This definition has led to an interest in research of health-related quality of life (McCarthy, et al., 1995). Health related quality of life may be either objective or subjective (Erickson & Patrick, 1993) and can be defined as a multidimensional concept made of an individual's functional abilities, symptoms, and their consequences, as to the way a person feels or functions (Loose & Fernhall, 1995). According to American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), quality of life has three domains: 1) Physical status and functional abilities 2) Psychological status and well being and 3) Social interactions and role functions (Guidelines for Cardiac Rehabilitation, 1995). Quality of life has become a topic of interest in cardiac rehabilitation outcomes as indicated through a survey at the 1993 AACVPR annual meeting (Pashkow, et al., 1995).

Cardiac rehabilitation positively affects quality of life, specifically the personal, social and physical aspects (Deshotels, et al., 1995). Psychological issues can also affect quality of life and therefore exert influence on mortality and morbidity (Taylor & Berra, 1993). Most often, quality of life data is self reported before and after some type of treatment. Sixty-two percent of cardiac rehabilitation programs use some form of quality of life assessment (Pashkow, et al., 1995).

With the changes anticipated in the health care system, it has become important to assess the outcomes of treatments. In the past, outcomes were measured and observed solely through mortality and morbidity rates and physiological data (Guidelines for Cardiac Rehabilitation Programs, 1995). By focusing on morbidity, mortality and physical functioning, quality of life data are acquired. Self-reported health perceptions allow for

this information to be obtained (McCarthy, et al., 1995). In addition, it has been observed that the traditional physiological tests only weakly relate to the energy needs of activities of daily living. The data collected by the physiological assessment tools are useful to the medical professional, but provide little information to the patients (Guyatt, et al., 1993). These measures are no longer enough (Deshotels, et al., 1995). First hand information obtained from the patient's perspective, allows clinicians to follow the progression of the patient as well as obtain the patient's view of his or her health status (McCarthy Jr., et al., 1995).

The AACVPR Outcome Committee developed guidelines for choosing outcome tools, which are as follows: the tool must be clinically relevant, reproducible, valid, sensitive to change, easy to administer and understandable (Pashkow, et al., 1995). Other characteristics that appear to be important may include brevity and standardized measures (McCarthy Jr., et al., 1995).

Oklahoma State University Wellness Center's Cardiac Rehabilitation Program

The Oklahoma State University Wellness Center's Cardiac Rehabilitation program is multifaceted and individualized. The patient is referred to the program by his or her physician. The patient participates in one hour monitored exercise sessions three times and week. The length of the program ranges from 6 to 12 weeks. The cardiovascular component involves walking on treadmills and biking on recumbent and/or airdyne bicycles. If able, the patient also participates in a strength training program approximately 6 weeks into the program. There is an educational component to this program. Anatomy

and physiology, medications and stress management are topics addressed in the education classes. Also one-on-one nutrition education with a dietician is available for the patient. If the need for psychological consultation is observed by the staff, the patient is referred for counseling (R. Purdie, personal communication, August 6, 1996).

Quality of Life, Outcomes and Health Care

Socrates said that he feared some things worse than death, and that it is not life itself, but the quality of life that matters most (Cohen, 1982). Health care reform has influenced the healthcare system in controlling the cost of health care expenses through pre-paid health plans, preferred provider organizations and professional review organizations. Unfortunately, many times this leaves out needs of the patient and ignores patient health status and functioning in daily activities (Tarlov, et al., 1989). Perhaps the best means for determining if patient goals in physical functioning and well-being are met is to ask the patient, however in the medical field, the patients are rarely approached for information (Ware & Sherbourne, 1992).

The term, "quality of life" has many contexts. In the context of cardiac rehabilitation, quality of life is the assessment of overall life quality, not just extended life, (Cohen, 1982). In addition, quality of life assessments are useful in evaluations and comparisons of health profiles in groups undergoing various treatment (McHorney, Ware, Lu & Sherbourne, 1994a). The use of health surveys to access patient outcomes has provided a measurement that is important to the patient in ways that are similar to daily

life such as going to the market, an outcome that cannot be measured by laboratory test (Jette and Downing, 1994). Obviously, to obtain these outcomes the patients must be asked directly for their input (Cella, 1995).

The rising need to assess an individuals health has also sparked interest in the field of survey research to develop practical, valid and credible instruments that encompass all domains of health (Read, Quinn & Hoefer, 1987). Because of the increasing interest in assessing the patient population for outcomes and not relying on medical tests for those outcomes, a demand existed for a tool that would permit the evaluation of patient responses as they relate to daily functioning and well-being such as physical, mental, social role function and general health (Stewart, Hayes & Ware, 1988).

Instruments Used in Outcome Studies

Previously, the Medical Outcome Survey SF-20 has proved to be an effective standardized tool for assessing general health (McHorney, Ware, & Raczek, 1993). However, there was a need to extend the Medical Outcome Survey SF-20 to SF-36. The effort to expand the Medical Outcome Survey SF-20 to include more ranges of health concepts and improving response choices has been successful (McHorney, et al., 1994a). The realm of health in the MOS Short Form 36, has grown to include more components, such as vitality and role function due to emotional problems (Stewart, et al., 1988). The Medical Outcome Survey SF-36 was improved by adding four new aspects in the activity questions and by re-scaling the role functioning scale to a continuum as well as including new items to the social, functioning and pain scales (Anderson, Aaronson & Wilkin,

1993). Precision in measuring each component has been improved by the MOS SF-36 (McHorney, et al., 1993). Specifically, when compared to the SF-20, the SF-36 has extended its responses to a three level continuum of extent of limitations instead of the dichotomous choices of limitations used in the SF-20 (Anderson, et al., 1993).

There are many assessment instruments available for use within various applications and groups. The Sickness Impact Profile, the Quality of Well-being Scale, and the Nottingham Health Profile are just some of the tools that can be used for different population groups. The Health Perceptions Questionnaire, the Mental Health Inventory, Sickness Impact Profile, the Quality of Well-being Scale, and Medical Outcome Study SF-20 Health Survey are useful in studying the reliability use in specific groups. However, studies utilizing the Medical Outcome Survey SF-36 found it to be valid when used by diverse groups (McHorney, et al., 1994a).

Each survey tool has its place within research. The Quality of Well-being scale could be useful when evaluating health care cost effectiveness. When measuring a broad range of specific dysfunction the Sickness Impact Profile is an appropriate tool. The General Health Rating Index is advantageous when a brief, self-administered instrument is needed. The Quality of Well-being Scale, which is most often used to compare the health status for individuals in the context of health program evaluation is rather lengthy and requires an interview. The Sickness Impact Profile is behaviorally based with the purpose to measure effects of outcomes in terms of evaluation, program planning and policy formulation. It is made up of 136 questions and requires judges for scoring (Read, et al., 1987). In cardiac rehabilitation research, a study of pre-cardiac rehabilitation patients

indicated the MOS-36 was well validated to examine the health of cardiac arrest patients as compared to the Sickness Impact Profile (Jette & Downing, 1994). Results from a study, suggest that the Sickness Impact Profile not be used to assess the health status of healthy older adults (Andresen, Patrick, Carter and Malmgreen, 1995). High correlations were found when comparing the MOS SF-36 and Angina Pectoris Quality of Life Questionnaire (APQLQ) with regard to physical activity, emotional distress and mental health. The somatic symptoms correlated more closely to the vitality, mental health and general health (Marquis, Fayol, Joire, & Leplege, 1995). Finally, a study by Garratt, et al., (1993), suggests that the MOS-36 be used with other questionnaires to form a more comprehensive battery of tests.

The Medical Outcomes Study

The Medical Outcome Study (MOS) was a longitudinal study developed to measure the health status of patients. The two main purposes were: "(1) determine whether variations in patient outcomes are explained by differences in system of care, clinician speciality, and clinicians' technical and interpersonal styles, and (2) develop more practical tools for the routine monitoring of patient outcomes in medical practice" (Tarlov, et al., 1989). The MOS had numerous areas of interest, including the summary systems of care, styles of practice, speciality issues and outcome assessment.

The Medical Outcome Survey was a four year study that has both a longitudinal and cross sectional component. The first sampling was taken from English speaking adults visiting various practices over 9 day periods in 1986 (Hayes, et al., 1993). The

longitudinal study sampled 2546 patients with hypertension, heart disease, diabetes or depression. Special properties of the study were that it measured both clinical end points as well as self-reported patient outcomes. These properties lend strong support to the use of patient reports along with medical reports. (Tarlov, et al., 1989).

The Medical Outcome Study wanted to observe how patient and physicians perception of outcome are different and how technology and personal variables affect outcomes (Reisenberg & Glass, 1989). According to patients, their main goal when under medical treatment was to have a more effective life and maintain functioning and well-being (Ware & Sherbourne, 1992). Findings from the Medical Outcomes Study indicate that in order to fully understand the effect disease has on the quality of life, the patient has to be assessed and they have to have input in all domains of health (McHorney, et al., 1993). The Medical Outcomes Study allows for identification and evaluation of various disease group, their treatment, and their perceptions of their health status. The Medical Outcomes Study has also been useful in observing differences in medical conditions. Andresen, et al., (1995) reported that the Medical Outcomes Study Short Form-36 Health Survey scores decrease as the medical condition increases and a decrease in scores with an increase in age for certain domains.

The Medical Outcome Study 36-item Short Form Health Survey (SF-36) originated from a RAND team of developers in the Medical Outcome Study. The Short Form-36 version came from a longer form of Medical Outcome Study health surveys (Anderson, et al., 1993). The SF-36 encompasses eight concepts of health including: physical functioning, bodily pain, role limitations due to physical health problems, role

limitation due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions (Hayes, Sherbourne & Mazel, 1993). These eight concepts were chosen based on literature supporting the need to assess these areas. Many adaptations from other long used surveys were used to create the new SF-36 (Ware and Sherbourne, 1992). The design of the Medical Outcome Study SF-36 survey had the goal of comprehensiveness. It was to be representative of the multidimensional health concepts and provide a full range of health states (McHorney, et al., 1993). Since it's creation, the Medical Outcome Survey SF-36 has been used in more than 200 studies. There were over 1 million forms of the Medical Outcome Survey SF 36 administered in 1992 (Anderson, et al., 1993).

The Structure of the MOS Short-Form 36 (SF-36)

The make-up of the Medical Outcome Survey SF-36 was designed with eight main sections: 1) physical functioning-10 items, 2) role function due to physical problems-4 items, 3) role function due to emotional problems-3 items, 4) social functioning-2 items, 5) mental health-5 items, 6) energy/fatigue-4 items, 7) health perceptions-6 items, and 8) bodily pain-2 items. Each component's method of assessment was created relative to their make-up and definition. Physical functioning scores were obtained by inquiring about limitations due to health in activities ranging from strenuous to basic. Well-being and psychological distress measures were used to access mental health. Role functioning due to physical limitations and social functioning status were obtained by limitations due to health. The pain component was included to assess physical discomfort. The health

perception questions were designed to identify how the patients rate their health (Stewart, et al., 1988). The multidimensional health survey SF-36 uses the Likert scale for increased response discrimination (McHorney, et al., 1994a).

Criteria for Assessment Tools

When using the MOS SF-36 as a tool, there are five psychometric requirements. They include: 1) data collection completeness, 2) assumptions underlying summated rating scales, 3) scaling success rates determined by test of item-discriminant validity, 4) internal-consistency reliability and 5) features of score distribution directly related to the precision and usefulness of the scale (McHorney, et al., 1994a).

McHorney and colleagues (1994a) found that the SF-36 met all five criteria when sampling diverse patient groups of chronic conditions (hypertension, diabetes, myocardial infarctions and congestive heart failure). Data completion rates were high and scaling assumptions for all eight scales were satisfied. Likert's criteria of equivalence of item means and variances was met. In addition, item internal consistency standards were met and strongly supported the content validity of each scale. Also, internal consistency reliability surpassed the standards of reliability. Finally, score distribution requirements were satisfied as they relate to the precision and usefulness of the scale (McHorney, et al., 1994a).

Components of the MOS SF-36

Physical

The physical component is assessed by providing a range of responses from basic to extreme activities, as well as by providing response choices that are able to estimate the extent or severity of each limitation by using a three level response continuum (Ware & Sherbourne, 1993). A study by Stewart and colleagues (1988), suggested that increased levels of exercise correlated with a higher functioning and well-being with chronic disease patients. Additionally, exercise has been associated with changes in not just the physical realm, but also in the role and social functions, pain and fatigue (Marquis, et al., 1995). In the Medical Outcomes Study, it was observed that the physical functioning questions were the most valid in identifying differences among the patients (McHorney, et al., 1993).

Mental

The mental health questions were taken from the five-item mental health scale which assess anxiety, depression, loss of behavioral or emotional control and psychological well-being (Ware & Sherbourne, 1992). McHorney and colleagues (1993) found (without the use of the psychiatric patient sample) the mental health scale was most valid scale followed by role-emotional and social functioning scale. When comparing the healthy population to the patients with chronic conditions, the patient population had 50% poorer mental health scores, and were lower in health perceptions and role limitations (Stewart et al., 1988).

Role Limitations (Physical and Mental)

The role limitation component of the MOS SF-36 was developed to assess the degree in which physical and mental problems interfere with various role functions. An adaption from the SF-20 to the SF-36 was the changing of questions to relate to retired individuals and those with more than one role. It also is different in that it uses both physical and mental problems to access role functioning problems (Ware & Sherbourne, 1992). Research indicates that the general health perceptions were highly sensitive in distinguishing between patients with severe and minor physical symptoms. However, they were not so sensitive in the mental health section of general health perceptions (McHorney, et al., 1993).

Bodily Pain

The bodily pain question originates from the MOS SF-20 by asking the frequency of pain or discomfort. The MOS SF-36 adds a second dimension to the question by asking how much the pain interferes with normal activities and was taken from the Behavioral Effects of Pain Survey. Having done this, there was an increase in reliability and precision, compared to that of the SF-20 (Ware & Sherbourne, 1992). Varying results in the McHorney, et al. (1993) study on convergent validity may be caused by the fact that some chronic diseases such as hypertension do not create a great amount of pain.

Social Functioning

Many instruments assess social functioning through activities or frequency of participation in various activities. However, the effects of emotional health are more sensitive than physical health problems with respect to social functioning (McHorney, et

al., 1993). The two social functioning questions on the SF-36, ask how physical and emotional health, affects social functioning.

Vitality

Vitality was a new addition to the SF-36. It is a subjective measurement of perceived well-being (McHorney, et al., 1993). The new items were added from the five-item mental health scale (MH 1-5) and from the Hanes survey (Ware & Sherbourne, 1992). The intent of these questions was to probe areas such as energy and fatigue (McHorney, et al., 1993). The sensitivity of these question to the impact of disease has been found in various clinical studies of chronic disease patients (Ware & Sherbourne, 1992).

General Health

The general health questions of the MOS SF-36 were taken from a combination of the Current Health Scale and the MOS SF-20 survey. The improvements from using a five-item scale MOS SF-36 included higher correlations with the General Health Rating Index, it was more acceptable to the respondents (seemed less redundant) and it was a more comprehensive sample of content in the Health Perceptions Questionnaire (Ware & Sherbourne, 1992).

Benefits of Using MOS SF-36

The MOS SF-36 has proven to be useful in measuring many areas of interest, specifically the benefits of treatments (McHorney, et al., 1994a). The structure of many health surveys is lengthy and this factor has lead others to develop shorter surveys. Some

researchers have developed single-item tools of measurements. The MOS SF-36 was designed as a compromise between the lengthy and the single-item tools (Stewart, et al., 1988). Even though it is relatively shorter than other surveys, it includes a unique component in vitality that allows for better representation of the health perception domain as well as providing increased measurement precision for various scales (McHorney, et al., 1993). Factors that make the SF-36 useful are: it is brief (five to ten minutes to complete), comprehensive and has a lower respondent burden than other instruments (Ware & Sherbourne, 1992). A study by Brazier and colleagues (1992) found the MOS SF-36 to be easy to use, acceptable to patients and both reliable and valid.

Validity and Reliability

In order to determine if the instrument to be used appropriately measures the variable it is intended to measure, the issue of validity must be addressed. Criterion, content and construct are three types of validity (Nunnally, 1978). Research on the MOS SF-36 has focused on several types of construct and criterion validity. The validity of the SF-36 sub-scales has demonstrated in earlier studies against clinically defined criterion groups (Anderson, et al., 1993). In a study that compared a combination of minor and serious chronic medical and/or psychiatric conditions, the results indicated that all scales were not equally valid within the group comparisons. Overall, patients with serious medical conditions compared to minor medical conditions scored lower in all eight scales, as would be expected. The physical function scale was the most valid subscale in

distinguishing differences between patients with minor and serious conditions (McHorney, et al., 1993).

Results of this study agreed in terms of psychometric and clinical tests of validity (McHorney, et al., 1993). The eight dimensions of the SF-36 were strongly correlated with patient reports of overall general health providing evidence of criterion validity (Jenkinson, Wright, & Coulter, 1994). Stewart and colleagues (1988) found all correlations between the eight health measures were statistically significant, supporting construct validity.

Item-discriminant validity was found to be higher than other scales at 99.5%. In 92.5% of all tests, item scales correlations exceeded other scales. Of the remaining 7.5% that did not meet item-discriminant standards, it was estimated that the cause for 94% of the low scores was due to a larger standard of error and 6% was due to the poorer item discrimination in some sub-groups. The problems in the item-discrimination occurred in the general health (39%), physical functioning (26%) and vitality (23%) questions across four various sub-groups (McHorney et al., 1994a).

Each scale of the SF-36 achieved the minimum internal consistency reliability standards of 0.50-0.70, but only 2 scales met the recommended standards of 0.90. The scales ranged from 0.78 in general health to 0.93 for physical functioning. When looking at reliability across group scores and scales, the minimum requirements were met (McHorney, et al., 1994a). In other studies reliabilities were acceptable for each scale for each group, even for groups over the age of 75 and with serious medical conditions (Stewart, et al., 1988). The study had reliability coefficients from 0.81 to 0.88 in the

health scales and 0.76 and 0.88 in the general population sample. The congestive heart failure groups reliability was 0.77 to 0.87 and for the myocardial infarction group it was 0.77 to 0.88. The internal consistency reliabilities were slightly lower in the SF-36 than the longer version of the MOS survey. In this study, alpha internal consistency reliablity coefficients were: total scale = .936, role functioning/emotional subscale = .684, physical functioning subscale = .875, general health subscale = .768, mental subscale = .819, vitality subscale = .910, role functioning/physical subscale = .715, pain subscale = .725 and social functioning subscale = .759.

Problems When Using the MOS SF-36

The recurrent problem found in the MOS SF-36 was with floor (lowest score possible) and ceiling (highest score possible) scores (Ware and Sherbourne, 1992). Andresen and colleagues (1995) found a tendency for scores of the SF-36 to have ceiling effect. The reason behind the substantial ceiling effect for the role functioning and social functioning scales is that the highest score is represented by the absence of limitations. A possible solution to this problem in the role functioning area would be to use categorical rating scales with more specific areas of limitations as opposed to the dichotomous response scale. The ceiling effect in the social functioning scale could be reduced by using different functions that represent the social realm (McHorney, et al., 1994a). The issue of floor effects was most often seen in physical functioning with severely ill patients however, the floor effect was not a major problems in other studies. Solutions to the problems would be to design scales that would include extreme low-level activities that encompass

daily self-care activities (Ware & Sherbourne, 1992). No one tool is perfect in assessing every population (Andresen, et al., 1995) and when looking for minor differences in health status a more precise, complex instrument that would limit the ceiling and floor effect would be more useful (Jenkinson, et al., 1994).

Data Quality of MOS SF-36 in Various Populations

Data quality for different populations including groups such as the elderly, socioeconomic disadvantaged and the ill patients has varied. However, the SF-36 has been successfully used across 24 subgroups with variations of sociodemographic characteristics, medical and psychiatric diagnosis and disease severity (McHorney, et al., 1994a). In research using the MOS SF-36 by Jenkinson, et al., (1994), they studied the results of a large community sample from the Family Health Services to determine validity and reliability in different levels of ill-health. Results in agreement with previous studies, indicated that the MOS SF-36 had strong evidence for assessing groups with varying extent of illness and an appropriate measure for measuring treatment outcomes. To date there has been limited research with cardiac rehabilitation programs using the MOS SF-36. However, in a study by Jette and Downing (1994), the MOS SF-36 was used as an assessment tool prior the entrance into the rehabilitation program and proved to be practical for measurement in the clinical setting with cardiac patients. The results were also comparable to the Sickness Impact Profile (SIP), a well established outcome tool.

Elderly patients (65 years old +) are the major users of health care (Lyons, Perry & Littlepage, 1994). A study by Andresen and colleagues (1995) assessed the health of

symptom free older adults. Three scales of MOS SF-36 were used within one of the tools used to assess this population. The results indicated that the MOS SF-36 scores decreased with an increase in medical conditions and age. The MOS SF-36 was found to be useful with the elderly population (Lyons, et al., 1994).

Data Completion

A previous study on the elderly found higher rates of missing data in 65-74 years old subjects when using a postal survey (Brazier et. al., 1992). However, another study proved only 1.2% rate of missing data (Lyons, et al., 1994). The completion of the survey depends greatly on sociodemographic subgroups. Overall, the MOS SF-36 rate of completeness across diverse groups of chronically ill patients was high. The high rate falters some when dealing with the elderly, minorities, and the socioeconomically disadvantaged. It was suggested that type print be larger when the survey is used for the elderly (McHorney, et al., 1994a). Research by Stewart and colleagues (1988) found high rates of missing data in the elderly, those with less than an high school education and diabetes and heart disease groups. They also found that the most frequent uncompleted data (8%) was in the physical and role functioning scales. The data collection procedures also have an effect of data completeness. The higher missing data was found in the mail respondents versus the telephoned respondents (McHorney, Kosinski, & Ware, 1994b).

Distribution of MOS SF-36

The distribution or administration of the survey influences the response rate, data

quality, missing data and non-response bias. McHorney, et al., (1994b) lead a national study to compare data collected from the SF-36 via mailing or telephone interview. Overall, mailing the surveys was cheaper, $27.07 per case compared to $47.86 per case (a 77% higher cost). The telephone interview had fewer missing data (0.49 items vs.1.59 items). This occurred in all domains except when looking at the sociodemographic characteristics. The total response rate for both administrations was 77.1%. The mailed responses were significantly higher at 70.2% compared to the telephone interview 68.9%. The issue of non-respondents was evident in both types of administration but not significantly different.

CHAPTER III

METHODS AND PROCEDURES

Research Approval

Appropriate forms were obtained and completed by the researcher and approved by the Internal Review Board (IRB) at Oklahoma State University. An explanation of the research design and methods of the study was presented in this proposal. Permission to survey patients of Dr. Pirzada Majid, the physician supporting the study, was documented and included with the Internal Review Board forms.

Selection of Subjects

The researcher, with approval and permission from Dr. Pirzada Majid, obtained names and addresses of patients. Subjects were selected based on criteria set by the researcher, which was that the subject must: 1) be between the age of 55-75 prior to July 1, 1996, 2) be a patient of Dr. Pirzada Majid and 3) have had a myocardial infarction or coronary artery bypass graph between May 1994 and May 1996. Information was

obtained from both Oklahoma State University Wellness Center Cardiac Rehabilitation and Dr. Pirzada Majid. The records were used to identify the patients who participated in the cardiac rehabilitation program. The non-participant group was deliberately over-sampled in anticipation that the response rate would not be as high as in those that participated in cardiac rehabilitation.

Survey Instrument

The entire Medial Outcomes Study Short Form 36 Health Survey (MOS SF-36) was used. In addition, sociodemographic questions of age and gender were included. The 11 questions from the MOS SF-36 contained 8 components of health which included: 1) physical functioning, 2) role limitations due to physical health problems, 3) role limitations due to mental health problems, 4) bodily pain, 5) vitality, 6) social functioning, 7) mental health, and 8) general health perception.

The size of print was enlarged to accommodate the 55-75 year old population. Also, extra spacing was included to make reading the survey easier. The MOS SF-36 health survey was the only instrument used in order to maintain a 15 minute or less completion time.

Distribution and Follow-up

The survey, consent form, introductory letter explaining the study, and a self addressed, stamped envelope was mailed to each potential participant. The return envelopes were coded by a research assistant with an identification number to enable the

investigator to distinguish between the participants who did and did not participate in the cardiac rehabilitation program. Two weeks after the first mailing was completed, a second mailing was sent to the non-respondents with a reminder letter. The research assistant, who had no knowledge of the study, research design or subject characteristics, used the identification numbers to distinguish those who were to receive the second mailing. This was done to avoid the possibility of identifying the participants and to ensure confidentiality.

The Analysis Plan

Data Entry

Data collected from the returned surveys were entered into a text file using Perfectworks software on an IBM computer. The data were then be transferred to a Power Macintosh computer at Oklahoma State University. All data cleaning, manipulation and analysis was conducted using SPSS software on the Macintosh computer.

Design

The research was a quasi-experimental treatment/control design. The independent variable was whether the patients did or did not participate in the Oklahoma State University cardiac rehabilitation program. The eight sub-scales of the Medical Outcome Study Short Form - 36 (physical functioning, role limitations due to physical problems, role limitations due to emotional problems, vitality, health perceptions, social functioning, bodily pain and mental health) were the dependent variables. The independent variable

was discrete data and the dependent variables were treated as continuous data.

Pearson product moment correlation coefficients were computed among the eight sub-scales of the MOS SF-36 to determine the degree of relation between the sub-scales. This was done to identify potential problems with multi-collinearity. If the average of the twenty-eight possible correlation coefficients was 0.3 or greater, indicating a potential problem with multi-collinearity between the sub-scales, then independent t-tests were to be used. If the average of all twenty-eight correlation coefficients was less than 0.3 and had no correlation coefficient greater than 0.70, a MANOVA with a Tukey's Post Hoc procedure was to be used to determine between group differences with respect to the dependent variables. Since there was a tendency toward multi-collinearity, independent t-test were used. Prior to conducting any analysis, the t-test equality of variance assumption was identified and checked.

CHAPTER IV

RESULTS

This study was performed to assess differences in cardiac rehabilitation participants and non-participants of cardiac rehabilitation with respect to the eight health components of the Medical Outcomes Study Short-Form Health Survey. The eight components of the survey were: physical functioning, role limitations due to physical problems, role limitations due to emotional problems, social functioning, pain, vitality, mental health and general health. The null hypotheses essentially stated that there would be no significant differences between the two groups for each health component. The independent variable was whether the subjects participated or did not participate in cardiac rehabilitation. The eight health components were the dependent variables.

Response Rates and Demographics

A total of sixty-seven questionnaires were mailed to potential participants that met the research criteria. Thirty-eight questionnaires were returned, 30 from the first mailing

and 8 from the second. Thus, the response rate was 57%. However, 4 subjects were excluded from the sample for not providing an informed consent, for providing incomplete data, or being too young to participate in the study. The useable questionnaire response rate was 50.7% (60% treatment group and 47% control group). Only 14.7% of the respondents were women (8.3% treatment group and 18.1% control group) and 85.3% were men in the study (91.6% treatment group and 81.8% control group). The mean age for the total group was 66.6 years old (67.25 years old, treatment group and 66.0 years old, control group).

Analysis

The software used to analyze data was SPSS 6.1 for the Power Macintosh. First, data cleaning was performed. Data recoding and transformation of raw data were done according to protocol suggested by the authors of the Short-Form 36 Health Survey (Medical Outcomes Trust, 1994). The formula used in the transformation was checked using sample data provided by the authors of the MOS SF-36. Based on the comparison with the sample data, all procedures were performed correctly. Missing data that was found on a particular general health question was substituted by using the mean score of the specified general health questions, as suggested by the authors (Medical Outcomes Trust, 1994).

Descriptive statistics were done on each health component. Results are presented in Table 1 (see Appendix A). T-tests for equality of means were used, which is an assumption for t-test procedures. The equal or unequal equality of variance scores were

used to determine the appropriated *t* statistic with which to identify significant differences. If the equality of variance was greater than .05, results from the *t*-test based on equal variances was used and if the equality of variance was less than .05, the unequal variance *t* statistic was used.

Because of the small number of participants, a .10 alpha level was used to avoid the chance of having a Type II error. Using an alpha level of .10, three components of the eight were found to be significantly different between the two groups. Results can be found in Table 2 (see Appendix A). Implications of these results may be found in the Chapter V.

Physical Functioning

A statistically significant difference was discovered between the two groups with respect to physical functioning ($t = 2.85$, $p \leq .10$). This suggested that the cardiac rehabilitation group had greater levels of physical functioning ($\bar{X}$=85.42 $\pm$9.64) than the control group ($\bar{X}$=68.86 $\pm$23.90), thus rejecting Null Hypothesis I. Difference in means can be seen in Figure 1 (see Appendix B).

General Health

A statistically significant difference was found between the treatment group and the control group for the general health variable ($t = 2.36$, $p \leq .10$). The cardiac rehabilitation group had significantly higher perceived general health ratings ($\bar{X}$=78.92 $\pm$14.25) than the control group ($\bar{X}$=65.01 $\pm$17.44). Therefore, Null Hypothesis VI was

rejected. Refer to Figure 2 (see Appendix B) for difference in means.

Pain

A significant difference was found between the two groups the pain variable of the MOS SF-36 ($t = 1.77$, $p \leq .10$). The treatment group ($\overline{X}$=80.83 $\pm$17.12) experienced less pain, measured by the pain scale than the control group ($\overline{X}$=67.23 $\pm$23.39). Thus, the Null Hypothesis VII was rejected. Differences in means can be seen in Figure 3 (see Appendix B).

Remaining Variables

No significant differences between group differences existed for the following variables: role limitations due to physical problems, role limitations due to emotional problems, vitality, social functioning and mental health. Therefore, Null Hypotheses II, III, IV, V and VIII failed to be rejected. Figures 4 through 8 (see Appendix B) show a trend between the means of the two groups for the remaining variables.

CHAPTER V

DISCUSSION

The purpose of this study was to assess various health outcomes and to determine if differences exist between cardiac rehabilitation participants and cardiac patients that did not participate in a rehabilitation program. Cardiovascular disease accounted for approximately 745,000 myocardial infarctions and 485,000 coronary artery bypass graphs in 1993 and accounted for $56 billion in health care costs in 1994 (Cardiovascular Disease Statistics, 1996). Cardiac rehabilitation programs have been implemented to bridge the recovery gap between hospital discharge and resuming everyday activities as well as to be an education tool for modifying risk factors. However, less than a third of CAD patients take advantage of this resource (Cardiac Rehabilitation - Beneficial But Underused, 1995).

There is little cardiac rehabilitation research that comprehensively assesses self-reported outcomes of patient well-being. The MOS SF-36 is a relatively new, comprehensive tool that can be used to measure cardiac rehabilitation outcomes such as physical functioning, social health, mental health and health perceptions. With positive

outcomes, cardiac rehabilitation research could be effective in demonstrating is benefits to physicians, encouraging them to prescribe cardiac rehabilitation for their patients and in turn providing patients with the opportunity to benefit from the cardiac rehabilitation programs.

Background of Study

This study was performed to determine whether differences existed between the cardiac rehabilitation participants and the non-participants on each of eight health components of the Medical Outcomes Study Short Form-36 Health Survey. The eight components being physical functioning, role limitations due to physical problems, role limitations due to emotional problems, social functioning, pain, vitality, mental health and general health. Subjects were selected based on criteria set by the investigator previously described.

Results

Results suggest that there was a significant difference between the treatment group (cardiac rehabilitation participants) and the control group (non-participants of cardiac rehabilitation) in three health components including physical functioning, general health and pain. The results failed to identify significant differences between the two groups in the other five health components: role limitations due to physical problems, role limitations due to emotional problems, social functioning, vitality and mental health.

Results of this study suggest that cardiac rehabilitation may be beneficial in

reducing pain, increasing physical functioning and general health perceptions. However, no causal associations may be made between the two groups in relation to the eight health variables. Even though no significant differences existed in the other five health components, the study did reveal that in seven of the eight sub-scales of the MOS SF-36, a trend existed toward healthier scores in the treatment group.

Physical Functioning and Pain

Significant difference were found between the two groups in which the treatment group reported experiencing less pain and increased physical functioning. Thompson (1988) found that with exercise training in cardiac rehabilitation patients, measurement of VO2 increased 11-66%. Exercise training also increases muscular strength and endurance allowing patients to participate in numerous activities that would previously be limited by lack of strength and/or endurance (Guidelines for Cardiac Rehabilitation Programs, 1995).

The reduction in pain may be attributed to the lower heart rate at specific sub-maximal work intensities that occurs in exercise training with an increased VO2. Thus, a lower heart rate would allow work at higher intensities without experiencing anginal pain due to ischemia. The MOS SF-36 did not specify if the pain the subjects incurred was anginal, muscular or joint. Therefore, no assumptions pertaining directly to ischemia causing anginal pain could be made. However, the pain scale questions could be used to assess a persons limitation due to overall pain or the questions could be modified to assess only anginal pain.

General Health

The general health questions assessed the subjects overall view of their health status, non-specific to any one aspect of health. The significant difference found in the general health scale may be attributed to a combination of all the other health scales. A trend of higher scores existed in the treatment group for all eight health components. A combination of all eight scales may be indicative of the significant difference found in the general health scale that assesses over-all perceived health status.

In the symptom free adult, exercise can increase perceived health ratings and lower the demand for follow-up medical services (Shepard, 1989). In 1989, there was a trend that participation in a comprehensive cardiac rehabilitation program decreases follow-up medical costs (Ades, 1993). Results from the Medical Outcome Study which used the MOS SF-36, suggest that increases in well-being as perceived by the patient may reduce health care costs and utilization (Stewart, et al., 1989).

Ades (1993) found a 20% decrease in cardiac and overall mortality rates over a three year period in cardiac rehabilitation patients. Various studies have indicated that individuals with "poor" perceived health, have reported high levels of isolation, negative life events, depression, job problems, unhappiness, life dissatisfaction, unemployment etc. (Kaplan and Camacho, 1983), all of which are factors that may impact in cardiac patients. Psychological factors such as these, are believed to influence perceived health, risk for disease, disease outcomes and risks of mortality (Kaplan and Camacho, 1983). Research by Mossey and Shapiro (1982) reported that "poor" scores compared to "excellent" scores on self-rated health (SRH) was associated with an increased risk of both early and

late mortality, at a rate of 2.92 and 2.77 times higher respectively. The general health scale may be a useful tool to assess perceived health and investigate lower re-hospitalization costs and mortality rates in cardiac patients.

Barriers to the Study

There are several issues that need to be addressed in this study. The original sample size was somewhat small (n=67). Also, there was a very small treatment group (n=20) compared to the control group (n=47). This inequality among subject numbers may have provided a skewed comparison between the two groups. The number of males and females in both the overall study and the groups was greatly unequal and may have resulted in a bias toward the male population. Also, the fact that the participants were all volunteers for the study may have influenced reported outcomes.

This assessment was performed only once, varying from 12 weeks to 2 years post hospital discharge. A point to be taken into consideration would be to perform the assessment directly after completion of cardiac rehabilitation programs and/or twelve to fifteen weeks post cardiac event or surgery if they did not participate in cardiac rehabilitation. This would reduce the chance of other health related problems interfering with the outcomes of cardiac rehabilitation.

Suggestions for Future Studies

This research study was the first attempt to assess cardiac rehabilitation participants and non-participants using the MOS SF-36. Future studies should include a

larger sample size as well as equal numbers in the two groups. The study should be broadened to include multiple cardiac rehabilitation programs that are similar and should work with several physicians.

To observe changes that occur in the cardiac rehabilitation patients, the MOS SF-36 could be administered as a baseline at hospital discharge or prior to entrance into the cardiac rehabilitation program. In addition, a post-test survey could be performed at the same time for both groups, either after a cardiac rehabilitation program or 12-15 weeks after hospital discharge. Then the appropriate comparisons and conclusions could be made between the two groups as related to the health components of the MOS SF-36 and the effects of cardiac rehabilitation.

This study may be used as a learning tool for researchers that may want to focus on one or more of the MOS SF-36 eight health components. This tool could also be used in the cardiac rehabilitation population to identify differences and/or changes that occur with or without cardiac rehabilitation in the eight aspects of health. Finally, this instrument could be used to determine if the health components are related within the population.

REFERENCES

Ades, P.A. (1993). Decreased medical costs after cardiac rehabilitation: a case for universal reimbursement. Journal of Cardiopulmonary Rehabilitation, 13 (2), 75-77.

Ades, P.A., Huang D., and Weaver, S. (1992). Cardiac rehabilitation participation predicts lower rehospitalization costs. American Heart Journal, 123 (4 Pt. 1), 916-921.

Anderson, R.T., Aaronson, N.K., and Wilkin, D. (1993). Critical review of the international assessments of health-related quality of life. Quality of Life Research, 2 (6), 369-395.

Andresen, E.M., Patrick, D.L., Carter, W.B. and Malmgreen, J.A. (1995). Comparing the performance of health status measures for healthy older adults. Journal of the American Geriatric Society, 43 (9), 1030-1034.

Balady, G.J., Fletcher, B.J., Froelicher, E.S., Hartley, L.H., Krauss, R.M., Oberman, A., Pollock M.L. and Taylor, C.B. (1994). Cardiac rehabilitation programs: a statement for health professionals from the American Heart Association. Circulation, 90 (3), 1602-1610.

Bär, F.W., Höppener, P., Diederiks, J., Vonken, H., Bekkers, J., Hoofd, W., Appels, A., and Wellens, H.J.J. (1992). Cardiac rehabilitation contributes to restoration of leisure and social activities after myocardial infarction. Journal of Cardiopulmonary

Rehabilitation, 12 (2), 117-125.

Berkman, L. and Syme, L. (1979). Social networks, host resistance and mortality: a nine year follow-up study of Alameda county residents. American Journal of Epidemiology, 109 (2), 186-199.

Brazier, J.E., Harper, R., Jones, N.M.B., O'Cathain, A., Thomas, K.J., Usherwood, T., Westlake, L. (1992). Validating the SF-36 health survey questionnaire: new outcome measure for primary care. British Medical Journal, 305 (1), 160-164.

Burden of Chronic Disease and Infant Mortality. National Center for Chronic Disease Prevention and Health Promotion, (1995). Internet materials, File: http://www.cdc.gov/nccdphp/burdis.htm

Cardiac Rehabilitation - Beneficial But Under-used. (1995). The Doctor's Guide to the Internet. Internet materials, File: http://www.pslgroup.com/dg951011b.htm

Cardiac Rehabilitation Guideline Panel. (1995). Cardiac rehabilitation as secondary prevention. American Family Physician, 52 (8), 2257-2264.

Cardiovascular Disease Statistics. (1996) American Heart Association. Internet materials, File: http://www.amhrt.org/heartg/cvstats.html

Cella, D.F. (1995). Methods and problems in measuring quality of life. Support Care Cancer, 3 (1), 11-22.

Cohen, C. (1982). On the quality of life: some philosophical reflections. Circulation, 66 (supp.III), III29-III33.

Denollet, J. (1993). Emotional distress and fatigue in coronary heart disease: the global mood scale (GMS). Psychological Medicine, 23 (1), 111-121.

Deshotels, A., Planchock, N., Dech, Z and Prevost, S. (1995). Gender differences in perceptions of quality of life in cardiac rehabilitation patients. Journal of Cardiopulmonary Rehabilitation. 15 (2), 143-148.

Erickson, P. and Patrick, D.C. (1993). Health Status and Health Policy. New York: Oxford University Press.

Froelicher V.F., Herbert, W., Myers, J. and Ribisl, P. (1996). How cardiac rehabilitation if being influenced by changes in health care delivery. Journal of Cardiopulmonary Rehabilitation, 16 (3), 151-159.

Garrett, A.M., Ruta, D.A., Abdalla, M.I., Buchingham, J.K. and Russell, I.T. (1993). The SF 36 health survey questionnaire: an outcome measure suitable for routine use within the NHS? British Medical Journal. 306 (6). 1440-1444.

Guidelines for Cardiac Rehabilitation Programs 2nd Edition. (1995). American Association of Cardiovascular and Pulmonary Rehabilitation. Champaign, Illinois: Human Kinetics.

Guyatt, G.H., Feeny, D.H. and Patrick, D.L. (1993). Measuring health-related quality of life. Annuals of Internal Medicine, 118 (8), 622-629.

Heart Attack and Angina Statistics. (1996). American Heart Association, Internet materials, File: http://www.amhrt.org/heartg/hastat.html

Hays R.D., Sherbourne, C.D. and Mazel, R.M. (1993). The RAND 36-item survey 1.0. Health Economics, 2 (2), 217-227.

House, J.S., Robbins, C. and Metzner, H.C. (1982). The association of social relationship and activites with mortality: prospective evidence from Tecumseh community

health study. American Journal of Epidemiology, 116 (1), 123-140.

Jenkinson, C., Wright, L. and Coulter, A. (1994). Criterion validity and reliability of the SF-36 in a population sample. Quality of Life Research, 3, 7-12.

Jette D.U. and Downing, J. (1994). Health status of individuals entering a cardiac rehabilitation program measured by the Medical Outcomes Study 36-Item Short Form Survey (SF-36). Physical Therapy, 74 (6), 521-527.

Kaplan, G.A. and Camacho, T. (1983). Perceived health and mortality: a nine year follow-up of the human population laboratory cohort. American Journal of Epidemiology, 117 (3), 292-304.

Kaplan, G.A., Salonen, J.T., Cohen, R.D., Brand, K.J., Syme S.L. and Puska, P. (1982). Social connections and mortality from all causes and from cardiovascular disease: prospective evidence from Eastern Finland. American Journal of Epidemiology, 128 (2), 370-381.

Kelly, T. and Donovan, K. (1995). Cardiac rehabilitation in time of health-care reform. American Association of Clinical Nursing, Clinical Issues, 6 (3), 432-442.

Levin, L.S., Perk, J. and Hedback, B. (1991). Cardiac rehabilitation - cost analysis. Journal of Internal Medicine, 230 (5), 427-434.

Leon, A.S., Certo, C., Comoss, P., Franklin, B.A., Froelicher, V., Haskell, W.L., Hellerstein, H.K., Marley, W.P., Pollock, M.L., Ries, A., Sivarajan, E.F. and Smith, L.K. (1990). Position paper of the American Association of Cardiovascular and Pulmonary Rehabilitation. Journal of Cardiopulmonary Rehabilitation, 10 (3), 79-87.

Loose, M.S. and Fernhall, B. (1995). Differences in quality of life among male and

female cardiac rehabilitation participants. Journal of Cardiopulmonary Rehabilitation, 15 (3), 225-231.

Lyons, R.A., Perry, H.M. and Littlepage, B.N.C. (1994). Evidence for the validity of the Short-Form 36 Questionnaire (SF-36) in an elderly population. Age and Aging, 23 (3), 182-184.

Marquis, P., Fayol, C., Joire, J.E. and Leplege, A. (1995). Psychometric properties of a specific quality of life questionnaire in angina pectoris patients. Quality of Life Research, 4 (6) 540-546.

McCarthy Jr., M.J., Shroyer, A.L., Sethi, G.K., Moritz, T.E., Henderson, W.G., Grover, F.L., London, M.J., Gibbs, J.O., Lansky, D., Miller, D., Clark, J. and Hammermeister, K.E. (1995). Self-reported measures for assessing treatment outcomes in cardiac surgery patients. Medical Care, 33 (10 Supp.), S76-S85.

McHorney, C.A., Kosinski, M. and Ware Jr., J.E. (1994). Comparisons of the costs and quality of norms for the SF-36 Health Survey collected by mail versus telephone interview: results from a national survey. Medical Care, 32 (6), 551-567.

McHorney, C.A., Ware Jr., J.E., Lu, R., and Sherbourne, C.D. (1994). The MOS 36-Item Short Form Health Survey (SF-36): III. Test of data quality, scaling assumptions and reliability across diverse patient groups. Medical Care, 32 (1), 40-66.

McHorney, C.A., Ware Jr., J.E. and Raczek, A.E. (1993). The MOS 36-Item Short Form Health Survey (SF-36): II. Psychometric and clinical tests in validity in measuring physical and mental health constructs. Medical Care, 31 (3), 247-263.

Medical Outcomes Trust, (1994). How to score SF-36 health survey. 2nd Ed.

Boston: Medical Outcomes Trust.

Monitoring Health Care in America (3/96). National Center for Health Statistics, Internet matertials, File: http://www.cdc.gov/nchswww/releases/fs_march.htm

Mossey, J.M. and Shapiro, M.A. (1982). Self-rated health: a predictor of mortality among the elderly. American Journal of Health Promotion, 72 (8), 800-808.

Murray, A.B., Munford, A.M. and Munford, P.R. (1993). Behavior therapy of psychological distress in patients after myocardial infarction or coronary bypass. Journal of Cardiopulmonary Rehabilitation, 13 (3), 201-210.

Murray, G.C. and Beller, G.A. (1983). Cardiac rehabilitation following coronary artery bypass surgery. American Heart Journal, 105 (6), 1009-1018.

Nunnally, J. (1978) Psychometric Theory. New York: McGraw-Hill.

O'Connor, G.T., Buring, J.E. Yusuf, S., Goldhaber, S.Z., Olmstead, E.M., Paffenbarger, R.S., and Hennekens, C.H. (1989). An overview of randomized trail of rehabilitation with exercise after myocardial infarction. Circulation, 80 (2), 234-244.

Oldridge, N.B. (1991). Compliance with cardiac rehabilitation services. Journal of Cardiopulmonary Rehabilitation, 11 (2), 115-127.

Pashkow, P., Ades, P.A., Emery, C.F., Frid, D.J., Miller, N.H., Peske, G., Reardon, J.Z., Schiffert, J.H., Southard, D. and ZuWallack, R.L. (1995). Outcome measurement in cardiac and pulmonary rehabilitation by the AACVPR Outcomes Committee. Journal of Cardiopulmonary Rehabilitation, 15 (6), 394-405.

Perk, J., Hedback, B. and Engvall, J. (1990). Effects of cardiac rehabilitation after coronary artery bypass grafting on readmission, return to work, and physical fitness. A

case-control study. Scandanavian Journal of Social Medicine, 18 (1), 45-51.

Purdie, R. (personal communication), May 14, 1996).

Read, J.L., Quinn, R.J. and Hoefer, M.A. (1987). Measuring overall health: an evaluation of three important approaches. Journal of Chronic Disease, 40 (1), 7S-21S.

Riesenberg, D. and Glass, R.M. (1989). The Medical Outcomes Study. Journal of the American Medical Association, 262 (7), 943.

Shephard, R.J. (1989). Exercise in secondary and tertiary rehabilitation: costs and benefits. Journal of Cardiopulmonary Rehabilitation, 9 (5). 188-194.

Stewart, A.L., Greenfield, S., Hays, R.D., Wells, K., Rogers, W., Berry, S.D., McGlynn, E.A. and Ware Jr., J.E. (1989). Functional status and well-being of patients with chronic conditions. Results from the Medical Outcomes Study. Journal of the American Medical Association, 262 (7), 907-913.

Stewart, A.L., Hays, R.D. and Ware Jr., J.E. (1988). Communication: the MOS Short-form general health survey reliability and validity in a patient population. Medical Care. 26 (7). 724-735.

Tarlov, A.R., Ware Jr., J.E., Greenfield, S., Nelson E.C., Perrin, E. and Zubkoff, M. (1989). The Medical Outcomes Study: an application of methods for monitoring results of medical care. Journal of the American Medical Association, 262 (7), 925-930.

Taylor, C.B. and Berra, K. (1993). Psychological factors in rehabilitation. Journal of Cardiopulmonary Rehabilitation, 13 (2), 78-79.

Thompson, D. (1995). Cardiac rehabilitation: how can it be improved? Journal of Psychomatic Research, 39 (5), 519-523.

Thompson, P.D. (1988). The benefits and risks of exercise training in patients with chronic coronary artery disease. Journal of the American Medical Association, 259 (10), 1537-1540.

Ware Jr., J.E. and Sherbourne, C.D. (1992). The MOS 36-Item Short Form Health Survey (SF-36): I. Conceptual framework and item selection. Medical Care. 30 (6), 473-483.

Winslow, E. (1995). Cardiac rehabilitation: clearly a lifesaver. American Journal of Nursing, 95 (9), 53.

World Health Organization. (1993). Need and action priorities in cardiac rehabilitation and secondary prevention in patients with coronary heart disease. Copenhagen: World Health Organization.

APPENDIX A

Table 1.

Descriptive Data Results on the MOS SF-36 Health Survey for Treatment and Control Groups.

Scales	$\bar{X}$	SD	SE of Mean
Role/Emotional			
Treatment	83.3333	26.591	7.686
Control	83.3333	30.429	6.487
Physical Function			
Treatment	85.4167	9.643	2.784
Control	68.8636	23.901	5.096
General Health			
Treatment	78.9167	14.254	4.115
Control	65.0114	17.440	3.718
Mental			
Treatment	84.3333	11.244	3.246
Control	77.8182	16.129	3.439
Pain			
Treatment	80.8333	17.124	4.943
Control	67.2273	23.393	4.987
Role/Physical			
Treatment	75.0000	30.151	8.704
Control	73.8636	34.049	7.259
Social Function			
Treatment	89.5833	19.094	5.512
Control	81.2500	27.209	5.801
Vitality			
Treatment	63.3333	26.400	7.621
Control	57.2727	21.477	4.579

Table 2.

Results of Independent t-tests of the MOS SF-36 on the Treatment and Control Group.

Scales	*df*	*t*	*p*
Role/Emotional	32	0.00	$p>0.1$
Physical Function	30.26	2.85	$p\leq0.1$*
General Health	32	2.36	$p\leq0.1$*
Mental Health	32	1.24	$p>0.1$
Pain	32	1.77	$p\leq0.1$*
Role/Physical	32	0.10	$p>0.1$
Social Function	32	0.94	$p>0.1$
Vitality	32	0.73	$p>0.1$

* = Significant Difference

APPENDIX B

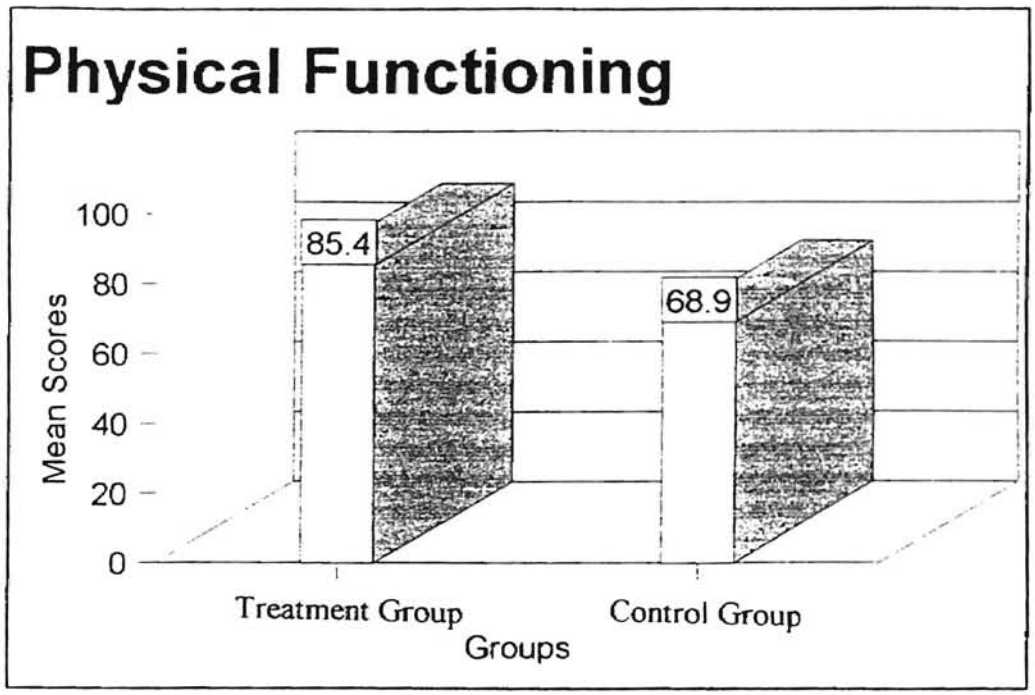

Figure 1

Mean Scores of Physical Functioning Scale.

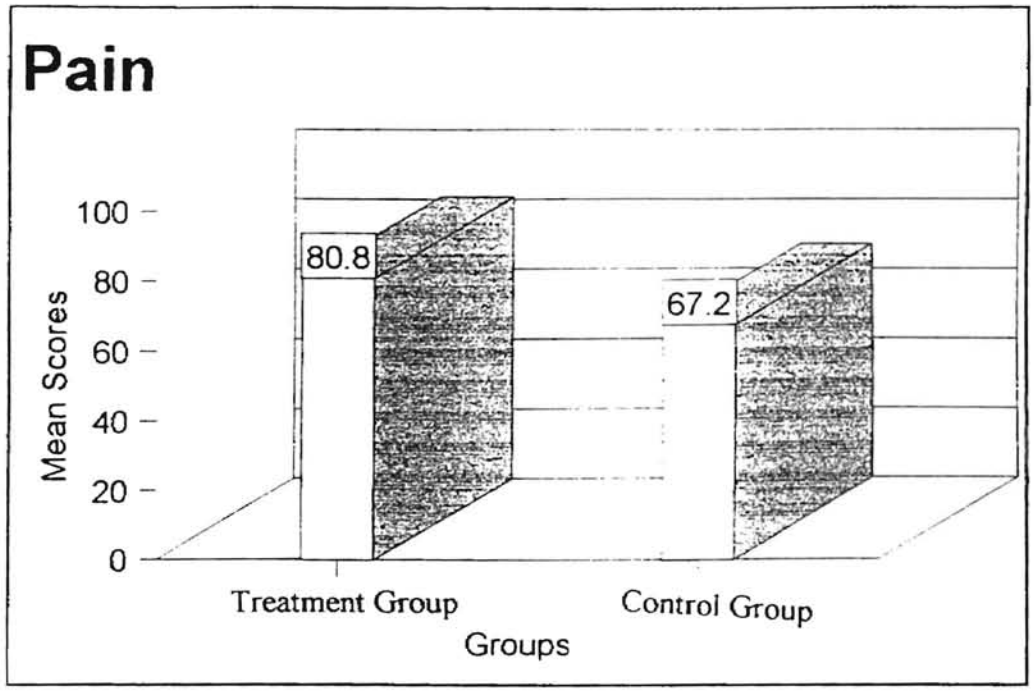

Figure 2.

Mean Scores of Pain Scale.

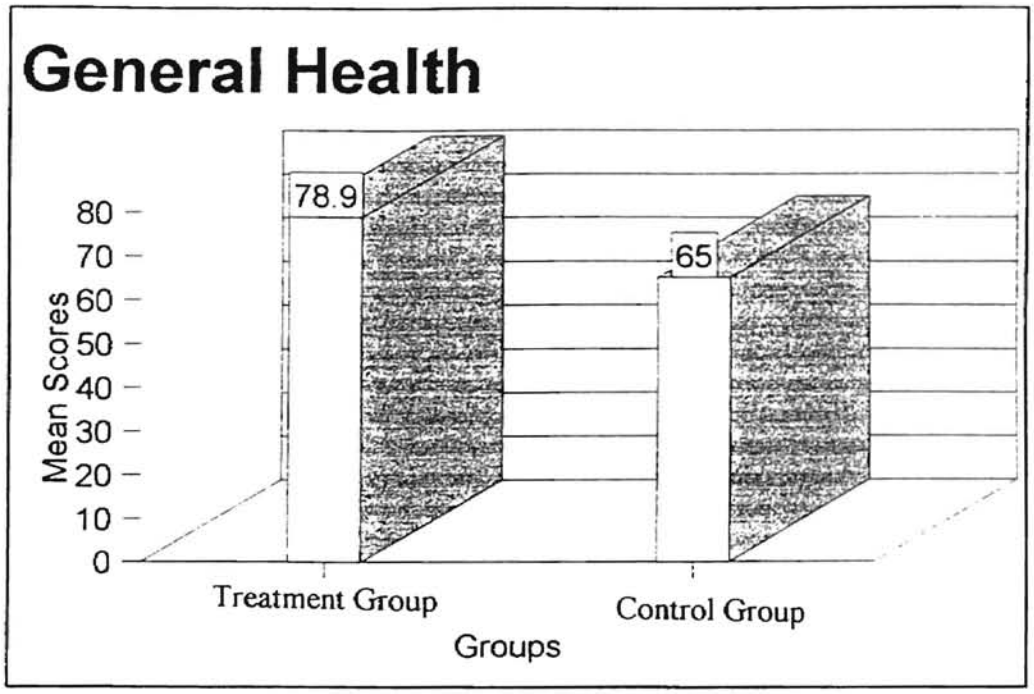

Figure 3.

Mean Scores of General Health Scale.

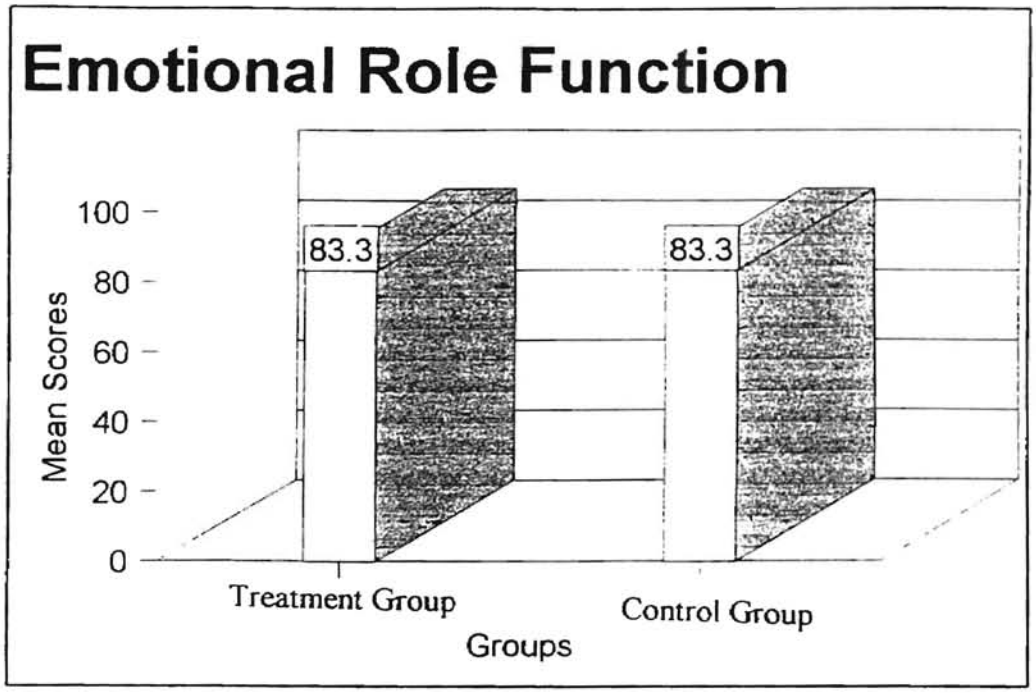

Figure 4.

Mean Scores of Role Limitations due to Emotional Functioning Scale.

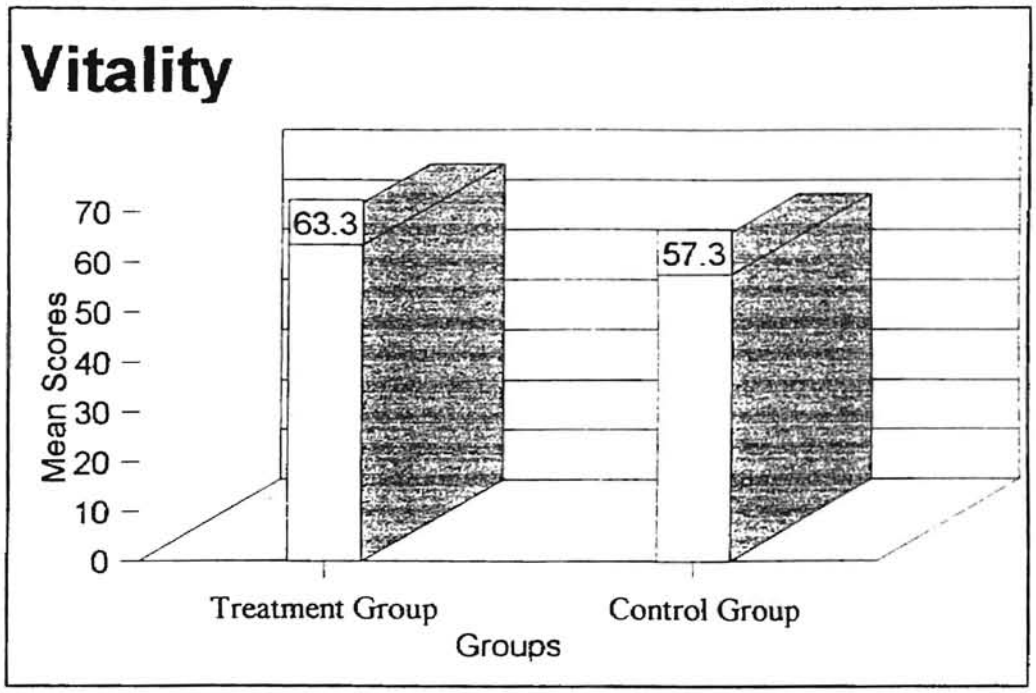

Figure 5.

Mean Scores of Vitality Scale.

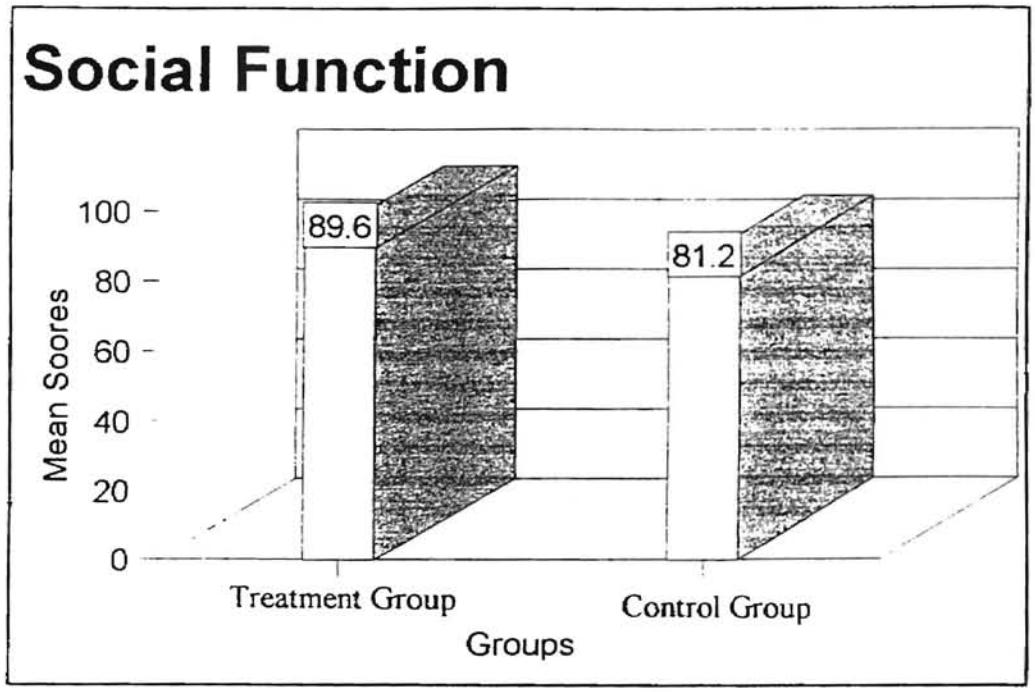

Figure 6.

Mean Scores of Social Funtioning Scale

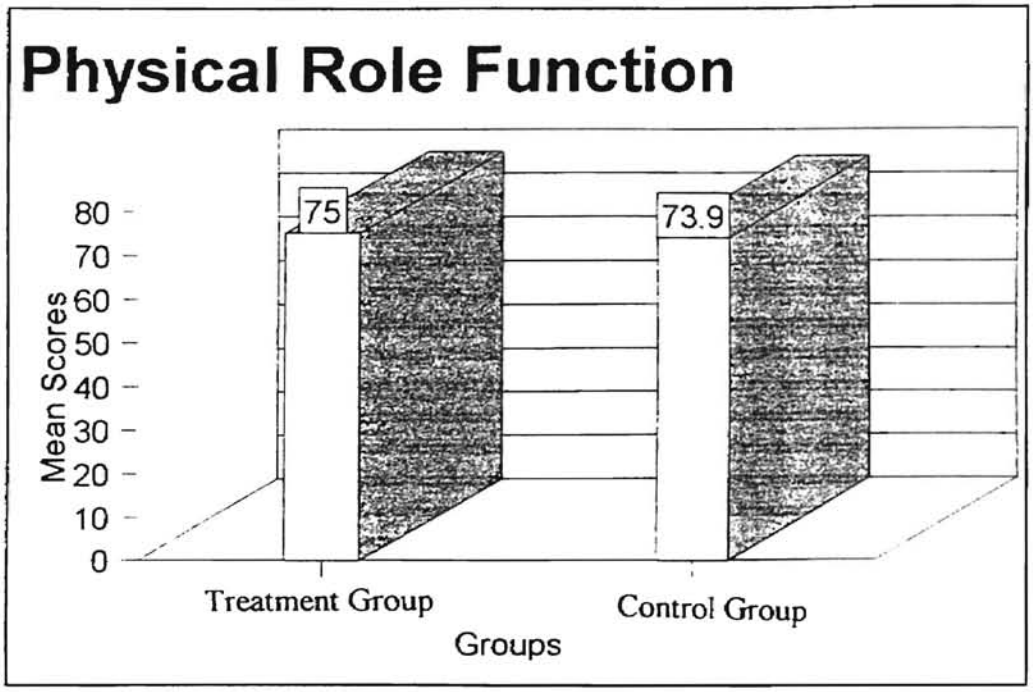

Figure 7.

Mean Scores of Role Limitations due to Physical Functioning Scale.

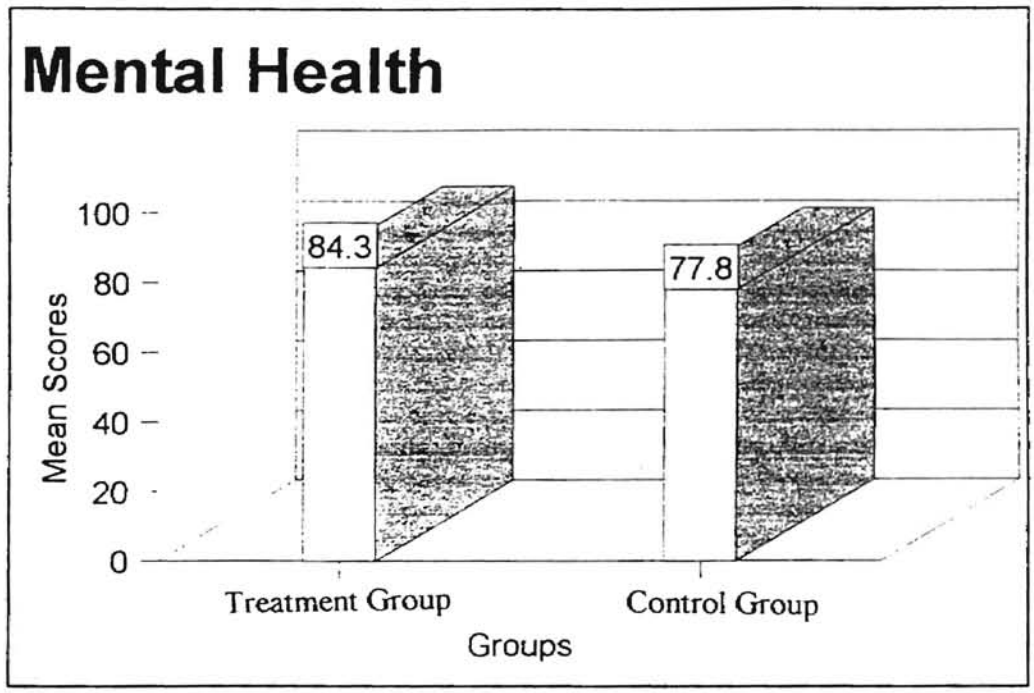

Figure 8.

Mean Scores of Mental Health Scale.

APPENDIX C

July 23, 1996

Dear Sir or Madam:

You are invited to participate in a research project entitled "Health Outcomes in Cardiac Patients." The research is being conducted by Amy Walterscheid, Masters of Science graduate student at Oklahoma State University.

To participate in this study, we ask that you:

1) Read and Sign the enclosed consent form,
2) Answer all questions on the enclosed survey,
3) Place the signed consent form and completed survey inside the self-addressed, stamped envelope,
4) Place the envelope in the mail.

The survey is fairly simple and will take less than 15 minutes of your time. Your cooperation will be greatly appreciated.

If your have any questions, please feel free to contact Amy Walterscheid at (405) 377-3023. You may also contact Dr. Troy Adams of Oklahoma State University at (405) 744-5499.

Thank you in advance for your participation.

Sincerely,

Amy Walterscheid
Graduate Student - Masters of Science
Oklahoma State University

CONSENT FORM

EXPLANATION OF STUDY

You are invited to participate in a research project entitled "Health Outcomes in Cardiac Patients." The study is being conducted by Amy Walterscheid, Masters of Science student at Oklahoma State University. The purpose of this study is to examine various health outcomes in cardiac patients.

You have been selected to participate because you are or have been a patient of Dr. Pirzada Majid, within the age range of 55-75 years old, and you have had a cardiac procedure or event. Your participation in this study is voluntary. You will not be identifiable in any way, nor will the results of this study be able to directly identify you. Finally, participation in this study will not place you at any physical risk whatsoever.

If you have any questions or would like more information, please feel free to contact me, Amy Walterscheid at (405) 377-3023 or my research advisor, Troy Adams Ph.D. at (405) 744-5499. You may also contact University Research Services, 001 Life Sciences East, Oklahoma State University, Stillwater, Oklahoma 74078, Telephone #: (405) 744-5700.

I understand that participation in this study is voluntary, there is no penalty for refusal to participate, and I am free to withdraw my consent and participation in this project at any time without penalty. I understand that all information will remain confidential and will only be used in a research manner.

I have read the foregoing and understand all that is involved with the study.

Signature _____ Date _____

HEALTH SURVEY

INSTRUCTIONS: Please read each statement carefully and answer every question by circling the answer that decribes you, best states how you feel or how well you are able to do your usual activites. If you are unsure about how to answer a question, please give the best answer you can.

1. In what Month and Year were your born?

   Birthdate: Month _____ Year _____

   (circle one)

2. Gender: Male Female

3. In general, would you say your health is:

   (circle one)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

4. Compared to one week ago, how would you rate your health in general now?

(circle one)

Much better than one week ago	1
Somewhat better now than one week ago	2
About the same as one week ago	3
Somewhat worse now than one week ago	4
Much worse now than one week ago	5

5. During the past week, have you had any of the following problems, with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

		Yes	**No**
a.	Cut down on the **amount of time** you spent on work or other activities	1	2
b.	**Accomplished less** than you would like	1	2
c.	Were limited in the **kind** of work or other activities	1	2
d.	Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

6. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle one number on each row)

	Activities	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a.	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c.	Lifting or carrying groceries	1	2	3
d.	Climbing **several** flights of stairs	1	2	3
e.	Climbing **one** flight of stairs	1	2	3
f.	Bending, kneeling, stooping	1	2	3
g.	Walking **more than a mile**	1	2	3
h.	Walking **several blocks**	1	2	3
i.	Walking **one block**	1	2	3
h.	Bathing or dressing yourself	1	2	3

7. During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

		Yes	No
a.	Cut down the **amount of time** you spent on work or other activities	1	2
b.	**Accomplished less** than you would like	1	2
c.	Didn't do work or other activities as **carefully** as usual	1	2

8. During the past week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

9. How much bodily pain have you had during the past week?

	(circle one)
None	1
Very Mild	2
Mild	3
Moderate	4
Severe	5
Very Severe	6

10. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?

	(circle one)
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

11. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling.
How much of the time during the past week -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have your felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

12. During the past week, how much of the time has your physical or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

13. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

APPENDIX D

OKLAHOMA STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS REVIEW

Date: 07-12-96 **IRB#:** ED-97-000

Proposal Title: HEALTH OUTCOMES IN CARDIAC PATIENTS

Principal Investigator(s): Troy Adams, Amy Walterscheid

Reviewed and Processed as: Expedited

Approval Status Recommended by Reviewer(s): Approved

ALL APPROVALS MAY BE SUBJECT TO REVIEW BY FULL INSTITUTIONAL REVIEW BOARD AT NEXT MEETING.
APPROVAL STATUS PERIOD VALID FOR ONE CALENDAR YEAR AFTER WHICH A CONTINUATION OR RENEWAL REQUEST IS REQUIRED TO BE SUBMITTED FOR BOARD APPROVAL.
ANY MODIFICATIONS TO APPROVED PROJECT MUST ALSO BE SUBMITTED FOR APPROVAL.

Comments, Modifications/Conditions for Approval or Reasons for Deferral or Disapproval are as follows:

Signature: Date: July 17, 1996

Chair of Institutional Review Board

Cardiology*Stillwater*

June 27, 1996

H. James Harmon
Coordinator of Intellectual
Properties and Research Compliance
Oklahoma State University
305 Whitehurst
Stillwater, Oklahoma 74078

RE: Research Project: Health Outcomes in Cardiac Patients
Ms. Amy Walterscheid

Dear Mr. Harmon:

Ms. Walterscheid has requested me to use data from my patients at Cardiology of Stillwater for the above mentioned research project. This is to let you know that I don't have any objections if the research project meets with the approval of the Oklahoma State University Institutional Review Board and an approved consent form is used.

Yours sincerely,

Pirzada A. Majid, M.D.

PAM:kdt

Pirzada A. Majid

Doctors Bldg.
1405 West Sixth Avenue, Suite
Stillwater, Oklahoma 74074
Telephone 405 377
Telefax 405 377

Cardiology*Stillwater*

June 27, 1996

H. James Harmon
Coordinator of Intellectual
Properties and Research Compliance
Oklahoma State University
305 Whitehurst
Stillwater, Oklahoma 74078

RE: Research Project: Health Outcomes in Cardiac Patients
Ms. Amy Walterscheid

Dear Mr. Harmon:

Ms. Walterscheid has requested me to use data from my patients at Cardiology of Stillwater for the above mentioned research project. This is to let you know that I don't have any objections if the research project meets with the approval of the Oklahoma State University Institutional Review Board and an approved consent form is used.

Yours sincerely,

Pirzada A. Majid, M.D.

PAM:kdt

Pirzada A. Majid

Doctors Bld.
1405 West Sixth Avenue, Suite
Stillwater, Oklahoma 74074
Telephone 405-[illegible]
Fax 405-[illegible]

VITA

Amy Theresa Walterscheid

Candidate for the Degree of

Master of Science

Thesis: HEALTH OUTCOMES IN CARDIAC PATIENTS

Major Field: Health, Physical Education and Leisure

Biographical:

Personal Data: Born in Sherman, Texas on November 29, 1971, the daughter of Sylvan and Theresa Mae Walterscheid.

Education: Graduated from Sacred Heart High School, Muenster, Texas in May 1990; received Bachelor of Science degree in Exercise Science from Texas Woman's University, Denton, Texas in December 1993. Completed requirements for Master of Science degree in Health, Physical Education and Leisure at Oklahoma State University in May 1997.

Experience: Employed as Fitness Specialist at Cosmopolitan Lady, Carrollton, Texas after undergraduate degree. Later worked at Methodist Medical Center, Dallas Texas as a Cardiac Rehabilitation Specialist until 1995. Employed as Aerobics Instructor at various facilities during graduate school. Presently employed an Exercise Physiologist in Cardiac Rehabilitation at Columbia Plaza Medical Center, Ft. Worth, Texas.

Professional Memberships: American College of Sports Medicine - Health Fitness Instructor, Texas Association of Cardiovascular and Pulmonary Rehabilitation.