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The Differences in patient recovery and depressive symptoms between clinical and non-clinical cardiac rehabilitation settings

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The Differences in Patient Recovery and Depressive Symptoms Between Clinical and Non-Clinical Cardiac Rehabilitation Settings

By

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B.A., Concordia College, 1995

presented in fulfillment of the requirements for the degree of Master of Science

The University of Montana

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Thesis Abstract

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The Differences in Patient Recovery and Depressive Symptoms between Clinical and Non-Clinical Cardiac Rehabilitation Settings

Chairperson: S.E. Gaskill, Ph.D.

The purpose of this study was to determine if there were differences in depressive symptoms between individuals participating in a clinical cardiac rehabilitation program and individuals who did not participate in clinical cardiac rehabilitation settings. The data was gathered from a patient population of individuals who had been hospitalized for cardiac stenting, cardiac bypass or myocardial infarction at two midsize medical centers in Montana. Pre, mid and post data was collected over a 12-week post intervention recovery period. The two self-report scales used to collect data were the Cardiac Depression Scale (CDS) and the Physical Activity Scale for the Elderly (PASE).

The subject population was divided into one of two self-selected categories where cardiac rehabilitation occurred in a clinical cardiac rehabilitation setting or a non-clinical setting. Eighteen subjects were included in this study, seven in the clinical group and eleven in the non-clinical group. Depression scores were analyzed and compared to level of activity. No statistically significant differences occurred between the clinical and non-clinical group. Activity scores for the clinical group were initially lower than the activity scores in the non-clinical group but the clinical group maintained a significant increase in activity level from pre to post where the non-clinical group plateaued. While the negative correlation between activity and depression scores were not significant, the trend indicates that with a larger subject population sample significance would likely be reached.

Cardiac rehabilitation in the clinical setting has the potential to effectively treat depression in cardiac patients. Further study in this area should require in-depth investigation into the logistics of patient flow from hospital admission to patient discharge, physician advocacy, financial feasibility and transportation options for the patient.
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The Differences in Patient Recovery and Depressive Symptoms between Clinical and Non-Clinical Cardiac Rehabilitation Settings

Heidi Schrock

The leading cause of death for adults in the United States is heart disease (Centers for Disease Control and Prevention [CDC], 2003, para. 1). In 1999, 725,000 deaths occurred as a result of heart disease and currently the total population prevalence of coronary heart disease and myocardial infarction combined is 20,500,000 Americans ages 20 and older (American Heart Association [AHA], 2002). America is rated as one of the most sedentary nations in the world because the majority of Americans have jobs, lifestyles and hobbies that lack physical activity. Cars, computers, elevators and remote controls have become necessities that enable a sedentary lifestyle. Thirty-eight percent of the American population is completely sedentary and an additional two-thirds of the population does not engage in the minimum recommended level of physical activity (AHA, 2002). In 2001 the cost of cardiovascular disease, including health expenditures and lost productivity reached 300 billion dollars (CDC, 2003, para. 3). The relative risk of coronary heart disease (CAD) associated with physical inactivity ranges from 1.5 to 2.4, which is an increase in risk comparable to that observed for hyperlipidemia, hypertension and cigarette smoking (Pate, Pratt & Blair et al., 1995).

Physical activity markedly reduces the risk of heart disease as well as protects against other chronic diseases such as diabetes, and some forms of cancer (CDC, 2002; Pollock, et al., 2000; Thompson, et al., 2003). Regular physical activity helps to ensure healthy bone density, connective tissue pliability and maintenance of skeletal muscle function and strength (Pollock et al., 2000; Thompson et al., 2003). In addition, physical
activity maintains the efficiency and increases the longevity of cardiac muscle function to
maintain a healthy life (Thompson et al., 2003). The connection between the heart and
skeletal muscle function is not often recognized but the link is vital. With all physical
activity the cardiac muscle is being put to a functional challenge as well as the exercised
skeletal muscle. Unfortunately, if the heart is exposed to multiple risk factors, such as a
sedentary lifestyle and an unhealthy diet, the heart becomes at increased risk for trauma.

Cardiac rehabilitation programs following cardiac trauma are a long and arduous
rehabilitative process that is physically and psychologically taxing. The psychological
distress of cardiac trauma is primarily a result of the dramatic change in physical
capability as well as increased dependence on others to complete activities of daily living
(ADL). Because of the psychological distress following cardiac trauma there is a high
incidence of depression among cardiac patients (Nemeroff, Musselman, & Evans, 1998).

The pathophysiology and neurochemistry of depression is posited to consist of
key neurotransmitters most commonly linked to one or a combination of norepinephrine
(NE), serotonin (5HT) and dopamine (DA). These three neurotransmitters function as
integral components of three major systems in the brain: (1) the hypothalamic-pituitary-
adrenal (HPA) axis and the cortico-trophin releasing factor (CRF), (2) the hippocampus,
and (3) the noradrenergic system (Sadek & Nemeroff, 2000). Within these systems lie
pathways regulated by neurotransmitters that moderate mood, emotion, appetite, energy,
drive and cognitive function. Depressive symptomology includes the development of
grief and sadness progressing into feelings of hopelessness and emptiness. Additional
symptoms include changes in sleep patterns, fatigue and lethargy, loss of appetite or
excessive gain in appetite, loss or gain of weight, increased isolation, lack of motivation
and inability to concentrate (American Psychiatric Association, 1994). Depression, in the presence of a chronic illness, tends to exacerbate the illness via increased sensitivity to pain and prolonged healing process (Wells, Rogers, Burnam, Greenfield & Ware, 1991).

Exercise has gained substantial attention as an alternative treatment for depression because of its elevating effects on energy and mood state (Ai, Peterson, & Bolling, 1997; Brassington & Hicks, 1995; Brown, 1982; DiLorenzo et al., 1999; Dishman, 1985; Emery & Gatz, 1990; Murphy et al., 2002). In addition to altering mood states and energy levels (DiLorenzo et al., 1999), exercise has also been shown to improve sleep quality (Brassington & Hicks, 1995), improve self-image and confidence (Emery & Gatz, 1990; Ossip-Klein et al., 1989), enhance mental performance and concentration (Brown, 1982; Dishman, 1985), and reduce feelings of anger and time urgency (Emery & Blumenthal, 1988). Many studies have suggested exercise is more effective than no treatment and exercise therapy can be as effective as other traditional forms of treatment (Byrne & Byrne, 1993; Craft & Landers, 1998; DiLorenzo et al., 1998; Gleser & Mendelberg, 1990; Martinsen, 1990, 1993, 1994). However, it is difficult to concretely quantify the neurochemical effects of exercise on depression because most experimental studies on human subjects have been conducted with postmortem brain tissue. To date, microdialysis is the most precise in vivo neurotransmitter sampling method available and has offered substantial insight into the neurochemical interplay between synapses during exercise (Meeusen, Piacentini & De Meirleir, 2001). Additionally, microdialysis has confirmed what other researchers have qualitatively argued, that exercise does positively influence depression. Meeusen and colleagues (2001) compiled data through microdialysis during exercise in animals and found that 60 minutes of exercise
significantly increased dopamine (DA) and noradrenaline (NA) (Meeusen et al., 1997). Other researchers have confirmed that endurance exercise stimulates a significant change in the neurotransmitters posited to be linked to depression (Sadek & Nemeroff, 2000). For instance, endurance exercise has been shown to stimulate extracellular dopamine release (Hattori, Naoi & Nishino, 1994), significantly increase the turnover and release of noradrenaline (NA) (Pagliari & Peyrin, 1995a, 1995b) and significantly peak hippocampal levels of serotonin (5HT) (Bequet, Peres & Gomez-Merino, 2000; Wilson & Marsden, 1996). Research using electrophysiological methods in rats during exercise (repetitive locomotion) revealed a significant increase in extracellular serotonin (5HT) as well (Jacobs, 1991; Meeusen, Piacentini & De Meirleir, 2001).

Depression among cardiac patients often goes undiagnosed and untreated (NIMH, 1999). Physical disabilities of individuals participating in clinical cardiac rehabilitation programs are aggressively monitored and treated until optimal cardiovascular function is restored. Psychological distress is neither normally monitored or aggressively treated in traditional cardiac rehabilitation programs in spite of the evidence supporting increased levels of depressive and anxiety symptoms among people with functional impairment (Gurland, Wilder, & Berkman, 1988; Kaplan et al., 1987; Turner, 1988).

Cardiac patients who are unable to take part in a structured clinical cardiac rehabilitation regimen are less likely to develop a regular routine of physical activity and thus the antidepressant benefits of regular physical activity may not occur. Therefore, not only does clinical cardiac rehabilitation offer maximum cardiovascular recovery but may also offer secondary antidepressant benefits through regular physical activity that may help to alleviate depression.
A. **Purpose**

The purpose of this study was to determine if there were differences in depressive symptoms between individuals participating in a clinical rehabilitation program and individuals who did not participate in clinical cardiac rehabilitation settings. Three specific research questions were addressed:

1) Do cardiac patients in a non-clinical setting exercise on an equal basis with those who participate in a supervised clinical setting?

2) Are there differences in depressive levels for patients who undergo cardiac rehabilitation in a clinical setting versus those in a non-clinical setting?

3) Is there a difference between those in a clinical vs. a non-clinical cardiac rehabilitative setting in changes in the level of depression after twelve weeks of recovery?

B. **Hypotheses**

The null hypothesis for this study is there is no difference between the clinical cardiac rehabilitation population and the non-clinical cardiac rehabilitation population in patient recovery and depressive symptoms. The research hypothesis for this study is the subjects in the clinical cardiac rehabilitation population will have significantly less depressive symptomology than the subjects in the non-clinical population. Additionally, subjects in the clinical population would exercise significantly more than those in the non-clinical population according to scoring on the activity inventory.

C. **Importance**

A greater decrease in depressive levels in the clinical setting versus the non-clinical setting would suggest that consistently monitored exercise within the clinical
setting has a greater effect on depressive levels than the generally less structured non-clinical setting. If a sustained or increased incidence of depressive symptoms were found in the non-clinical group it would imply the need for improvements in phase two rehabilitative procedures for the non-clinical population. If the non-clinical group is found to exercise less than the clinical setting group it would suggest a need for an increase in physical activity and psychological monitoring for individuals undergoing non-clinical rehabilitation. Furthermore, psychological and emotional impacts that occur postoperatively can last 6 months to a year or more. In studies by Frasure-Smith, Lesperance and Talajic (1995) major and clinical depression were identified as significant predictors over the first year in patients after myocardial infarct and of cardiac mortality up to at least 18 months after discharge. In an effort to prevent hospital readmission and premature mortality in cardiac patients implementing depression screening, intervention and treatment for both the clinical and non-clinical cardiac rehabilitation populations could provide a more successful recovery rate for depressed cardiac patients.

D. Limitations

The limitations for the present study were as follows:

1) Interpretation of results must be done cautiously when compared to other populations.

2) Results can only be generalized with frequency and duration of physical activity. Fitness level is not a variable included within this study.

3) Administration of the self-report scales will vary due to the rural location of the non-clinical population.
4) The sample population is a non-randomized sample, as the study relies on the unpredictable occurrence of cardiac illness in the community at large.

E. Delimitations

The sample consists of both males and females and is limited to cardiac patients who have undergone invasive surgical procedures at a local acute care medical facility. Only subjects between the ages of 45 to 85 were included in the study. The chronic diseases for which the participants are diagnosed and undergoing cardiac rehabilitation for are limited to coronary artery disease (CAD), cardiomyopathy, and myocardial infarction (MI).

F. Definition of Terms

1. Cardiac patient – a 45 to 85 year old patient that has been hospitalized for coronary artery disease, cardiomyopathy or myocardial infarction requiring successful completion of phase one rehabilitation.

2. Clinical setting – a phase two fully equipped, cardiac rehabilitation program set within an acute care medical facility. Patients receive prescribed exercise programs monitored by ECG telemetry, medical surveillance and educational recovery classes. The goal of the program is generally to help individuals achieve a functional capacity allowing them to return to work or live independently if possible.

3. Non-Clinical setting – an outpatient, home based, physician recommended recovery regimen for patients who have completed phase one of cardiac rehabilitation including risk factor modification counseling, activity counseling and patient and family education at an acute care medical facility. Due to their
rural residence, patients are unable to travel the distance to participate in a structured, clinically based phase two rehabilitation program.

4. Depression – indicated by scores on the Cardiac Depression Scale, depression is an abnormal emotional state characterized by exaggerated feelings of sadness, dejection, melancholy, worthlessness, emptiness, and hopelessness that are inappropriate and out of proportion to reality (Anderson et al., 1998).

Chapter 2: Review of the Literature

A. Overview of the Occurrence of Depression in the Cardiac Patient Population

The National Institute of Mental Health (NIMH) (1999) has reported that at least 2 million Americans, or about 6 percent of the 34 million Americans over the age of 65, suffer from some form of depression. Depression has been reported to be the leading cause of disability in the United States and ranks worldwide above ischemic heart disease and cerebrovascular disease (Murray & Lopez, 1996). NIMH also reported “13 to 27 percent of older adults have sub-clinical depressions that do not meet the diagnostic criteria for major depression but are associated with increased risk of major depression, physical disability, medical illness and high use of health services” (2002, paragraph 2).

Like other chronic diseases, depression has residual effects on all areas of life. According to the National Institute of Mental Health (1999, paragraph 2), on the job production and sick leave are commonly the first to absorb the effects of depression. Specifically, employers see lower productivity and higher frequency of absence from work due to illness. NIMH reported depression costs America over 30 million dollars per
year in direct (medication, hospitalization & physician care) and indirect (loss of productivity, worker absenteeism) costs (1999, paragraph 3).

According to Roose, Devanand and Suthers (1999), depression in the cardiac patient population is frequently encountered by clinicians who work with the cardiac population. Carney, Rich and Freedland (1988) report the prevalence of major depression in persons with newly diagnosed coronary artery disease may be as high as 18 percent.

B. Summary of Research on Depression in the Cardiac Patient Population

There have been many suggestions as to why there is a high prevalence of depression in the cardiac patient population. Although it is difficult to distinguish depressive symptoms associated with clinical depression from symptoms associated with CVD or pulmonary disease and associated medical intervention, studies have hypothesized that the type of disease may play a role in the incidence rate and severity of depression (Palinkas, Wingard, & Barrett-Conner, 1990). Others have argued that the loss of functional ability and sense of control following a debilitating disease may be an integral explanation for a decrease in mood stability (Penninx, Beekman, Ormel, Kriegsman, Boeke, VanEijk & Deeg, 1996; Sullivan et al., 1999). Additional causal arguments for the onset of depression are deficits in social support during recovery (Brummett et al., 1998; Busselli & Stuart, 1999), hostility (Brummett et al., 1998), and coping skills (Terry, 1992).

1. Disease specificity

A study done by Palinkas, Wingard & Barrett-Conner (1990) that focused on the distribution of depressive symptoms in elderly patients with chronic illnesses over the
span of 15 years, revealed mean depressive symptom scores were significantly related to self-perceptions of current health status, increasing number of reported chronic diseases and increasing number of reported medications. Interestingly, subjects who reported taking angina medication, aspirin, anti-arrythmics and medication for hypertension had significantly higher depressive symptom scores and exhibited higher rates of mild or more severe forms of depressive symptoms than those subjects not taking these medications. Results also indicated women with hypertension had significantly more depressive symptoms than their non-hypertensive counterparts. Although significance was not reached, male and female subjects with the medical condition “heart surgery” showed greater amounts of depressive symptoms than their counterparts. For both men and women, analysis of the relationship between health behavior and depressive symptoms indicated mean depressive symptom scores were significantly related to physical exercise. Exercise over the past ten years was significantly and positively related to lower depressive symptom scores in both genders (Palinkas et al., 1990).

2. Locus of control

Penninx et al. (1995) conducted a similar study investigating psychological status and chronic diseases. A large sample of 3,076 chronically ill subjects was divided into eight categories, one of which included individuals with cardiac disease (myocardial infarction included). Three outcome measures were used (depressive symptoms, anxiety and mastery) to indicate psychological status. Results indicated the chronically ill subjects experienced significantly lower feelings of mastery (a sense of control over the disease) and greater psychological distress than their healthy counterparts. Cardiac patients specifically reported more mastery, less anxiety and lower depressive symptoms
compared to other less controllable chronic diseases such as rheumatoid arthritis. Further analysis revealed women versus men and all unmarried individuals had greater psychological distress regardless of the presence of chronic diseases. As in the Palinkas et al. (1990) study, a positive linear relationship occurred between number of chronic diseases and degree of psychological distress. Results also suggested that the greater control or “mastery” an individual perceived they had over the disease(s), the more positive the outcome of their psychological status.

3. Loss of functional ability

In a study done by Sullivan et al. (1999), diagnostic threshold for depression was investigated via the role of major and minor depression in the functional status of patients with coronary artery disease. Those subjects who had greater than 70% of their main vessels occluded were chosen for further analysis. Seventy percent of coronary occlusion is hemodynamically significant and, of all disease severity measures, had the strongest relation to self-reported physical function measures. Based on the depression diagnostic score and DSM-IV criteria, subjects were divided into three groups: 1) major depression 2) minor depression and 3) no depression. Results indicated no significant differences in overall functioning (physical function, activity interference, social/family function, and work disability) between the major and minor depression groups. Significantly poorer functioning occurred between both depression groups and the group with no depression at the time of assessment and 1 year later. After correcting for age, gender, education, coronary disease severity, comorbidity and medical management, exploratory analysis showed a significant difference in the three depression groups for reported heart symptoms. Further analysis indicated differences in functional ability could not be
explained exclusively by differences in reported symptoms, therefore dismissing the cause and effect relationship between disease state and function (for this study only).

Overall, results suggested minor depression might impair function as much as major depression, therefore lowering the threshold at which overall functioning is affected.

4. Social support

Social support as a contribution to the initiation, persistence or worsening of depression during recovery has been thoroughly examined in the past decade (Anderson, Deschais & Jobin, 1996; Brummett et al., 1998; Holohan, Holohan & Moos, 1997; Oxman, Freeman & Manheimer, 1994; Yates, 1995). In a meta-analysis examining the role of social support and coronary artery disease (CAD), Anderson et al. (1996) concluded that social support plays a vital role in the recovery from CAD as well as primary and secondary prevention measures. Krishnan, George & Pieper et al., (1998) discovered lack of social support and negative life events were related to major depression associated with CAD. The authors suggested that a deficit in social support is important in the development of depressive disorder.

King, Taylor and Haskell (1993) discovered exercising alone had no negative effects on depressive symptomology. Furthermore, studies have indicated most Americans prefer to engage in physical activity on their own, outside of a formal group structure (Iverson, Fielding, Crow & Christenson, 1985; King, Taylor, Haskell & DeBusk, 1990). However, compliance with exercise is most likely to happen in structured programs or group exercise classes. Group settings offer peer approval and encouragement that humans need to achieve behavior change. Group camaraderie and peer accountability provides enough extrinsic motivation to influence exercise adherence.
A study by Brummett et al., (1998) examined the value of trait hostility, social support and levels of depressive symptoms tested during hospitalization for coronary artery disease as predictors of depressive symptoms one month post-hospitalization. Male and female patients ($N=506$) between 36 and 93 years were assessed. Almost half of the patient population ($N=215$) showed signs of mild to moderate depression at baseline. In addition, 137 of the 215 patients remitted after discharge from the hospital also exhibited signs of moderate to mild depression. Overall, total depression scores significantly decreased from baseline to 1-month follow-up. By using a series of structural equation models, depressive symptoms were predictable by perceived social support during hospitalization. Depression scores (baseline and 1 month follow-up) were inversely related to social support. Therefore, patients with lower scores on the depression scale had a positive perception of social support. Because follow-up occurred only 1 month after hospitalization, and perceived social support rather than actual social support was assessed, generalizations derived from the data may be questionable.

5. Hostility

Hostility is a defining personality trait found in Type A personalities and in those at higher risk for CVD (Buselli & Stuart, 1999). Although large-scale studies have refuted the relationship between Type A personalities and CAD, hostility has been shown to be toxic to the cardiac patient, as it has been linked to CAD and mortality (Everson, Kauhanen & Kaplan, 1997). Hostility has been considered an indirect predictor of depression during recovery. This may be due to the isolation a hostile personality can manifest, possibly influencing social support. Brummett (1998) and colleagues concluded that knowledge of hostility levels and their relation to CAD and depression
might provide critical information in determining how a person may benefit from social support.

6. **Self-efficacy**

Self-efficacy and coping strategies have been suggested as possible variables in cardiac incident adaptation. Self-efficacy is the extent to which individuals perceive that they can adapt the necessary behaviors to successfully deal with a cardiac event (Bandura, 1982). Individuals with low self-efficacy in a stressful situation tend to focus on their feelings of incompetence and distress rather than engaging in strategies to deal with the stressful situation. Low levels of self-efficacy may indicate that adaptation to coronary events might be negatively affected (Terry, 1992). Terry (1992) examined two coping strategies in congruence with self-efficacy. 1) Focus on management of the problem is called *problem-focused coping* and 2) *emotion-focused coping* is the use of strategies that focus on the emotional distress of the problem. The latter of the two has been reported as having a negative influence on adaptation to chronic disease (Felton & Revenson, 1984). Data indicated that high levels of self-efficacy were associated with low scores of anxiety and depression. In addition, results showed emotion-focused coping impaired adaptation but did not indicate that problem-focused coping had a positive effect on adaptation (Terry, 1992). The data generally supported the notion that coping strategies focused on emotional distress, particularly in individuals who were low efficacious, may have a significantly negative effect by causing higher levels of anxiety and depression.

**C. Treating Depression in the Cardiac Patient Population**
Depression and symptoms associated with depression have been found to last from six months to one-year post-cardiac incident (Eriksson, 1988, 1989; Folks, Blake, Freeman, & Sokol, 1989; Lindal, 1990; Magni et al., 1987; Sokol, Folks, Herrick & Freeman, 1987; Sullivan et al., 1999; Townes et al., 1989; Venn, Klinger & Smith, 1987). The treatment for depression most often consists of psychotherapy, medication, or both. Because the traditional treatments of psychotherapy and medication have become so costly (Simon, VonKorff & Barlow, 1995), and may not be adequately covered by insurance, alternative treatments are gaining attention from the research world. Suggested alternative therapies have ranged from exercise and lifestyle changes, including diet, to prayer and relaxation techniques (Ai, Peterson & Bolling, 1997).

Psychotherapeutic and/or psychopharmacologic interventions have proven to be very effective in treating depression in the cardiac patient population (Nemeroff et al., 1998; Roose et al., 1999). Although time consuming and expensive, psychotherapy is generally recognized as one of the cardinal interventions for depression (Craft & Landers, 1998). A 12-month follow-up study investigated the course of depression in 200 patients with coronary heart disease. During the 12-month follow-up only 6 patients sought treatment (psychotherapy) for depression, all of whom had major depression at baseline. Four of the six patients fully remitted within the year without relapse (Hance et al., 1996). Over the last decade medication for depression also has become a common and effective treatment for depression.

Treating depression for the cardiovascular patient can be dangerous and requires care and attention to drug interactions. Monoamine oxidase inhibitors (MAOIs) are selectively effective for depression and are believed to be free of conductivity effects.
slowing or interference of electric type impulses that travel through the myocardium) but do cause orthostatic hypotension (abnormally low blood pressure while standing) (Arana & Hyman, 1991). Tricyclic antidepressants (TCAs) are the most studied class of antidepressants with respect to cardiovascular effects (Roose, Devanand & Suthers, 1999). Known cardiovascular side effects include a 10% increase in heart rate, orthostatic hypotension, slowing of sinoatrial (SA) conduction and decreased ventricular ectopy (Nemeroff et al., 1998; Roose, Devanand & Suthers, 1999). A more recent class of antidepressants, serotonin reuptake inhibitors (SSRIs), also has been tested in the cardiac patient population and is promising, as they appear to have fewer negative cardiovascular side effects. Side effects of SSRIs include significant decrease or increase in heart rate, SA conduction slowing, drop in orthostatic blood pressure and suppression of ventricular arrhythmia. Physiological side effects found in healthy population studies for both TCAs and SSRIs include weight gain or weight loss, insomnia, constipation, profuse sweating, gastrointestinal discomfort, headaches, dry mouth and gas and bloating (Nemeroff et al., 1998). In most circumstances a favorable benefit-to-risk ratio is assumed with benefits outweighing negative side effects.

The drawbacks of psychotherapy and psychopharmacology appear to have stimulated the investigation of alternative therapies for depression. In 1998, 40% of the American population used at least 1 complimentary or alternative therapy for 1 year (Astin, 1998). In a study involving 151 coronary artery bypass graft (CABG) patients, the utilization of complimentary therapies for psychological recovery included prayer, which was used by 67.5% of the patients, exercise was used by 45.7% of the patients, and lifestyle-diet modification was used by 9.9% of the patient population. The remainder of
the patients used therapies such as an individual counselor (6.6%), megavitamin therapy (2.6%) and relaxation (1.3%) (Ai et al., 1997). The users of exercise as a complimentary therapy tended to have a college education, and the indicator for those who used prayer placed high importance on religion and were under the age of 65. Results also indicated that those who used complimentary therapies (especially prayer and exercise) had less depression and general stress at six months and one-year post CABG than those who did not employ any therapy (Ai et al., 1997). Additional therapies used for depression include acupuncture, herbal medicine, aromatherapy, homeopathy, hypnotherapy, massage therapy and music therapy (Ernst, Rand & Stevinson, 1998). The evidence for acupuncture, massage and relaxation therapy is promising but not compelling, as the majority of information lacked quantifiable data.

Concrete scientific data to support the effectiveness of alternative or complimentary therapies is very limited. The research that is available has many limitations including lack of control groups, small sample size and lack of adequate outcome measures. Additional research with concrete scientific data is necessary in order to support or refute therapy efficacy.

D. Treating Depression with Exercise

The relationship between exercise and depression has been examined since the early 1900’s. Franz and Hamilton (1905) investigated the effects of a long walk and bowling in two depressed individuals. Franz and Hamilton additionally evaluated the effect of the two activities on pain threshold, rapidity and accuracy of movement and speed of reading. Response improved in one of the subjects while the other became fatigued. Since 1905, investigations relating exercise and depression have continued.
The effects of exercise among different populations such as the mentally ill, the elderly and the chronically ill are being studied. Different exercise modes, durations and intensities are being applied in order to identify the optimal application of physical exercise in the treatment of depression.

A review by Byrne & Byrne (1993) evaluating the relationship of exercise and depression included 30 studies, including clinical and non-clinical samples, published in refereed journals after 1975. Of the 30 studies reported, 27 supported the positive effect of exercise in combating depressive symptoms and anxiety. Most studies used aerobic exercise as the exercise intervention. While the majority of the aerobic studies did not report fitness gains (i.e. gains in VO₂max) they did find significant mood improvement. Whether fitness gains are necessary for exercise to be effective in lowering depression is unclear (Byrne & Byrne, 1993; Craft & Landers, 1998; Martinsen, 1994).

Martinsen (1994) conducted a review of 12 studies that involved treating depressed subjects with exercise interventions. Each of the studies resulted in a similar conclusion: Aerobic exercise is more effective in treating depression than no treatment. Three of the studies included in the review compared exercise with psychotherapy or counseling and found no significant differences between treatments (Freemont & Craighead, 1987; Greist et al., 1979; Klein, Greist & Gurman, 1985). For example, the study by Greist and colleagues (1979) compared a consistent 10-week running schedule to two different types of psychotherapy (time-limited & time-unlimited). Efficacy of the running treatment was not significantly different from the two different types of psychotherapy.
Through meta-analysis, Craft and Landers (1998) compared 30 studies with subjects diagnosed with clinical depression and depression resulting from mental illness. Effect analysis showed a significant main effect for initial level of depression and exercise characteristics. Therefore, individuals who were initially the most depressed, and individuals who exercised for 9 to 12 weeks (as opposed to 8 weeks or less) showed the greatest reduction in depression. Mode of exercise analysis found no significant main effects. Results indicated that all types of examined exercises reduced depression scores and exercise intervention was just as effective in alleviating depression as more traditional types of treatment.

DiLorenzo and colleagues (1999) investigated the short and long-term effects of aerobic exercise on psychological outcome in 82 healthy adults. Following a 12-week cycle ergometry aerobic fitness program, subjects’ mood states, anxiety, depression and self-concept were assessed. Subjects were randomly assigned to one of three groups: control, interval training, and fixed intensity. Subjects were re-assessed post-intervention at 3, 6 and 12 months. The exercise subjects had greater decreases in depressive symptomology over time than did the control group. Similar positive results were found for anxiety and self-concept in the exercise groups. Long-term results revealed a significant improvement in all psychological variables from baseline to the end of the 12 weeks of exercise. From 12 weeks to the 3-month assessment, participants’ scores declined and then tended to stabilize between the 3-month assessment and subsequent 6 and 12-month assessments. Fitness gains appeared to follow the same pattern. The 3, 6, and 12-month follow-up indicated strong maintenance of the psychological gains, as scores remained significantly higher than the control group. Although the exercise
program lasted 12-weeks, the authors claimed psychological improvements were maintainable without the continuing effects of a formal physical fitness program.

Based on data showing reduced severity and duration of depressive reactions in individuals who exercise following stressful life changes, Segar et al. (1998) investigated how exercise can facilitate the well being and psychosocial health of breast cancer survivors. Subjects were randomly assigned to one of three groups: exercise, exercise and behavior modification, and control (waiting list). The exercise protocol lasted for 10 weeks at which point crossover occurred where the exercise groups stopped exercising for 10 weeks and the control group began exercising. Depression, anxiety and self-esteem were assessed at baseline, at crossover and post-intervention. Baseline to post-intervention data revealed that the women in the exercise groups had significantly lower anxiety and depression than the control group. At crossover, the exercise groups showed a 44% increase in depressive symptoms. The control group showed a decrease in depression by 42% as well as a decrease in anxiety by 26%. Self-esteem levels changed very little in all three groups. Self-esteem is made up of many personality components, and thus may not be affected by a single behavior change. Another interesting finding in this study revealed that the subjects who had been recommended to exercise by their physicians (50%) exercised significantly more than the subjects who did not have a physician recommend exercise.

E. Treating Depression with Exercise in the Geriatric and Cardiac Disease Population

The aging process of the human body is natural. In the presence of disease or illness, aging can occur at a quicker pace than that of a healthy body. Unfortunately,
science cannot always definitively determine the cause of a fast (or slow) aging process. Therefore the use of research to definitively pinpoint the cause for health in individuals is difficult, if not impossible. In an effort to maintain generalizability without sacrificing internal validity, King, Taylor and Haskell (1993) evaluated the effects of long-term exercise under differing formats and intensities. Of note in this endurance exercise study was the inclusion of smokers and non-smokers with no attempt to change smoking status. Three hundred fifty-seven, randomly chosen, older adult men and women were randomly assigned to one of four different groups: high intensity group exercise, high intensity home-based exercise, low intensity home-based exercise and assessment only (control). The high intensity exercise groups exercised for 60 minutes 3 times per week for 12 months at 73 – 88% maximal heart rate. The home-based groups walked at home and the group-based exercisers trained together in a class. The low-intensity group trained for 30 minutes 5 times per week at 60% to 73% maximum heart rate. The subjects assigned to the control group were requested not to change their activity habits during the 12-month study period. To monitor progress, subjects were contacted by telephone and mailed in weekly activity logs providing information regarding exercise adherence, heart rate, RPE, etc. To insure validity, randomly chosen subjects wore a microprocessor, which recorded heart rate and body movement for 3-day periods. Physiological measures were obtained at baseline, 6 months and 12 months. Subjects performed an ECG treadmill test (Balke protocol) to determine \( VO_2 \text{max} \). Body weight and height were measured and body mass index (BMI) was calculated. Psychological measures recorded were depressive symptoms, anxiety, stress and ratings of perceived change.
Results indicated that over the 12-month period subjects in the home-based programs had much higher rates of adherence (75%) compared to the subjects in the group-based program (56%). Changes in psychological variables indicated exercise was effective in significantly lowering stress and anxiety levels regardless of intensity and format. Depression levels were lowered but without significance. Anxiety levels for the subjects who smoked appeared to be positively effected to a larger degree as a result of the exercise intervention. For ratings of perceived change on psychological outcomes (how the subjects perceived they changed due to the exercise), the exercise groups reported significant improvements in stress, anxiety, depression, sleep quality, shape and appearance, confidence and well-being, energy, general mood and physical fitness. Further analysis indicated exercise participation rate was more predictive of 12-month changes in depression levels than were changes in fitness or exercise intensity or format (King et al., 1993).

With the knowledge that exercise participation rate is more predictive of reductions in depression than are changes in fitness, exercise mode or intensity, cardiac rehabilitation programs that advocate consistent attendance may be an important exercise arena. Lavie et al. (1999) assessed the effects of a cardiac rehabilitation and exercise training program on women with CAD and depression. The subjects had completed a phase two cardiac rehabilitation program of 12 weeks consisting of 36 exercise and educational sessions. At the beginning of the phase two program (baseline), anxiety, somatization, hostility and depression were assessed by validated questionnaires. Twenty-three of the 102 subjects met criteria for depression. Compared to the non-depressed women, the depressed women at baseline had higher scores for anxiety,
somatization and hostility, and lower quality of life scores, which include mental health, energy, general health, pain, function, and well being. They also had lower exercise capacities and high-density lipoprotein cholesterol (HDL-c) as well as higher blood triglyceride levels. All of the subjects were statistically similar in age, BMI, total cholesterol and low-density lipoprotein cholesterol.

After cardiac rehabilitation, only seven of the initial 23 women who were depressed at baseline remained depressed. However, 5 of the 79 non-depressed women at baseline met criteria for depression post-cardiac rehabilitation. Other areas of significant improvements in the women included anxiety, somatization, hostility, quality of life and all 6 quality of life components. In addition, exercise capacity and HDL-c significantly improved.

Claims that one specific aspect of the cardiac rehabilitation program was responsible for reducing depressive levels would be obtuse, as many factors including the exercise program, educational classes and social support could all have contributed to the overall effect. However, as demonstrated in this study, cardiac rehabilitation not only improved the subjects’ cardiovascular risk factors but also served as a probable treatment for depression.

Chapter 3: Methodology

A. Participants

The subject population for this study consisted of 18 cardiac patients, aged 45 to 85 years, who had been hospitalized for coronary artery disease, cardiomyopathy or myocardial infarction at two midsize medical centers in Montana. Each subject was
required to have successfully completed phase one of cardiac rehabilitation. The subjects were self-divided into two groups based on the location of their phase two cardiac rehabilitation. Subjects who participated in a structured phase two cardiac rehabilitation program 3 times per week were assigned to the clinical group. Subjects who chose to do their rehabilitation in a non-clinical setting were assigned to the non-clinical group. The non-clinical group generally consisted of the patients who, due to rural residence or other inability to participate in a structured clinically based phase two rehabilitation program, exercised at home.

B. Instrumentation

1. Cardiac Depression Scale (CDS): The CDS (Hare & Davis, 1996) is a short self-report, 26-item scale designed to measure current levels of depressive symptomology commonly found in the cardiac patient population. Scores range from 26 to 129 with the lower scores indicating less depressive symptoms. The CDS focuses on factors such as sleep, anhedonia (lack of pleasure), uncertainty, mood, cognition, hopelessness and inactivity (See appendix).

The CDS has high internal consistency with $\alpha$ reliability coefficient of .90. External validity was correlated with the Beck Depression Inventory and clinical assessment. CDS correlation with the Beck Depression Inventory is moderately high with a .73 and correlation with clinical assessment is .67 (Hare & Davis, 1996). Hare & Davis (1996) reported content validity of the CDS was evaluated by expert judgment of health professionals well studied in the management and psychological assessment of cardiac patients.
2. Physical Activity Scale for the Elderly (PASE): The PASE (Washburn, Smith, Jette & Janney, 1993) is a 10 -item self-report scale that estimates the level of physical activity in elderly individuals. It is comprised of questions regarding occupational, household and leisure activities during a one-week period (See appendix). The test-retest reliability coefficient was $r=0.75$ over a 3-to-7 week period (Washburn, Smith, Jette & Janney, 1993). Physiologic characteristics affected by activity levels and specific aspects of health status were used as validation measures for the PASE. Washburn et al. (1993) reported PASE scores were significantly associated with the Sickness Impact Profile scores ($p = 0.42$) and perceived health status ($p = 0.34$). In addition, a positive correlation with PASE scores was reported with heart rate, grip strength, static balance and leg strength (Washburn et al., 1993).

C. Procedures

After completing the acute rehabilitation of phase one, the lead investigator gave the individual subjects a brief overview of the study without revealing the expected results. If a subject agreed to participate in the study and signed the consent form, a subsequent meeting was set up at which time the subject completed the Cardiac Depression Scale and the PASE scale. This second meeting occurred before the subject's initial phase two session or within the week following discharge from phase one cardiac rehabilitation. The lead investigator was readily available to the subjects for questions relating to this research. Six weeks after the beginning of phase two rehabilitation, at approximately the midpoint of the normal phase two cardiac rehabilitation program, the third meeting took place where the subject again completed the CDS and PASE scales. The final meeting occurred after twelve weeks of recovery where each subject completed
the CDS scale and PASE scale for the third and final time. Upon completion of filling out the scales the third time, each subject was informed of the purposes of the study and thanked for their participation. A summary of the results was made available to the subjects upon request.

D. Data Analysis

Due to the small sample size data analysis was restricted. Demographics data was analyzed by calculating the mean and standard deviations. Changes in and the correlation of the activity and depression scores were assessed using a 2-tailed Pearson Correlation with significance at the 0.05 level. Alpha coefficient was used to test the reliability of the Cardiac Depression Scale and reliability for the activity scale was not possible due to limited number of items. The “Statistical Package for Social Sciences” (SPSS release 10.1 for Windows, located in Chicago, IL) was used to analyze the data. A two way ANOVA (time x treatment) was used to compare the treatments of clinical versus non-clinical groups.

Chapter 4: Results

A. Subjects

During the time of this study there were 35 patients referred to this investigator. Of the 35, 7 patients cancelled their initial appointment and chose not to reschedule, 6 became ineligible due to further medical problems, travel or death. An additional 4 patients withdrew due to the cost of the clinical program and were not included in the analyses. A total of 18 subjects were included in this study. There were seven subjects in the clinical group and eleven subjects in the non-clinical group.
B. **Baseline characteristics**

Both groups had similar medical histories which consisted of post stent, post bypass or post myocardial infarction. The average age was 67.5 within a gender spread of 8 females and 10 males. The marital status of the subject population consisted of 66.7% married and 33.3% single or widowed. Living status consisted of 83.3% of the 18 subjects lived with a spouse, relative or friend and the remaining 16.7% subjects lived alone.

C. **Depression scores and physical activity**

Self-selected assignment of subjects resulted in two groups that did not differ in any measured characteristic. Descriptive characteristics are shown in Table 1 (page 29). No significant differences occurred in depression scale scores between the clinical group and the non-clinical group as well as no difference within groups across time. CDS depression score means and standard deviations are shown in Table 2 (page 30). However, while not statistically significant, the subjects in cardiac rehabilitation had lower depression scores at each tested interval. Physical activity scores (Table 3, page 31) indicated that subjects in the clinical group had lower activity scores than those in the non-clinical group. However, the activity scores of the clinical group steadily increased while the non-clinical group remained the same. Again, this data was not statistically significant but a trend was evident. Physical activity scores did significantly increase in the clinical group from pre- to post-testing. The interactions between time and treatment were not significant, as all probability values were >.05 (see Tables 4 & 5, page 32-33), indicating in the 12-week duration the two protocols did not differ. Although significance
was not reached, the trends did suggest that with a larger population significance is likely to occur. As expected, there was an inverse correlation between age and activity.
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Table 1
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<tr>
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<td>Pre</td>
<td>Post</td>
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<tr>
<td>Clinical</td>
<td>76.9</td>
<td>± 14</td>
<td>73.7</td>
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<tr>
<td>Non-clinical</td>
<td>79.6</td>
<td>± 19.5</td>
<td>82.9</td>
<td>± 33</td>
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Table 2
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<td>Post</td>
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<tr>
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<td>31.7</td>
<td>± 24.7</td>
<td>104.1*</td>
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<td>Non-clinical</td>
<td>93.5</td>
<td>± 93.5</td>
<td>158</td>
<td>± 131.2</td>
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* = significant at $P < .05$

Table 3
CDS ANOVA Summary

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Table 4
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</table>

Table 5
Chapter 5: Discussion and Recommendations

Throughout the course of this study, observations were made by the researcher pertaining to exercise as an intervention for depression in cardiac patients in Montana. Quantitatively, results of this study did not reach significance but trends suggest that with a larger population sample significance would likely be reached. The difference in depression scores (see Table 2) between the clinical group and the non-clinical cardiac rehabilitation group appears minimal however, the depression scores for the non-clinical group from pre- to post-testing increased which suggests increases in depressive symptoms over time. The CDS post-test standard deviation indicated a transition to severe depression for those subjects with a score over 100, which suggests that the antidepressant benefits of clinical cardiac rehabilitation could be substantial enough to prevent further depressive decline in the cardiac patient population. The post-test standard deviation for the clinical group slightly declined from pre- to post-testing which, in this researcher’s opinion, further supports the antidepressant benefits of clinical cardiac rehabilitation. The activity scores (see Table 3) between the clinical and non-clinical groups did not significantly differ but the difference between the pre-test activity scores should be noted for several reasons. The difference suggests that when a patient is discharged into the non-clinical cardiac rehabilitation setting, due to rural proximity, the at home duties and activities may resume much quicker compared to the clinical group. Or the lower pre-testing scores in the clinical group could indicate that the greater amount and intensity of the exercise within the clinical cardiac rehabilitation setting yields a lower degree of activity around the home, due to physical tiredness. Finally, misrepresentation or overestimation of physical activity by the non-clinical group should
be considered when weighing the activity scores as the physical activity for the non-clinical group was unmonitored and unsupervised. If the non-clinical group had been monitored by portable activity tracking devices in conjunction with the PASE self-report scale, variance in the activity scores could be accurately accounted for as opposed to speculation.

Qualitatively, the beneficial components of a formal cardiac rehabilitation program provide the opportunity for cardiac patients to glean the antidepressant benefits of regular exercise and the unmeasured (in this study only) benefits of cardiac rehabilitation components like social support, health education and medical supervision. Patients have the opportunity to develop friendships with other patients who have endured similar health challenges, which offers a sense of camaraderie, and hope to a newly diagnosed patient facing life with cardiac disease. The education classes give the patients and family members a chance to learn about heart disease as well as ask questions and express individual concerns. The classes provide the confidence and knowledge base for the patient and family members to begin making lifestyle changes at home. The medical supervision and components such as daily blood pressure checks by an exercise physiologist provide a sense of safety and security that gives the patient confidence to exercise to their fullest potential whereas they may not have this sense of safety at a local health club or gym. The reduction in cardiac patients’ depressive symptoms is a result of the atmosphere and multiple components encompassed in formal cardiac rehabilitation. In an effort to improve the transitional services for rural cardiac out-patients, healthcare organizations should consider providing remote activity & telemetry monitors with weekly nurse tele-management services. This kind of out-patient
service would be a safe and supportive transitional program used to encourage the rural patient to exercise daily and make healthy lifestyle changes that could prove to be cost-effective in preventing depression and cardiac related re-admission.

The trend from this study indicates that subjects who participate in a clinical cardiac rehabilitation program have significantly less depressive symptoms than their non-clinical counterparts, it is evident, in this researcher’s opinion that with a larger population statistical significance would be reached.

The following three sections of this chapter consist of a) identifying the key components of a formal cardiac rehabilitation program that maximize the potential for positively impacting depression in cardiac patients compared to the non-clinical group, b) identifying the barriers that occur prior to and/or during cardiac rehabilitation that impact the exercise potential for the cardiac patient and c) recommendations for future studies of this nature with the cardiac patient population.

A. Key components of cardiac rehabilitation

The trend toward significance in this study with such a small population leads this researcher to believe that the exercise in conjunction to the many other components of formal cardiac rehabilitation cumulatively effective in treating depressive symptoms and that further research will show this to be true. Due to the structure of a clinical cardiac rehabilitation program, the cardiac patient is not only exposed to the benefits of exercise but also the supplemental programs within cardiac rehabilitation such as telemetry and blood pressure monitoring, educational classes, spousal and family support classes, peer social support, secondary disease maintenance and on-hand medical staff. Without minimizing the effect of exercise specifically on depression, it is important to note that
the holistic components of cardiac rehabilitation should be considered. While there is no data from this study to substantiate this researcher's observation, informal qualitative interviewing of cardiac rehabilitation patients suggests the supplemental components within cardiac rehabilitation are considered by the patients to be very important. Specifically, other than the exercise, the social support and sense of safety ranked high in the patients' opinions, as these components tended to offer feelings of happiness and relief under the duress of living with a chronic illness and made them want to continue to attend cardiac rehabilitation as a phase three patient. Conversely, the non-clinical group missed out on the qualitative impact of cardiac rehabilitation that very likely added to the therapeutic benefit of exercise on depression.

B. Barriers to cardiac rehabilitation

Throughout this study, this researcher quickly learned there are many barriers a patient will encounter when entering into a cardiac rehabilitation program. This section will discuss three primary barriers a cardiac patient encounters upon attempting to enter a cardiac rehabilitation program.

1. Physician referral

Prior to being discharged from the hospital after a cardiac procedure, physicians are encouraged to refer their patients to cardiac rehabilitation. This referral initiates a protocol where one of the cardiac rehabilitation staff contacts the patient in the hospital and later over the phone within one week of being discharged. Through experience and observation this researcher found that the cardiac rehabilitation staff does not rely on physician referrals as the majority of physicians either fail to remember to refer or do not believe cardiac rehabilitation is necessary. Therefore, cardiac rehabilitation does daily
rounds in the telemetry unit explaining the purpose and benefits of cardiac rehabilitation to each new cardiac patient. Many patients are discharged quickly and may not be reached by the cardiac rehabilitation staff which presents a significant barrier. Additionally, patients choose not to enroll in cardiac rehabilitation because it was not encouraged by the physician. Furthermore, if the patient is not referred by the physician until several weeks post surgery it is unlikely that the younger working age patients will enroll due to returning to work and time constraints. For rural patients, even with a physician referral, it is simply an issue of proximity that hinders their ability to enroll in cardiac rehabilitation.

2. Insurance coverage and financial feasibility

Upon entering a cardiac rehabilitation program, the patient’s initial appointment consists of a thorough nursing assessment, disease stratification, medication review and insurance coverage. If the patient is eligible for Medicare, it will cover 80 percent of the phase one and two cardiac rehabilitation charges if the patient was diagnosed with CABG or MI. Medicare rarely covers patients who have a stent and/or angioplasty procedure unless the patient is diagnosed with unstable angina. The diagnosis of CAD is never financially covered by Medicare nor is phase three cardiac rehabilitation. Patients with private insurance coverage range from 60% to 90% coverage for phase one and two cardiac rehabilitation yet again stenting, angioplasty and CAD is rarely covered. Phase three is sometimes covered by private insurance however at a very low percentage. Normal out of pocket charges incurred for patients often range from $100 to $140 per week of phase two rehabilitation, resulting in at $400+ for a risk stratified patient over 4 weeks (12 sessions) and $800+ for eight weeks. If a patient is risk stratified to attend the
maximum 36 sessions they will pay out of pocket at least $1,200. Frequently, financial feasibility is a significant barrier to attending and completing phase two cardiac rehabilitation.

3. Transportation

It is common for a patient not to attend cardiac rehabilitation simply due to transportation unavailability. Patients who have undergone open heart surgery rarely are cleared to drive until 4 to 6 weeks post surgery. Unfortunately, if the patient does not have a friend or family member willing to commit to rides back and forth to the cardiac rehabilitation center the commitment to attend cardiac rehabilitation becomes impossible. In addition, there are patients who no longer possess a drivers license primarily due to age. Thus age and severity of procedure may also limit participation.

Patients who have undergone a procedure of lesser risk are often cleared to drive at two weeks post procedure allowing easier access to cardiac rehabilitation. As discussed previously, for the rural patients, cardiac rehabilitation is often infeasible due to driving distance and the added time commitment. In an effort to aid the transportation conflicts for the older or non-driving patients, hospitals have developed a volunteer based service where patients can be picked up and taken to their cardiac rehabilitation appointments and returned home upon completion. For many patients living within city limits this is a valuable asset. However, for patients with time constraints the volunteer ride service is deemed slow and unreliable. For rural patients this is not an option.

C. Recommendations for future studies

It is the opinion of this researcher that future studies conducted on the topic of depression in cardiac rehabilitation patients should be done by individual(s) that initially
meet with the cardiac patients during the hospital stay in the telemetry unit. Most often this is a unit nurse, a phase one cardiac rehabilitation therapist or cardiac rehabilitation staff that does in-patient rounds. This component is crucial in the success and outcome of obtaining a large subject population. Additionally, future studies would benefit from physician support. Specifically, if the cardiology practitioners agreed to encourage patients to participate in the study patients would be more likely to agree to participate. It is this researchers opinion that with a larger subject population and direct access to the subjects as inpatients the expected impact of regular exercise through a clinical cardiac rehabilitation program on depression would be significant.
References


Appendix A

Informed Consent
Subject Information and Informed Consent Statement

Lead Investigator: Heidi A. Hagstrom
Graduate Student
HHP Department
The University of Montana
Missoula, MT 59812
406-670-8245

Study Director: Dr. Steve Gaskill Ph.D.
Professor
HHP Department
The University of Montana
Missoula, MT 59812
406-243-4268

The Department of Health and Human Performance at the University of Montana and Deaconess Billings Clinic of Billings, Montana supports the practice of protection for human subjects participating in research activities. The following information is provided so you can decide whether or not you wish to participate in this study. If you do not understand a statement or particular words, which may be new to you, feel free to ask for further explanation from the investigator.

This study will evaluate cardiac patients’ emotional rehabilitation progress. Specifically, it will investigate your feelings and daily habits after you are released from the hospital. You will be asked to complete two questionnaires, three times within the next 12 weeks. If you agree to participate in the study, the questionnaires will be administered upon release from the hospital, 6 weeks following release and at 12 weeks following release. The PASE questionnaire will ask questions regarding daily activities and the CDS questionnaire will ask questions regarding your feelings and emotions for that present day. These questionnaires do not suggest you should change your daily activity routine. If you should choose to change your daily activity routine you must check with your personal physician before doing so. You will be asked to complete the questionnaires at your home with the lead investigator, during a scheduled time of your choice. The questionnaires will take no more than 30 minutes of your time per session. If you are planning to attend cardiac rehabilitation at Deaconess Billings Clinic you will also be asked if the lead investigator can view your rehabilitation records. We are asking to see, on a confidential basis, your rehabilitation records only to verify your activity level. Be assured no information will be replicated from your rehabilitation records and only the lead investigator will have access to the records. Your participation may help determine how recovery from a cardiac incident may be improved upon for future patients. There is no expectation that you personally will receive any benefit from taking part in this study.

Your participation is solicited, but is strictly voluntary. You are not required to participate in the study and even if you agree to participate, you are free to withdraw at any time without penalty or loss of benefits to which you are normally entitled. YOUR NAME WILL NOT BE ASSOCIATED WITH THE RESEARCH FINDINGS IN ANY WAY. Your questionnaires will be numbered and the identifying key and data will be destroyed upon collation. The signed consent form will be stored in a locked cabinet separate from the data. Do not hesitate to ask questions about the confidentiality of your responses at this time or any time in the future. Please feel free to contact me by phone.
or mail with concerns you may have at the above address and phone number. A copy of this consent for will be given to you.

Although, we believe the risk of taking part in this study is minimal, the University of Montana requires that the following statement be included in this informed consent. In the event you are injured as a result of this research, you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement or compensation pursuant to the Comprehensive State Insurance Plan established by the Department of Administration under the authority of M.C.A., Title 2, Chapter 9. In the event of a claim for such injury, further information may be obtained from the University’s Claims Representative or University Legal Counsel.

I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured a member of the research team will also answer any future questions I may have. I voluntarily agree to take part in this study as well as agree to the confidential viewing of my cardiac rehabilitation records by the lead investigator.

I understand I will receive a copy of this consent form.

Printed Name of Subject  Date

Signature of Subject  Date
Appendix B

Instrumentation
Demographics Questionnaire

Please answer the following questions. Be assured your answers will not be associated with your name in any way. They are for general information purposes only.

Please circle your gender. Male Female

Date of birth: __________________________

Are you married or single?
Please circle one. Married Single

Please check the correct statement.

_____ I live alone.

_____ I live with my spouse / companion.

_____ I live with a housemate / friend / relative.
The following questionnaire will ask you questions about your daily activities within the past seven days. The answers range from never to always and yes or no. Please answer all questions to the best of your ability by circling the answer that fits best. There are no wrong answers. In each question a variety of examples of activities are provided. If you have any questions regarding the examples feel free to ask the investigator at any time. The questions are only for gaining information about your daily activity. This questionnaire does not suggest you should change your daily activity routine. If you should choose to change your daily activity routine you must check with your personal physician before doing so.
INSTRUCTIONS:

Please complete this questionnaire by either circling the correct response or filling in the blank. Here is an example:

During the past 7 days, how often have you seen the sun?

[0.] NEVER [1.] SELDOM [2.] SOMETIMES [3.] OFTEN
(1-2 DAYS) (3-4 DAYS) (5-7 DAYS)

Answer all items as accurately as possible. All information is strictly confidential.
LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

  [0.] NEVER  
  [1.] SELDOM (1-2 DAYS)  
  [2.] SOMETIMES (3-4 DAYS)  
  [3.] OFTEN (5-7 DAYS)  
  GO TO Q.#2

   1a. What were these activities?
   ______________________________________

   1b. On average, how many hours per day did you engage in these sitting activities?

   [1.] LESS THAN 1 HOUR  
   [2.] 1 BUT LESS THAN 2 HOURS  
   [3.] 2-4 HOURS  
   [4.] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

  [0.] NEVER  
  [1.] SELDOM (1-2 DAYS)  
  [2.] SOMETIMES (3-4 DAYS)  
  [3.] OFTEN (5-7 DAYS)  
  GO TO Q.#3

   2a. On average, how many hours per day did you spend walking?

   [1.] LESS THAN 1 HOUR  
   [2.] 1 BUT LESS THAN 2 HOURS  
   [3.] 2-4 HOURS  
   [4.] MORE THAN 4 HOURS
3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

<table>
<thead>
<tr>
<th>[0.] NEVER</th>
<th>[1.] SELDOM</th>
<th>[2.] SOMETIMES</th>
<th>[3.] OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1-2 DAYS)</td>
<td>(3-4 DAYS)</td>
<td>(5-7 DAYS)</td>
<td></td>
</tr>
</tbody>
</table>

GO TO Q.#4

<table>
<thead>
<tr>
<th>3a. What were these activities?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3b. On average, how many hours per day did you engage in these light sport or recreational activities?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1.] LESS THAN 1 HOUR</td>
</tr>
<tr>
<td>[3.] 2-4 HOURS</td>
</tr>
</tbody>
</table>

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1-2 DAYS)</td>
<td>(3-4 DAYS)</td>
<td>(5-7 DAYS)</td>
<td></td>
</tr>
</tbody>
</table>

GO TO Q.#5

<table>
<thead>
<tr>
<th>4a. What were these activities?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4b. On average, how many hours per day did you engage in these moderate sport and recreational activities?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1.] LESS THAN 1 HOUR</td>
</tr>
<tr>
<td>[3.] 2-4 HOURS</td>
</tr>
</tbody>
</table>
5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SELDOM</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[0.]</td>
<td>[1.]</td>
<td>[2.]</td>
<td>[3.]</td>
</tr>
<tr>
<td></td>
<td>[1-2 DAYS]</td>
<td>[3-4 DAYS]</td>
<td>[5-7 DAYS]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GO TO Q. #6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5a. What were these activities?

5b. On average, how many hours per day did you engage in these strenuous sport and recreational activities?

<table>
<thead>
<tr>
<th></th>
<th>LESS THAN 1 HOUR</th>
<th>1 BUT LESS THAN 2 HOURS</th>
<th>2-4 HOURS</th>
<th>MORE THAN 4 HOURS</th>
</tr>
</thead>
</table>

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SELDOM</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[0.]</td>
<td>[1.]</td>
<td>[2.]</td>
<td>[3.]</td>
</tr>
<tr>
<td></td>
<td>[1-2 DAYS]</td>
<td>[3-4 DAYS]</td>
<td>[5-7 DAYS]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GO TO Q. #7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6a. What were these activities?

6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

<table>
<thead>
<tr>
<th></th>
<th>LESS THAN 1 HOUR</th>
<th>1 BUT LESS THAN 2 HOURS</th>
<th>2-4 HOURS</th>
<th>MORE THAN 4 HOURS</th>
</tr>
</thead>
</table>

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HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?
   [1.] NO  [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?
   [1.] NO  [2.] YES

9. During the past 7 days, did you engage in any of the following activities?
   Please answer YES or NO for each item.
   a. Home repairs like painting, wallpapering, electrical work, etc.  NO  YES
      1  2
   b. Lawn work or yard care, including snow or leaf removal, wood chopping, etc.  NO  YES
      1  2
   c. Outdoor gardening  NO  YES
      1  2
   d. Caring for an other person, such as children, dependent spouse, or an other adult  NO  YES
      1  2

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WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1.] NO  [2.] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

________________________ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

   [Examples: office worker, watchmaker, seated assembly line worker, bus driver, etc.]

[2] Sitting or standing with some walking.
   [Examples: cashier, general office worker, light tool and machinery worker.]

[3] Walking, with some handling of materials generally weighing less than 50 pounds.
   [Examples: mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

   [Examples: lumberjack, stone mason, farm or general laborer.]
THANK YOU FOR TAKING THE TIME AND EFFORT TO COMPLETE THIS QUESTIONNAIRE!
This questionnaire consists of a number of statements about the way you feel at present.

Next to each statement there is a rating scale from 1 to 7 for you to indicate how much you agree or disagree with the statement.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Please indicate how strongly you agree or disagree with each statement by circling one of the numbers on the scale.

For example, a score of a 4 would indicate that you neither agree nor disagree with the statement, a score of 1 that you strongly disagree, and a score of 7 that you strongly agree.

EXAMPLE

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

This indicates that you quite strongly disagree with the statement.

THERE ARE NO RIGHT OR WRONG ANSWERS

PLEASE ENSURE YOU HAVE COMPLETED ALL ITEMS

© D.L. Hare, 1993
<table>
<thead>
<tr>
<th>CHECK TO MAKE SURE YOU HAVE ANSWERED ALL QUESTIONS</th>
<th>Strongly Disagree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I have dropped many of my interests and activities...</td>
<td>1 2 3 4 5 6 7 None dropped</td>
<td>All dropped</td>
</tr>
<tr>
<td>2. My concentration is as good as it ever was...</td>
<td>1 2 3 4 5 6 7 Very Poor concentration</td>
<td>Excellent concentration</td>
</tr>
<tr>
<td>3. I can't be bothered doing anything much...</td>
<td>1 2 3 4 5 6 7 Keen to do things</td>
<td>Can't be bothered</td>
</tr>
<tr>
<td>4. I get pleasure from life at present....</td>
<td>1 2 3 4 5 6 7 No pleasure</td>
<td>Great pleasure</td>
</tr>
<tr>
<td>5. I am concerned about the uncertainty of my health...</td>
<td>1 2 3 4 5 6 7 Not concerned</td>
<td>Very concerned</td>
</tr>
<tr>
<td>6. I may not recover properly...</td>
<td>1 2 3 4 5 6 7 Will recover completely</td>
<td>Will not recover</td>
</tr>
<tr>
<td>7. My sleep is restless and disturbed...</td>
<td>1 2 3 4 5 6 7 Not restless</td>
<td>Very restless</td>
</tr>
<tr>
<td>8. I am not the person I used to be...</td>
<td>1 2 3 4 5 6 7 Just the same</td>
<td>Completely different</td>
</tr>
<tr>
<td>CHECK TO MAKE SURE YOU HAVE ANSWERED ALL QUESTIONS</td>
<td>Strongly Disagree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>9. I wake up in the early hours of the morning and cannot get back to sleep...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>10. I feel like I'm living on borrowed time...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>11. Dying is the best solution for me...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>12. I feel in good spirits...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>13. The possibility of sudden death worries me...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>14. There is only misery in the future for me...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>15. My mind is as fast and alert as always...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>16. I get hardly anything done...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>17. My problems are not yet over...</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>CHECK TO MAKE SURE YOU HAVE ANSWERED ALL QUESTIONS</th>
<th>Strongly Disagree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>18. Things which I regret about my life are bothering me...</td>
<td>1 2 3 4 5 6 7</td>
<td>Absolutely no regrets</td>
</tr>
<tr>
<td>19. I gain just as much pleasure from my leisure activities as I used to...</td>
<td>1 2 3 4 5 6 7</td>
<td>No pleasure at all</td>
</tr>
<tr>
<td>20. My memory is as good as it always was...</td>
<td>1 2 3 4 5 6 7</td>
<td>Very poor memory</td>
</tr>
<tr>
<td>21. I become tearful more easily than before...</td>
<td>1 2 3 4 5 6 7</td>
<td>Not at all tearful</td>
</tr>
<tr>
<td>22. I seem to get more easily irritated by others than before...</td>
<td>1 2 3 4 5 6 7</td>
<td>Never irritated</td>
</tr>
<tr>
<td>23. I feel independent and in control of my life...</td>
<td>1 2 3 4 5 6 7</td>
<td>No independence</td>
</tr>
<tr>
<td>24. I lose my temper more easily nowadays...</td>
<td>1 2 3 4 5 6 7</td>
<td>Never lose temper</td>
</tr>
<tr>
<td>25. I feel frustrated...</td>
<td>1 2 3 4 5 6 7</td>
<td>Not at all frustrated</td>
</tr>
<tr>
<td>26. I am concerned about my capacity for sexual activity...</td>
<td>1 2 3 4 5 6 7</td>
<td>No concern at all</td>
</tr>
</tbody>
</table>