

PARTNERS TOGETHER IN HEALTH: HEALTH-RELATED QUALITY OF LIFE
OUTCOMES IN CORONARY ARTERY BYPASS PATIENTS AND PARTNERS

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TITLE

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Bypass Patients and Partners

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PARTNERS TOGETHER IN HEALTH: HEALTH-RELATED QUALITY OF LIFE
OUTCOMES IN CORONARY ARTERY BYPASS PATIENTS AND PARTNERS

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University of Nebraska, 2012

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Coronary artery bypass (CAB) surgery patients experience profound declines in physical, psychological, and relational health-related quality of life (HRQOL) following surgery. The purpose of this study was to examine HRQOL outcomes in CAB surgery patients and partners enrolled in either the innovative Partners Together in Health (PaTH) intervention or usual care cardiac rehabilitation (CR).

An experimental, two-group, repeated measures design was used to examine patients and partners randomly assigned to the groups. Instruments used to measure HRQOL were: the SF-36 Physical Functioning subscale, the Patient Health Questionnaire (PHQ-9) for depression, and the Dyadic Adjustment Scale for marital quality. Thirty-four couples were recruited for the primary study. HRQOL data were collected close to the start of CR (T1), the end of CR (T2), and 3 months after CR (T3). Data were analyzed using Wilcoxon signed rank tests for changes over time; and Mann Whitney U test were used to examine group differences.

Findings indicated that physical functioning was lowest for patients at baseline and improved over time. Partners' physical functioning was relatively high and remained stable. Partners in the PaTH group significantly improved physical function between T1 and T2. Patients in both groups significantly improved their depression scores between T1 and T2: 18% of patients and 12% of partners were *depressed* at T1. Marital

adjustment scores indicated that both patients and partners were in the maritally *adjusted* category. However, about 12% of patients and partners rated themselves as maritally *distressed* at T1; and increased to almost 15% at T2 and T3 for partners. Overall, there was no evidence of differences on any of the HRQOL variables between patients, or between partners, in the PaTH or usual care groups. There was a trend toward greater improvement in patients' submaximal exercise performance during CR in the PaTH group compared the usual care group (55% vs. 43%). This study adds to our understanding of the trajectory of HRQOL outcomes following CAB surgery for patients and their partners. Because patients and partners are impacted by the CAB surgery as a shared life experience, interventions focusing on the couple are needed to improve their HRQOL outcomes.

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Chapter One

Coronary heart disease (CHD) remains the leading cause of morbidity and mortality in the United States. The most recent statistics by the American Heart Association (AHA) (Roger et al., 2012) reported there were over 785,000 new heart attacks each year in the U.S., and over 415,000 coronary artery revascularizations (CDC, 2012). For the approximate 232,000 patients who undergo coronary artery bypass (CAB) surgery their physical and mental health, along with their daily relationships, is significantly impacted following heart surgery. As CAB surgery mortality rates have dramatically improved over the past 10 to 20 years, health-related quality of life (HRQOL) has become an important measurement for interventions aimed at improving outcomes following CHD events (American Association of Cardiovascular and Pulmonary Rehabilitation [AACVPR], 2004; Ferrans, Zerwic, Wilbur, & Larson, 2005; Verrill et al., 2009). The overall concept of HRQOL integrates the biophysical and psychosocial aspects of a person's subjective response to the illness experience (Sousa & Kwok, 2006; Wilson & Cleary, 1995). The three most common HRQOL dimensions identified in the literature are the physical, psychological, and social domains (Haas, 1999; WHO, 1998).

Patients often report diminished overall HRQOL prior to and immediately following CAB surgery (Barnason, Zimmerman, Anderson, Mohr-Burt, & Nieveen, 2000; Jokinen, Hippelaniene, Turpeinen, Pitkanen, & Hartikainen, 2010; Mathisen et al., 2007; Penckofer, Ferrans, Fink, Barrett, & Holm, 2005). Studies examining overall HRQOL, physical function, and psychological HRQOL have generally shown improvement by six months post-CAB surgery for most patients (Barnason et al., 2000;

Muller-Nordhorn et al., 2004; Rantanen et al., 2009). However some patients continue to have depression and diminished physical health status (Rumsfeld et al., 2003) associated with overall worse HRQOL (Tully, Baker, Turnbull, Winefield, & Knight, 2009) at six months post-CAB surgery and beyond (Mathisen et al., 2007).

When one member of a family becomes ill, undergoes surgery, or needs assistance during recovery, family members, especially spouses take on extra responsibilities (Brecht, Dracup, Moser, & Riegel, 1994; Joeckes, Van Elderen, & Schreurs, 2007). Cardiac illness or surgery in one member of a familial dyad, may impact both the patients' and the partners' quality of life as a shared life experience, including their relational quality of life. However, few studies were found that examined HRQOL in partners of CAB surgery patients. Rantanen et al. (2008) reported that patients' HRQOL was significantly worse during the first month post-CAB surgery compared to their significant others and compared to the general population. However both the patients' and the partners' HRQOL scores were the lowest at one month, and improved at 3 and 6 months post-CAB surgery (Rantanen et al., 2009). Also, negative psychological characteristics such as depression and stress in partners have been found to negatively impact the patients' HRQOL (Molloy, Perkins-Porras, Strike, & Steptoe, 2008).

Recently several authors have called for examining patient-family member dyads in cardiovascular research, because family members often have an important role in the post-event treatment of cardiovascular patients (Chung, Moser, Lennie, & Rayens, 2009; Quinn, Dunbar, Clark, & Strickland, 2010). Marital status was found to be associated with better survival following CAB surgery when compared to survival rates for

unmarried CAB surgery patients (King & Reis, 2011). Furthermore, for married patients, those who perceived high levels of relational quality also had higher rates of survival up to 15 years following CAB surgery (King & Reis, 2011). In addition to mortality outcomes, one study found that psychological adjustment to CHD was influenced by the patients' perceptions of marital quality, which was measured as marital adjustment (Brecht et al., 1994). However, few studies were found that examined HRQOL variables and dyadic adjustment in CAB surgery patients and partners. The few studies that examined these variables typically measured the patients' outcomes, but often omitted the partners' HRQOL outcomes.

Couple-centered interventions in chronic illnesses such as cancer and dementia were found to have positive outcomes including reduced patients' depression and improved marital quality (Martire, Schulz, Helgeson, Small, & Saghfi, 2010). Findings for couple-centered interventions in patients with CHD have been inconsistent and most findings focus on psychological HRQOL outcomes. CAB surgery patients and partners in family-centered interventions had decreased anxiety when compared to usual care patient-centered interventions (Buls, 1995; Hartford, Wong, & Zakaria, 2002). Conversely, Gortner et al. (1988) reported that usual care CHD patients had less emotional distress than patients in a couples-centered intervention. Martire et al. (2010) found that only 2 of the 7 couple-oriented studies involving CHD patient-partner dyads in this meta-analysis reported both patients' and partners' outcomes, thus limiting our understanding of how CAB surgery impacts both members of the patient-partner dyads.

CR has been widely recognized as the standard of care for comprehensive patient-centered interventions following CHD events (AACVPR, 2004; Thomas et al., 2007).

Despite short-term improvements in HRQOL immediately following CR, these changes may not be sustained after the CR program ends (Davidson et al., 2008; Lear et al., 2006; Mildestvedt, Meland, & Eide, 2007). Since a majority of CR patients are in long-term dyadic relationships (Shanks, Moore, & Zeller, 2007), CR interventions aimed at the patient-partner dyad may result in improved and longer-lasting HRQOL outcomes than interventions aimed solely at the patient.

Background and Significance

The most recent 2008 data reported that direct and indirect costs for CHD were estimated to total \$297.7 billion annually (Roger et al., 2012). Direct costs include physicians and other professionals, drugs, and hospital costs; and indirect costs are for lost productivity due to mortality. The total costs for CHD was higher than any other diagnostic group for health expenditures in the U.S. (Roger et al., 2012). All cancers and benign neoplasms, the next leading cause of morbidity and mortality in the U.S. was estimated to cost \$228 billion (Roger et al., 2012). The mean hospital charge for CAB surgery procedure was \$117,094 per case with a 1.89% in-hospital death rate (Roger et al., 2011).

Between 1980 to the present, 47% of the decline in death rates due to CHD was attributable to treatments, including 11% reduction in mortality as a result of secondary preventive therapies such as CR (Roger et al., 2011). Furthermore, a 44% reduction in CHD mortality was attributable to improving risk factors, which is a major component of CR interventions. A recent analysis of Medicare claims data indicated that only 31% of eligible patients enroll in CR following CAB surgery (Roger et al., 2011). Also, CHD is

a primary diagnosis among the 45 million Americans with functional disabilities (Roger et al., 2011).

The AHA 2020 Goals (Lloyd-Jones et al., 2010) for achieving cardiovascular health for “healthy” adults (without known CHD) over the age of 20 years complements the secondary prevention goals for CR patients (AACVPR, 2004). The AHA (Lloyd-Jones et al., 2010) recently identified seven specific clinical and behavioral outcomes to target for general health promotion in the United States of which two of the behaviors, physical activity and healthy eating, are focused on in this study. For CAB surgery patients and their apparently healthy partners, engaging in CR would promote HRQOL and potentially reduce disability, morbidity and mortality.

Purpose of the Study

The purpose of this study was to examine physical, psychological, and relational HRQOL in CAB surgery patients and partners enrolled in a randomized clinical trial. The parent study, from which these outcomes were measured, examined the effects of the Partners Together in Health (PaTH) Intervention on the primary outcome variables of physical activity/exercise and healthy eating behaviors (Yates, 2009). Patients and partners in the PaTH intervention formally joined and participated in the CR program. In the usual care group, only CAB surgery patients received the exercise and education/counseling components. The usual care partners were invited to attend group education sessions; but they did not receive individual counseling or exercise that the CAB surgery patients and PaTH partners received.

Specific Aims

The objective of this study, using an experimental, two-group, repeated measures design, was to compare the HRQOL outcomes between the PaTH experimental intervention and usual care CAB surgery patients and their partners. Data collection time points are baseline or Time 1 (T1) which was close to the start of CR, Time 2 (T2) was at the end of CR, and Time 3 (T3) occurred 3 months after completing CR.

Aim One. The first aim of this study was to examine the differences between patients in two groups (PaTH intervention vs. usual care groups) in changes overtime from baseline to T2, and from T2 to T3 in physical, psychological, and relational HRQOL outcomes.

Aim Two. The second aim of this study was to examine the differences between partners in two groups (PaTH intervention vs. usual care groups) in changes overtime from baseline to T2, and from T2 to T3 in physical, psychological, and relational HRQOL outcomes.

Aim Three. The third aim of this study was to examine the differences in physical, psychological, and relational HRQOL between patients and partners from baseline to T2, and from T2 to T3, separately by group: (a) PaTH intervention group and (b) the usual care group.

Aim Four. The final aim for this study was to examine the differences between CAB surgery patients in the PaTH intervention group versus the usual care group, in changes in exercise performance (treadmill submaximal MET level) from baseline to T2.

The main hypothesis for this study is that patients and partners working together in the CR intervention will show greater improvements in physical, psychological, and relational HRQOL compared to patients and partners in the usual care CR group. The

proposed research is innovative because the PaTH intervention encourages the partner to make the same lifestyle changes that the cardiac patient has been instructed to make. No research has been conducted that examines HRQOL outcomes in both CAB surgery patients and their partners who participated in a CR intervention program. It was anticipated that the results of this study will inform intervention researchers and CR clinical nurses seeking evidence-based practice interventions that support HRQOL outcomes.

Limitations

Because this is an analysis of secondary outcomes from an existing randomized clinical trial, this study was limited by the type and timing of data that were collected for the parent study. Potential threats to internal validity in this longitudinal, experimental design study were reduced due to the randomization of subjects to two groups. However, selection bias may have occurred in terms of patients and partners who were willing to participate versus those who refused to be part of the study. The use of two existing CR programs to apply the intervention strategies was a limitation because one of the programs had an existing “partnership program” that allowed partners to exercise with patients and the other program did not. However, only partners in the PaTH intervention group received individual counseling about risk factors and goal setting; and partners in the usual care control group did not receive this individualized intervention regardless of the clinical setting. Generalizability was limited by use of a convenience sample in two Midwestern, urban medical centers.

Chapter Two

Conceptual Framework

The research model (see Figure 1) conceptualized for this study integrated selected biophysical and psychosocial variables that have been previously identified in the HRQOL model by Ferrans et al. (2005). The HRQOL model (Ferrans et al., 2005) posits that there are socio-demographic, biological, and psychological characteristics of individuals that ultimately influence health outcomes. While demographic factors such as “sex, age, marital status, and ethnicity” (Ferrans et al., 2005, p. 337) are relatively unchangeable, these factors may be targeted for specific health interventions. Targeting the naturally occurring patient-partner dyads was one socio-demographic characteristic that was used in the design of this study. It was hypothesized for this study that CR influences both the CAB surgery patients’ and partners’ individual HRQOL, as a shared life experience.

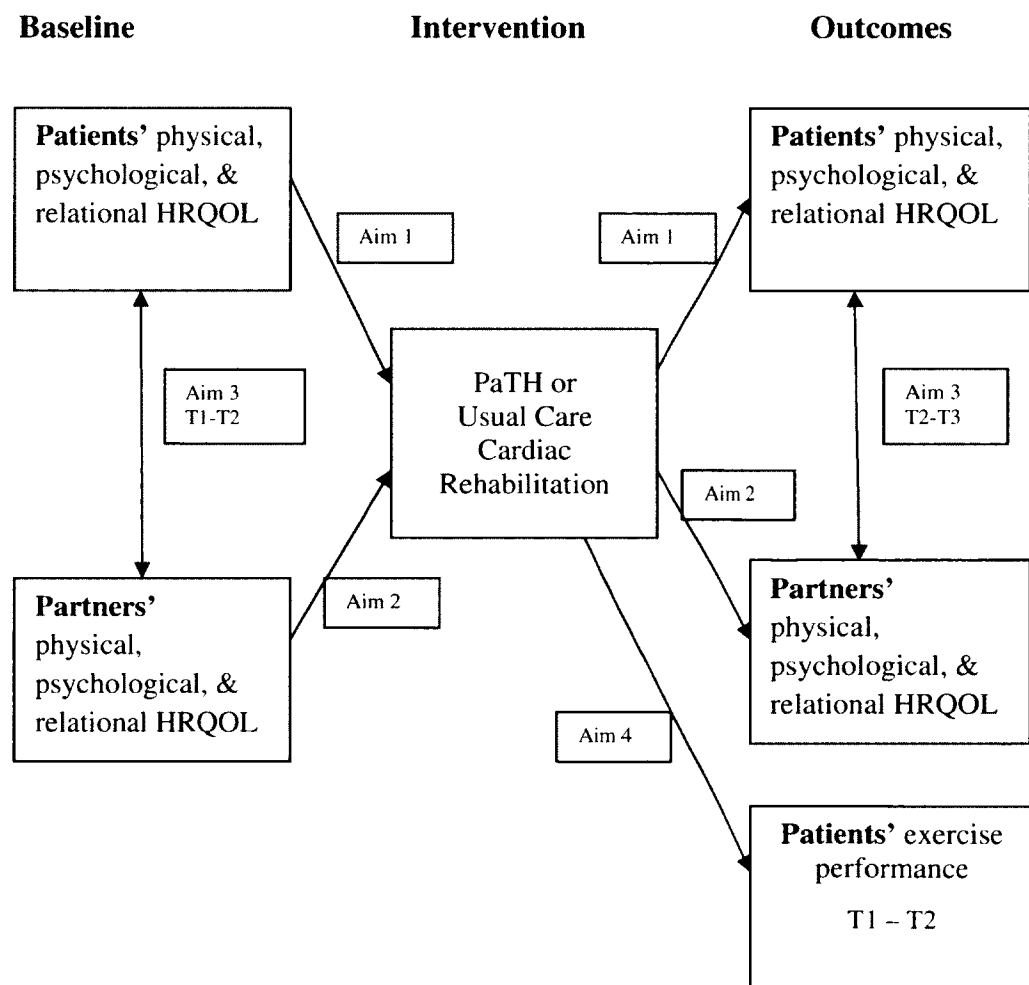
Physical and psychological characteristics of the individual are more likely to be changeable and responsive to interventions (Ferrans et al., 2005) than non-modifiable demographic factors. In the research model (see Figure 1), the individual characteristics of the patients and partners are depicted separately – as both the patients’ and the partners’ responses are measured as dependent variables. Although patients and partners are depicted separately, it is expected that the members of the dyad in the PaTH intervention will change similarly in regards to their HRQOL outcomes. Nurses and other CR staff implement the PaTH intervention and usual care programs, thus influencing the HRQOL outcomes. While Ferrans et al. (2005) used the conceptual term *social functional status*, the more specific concept called *relational HRQOL* has been

used in this study, to focus on the patient-partner dyads. The functional status outcomes for physical, psychological, and relational HRQOL were measured longitudinally from baseline which was close to the start of CR (approximately 2-3 weeks post-CAB surgery) (T1), at the end of CR which is approximately 3 months after starting the intervention (T2), and at 3 months after completing the CR intervention (T3) so that patterns of change over time and between groups are detected. In addition to examining the differences between patients in the PaTH intervention and usual care groups and partners in the PaTH intervention and usual care groups, it was expected that differences between patient-partner dyads may be detected. For example differences in baseline physical HRQOL are likely between patients and partners at baseline due to the patient's physical response to the recent CAB surgery. Changes over time (from baseline to T2, and from T2 to T3) were examined to detect difference in changes in HRQOL over time between the patients and partners in the PaTH intervention and in the usual care groups. Finally, exercise performance outcomes during CR were measured only in patients since there were no exercise performance data available for usual care CR partners. Exercise performance from baseline to T2 was examined to detect differences between patients in the PaTH intervention and patients in the usual care group over the course of the CR program.

The combined interaction of patients and partners working together towards common goals is believed to be more beneficial, as compared to individual, patient-centered usual care. The interpersonal relationships between the patient-partner dyads were expected to influence the HRQOL outcomes in favor of the PaTH intervention group. Key characteristics of the PaTH intervention group include participation in

exercise, education, and counseling both as an individual and as a couple that is missing in the usual care CR group. Since CAB surgery patients are expected to make dramatic and long-lasting lifestyle changes, enhanced social support and self-efficacy as patient-partner dyads are expected to strengthen both HRQOL outcomes and physical performance outcomes in the intervention group compared to usual care.

Figure 1: HRQOL Outcomes in Coronary Artery Bypass Surgery Patients and Partners Enrolled in the PaTH Intervention or Usual Care Cardiac Rehabilitation.



Note: HRQOL = Health-related Quality of life. PaTH = Partners Together in Health, T1 = close to the start of CR, T2 = close to the end of CR, T3 = 3 months after CR.

Review of the Literature

Health-related Quality of Life.

One of the most frequently cited models of HRQOL was originally described by Wilson and Cleary (1995) and later revised by Ferrans et al. (2005). Both authors noted that HRQOL has become an important measurement for health care outcomes research. However, there has been a great deal of discussion over the meaning of – and even the use of - the term, HRQOL. Therefore, it is important to examine how HRQOL was defined at the outset of this study.

First, one logical method in understanding what is meant by HRQOL would be to parse the phrase and examine the root term, “Quality of Life” (QOL). Most definitions of QOL emphasize a *subjective evaluation* of one’s own life, as opposed to an outsider’s objective evaluation (Beckie, Beckstead, & Webb, 2001; Echteld, van Elderen, & van der Kamp, 2003; Meeberg, 1993; Moons, Budts, & De Geest, 2006). Given that the person’s life in question belongs to that individual, many current definitions promote *only* a subjective evaluation (Beckie et al., 2001; Echteld et al., 2003). Moons et al. (2006) declare that QOL is *purely* subjective; “one’s subjective appraisal of one’s life condition” (p. 895). However, some authors (Meeburg, 1992; WHO, 1998) argue that an objective component is justified when assessing QOL. Meeberg (1993) proposed a traditional nursing concept analysis for QOL and included “an objective assessment by another that the person’s living conditions are adequate and not life-threatening” as one of four defining attributes of the concept QOL. There continues to be a great deal of controversy about including an objective evaluation when investigating QOL. Moons et al. (2006) examined different QOL theories and noted that three of the nine models included an

objective component. The WHO (1998) defines QOL as the “individuals’ perceptions of their position in life in the context of culture and values in the societies in which they live and in relation to their goals, expectations, standards and concerns” (p.17). Despite the trend towards acknowledging the subjectivity of QOL, many authors opt for a combination of subjective and objective evaluation.

Historically, HRQOL has been linked to outcomes research (Stewart, 1992; Haas, 1999; Staniszewski, 1999) and conceptualizations (Wilson & Cleary, 1995; Ferrans et al., 2005). Haas (1999) stated that HRQOL is a “narrow term, used in medicine (for) changes that occur as a result of medical interventions” (p. 216). Apostolakis et al. (2006) stated that HRQOL specifically focuses on aspects of life related to health, disease, and treatments or interventions. In particular, within the context of health care outcomes, an objective evaluation is inherent for the purpose of measuring the effectiveness of different treatments from the provider’s perspective. The WHO (1998) stated that in order to completely assess the quality of health care services, providers must assess the patients’ perceptions of their QOL, health status, and health care. Ultimately, the individual’s subjective assessment of his or her personal quality of life and health remains the focus of HRQOL research outcomes (Falcoz et al., 2003; Azzopardi & Lee, 2009).

Those authors who support a ‘subjective-only’ type of QOL definition, also typically subscribe to a one-dimensional concept of QOL: personal goals/goal setting (Echteld et al., 2003), aspirations/achievements (Beckie et al., 2001), or life satisfaction (Haas, 1999; Moons et al., 2006). Plummer and Molzahn (2009) examined the concept, QOL from a nursing theory perspective and defined QOL as “an intangible, subjective

perception of one's lived experience" (p. 140) which reflects a subjective and global assessment of an individual's life. The WHO measurement of QOL incorporates a subjective assessment of both global and multidimensional aspects of QOL. The WHO QOL survey has one overall QOL item that asks, "How would you rate your quality of life?" scored on a five-point Likert scale ranging from (1) *very poor* to (5) *very good* (WHO, 1998). In addition to assessing an overall or global evaluation, the WHO survey follows up with multi-dimensional items related to one's QOL and health status (Skevington, Lotfy, & O'Connell, 2004; WHO, 1998).

When the term "health" is added to scientific discourse about the conceptualization and measurement of QOL, then dimensions and domains flourish, as with outcomes research. In fact, the WHO (Skevington et al., 2004; WHO 1998) identified four major HRQOL domains: physical, psychological, social relationships, and the environment. Many other conceptualizations of HRQOL consider domains, including: physical, psychological, social, and spiritual (Meeberg, 1993; Nauser, Bakas, & Welch, 2011); biophysical, psychological/spiritual, and sociocultural (Kiefer, 2008); or symptoms and side effects, physical functional status, social functioning, and psychological status (Kinney, Burfitt, Stullenbarger, Rees, & DeBolt, 1996). Therefore, there is no consistent agreement about what specific HRQOL domains should be assessed. Thus, when investigating HRQOL, researchers and clinicians must identify the domains that are most salient to their research or clinical problems. For this paper, HRQOL is defined as an overarching concept with the intent to elicit subjective evaluation of the individual's multi-dimensional health status in the context of treatment outcomes. The conceptual domains of interest were physical, psychological, and

relational HRQOL. These conceptual domains were operationalized in both patients and partners as physical function, depression, and dyadic adjustment, and as exercise performance in patients only.

The following literature review section examines overall HRQOL and the individual domains of physical, psychological, and relational HRQOL outcomes in CHD and CAB surgery patients and partners. Due to a paucity of data specific to the CAB surgery patients and partners, studies of patients with CHD have been included to expand the literature review.

Overall HRQOL in CHD.

Two studies were found that examined overall HRQOL in CAB surgery patients (Apostolakis et al., 2006; Mathisen et al., 2007). Citing the WHO definition of QOL as the conceptual framework for the study, Apostolakis et al. (2006) administered the MacNew Heart Disease HRQOL questionnaire via interviews to patients waiting for elective CAB surgery in a large, metropolitan hospital in Athens, Greece. Overall HRQOL was operationalized as a global score; with physical, emotional, and social dimensions. The questionnaire was administered prior to surgery, and at 4, and 12 months after CAB surgery. Compared to baseline (prior to CAB surgery), overall HRQOL improved significantly at 4 months and 12 months ($M = 4.55$, $M = 5.82$, $M = 6.08$, $p < .001$) respectively (Apostolakis et al., 2006). Although 88% ($n=88$) of subjects reported improvement in overall HRQOL from baseline to one year after CAB surgery, 12% ($n=12$) showed deterioration from baseline HRQOL scores (Apostolakis et al., 2006).

In another study investigating QOL of CAB surgery patients, Mathisen et al. (2007) used the HRQOL model from Wilson and Cleary (1995) and operationalized *global* QOL as a single dimension assessment of life satisfaction and *overall* HRQOL as a multidimensional concept with physical, psychological, and social domains. Mathisen et al. (2007) measured HRQOL in 108 Norwegian patients at hospital admission for CAB surgery, and follow up at 3, 6, and 12 months post-surgery. They reported that global HRQOL improved the most from baseline to 3 months following CAB surgery, with no significant changes at 6 and 12 months from baseline. Global QOL mean scores (higher scores indicated greater QOL) were: 5.0, 5.6, 5.5, and 5.6 respectively. Overall HRQOL mean scores were: 86.5, 88.0, 87.4, and 88.1 at baseline, 3, 6, and 12 months post-CAB surgery respectively. While the mean scores over time were reported in this study, the authors did not report levels of significance (Mathisen et al., 2007). Comparisons between these two studies (Apostolakis et al., 2006; Mathisen et al., 2007) are limited due to the differences in conceptualizing and operationalizing overall HRQOL; but suggest that changes in overall HRQOL are not consistent during the first year following CAB surgery. Neither of these studies investigated HRQOL in CAB surgery partners or significant others.

Rantanen et al. (2008; 2009) are some of the few authors who investigated HRQOL in both CAB surgery patients and their significant others. In these studies (Rantanen et al., 2008; 2009), HRQOL was conceptualized in accordance with the WHO definition as stated above. In addition to a global measure of HRQOL, they also measured physical, psychological, and social dimensions of HRQOL (Rantanen et al., 2009). Recruiting 163 patient-partner pairs from one university hospital in Finland

between the years 2001 – 2005, Rantanen et al. (2009) used a questionnaire called the “15 D” (p. 1928) to measure both overall HRQOL and 15 dimensions of HRQOL at one month post-CAB surgery (Rantanen et al., 2008) and in their subsequent paper at 1, 6, and 12 months post-CAB surgery (Rantanen et al., 2009). Overall HRQOL was computed as a single index score on a 0 – 1 scale, with 0 being the worst and 1 being the best possible ratings. At one month post-CAB surgery, patients rated their overall HRQOL significantly lower ($M = 0.845$, $SD = 0.097$, $p < .001$) than their partners ($M = 0.905$, $SD = 0.085$) (Rantanen et al., 2008). Also, at one month post-op, CAB surgery patients had lower HRQOL compared to the gender- and age-adjusted general population ($M = 0.877$, $SD = 0.106$, $p < .001$); while significant others did not differ from the general population on overall HRQOL ($M = 0.894$, $SD = 0.092$, $p = 0.089$) (Rantanen et al., 2008). Overall HRQOL scores for patients at 6 and 12 months post-CAB surgery were: $M = 0.868$ and $M = 0.876$; while the overall HRQOL scores for partners were: $M = 0.907$ and $M = 0.910$ respectively ($p < .001$). Therefore, although CAB surgery patients’ HRQOL improved more than their partners at each time point, they never regained the level of HRQOL similar to their partners or the general population. These two studies by Rantanen et al. (2008; 2009) have established preliminary, basic differences between CAB surgery patients and their partners in regards to the trajectory of overall HRQOL.

In summary, when HRQOL is conceptualized as a single (global) dimension, CAB surgery patients reported (a) lower HRQOL scores than the general population, (b) lower scores than their partners, (c) the lowest HRQOL scores immediately following the CAB surgery, and (d) improvements in overall HRQOL between three and four months post-surgery. Inconsistent findings for overall HRQOL in CAB surgery patients have

been reported as the time since surgery lengthens beyond six to twelve months. A portion of CAB surgery patients never regained a level of overall HRQOL equal to that of the general population. Partners' HRQOL was rarely reported. Due to the secondary analysis constraints, this paper does not examine overall (global) HRQOL outcomes.

Physical HRQOL.

Physical function is one of the most frequently reported physical HRQOL variables for CHD and CAB surgery patients. Physical HRQOL has been defined as the perception of one's ability to perform physical activities with and without limitations (Ware & Sherbourne, 1992). One particular goal of medical care for most patients is to preserve physical functioning (Ware & Sherbourne, 1992, p.473). DiMattio and Tulman (2003) found overall improvement ($p < .0001$) in patients' physical function with significant increases between each time period (2, 4, and 6 weeks post-CAB surgery). In this study, the largest increases in functional status occurred between 4 and 6 weeks after CAB surgery. However, patients' physical function scores at 6 weeks had not returned to pre-surgery levels.

Kristofferzon, Lofmark, and Carlson (2005a) found mean physical function scores were significantly ($p = .000$) improved over time at 1, 4 and 12 months post-myocardial infarction in 171 Swedish patients. Physical functioning mean scores for women were: 53.1, 59.5, and 60.4; mean scores for men were: 60.9, 65.8, and 69.6 at 1, 4, and 12 months respectively. Differences in physical function in this sample occurred between 1 and 4 months ($p = .000$ -.003) and between 1 and 12 months ($p = .000$ -.008) (Kristofferzon et al., 2005a). Rumsfeld et al. (2003) found no significant difference at 6 months post-procedure in physical HRQOL between CHD patients randomly assigned to percutaneous

coronary intervention (PCI) or CAB surgery. In this cross-sectional study of 389 veterans, the mean physical function score 6 months after procedure was 53.7 for CAB surgery patients and 56.7 for the percutaneous intervention patients. Comparing the mean physical function scores reported in the Kristofferzon et al. (2005a) and the Rumsfeld et al. (2003) studies, physical function was lower in the CAB surgery patients than the myocardial infarction patients. Although the mean age of subjects in the studies was similar ($M = 65.7$ years vs. $M = 67.3$ years), comparison is limited by the longitudinal versus cross-sectional designs and the differences in data collection time frames (1, 4 and 12 months vs. 6 months only) (Kristofferzon et al., 2005a vs. Rumsfeld et al., 2003). Typically, physical function is at its lowest in the first month following CAB surgery (DiMattio and Tulman, 2003; Kristofferzon et al., 2005a; Rantanen et al., 2008).

Physical HRQOL of CHD patients in CR.

Exercise training is a primary component in CR in which interventions are targeted to improve exercise performance and ultimately physical function (AACVPR, 2004; Lavie, Thomas, Squires, Allison, & Milani, 2009; Lavie, Milani, O'Keefe, & Lavie, 2011). The following studies (Arthur, Smith, Kodis, and McKelvie, 2002; Grace, Grewal, Arthur, Abramson, and Stewart, 2008; McKee, 2009; Morrin, Black, & Reid, 2000; Muller-Nordhorn et al., 2004) operationalized the concept of physical HRQOL as physical function. All five of these studies investigated physical function in CHD patients who participated in CR. Furthermore four of the five studies used the SF-36 to measure physical function; while one study (Grace et al., 2008) used the Duke Activity Status Index. Morrin et al. (2000) reported improvement in physical function in 126

CHD patients from baseline to 3 months after starting a CR program in Ottawa, Canada. Physical function (PF SF-36) mean scores showed significant ($p < .025$) improvement between baseline ($M = 62.7$, $SD = 19.9$) and 3 months ($M = 78.7$, $SD = 17.5$); however there was only a non-significant trend for physical function to improve between the third and sixth month of the CR program. McKee (2009) also failed to show significant improvement in physical HRQOL from immediately post-CR ($M = 74.4$, $SD = 19.6$) to 6 months after the CR program ended ($M = 75.3$, $SD = 19.3$). Although there was significant improvement from baseline ($M = 67.5$, $SD = 23.1$) to the end of the CR program (about 3 months post CHD event) ($T = -3.596$, $df = 97$, $p < .001$) (McKee, 2009). Barnason et al. (2000) found improvement in physical function in CHD patients from baseline to 6 months post event ($F = 31.49$, $df = 3, 132$, $p < .0001$). However, Barnason (2000) also reported no significant difference in physical HRQOL between those who did (45%, $n = 23$) or did not attend CR. Arthur et al. (2002) found improved ($p < .0001$) physical function, measured with the Physical Component Summary of the SF-36, for 242 CAB surgery patients in CR from baseline to 3 months, and baseline to 6 months post-surgery. Continued improvement in physical function from baseline to 12 months was found for CAB surgery patients in Germany; however myocardial infarction patients in this same study showed no significant improvement in their mean physical function scores from baseline to 12 months post-event (Muller-Nordhorn et al., 2004). Examining changes in physical function beyond 12 months after CHD event, Grace et al. (2008) found significant ($p < .05$) improvement in physical HRQOL for both CR participants and non-participants between hospitalization and 9 months and 18 months post-CHD event.

In the few studies that compared physical function of CHD patients to the general population, CHD patients were consistently lower at baseline, immediately post-CHD event. Muller-Nordhorn et al. (2004) found that the CHD patients' physical function scores were lower than the general, German population ($M = 64$ vs. $M = 84$). Also, patients' physical function has been found to be lower than the general population's physical function overtime (McKee, 2009). Although physical function scores improved in 187 CHD patients who completed a 6-week CR program in the United Kingdom, physical function never reached the level of the general population (McKee, 2009). In this study, physical function scores were reported at the beginning of the CR program, the end of CR (6 week program), and 6 months after the end of the CR program as follows: $M = 67.5$, $SD = 23.1$; $M = 74.4$, $SD = 19.6$; and $M = 75.3$, $SD = 19.3$, respectively. These scores were far below the age-matched, United Kingdom general population physical function score ($M = 78.0$, $SD = 22.6$).

In summary, these studies of CHD and CAB surgery patients showed significantly improved physical function over time (Arthur et al., 2002; Kristofferzon et al., 2005a). Physical function is typically the lowest during the first 2 to 6 weeks post-CHD event but shows significant improvement during that period of time (DiMattio & Tulman, 2003; Kristofferzon et al., 2005a). Significant improvement in physical function from baseline to 3 months post-CHD event has been found (Barnason et al., 2000; Arthur et al., 2002; Hsu et al., 2011; Morrin et al., 2000). However, there have been inconsistent findings for improved physical function from 3 to 6 months post-CHD event (Arthur et al., 2000; Barnason et al., 2000; McKee, 2009; Morrin et al., 2000; Muller-Nordhorn et al., 2004). Significant improvements in physical function at 12 months post-CHD event (Muller-

Nordhorn et al., 2004) and at 18 months post-CHD event (Grace et al., 2008) have been reported. Subjects in the Grace et al. (2008) study reported that their physical function improved from baseline to 9 and 18 months following their cardiac event, regardless whether they participated in CR or not. However, only CR participants in this study improved their exercise behavior ($p=.001$) (Grace et al., 2008). Of the few studies that compared patients to the general population, CHD patients' physical function remained below the level of the general population at all time points: baseline (Muller-Nordhorn et al., 2004), 6 weeks, and 6 months following the cardiac event (McKee, 2009).

Physical HRQOL in CHD partners.

While some studies have examined overall HRQOL in CHD partners (Rantanen et al., 2008; 2009), very few studies have examined partners' physical HRQOL. Often the partners take on significant physical burdens such as additional housework, yard work, child rearing, and patient-related caregiving activities following myocardial infarction (Stewart, Davidson, Meade, & Hirth, 2001) and CAB surgery (Halm, Treat-Jacobson, Lindquist, and Savik, 2006). Halm and Bakas (2007) measured 166 CAB spouses' physical HRQOL, operationalized as perceived physical health and measured with the SF-12 physical component score. In this cross-sectional study, CAB surgery occurred during the prior year and average length of time since surgery was divided equally at 3, 6, and 12 months. Halm and Bakas (2007) reported that spouses' low health status rating of the CAB patient was a significant ($p<.001$) predictor of poorer spousal physical HRQOL. The two studies by Rantanen et al. (2008; 2009) found that significant others reported higher levels of moving ability ($p=.002$) and usual activities ($p<.001$) than CAB patients over time (1, 6 and 12 months post-CAB surgery). However, while the

CAB patients had lower levels of usual activities than their partners, the improvement in usual activities for CAB surgery patients was greater than their partners.

Although patients' physical HRQOL outcomes have been reported in couple-oriented studies, partner physical HRQOL outcomes are not typically reported (Gortner et al., 1988; Fridlund, Hogstedt, Lidell, & Larsson, 1991; Martire et al., 2010). Typically, spouses have been surveyed on their perception of the patients' physical function. One early study reported that spouses perceived greater efficacy for the *patients'* physical health when they observed and participated in treadmill walking during stress testing (Taylor, Bandura, Ewart, Miller, & DeBusk, 1985). Similarly, Lee (2008) examined the spouses' proxy evaluation of the patients' perceived HRQOL at 5 years after CAB surgery. Lee (2008) found that spouses rated the physical function of the CAB surgery patients higher than the patients themselves; but there were no significant difference found, only a trend. Few studies were found that measured the CHD or CAB surgery partners' physical HRQOL. More studies (Van Horn, Fleury, and Moore, 2002; Martire et al., 2010) were found that examined spouses' psychological HRQOL which is discussed below.

In summary, physical function was a primary outcome in numerous studies of CAB surgery patients and has shown significantly decreased physical function immediately post-surgery through the first four to six weeks, and continued to improve during the first 3 months post-CAB surgery. Inconsistent findings of continued improvement in physical function have been reported; with smaller gains usually reported between six and twelve months post-surgery. The few studies that have examined partners suggest that patients, starting at significantly lower levels of physical function

improve more overtime but do not consistently reach the level of the general population or their partners within one year of surgery.

Exercise Performance.

Cardiorespiratory endurance, also called aerobic fitness, is a primary goal and measured outcome for CHD patients in exercise-based CR programs (AACVPR, 2004; Franklin, Trivax, & Vanhecke, 2008). Given the well known declines in physical function following CHD events, numerous studies have documented improvements in cardiorespiratory fitness as a result of exercise-based and CR interventions (AACVPR, 2004; Franklin et al., 2008; Lavie et al., 2009; Lavie et al., 2011). Furthermore, exercise-based CR has been associated with a 20% reduction in all cause mortality and a 26% reduction in cardiovascular mortality when compared with usual care (patients were not in a CR program) (Franklin et al., 2008; Taylor et al., 2004). The meta-analysis by Taylor et al. (2004) examined 48 randomized controlled trials in which 19 of the total 49 trials included exercise-only and the remaining 30 CR interventions included comprehensive exercise plus psychological and educational components.

Aerobic conditioning is a cornerstone strategy for improving aerobic capacity in all people and particularly in CHD patients who participate in CR. Aerobic capacity is typically expressed as metabolic equivalents (METs). One MET is equivalent to 3.5 ml/kg of body weight per minute of oxygen uptake and represents a resting metabolic state (Ainsworth et al., 2000; 2011; Franklin et al., 2008). The higher the level of aerobic fitness in both healthy and cardiac subjects, the lower the risk of mortality (Franklin et al., 2008). One way to directly measure oxygen consumption is through maximal graded exercise testing with the collection of expired respiratory gases. This method is costly

and somewhat burdensome to the subjects, but represents the gold standard for cardiorespiratory fitness (ACSM, 2010). The estimation of aerobic capacity through graded exercise testing, such as exercise tolerance tests (ETTs), calculates aerobic capacity with standard estimating equations. An important distinction in interpreting findings for aerobic capacity requires attention to differences between maximal oxygen uptake ($\text{VO}_{2\text{ max}}$) versus submaximal aerobic capacity ($\text{VO}_{2\text{ submax}}$). Valkeinen, Aaltonen, and Kujala (2010) conducted a meta-analysis of 18 randomized clinical trials that included 922 CHD patients. This meta-analysis examined the effects of exercise training in CHD patients. Training ranged from 2 weeks to 1 year ($M = 15.5$ weeks, $SD = 13.2$ weeks), exercise frequency varied from six times a day to four times a week ($M = 3.1$ times per week, $SD = 0.4$), and $\text{VO}_{2\text{ max}}$ was directly measured in all studies. $\text{VO}_{2\text{ max}}$ did not differ significantly between training or control groups at baseline. Valkeinen et al. (2010) reported that directly measured $\text{VO}_{2\text{ max}}$ improved by 2.6 ml/kg per minute in the exercise training CHD patients ($SD = 1.6$ ml/kg·min), but only increased by 0.3 ml/kg per minute in the control groups ($SD = 1.4$ ml/kg·min). The net difference in the change in $\text{VO}_{2\text{ max}}$ between the exercising and control groups was significant ($p < .001$). In addition to the absolute improvement in aerobic fitness of CHD patients participating in exercise-based interventions, Valkeinen et al. (2010) also reported that patients who began exercising soon after the CHD event (within 3 months of the event), and those who continued to exercise for long periods of time (≥ 6 months) showed the most improvements in cardiorespiratory fitness. Lavie et al. (2009) reported that a 1 MET (3.5 ml/kg·min) increase in maximal aerobic fitness was associated with a 10-13% improvement in survival in CHD patients. Also, CHD patients with the lowest maximal

aerobic capacity ($M \leq 4.4$ METS [15.4 ml/kg·min]) had the highest all cause and CHD mortality compared to CHD patients with the highest maximal aerobic capacity ($M = 9.2$ METs [32.2 ml/kg·min]) within six years of the CHD event (Vanhees, Fagard, Thijs, Staessen, & Amery, 1994; Franklin et al., 2008).

Aerobic conditioning in CR programs includes the following: (a) aerobic exercises such as walking, cycling, jogging, and combined arm-leg ergometry, (b) submaximal intensity threshold ranging from 60-70% of the highest heart rate achieved during peak or symptom-limited graded exercise testing, (c) duration of 30 or more minutes of aerobic exercise (typically up to 60 minutes), and (d) includes a 5 to 10 minute warmup and cool down phase (AACVPR, 2004; Franklin et al., 2008; Verrill et al., 2009). The exercise guidelines are expected to result in cardiorespiratory benefits for people with CHD (AACVPR, 2004; Franklin et al., 2008; Verrill et al., 2009).

Basically, MET levels during submaximal exercise conditioning are used to determine exercise intensity and have practical uses in both the exercise setting and in clinical research. Activities can be categorized into light, moderate, and vigorous intensities based on measured and estimated submaximal MET levels (Ainsworth et al., 2000; 2011; Haskell et al., 2007). For example, activities such as walking (2 mph pace), using a computer, or doing the dishes has been measured at <3.0 METs (light); walking (3 mph pace), washing windows, and vacuuming has been measured between 3.0 and 6.0 METs (moderate); and jogging, shoveling, and carrying heavy loads has been measured at greater than 6.0 METs (vigorous) (Ainsworth et al., 2000; 2011; Haskell et al., 2007). Submaximal MET levels are readily calculated in the CR setting, often with computer software that uses standard equations based on the subjects' body weight and workloads.

For healthy adults, moderate intensity exercises (3.0 to 6.0 METs) for the minimal target of 150 minutes per week have been recommended (Haskell et al., 2007, p.1086).

Intensity and duration recommendations for CHD patients depend upon a variety of factors including exercise risk stratification, time since CHD event, baseline exercise capacity, and individual response to the exercise bout (AACVPR, 2004; ACSM, 2010).

One especially interesting study investigated improvements in submaximal exercise capacity in 500 CHD patients who completed 12 weeks of CR (Chai, Feuerstadt, & Kligfield, 2005). Submaximal exercise capacity increased by 80% (from 3.8 METs to 6.8 METs, $p < .001$) from baseline to 12 weeks. In addition, 25% of the improvement occurred during the final month of the CR program (from 6.1 METs to 6.8 METs, $p < .001$). Unfortunately there seems to be a typographical error in the published manuscript, because while the narrative clearly defines the duration of the exercise in terms of CR sessions (1 to 36 sessions provided for Medicare recipients), Table 1 (p. 212) substitutes the word “weeks” in place of the apparently intended word “sessions”, making interpretation inconsistent and questionable. However, in a subsequent analysis by these same authors, Feuerstadt, Chai, and Kligfield (2007) reported that submaximal exercise training in 600 CHD patients enrolled in a 12-week CR program was the most significant predictor of all cause mortality at follow-up 4.5 years later. With each 1 MET increase in submaximal exercise capacity at the end of the 12-week program, there was an associated 34% decrease in mortality (Hazard ratio [HR] 0.66, CI 0.56-0.77) with a similar decrease (28%, HR = 0.72, CI 0.60-0.85) when adjusted for age (Feuerstadt et al., 2007). The studies by Chai et al. (2005) and Feuerstadt et al. (2007) provided longitudinal submaximal exercise performance data (in terms of METs) for CHD patients enrolled in

a CR program; showing that with small increases in the patients' submaximal exercise performance, there were associated, significant decreases in mortality. In summary, very few studies have examined submaximal exercise performance in CAB surgery patients. This study compared submaximal exercise performance between the intervention and usual care CR patient groups based on treadmill speed and grade at baseline (sessions #4, #5, and #6) and last 3 exercise sessions. It was expected that patients in the PaTH intervention group would demonstrate higher exercise performance than patients in the usual care group because the spouses are participating in the CR program with the patients, and providing social support.

Psychological HRQOL in CHD.

Following CHD events and CAB surgery, psychological HRQOL shows similar initial declines as physical HRQOL. Patients' and partners' psychological HRQOL has been measured as anxiety (Buls, 1995; Grace et al., 2008), psychological distress (Moser & Dracup, 2004; Penckofer et al., 2005), emotional well being (Dracup et al., 2004), negative emotions (Tully et al., 2009), or psychological burden (Halm et al., 2006). Recently, depression has been recognized as affecting 45% of myocardial infarction patients (AACVPR, 2005), almost a quarter of CHD patients (McManus, Pipkin, & Whooley, 2005; Ruo et al., 2003), 19 to 61% after heart surgery (Pignay-Demaria, Lesperance, Demaria, Frasure-Smith, & Perrault, 2003), and from 15% (Todaro, Shen, Niaura, & Tilkemeier, 2005) to 50% (Beckie, Fletcher, Beckstead, Schocken, & Evans, 2008) of CHD patients enrolled in CR studies. Depression is conceptualized as the self-reported persistent feelings of hopelessness or sadness that interfere with the ability to work, sleep, eat or enjoy once pleasurable activities (Kroenke, Spitzer, & Williams,

2001). For the purpose of this study, the literature review focuses on studies that report both psychological HRQOL and depression in CHD and CAB surgery patients and their partners.

Psychological HRQOL in patients with CHD.

Psychological distress and especially depression has been shown to negatively impact both the development of CHD and outcomes after CAB surgery (Pignay-Demaria et al., 2003; Rollman & Belnap, 2011). Depression in patients with CHD was found to be associated with worse overall HRQOL and physical function in a cross-sectional study by Ruo et al. (2003). Twenty percent of subjects (n=201) in this study reported major depressive symptoms. Depressed CHD patients were significantly more likely to report greater physical function limitations ($p<.001$), poorer overall QOL ($p<.001$), and poorer overall health status ($p<.001$) than patients who did not report major depressive symptoms (Ruo et al., 2003). Similar findings were reported by Tully et al. (2009) in a study that measured depression in patients at baseline while waiting for elective CAB surgery, and 6 months post-surgery. Pre-operative depression was significantly ($p<.001$) associated with worse HRQOL at 6 months; and depression was a significant ($p<.001$) predictor of HRQOL whether it occurred prior to, after, or both prior to and after the CAB surgery (Tully et al., 2009). Furthermore, pre-operative depression was a stronger predictor of post-operative declines in HRQOL than pre-operative anxiety or stress. Penckofer et al. (2005) reported no significant change in depression scores from pre- to 3 months post-CAB surgery; although HRQOL significantly improved when measured as overall well being ($p<.001$), general health ($p<.001$), and overall QOL ($p=.004$). In this

sample, 25% (n=15) of CAB patients reported severe psychological distress at 3 months post- surgery (Penckofer et al., 2005).

In an integrative review evaluating the functional status trajectory following cardiac events, Barnason, Zimmerman, Nieveen, Schulz, and Young (2012) included 25 studies of recovery following cardiac surgery. The most frequent forms of psychological distress for cardiac surgical patients were anxiety and depression; and surgical patients with depression reported poorer physical function and worse symptoms than those without depression. In general, this review concluded that depression and/or anxiety was present in most CHD patients in the first days following the cardiac event and decreased in severity during the first four months of recovery (Barnason et al., 2012, p.181, 186).

Psychological HRQOL in CHD partners.

Several studies have investigated psychological HRQOL in CHD partners. One cross-sectional, descriptive study by O'Farrell, Murray, and Hotz (2000) found that 66% (n=141) of spouses of CHD patients enrolled in a Canadian CR program met the criteria for psychological distress as measured with the Brief Symptom Inventory. Symptoms included feeling stressed, trouble falling asleep, and feeling emotionally fragile. Two other cross-sectional studies have identified reduced psychological HRQOL in CHD partners compared to the CHD patients themselves (Moser & Dracup, 2004), and compared to the age-matched general population (Dracup et al., 2004). Dracup et al. (2004) reported that spouses had significantly lower Mental Health scores as measured by the SF-36 than age adjusted norms for the general population (Mental Health mean scores were not reported, but displayed in a graph such that actual scores were not distinguishable). While the study by Dracup et al. (2004) investigated the emotional

well-being of spouses of patients with advanced heart failure, the study by Moser and Dracup (2004) investigated 417 patient-spouse pairs following hospitalization for MI, CABG, or PCI. Overall, spouses reported higher levels of anxiety ($p < .001$) and depression ($p < .001$), and lower levels of perceived control ($p < .001$) than patients (Moser & Dracup, 2004). In relation to the standard norm for depression, 57% ($n = 237$) of patients and 67% ($n = 279$) of spouses were above the norm, as measured by the Multiple Affect Adjective Check List (Moser & Dracup, 2004). In that study, patients' psychosocial adjustment to the cardiac illness was worse when spouses were more anxious and depressed than patients. Patients' psychosocial adjustment was best when the spouses' emotional levels were higher than the patients' reported anxiety and depression (Moser & Dracup, 2004). In contrast to these cross-sectional studies, Rantanen et al. (2008) found that CAB patients reported worse levels depression than spouses at 1 month post-surgery (mean scores were not reported). Furthermore when examined longitudinally (Rantanen et al., 2009), both CAB patients' and partners' depression improved significantly ($p = .005$) from 1 month, to 6 months, and 12 months post-surgery (mean scores were not reported). Therefore some studies found partners to have worse psychological HRQOL compared to the patients (Moser & Dracup, 2004) and compared to the general population (Dracup et al., 2004); while other studies found patients to have worse psychological HRQOL than partners (Rantanen et al., 2008; 2009). These few studies were limited by the different instruments used to measure psychological HRQOL, samples with mixed CHD diagnoses, and study design (cross-sectional vs. longitudinal) (Dracup et al., 2004; Moser & Dracup, 2004; O'Farrell et al., 2000; Rantanen et al., 2008; Rantanen et al., 2009).

Psychological HRQOL in intervention studies.

Studies that examine the trajectory of changes in psychological HRQOL in CHD patients who participated in CR programs suggest that psychological changes occur later in the recovery phase than physical HRQOL changes (Apostolakis et al., 2006; Morrin et al., 2000; Muller-Nordhorn et al., 2004; Wintz & LaPier, 2007). Psychological HRQOL did not significantly improve between baseline (entry into CR) to 3 months (after the start of CR) in a retrospective study of CHD patients enrolled in a CR program in Canada (Morrin et al., 2000). However, there were significant ($p < .025$) improvements in psychological HRQOL from baseline to 6 months, and from 3 months to 6 months ($p < .025$) (Morrin et al., 2000). Similar improvements in psychological HRQOL of CAB patients during the first six months following surgery were found in a study by Muller-Nordhorn et al. (2004). Psychological HRQOL measured with the Mental Component Scores of the SF-36 primarily improved from baseline ($M = 45, SD = 12$) to 6 months ($M = 50, SD = 11$); but did not change from 6 months ($M = 50, SD = 11$) to 12 months ($M = 50, SD = 11$) after the CR program (Muller-Nordhorn et al., 2004). Similarly, McKee (2009) reported that mean Mental Health scores of the SF-36 showed a trend towards improvement from pre-program to post-program, but remained unchanged at 6 months post-program ($M = 72.4, 74.9$, and 74.4 respectively) in 187 Irish CHD patients enrolled in CR. Similar pre- and post-program trends for improved psychological HRQOL, measured with the Depression, Anxiety, and Stress Scales, were found in CHD patients enrolled in an 8-week tailored discussion program in addition to usual CR (Davidson et al., 2008). These studies of psychological HRQOL outcomes for CHD patients are limited by differences in how the dependent variables were measured, differences in

length and components of CR programs, relatively small sample sizes, and no control groups (Davidson et al., 2008; McKee, 2009; Morrin et al., 2000; Muller-Nordhorn et al., 2004).

None of these CR convenience sample studies measured partners' HRQOL. However, when compared to the general population, psychological HRQOL of CHD patients was found to be lower at baseline compared with U.S. norms (Morrin et al., 2000) and the general German population (Muller-Nordhorn et al., 2004). Psychological HRQOL reached the U.S. norm by 6 months following the CHD event in patients enrolled in a CR program (Morrin et al., 2000). Conversely, McKee (2009) reported that the mean Mental Health Component scores remained below the U.K. norm 6 months following a CR program ($M = 74.4$ vs. $M = 76.1$ respectively). Compared to myocardial infarction patients, Muller-Nordhorn et al. (2004) found that psychological HRQOL improved significantly ($p < .01$) only in CAB surgery patients one year post-CHD event. Several authors (Kristofferzon et al., 2005b; Morrin et al., 2000; Muller-Nordhorn et al., 2004) have found that physical and psychological HRQOL outcomes improved at different rates in CHD patients; and that psychological HRQOL typically lagged behind improvements in physical HRQOL following CHD events and CAB surgery.

Psychological HRQOL outcomes of interventions aimed at patient-partner pairs have not shown consistent findings. Home visits and telephone follow-ups to CAB surgery families were found to significantly lower anxiety levels of both patients and spouses (Buls, 1995; Hartford, et al., 2002). However, usual care heart surgery patients showed greater tolerance for emotional distress ($p = .007$) than patients in the couple-oriented telephone follow-up intervention at 3 months post-surgery (Gortner et al., 1988).

In the study by Gortner et al. (1988), 67 cardiac surgery patients and spouses were randomly assigned to the usual care or experimental group. Both groups received routine discharge instructions, but the intervention group received an 8-minute slide presentation on emotional responses post-surgery followed by a nurse-lead counseling session. The intervention group also received weekly phone follow up calls for 4 weeks, then bi-weekly calls for 8 weeks. Data collection occurred in the hospital prior to the surgery, and by mail at 3 months and 6 months post-surgery. There were no specific reasons discussed by Gortner et al. (1988) for the significant finding that the usual care group reported better tolerance to emotional distress and anger ($p=.007$). However Gortner et al. (1988) attributed the overall lack of significant findings to the small sample size ($n=67$), missing data (15% attrition at 3 months), insufficient intensity and duration of the treatment, and the suggestion that the expected changes may have occurred prior to the 3-month and 6-month data collection time frame. Myocardial infarction patients and partners randomly assigned to an educational and psychosocial support intervention were found to have lower anxiety mean scores at 5, 30, 90, and 180 days than usual care patients and partners (Thompson & Meddis, 1990a; Thompson & Meddis, 1990b). Patients in the intervention group reported less depression than control patients at 5, 30, and 90 days ($p<.05$); but there were no significant differences in depression for the treatment or control partner groups (Thompson & Meddis, 1990b). Lenz and Perkins (2000) found greater depressive symptoms in partners compared to CAB surgery patients preoperatively ($p=.001$), at 6 weeks ($p=.05$), and at 12 weeks ($p=.02$), regardless of treatment or control group status. The experimental group in this study received additional hospital discharge counseling about physical and emotional adjustment,

compared to the usual discharge instructions given to patients and family members.

Although not statistically significant, there was a trend for patients' and partners' depression scores to decrease over time in this study (Lenz & Perkins, 2000).

Psychological HRQOL outcomes in these few couple-centered intervention studies have resulted in mixed findings. These studies are limited by different definitions and measurements of psychological HRQOL, samples with mixed CHD diagnoses, and a wide variety of couple-centered intervention strategies.

In summary, psychological HRQOL has been found to be lower immediately following a CHD event and improved typically at a slower rate than physical HRQOL, with greater improvements occurring six to twelve months post-event for patients. Few studies examined only CAB surgery patients and their partners. While some studies reported worse psychological HRQOL for partners compared to patients, findings have been inconsistent and vary over time from the CHD event.

Relational HRQOL.

Dyadic relationships, such as married patient-partner pairs, are one of the most constant and intimate of family relationships and family social support (Brecht et al., 1994). In addition, family members both influence, and are influenced by patients' physical, behavioral, and psychological responses to acute and chronic illnesses and recovery (Panagopoulou, Triantafyllou, Mitziori, & Benos, 2009). Marital status alone has been associated with better overall QOL, morbidity, and mortality (Verbrugge, 1979) and to long-term survival post-CAB surgery (King & Reis, 2011). More recently, the quality of the couple relationship, and specifically marital adjustment, has been found to influence health outcomes in CHD patients and their partners (Kazemi-Saleh et al., 2008;

Mahrer-Imhoff, Hoffmann, & Froelicher, 2007; Stewart et al., 2001) and CAB surgery patients (King & Reis, 2011).

In this study, relational HRQOL was conceptualized as dyadic adjustment which reflects the relational quality of the patient-partner dyad and is synonymous with marital quality in patient-spouse pairs. Adopting the conceptual definition from Spanier (1976), dyadic adjustment is a process, rather than a static state, of relational quality that moves along a continuum from well adjusted to maladjusted. For partners in the dyadic relationship, dyadic cohesion, consensus, and satisfaction comprise the primary components of relational adjustment (Hunsley, Best, LeFebvre, & Vito, 2001). The process of marital adjustment is affected by “events, circumstances, and interactions” (Spanier, 1976, p. 17). Dyadic adjustment is relevant for both married and cohabitating couples (Spanier, 1976). In this study, relational HRQOL, conceptualized as dyadic adjustment, reflects how patients and partners feel about their marital relationships over the course of the CAB surgery, CR intervention, and recovery period.

Marital quality.

Marital status and marital quality have been found to influence recovery in CHD patients (Hilscher, Bartley, & Zarski, 2005; Rankin-Esquer, Deeter, Forelicher, & Taylor, 2000). King and Reis (2011) reported that married CAB surgery patients were 2.5 times ($p < .001$) more likely to be alive 15 years after CAB surgery than their unmarried peers; and highly satisfied CAB surgery patients were 3.2 times ($p < .001$) more likely to survive than those patients who reported low marital quality. Brecht et al. (1994) examined marital quality, dysphoria (anxiety, depression, and hostility), and psychosocial adjustment to CHD at baseline (study entry) and 3 months later. Marital quality was

measured with the Spanier Dyadic Adjustment Scale (DAS) which reports dyadic cohesion, consensus, satisfaction, and affectational expression subscales; although the fourth subscale was not reported in this study due to missing data. Of note, only patients, not partners, were measured for their perception of marital quality in their relationships in that study (Brecht et al., 1994). Brecht et al. (1994) reported that both marital quality and dysphoria were inter-correlated and predicted patients' psychosocial adjustment to CHD at baseline. When examined three months later, marital quality did not predict patients' psychosocial adjustment to CHD; but higher levels of marital quality predicted lower levels of dysphoria (Brecht et al., 1994). Interpretation of the findings was limited because subjects in this study had a wide variance in time since CHD event ($M = 17$ months). Although statistically controlled for, all of the patients' CHD events occurred more than 3 months prior to baseline data collection. Franks et al. (2006) reported that marital satisfaction, measured with the Quality of Marriage Index, was an independent predictor of CHD patients' health behaviors ($\beta = .33, p < .001$) for diet, exercise, and stress management. Marital satisfaction also predicted the patients' mental health ($\beta = .41, p < .001$), which was measured with the Mental Health subscale of the SF-36.

Several qualitative studies investigated the range of marital quality through the meanings that couples attach to cardiac events (Mahrer-Imhoff et al., 2007; Panagopoulou et al., 2009). Three relational outcomes were described by these investigators: positive, negative, and a mixed response. Positive outcomes included couples perceiving the event as being life-changing, which improved their relational HRQOL (Mahrer-Imhoff et al., 2007; Panagopoulou et al., 2009). Negative outcomes focused on both the patients and partners failing to see any benefit or meaning in the

cardiac event; these subjects returned to their old behaviors and former (poor) patterns of marital adjustment. The mixed response involved the couples assessing the cardiac event as a threat, and working together towards behavior change and mutual goals (Mahrer-Imhoff et al., 2007); or having survived, they felt invincible or protected (Panagopoulou et al., 2009). In a phenomenological study of three CAB surgery patient-partner dyads, Whitsitt (2010) reported that couples with high levels of marital quality held shared beliefs about the meaning of the illness experience, compared to those with a low quality marriage. Furthermore, couples' pre-existing levels of marital quality influenced post-CAB surgery marital satisfaction. Couples with pre-existing high marital quality were able to use the CAB surgery experience to grow in their relationship; while the CAB surgery experience exacerbated relationship weaknesses in couples with pre-existing low quality marriages.

One mechanism of improved HRQOL outcomes for married CHD patients is the availability and proximity of social support in intimate dyadic relationships. Kulik and Mahler (1993) investigated marital status and emotional support in a sample of 85 CAB surgery patients at 1, 4, and 13 months following hospital discharge. At 4 months, the CAB surgery spouses completed questionnaires for comparison of the patients' responses to health behaviors, specifically about smoking and ambulation; but spouses in this study were not measured on the dependent variables themselves. Married patients reported higher emotional support than unmarried patients ($p < .02$) (Kulik & Mahler, 1993). Higher emotional support, independent of marital status, was predictive of lower anxiety and lower depression ($p < .01$), better QOL ($p < .001$), and compliance with recommended health behaviors such as more ambulation ($p < .01$) and less smoking ($p < .001$) (Kulik &

Mahler, 1993). In contrast to emotional support, marital status did not predict any of these outcome variables: emotional distress, QOL, ambulation, or smoking (Kulik & Mahler, 1993).

Other investigators examined support as a characteristic of dyadic relationships in CHD patients and their partners, although support was operationalized in different ways. Low levels of social support, measured as perceived overprotection from spouses, was found to be correlated with depression ($r = .267$, $p < .05$) and lower HRQOL ($r = -.305$, $p < .01$) in 82 patients with myocardial infarction or congestive heart failure (Joeke, Van Elderen, & Schreurs, 2007). Similarly, spousal support was shown to predict CHD patients' increased mental health ($\beta = .24$, $p < .05$); while spousal control, a negative perception by patients, predicted patients' decreased mental health ($\beta = -.28$, $p < .01$) and health behaviors ($\beta = -.49$, $p < .001$) (Franks et al., 2006).

Few studies measured relational HRQOL outcomes in both the patients and the partners; and often the focus of inquiry remained on the patients' perspectives and patients' outcomes. Joeke, Maes, and Warrens (2007) conceptualized partner support as active engagement by the partner with the patient for the purpose of emotional support and problem solving. High levels of partner support, as perceived by the patients, was related to patients' emotional HRQOL ($r = .309$, $p < .05$), physical HRQOL ($r = .235$, $p < .05$), social HRQOL ($r = .342$, $p < .01$), and global HRQOL ($r = .309$, $P < .05$). Despite this reported health benefit when CHD patients and partners are actively engaged in sharing emotional support and problem solving as described above (Joeke, Maes, & Warrens, 2007), Denton, Burleson, and Brubaker (2009) found that CHD patients in a CR program were less likely to initiate relationship discussions with their partners than

community controls. CHD patients in that study were also less likely to initiate relationship problem discussions than their partners (Denton et al., 2009). In that study, a convenience sample of 40 CHD patients were invited at entry into CR to complete questionnaires on their style on initiating relationship discussions, referred to as “initiate-avoid” or “demand-withdraw” styles (Denton et al., 2009). Patients were matched with a convenience sample of community controls; no partners’ data were collected. Consistent with the authors’ hypothesis, CR patients rated themselves as less initiating ($M = 39.12$) compared to their ratings of their partners’ initiating style ($M = 58.54$). Community dwelling matched controls rated themselves higher on initiating ($M = 63.04$), compared to their partner’s initiating style ($M = 58.54$). The authors suggested that relationship discussion avoiders, as self-reported in this CR sample, may be more likely to develop increased cardiovascular reactivity over an extended period of time, which may ultimately lead to illnesses such as CHD.

In summary, relational HRQOL has been shown to influence outcomes in CHD patients. Relational HRQOL has been measured in a variety of ways including social support, emotional support, emotional distress, active engagement/overprotection, marital satisfaction, marital quality, and dyadic adjustment. Although marital quality presumes a dyadic relationship, few studies investigated both the patients’ and the partners’ perception of marital quality. Furthermore, marital quality has been found to influence HRQOL outcomes following CAB surgery; and in turn, the CAB surgery event influences the couples’ marital relationship (Whitsitt, 2010).

Couple-centered interventions.

Couple-centered interventions have been designed and tested in numerous studies of chronic diseases such as cancer, osteoarthritis, heart failure, stroke, dementia, cardiovascular disease, and hypertension (Martire et al., 2010). A recent meta-analysis of randomized couple-oriented interventions in chronically ill patients and their partners found significant effects for depressive symptoms ($d = 0.18$, $p < .01$, $k = 20$) and marital functioning ($d = 0.17$, $p < .01$, $k = 18$) compared to usual care and patient-only psychosocial interventions (Martire et al., 2010). Criteria for inclusion of studies in this meta-analysis were: (a) inclusion of a control or usual care group, (b) inclusion of complete dyads of patients and their family partners (c) 75% of the samples included patient-partner dyads (as compared to patient-other caregiver dyads), and (d) assessment of health, psychological, or relationship outcomes. This resulted in 33 couple-oriented studies included in the meta-analysis of chronically ill patients and partners (Martire et al., 2010, p. 326-327). Most of the interventions were disorder-specific (i.e. cancer, cardiovascular disease, diabetes) in that the strategies were targeted towards illness management for the patients and partners. Interventions ranged between 3 to 20 sessions, one-fourth of the studies were implemented either partially or wholly by telephone, and almost half followed a group format. For patients, 56% ($n = 18$) of the studies found significant improvements in psychological and physical functioning, marital adjustment, and medication adherence with couple-interventions compared to usual care or other psychosocial interventions (Martire et al., 2010). Partner outcomes were examined in less than half ($n = 17$) of these couple-oriented studies that were included in the meta-analysis. For partners, 35% ($n = 6$) of the studies included in this meta-analysis found improved psychological functioning (self-efficacy, mastery, stress management), marital

quality, and coping in the couple-oriented groups compared to usual care. These positive findings were found in studies that investigated outcomes for cancer, hypertension, and osteoarthritis patient samples. Also, 59% (n=10) of the studies reported no significant differences in the partners' outcomes between the couple-oriented intervention and usual care groups. Martire et al. (2010) noted several limitations to the studies including: (a) not able to determine if subjects actually received the intervention, (b) lack of detailed information about number of sessions attended by patients and partners, and (c) studies were statistically underpowered.

Family-centered studies are designed to deliver the intervention to patients and family members (Van Horn et al., 2002). In this review of eight family-centered interventions during cardiac recovery from myocardial infarction or CAB surgery, Van Horn et al. (2002) reported that the majority of cardiac intervention studies were conducted with patient-spouse pairs, usually carried out in CR centers or patients' homes, consisted of multiple sessions, and occurred from 1 week to 3 months post-hospital discharge. Interventions in the studies reviewed by Van Horn et al. (2002) included education, counseling, exercise conditioning, home visits, and telephone follow-ups. None of these studies included participation of the family member in a usual care CR program. The primary goals of these family-centered interventions have included risk factor modification, improved physical function, problem solving, family coping, social support, stress management skills, and family functioning (Van Horn et al., 2002). An inpatient nursing intervention designed to address relational strategies for cardiac surgery patients and partners found no significant differences in family functioning between the intervention subjects and their partners and the usual care subjects and their

partners, at 3 months and at 6 months post-cardiac surgery follow-up (Gilliss, Neuhaus, & Hauck, 1990; Gortner et al., 1988). There were no significant differences between baseline patients' scores on family functioning ($M = 17.35$ control group; $M = 18.28$ experimental group); and between baseline partners' scores of family functioning ($M = 16.77$ control group; $M = 18.12$ experimental group). Family function mean scores were not reported at 3 and 6 months time periods. However, the spouses' mean scores for family functioning in the experimental and control groups were reported to be lower than patients' mean scores for family functioning at each time period (3 months and 6 months post-cardiac surgery) (Gilliss et al., 1990). Furthermore, marital adjustment scores increased ($p=.05$) for cardiac surgery patients but decreased for spouses between baseline and 6 month (Gilliss et al., 1990). Gilliss et al. (1990) summarized that the cardiac surgery event appeared to have a more disorganizing effect on spouses than on patients.

Limitations in family-centered studies included non-randomization to groups (Fridlund, Stener-Bengtsson, & Wannman, 1993), statistically underpowered (Gilliss et al., 1990; Gortner et al., 1988), lack of data on partner outcomes (Fridlund et al., 1991), or failure to describe the intervention adequately (Martire et al., 2010). Also, no studies were found that included the CHD or CAB surgery patients and their partners participating together in a CR program. Findings from the Van Horn et al. (2002) review and the Martire et al. (2010) meta-analysis support further investigation into the effects of couple-centered interventions, such as the PaTH intervention in the proposed study. This current study examined the relational HRQOL conceptualized as dyadic adjustment in patients and partners from baseline (T1, entry into CR) to T2 (end of CR program), to T3

(3 months after completing the CR intervention) in both patients and partners in the intervention and usual care groups.

In summary, the examination of relational HRQOL and specifically dyadic adjustment provided a conceptually consistent and important outcome in this study in which the experimental condition was based on a couple-centered intervention compared to usual care CR. Very few studies have examined dyadic adjustment, despite focusing on the partners' role in illness recovery. Even fewer studies of CHD patients and their partners have considered marital quality outcomes. This study contributed a unique perspective of dyadic adjustment by measuring both the CAB surgery patients' and partners' relational HRQOL.

Chapter Three

Design

The parent study was an experimental, two-group, repeated measures pilot design which examined healthy eating and physical activity/exercise outcomes in patients and partners enrolled in the PaTH intervention or usual care CR. This current study examined HRQOL outcomes which were the secondary outcomes of the PaTH pilot study (Yates, 2009). Couples were randomly assigned to the PaTH intervention or usual care CR program (see Procedures below).

Data collection occurred at baseline or T1, which was close to the start of CR; T2 which was at the end of CR; and T3, which occurred 3 months after completing CR. Rationale for the data collection points was as follows: Baseline was selected as one to three weeks post hospital discharge for CABS, and close to the start of CR. Time 2 (approximately 3 months after the start of CR) coincided with completion of CR so that outcomes measures reflected improvements made as a result of participation in the CR interventions. Time 3 (3 months after the end of CR) was selected to show continued change or maintenance of the outcomes three months after the CR interventions. These follow-up time points have been used in other CR intervention studies (Grace et al., 2008; Jokinen et al., 2010; Mathisen et al., 2007), and allows for comparison with these studies.

Setting and Target Population.

The clinical recruitment sites for the parent study were the University of Nebraska Medical Center (NMC) and Methodist Hospital both located in Omaha, NE. The target population was consecutive CABS patients and their partners who were hospitalized at the NMC and planned to participate in CR at NMC or Methodist Hospital. The HRQOL

questionnaires were completed at the subjects' homes at all three testing times. The NMC and Methodist CR programs are certified by the AACVPR.

Inclusion and Exclusion Criteria

Inclusion criteria for patients were: (a) diagnosis of CABS, (b) age 19 years or older, (c) enrollment in outpatient CR, (d) married or living with partner for more than 1 year, (e) partner is willing to participate, (f) no history of psychiatric illness, and (g) classified as low to moderate risk for occurrence of cardiac events during exercise (AACVPR, 2004). Eligible partners included: (a) 19 years of age or older, (b) no history of psychiatric illness, (c) permission from the partner's primary health care provider to participate in the study, and (d) classified as low to moderate risk for occurrence of cardiac events during exercise (AACVPR, 2004).

Exclusion criteria for patients and partners were: (a) orthopedic problems that would prevent walking on a treadmill while speed and incline are gradually increased until maximum effort is reached, (b) history of cardiac arrest, sudden death, or complex dysrhythmias at rest, (c) resting systolic BP > 200 mmHG or diastolic > 100 mmHG, (d) a concomitant diagnosis of renal failure or anemia, (e) severe chronic obstructive pulmonary disease (FEV1 < 1 liter), or (f) poorly controlled diabetes (diabetic ketoacidosis within past six months or a current HgA1C > 11), (g) a diagnosis of Heart Failure class I – III with an ejection fraction $\leq 35\%$ and is unstable (*unstable* was defined as not being on the same medications for 1 month and clinical evidence of decompensated Heart Failure).

Sample.

A convenience sample from a mid-western university medical center and a large metropolitan hospital was used for the primary study and to analyze the secondary outcomes for this study. Due to the relatively small sample size ($n = 34$ couples, 68 individuals) from the parent study, nonparametric statistics were used to analyze the data (see Data Analysis below). Every effort was made to include women and minorities in the sample. Men make up the majority (65-70%) of CABS patients in these two clinical settings (Yates, 2009) and in CR programs in general (68% male) (Brown et al., 2009).

Threats to Validity.

Potential threats to internal validity were reduced due to the randomization of subjects to two groups. While the researchers were blinded to subject group assignment, the CR staff members were not blinded and therefore may have influenced the intervention and usual care strategies. There were no relevant historical events that occurred that may have influenced the participants' responses. Testing effects and maturation were controlled by random assignment. Selection bias was a potential threat in that couples who work well together may have been more inclined to participate in the study than couples who have lower marital quality. Finally, mortality from subject drop-out due to lack of interest or preference for group assignment did not occur.

Measures

Measures reported in this study are secondary outcomes from the PaTH Intervention. A demographic questionnaire and illness questionnaire (patients only) were developed as part of the primary study (Yates, 2009). Measures specific to this study are discussed below.

Physical HRQOL.

Physical HRQOL was examined using the Physical Functioning subscale of the Short Form Health Survey (SF-36v2™) from the Medical Outcomes Study (MOS) (McHorney, Ware, Lu, & Sherbourne, 1994; Ware & Sherbourne, 1992). The physical functioning subscale consists of 10 items representing physical activity limitations due to illness. Transformed scores using the algorithm developed by the MOS, range from 0 to 100 with higher scores indicating more favorable physical functioning. Internal consistency reliability estimates were reported to be excellent with Cronbach's alpha of 0.93 (McHorney, et al., 1994). Construct validity was examined in a large study by McHorney et al. (1993) that showed physical functioning mean scores to be higher ($M = 80.53$, $S.E. 0.89$) in minor medical conditions compared to serious medical conditions ($M = 57.35$, $S.E. 2.34$) (McHorney, Ware, & Raczek, 1993). Furthermore, the mean difference score between serious versus minor medical conditions was significant (mean difference -23.18 , $F = 85.9$, $p < .001$). The SF-36 has been used for HRQOL outcome measurement in multiple studies of CABS (Arthur et al., 2002; Joikinen et al., 2010) and MI patients (Izawa et al., 2004).

Exercise performance.

This study examined submaximal treadmill performance achieved during the sessions number 4, 5, and 6 and the final 3 CR exercise sessions between patients in the PaTH and usual care groups. Submaximal exercise performance was quantified in METs (1 MET = 3.5 ml/kg·min) calculated from workloads with standard equations available with telemetry monitoring software. Calculated METs have been widely used in physical activity and exercise studies (Ainsworth et al., 2000; 2011; Franklin et al., 2008; Haskell

et al., 2007). Treadmill exercise was chosen due to the relative commonality as the primary exercise mode in CR settings; and the wide variability in determining accurate intensities of other typical exercise modes such as recumbent trainers, elliptical machines, stair steppers, and/or arm ergometers in two different CR settings. Duration of aerobic exercise was not examined because duration was dictated by the CR program structures. However, a minimum of 3 minutes (ACSM, 2010) duration of submaximal treadmill performance was necessary to achieve an aerobic steady state for the purpose of this study. Baseline treadmill data were calculated on sessions number 4, 5, and 6 because these three sessions represent the second week of the CR program. CR session number 1 typically does not include any treadmill exercise, especially when an initial six-minute walk test is performed. During the next two sessions, patients are typically becoming accustomed to using the treadmill. Therefore the decision was made to measure exercise performance during sessions number 4, 5, and 6 to represent a week of data in which the patients had become accustomed to using the treadmill. These same baseline sessions were used by Kligfield et al. (2003) to reduce potential effort variability that may occur as patients become familiar with the treadmill exercise itself.

Baseline (T1) and end of CR (T2) exercise performance in patients were calculated as follows:

Step 1: For sessions number 4, 5 and 6 (T1):

- (a) Determine the speed and grade achieved during the treadmill exercise mode and estimate the submaximal MET level for session number 4, session 5, and session 6.

- (b) Add the 3 treadmill submaximal MET levels (estimated in [a] above) for total treadmill MET level and divide by 3 (sessions) = mean treadmill submaximal MET level at baseline (T1)

Step 2: For the last 3 sessions (T2):

- (a) Repeat steps (a) and (b) above to estimate the mean submaximal treadmill MET level for end of CR (T2)

Psychological HRQOL.

Psychological HRQOL was measured using the Patient Health Questionnaire (PHQ-9) (see Appendix A), a 9-item depression module. PHQ-9 total scores range from 0 to 27, with higher scores indicating greater severity of depression (Kroenke, Spitzer, Williams, & Lowe, 2010). Acceptable construct validity ($r = .73$) and criterion validity have been reported (Kroenke et al., 2001). Internal reliability of the PHQ-9 has been very good with Cronbach's alpha of 0.86 to 0.89, test-retest ($r = .84$), and self-rated versus interviewer-rated ($r = .84$) (Kroenke et al., 2010). In this study, depression severity was examined as a continuous variable. The PHQ-9 has been used in several studies investigating depression in CHD patients (McManus et al., 2005; Ruo et al., 2003) and has been recommended by the AHA for depression screening in cardiac patients (Lichtman et al., 2008).

Relational HRQOL.

Relational HRQOL was measured using the 7-item Dyadic Adjustment Scale (DAS-7) (Sharpley & Rogers, 1984; Hunsley et al., 2001) (see Appendix B). The DAS-7 is a 7-item self report measurement of relationship adjustment for dyadic partners in

marriage or cohabitating couples revised from the full length DAS (Spanier, 1976). The items in the DAS-7 measure dyadic cohesion, dyadic coherence, and global relationship satisfaction (Hunsley et al., 2001). Respondents indicate the degree to which they agree or disagree with their partner on specific relationship issues, using a Likert-type scale ranging from 0 to 7. Total scores range from 0 to 35, with higher scores indicating greater relational adjustment. Internal consistency was satisfactory with Cronbach's alpha reported at .80 (Hunsley et al., 2001). Criterion validity was established comparing couples in marital therapy clinic sample with a community sample. The community sample ($M = 25.8, SD = 4.7$) was significantly different compared to the clinic sample ($M = 17.8, SD = 5.5, p < .001$) (Hunsley et al., 2001). When these subjects were categorized as maritally *adjusted* or *maladjusted* using the DAS as the criterion measure, the groups were found to be significantly different when measured with the DAS-7 (*maladjusted* $M = 15.7, SD = 4.2$, *adjusted* $M = 26.2, SD = 4.0, p < .001$), thus establishing further criterion validity of the DAS-7. The DAS-7 has been used in studies of community-based couples, couples in marital counseling (Hunsley et al., 2001) and in CABS patients (Brecht et al., 1994).

Procedures

Recruitment and Enrollment

The target population was consecutive CABS patients and their partners who planned to participate in outpatient CR at NMC and Methodist Hospital, Omaha, NE. Potential participants were recruited for the PaTH primary study from the inpatient CABS units or the outpatient CR programs. Following referral, the project staff described the study to potential participants, using a visual representation (flip chart) of

the study procedures. This allowed the research staff to be more consistent about presenting study information to the potential subjects. Privacy, confidentiality, and voluntary participation were addressed in the informed consent. It was recognized that the CABS recovery period represents a stressful time for patients and families; and the amount of time needed by the individual to ensure understanding of the study was provided. The signed consent forms were kept in a locked file in the research project office and a copy was given to each study participant.

Participants were randomly assigned as a couple (patient and partner) to either the PaTH intervention or usual care CR groups, using a previously generated randomization schedule developed by the statistician. Randomization was stratified by both clinical site and patient gender to ensure balance between the intervention and usual care groups on both strata. For every one female participant, it was projected to enroll two males. This technique ensured that the ratio of male to female patients reflected the gender distribution in the CR population. It was also projected that we would enroll twice as many patients at one clinical site (Methodist Hospital) compared to the second clinical site (NMC). Thus, the randomization process took this factor into consideration. The randomized group assignments were placed in numbered, sealed envelopes and were not opened until the couple had granted informed consent.

Data Collection Procedures and Timeline.

Project staff informed the CABS patients that the primary study did not take the place of medical care. Partners were instructed to seek medical care from their primary care physicians, if medical problems arose. Questionnaires were mailed to the participants' homes prior to the scheduled in-person testing: baseline (T1 – close to

starting CR), T2 (at the end of the CR program), and T3 (3 months after the end of CR). Participants brought the completed questionnaires with them to the clinical site and project staff checked for completeness. Patients and partners in both groups were paid \$10 for completing three data collection time points, for a total of \$30.00 to each participant.

Interventions

Patients in both groups and partners in the PaTH intervention group began CR two to three weeks post hospital discharge, close to completion of baseline data collection. Both CR programs are nationally certified by the AACVPR (2004) representing standardized program components including an entrance evaluation for exercise capacity, individual risk factor modification, medication compliance, relevant lab data such as blood lipid levels, and a pre- and post-program measures of physical, psychological, and knowledge outcomes (see Appendix C). Nurses provide the majority of individual counseling with consultation and/or education provided by dietitians, pharmacists, exercise physiologists, psychologists, the patients' personal physician, and the program Medical Director. Individualized exercise plans are implemented in a hospital-based, rehabilitation facility that includes aerobic, strength, and flexibility exercises, 3 days a week for 8 to 12 weeks (24 to 36 sessions). In this study, the number of weeks of CR (and therefore the total number of sessions) depended on the patients' insurance coverage limitations and/or progress towards goals achieved. Monitoring the patients' cardiovascular response to increasing levels of exercise intensity and duration were adjusted and documented by the CR nurses and other staff members such as exercise specialists. Group education classes in nutrition, smoking cessation, cardiac

knowledge, stress management, medications, and lifestyle change were regularly offered. Re-assessments of progress towards goals were provided for participant feedback at regular intervals. In the PaTH group, patients and partners received the individualized treatment plan and counseling. In the usual care CR group, only patients received the individualized treatment plan and counseling. Participants in the PaTH intervention group and usual care CR group met separately for both the exercise sessions and educational class participation.

Procedures for Training.

The CR intervention was delivered within an existing CR program and staff included program managers, RNs, dietitians, and exercise specialists. CR program activities at both sites were reviewed on a regular basis. Any observed variability in program delivery was discussed, and if needed, procedures were established for ensuring greater consistency in program activities. Research staff observed randomly selected intake, educational, and exercise sessions. Adherence rates for the research activities were computed for patients and partners in both groups.

Human Subjects

The study was approved by the UNMC Office of Regulatory Affairs, Institutional Review Board (IRB) Number 080-12-EX (see Appendix D). IRB approval was obtained for the parent study at the institutional and clinical sites. The current proposal qualifies as an exempt study because the data were already available and because the data sets are de-identified. Existing data were defined as information used in research that is ready for approval by exemption and no additional information was collected for research purposes. The risk category for this study was minimal risk. There may be direct

benefits for participants in this study who were involved in the CR interventions. Benefits to society may be possible through the generation of knowledge about HRQOL outcomes of CAB surgery patients and partners. This information can facilitate the continued development of this PaTH intervention to improve outcomes in this population. Thus, this research offered participants an acceptable risk/benefit relationship. Confidentiality of each participant was protected through the assignment of code numbers for each participant's questionnaires. All information collected was kept in a locked file cabinet in the investigator's office. All research-related computer files were password protected. All data were reported as group data.

Data Analysis

Data analysis followed an intent-to-treat paradigm. Data were entered into SPSS Version 20.0 software program. Prior to analysis, data were examined for accuracy of data entry and missing values. Frequency distributions were used to examine histograms and box plots for outliers. If outliers were identified, data were inspected for data entry errors or extreme values from unusual cases. Due to the small sample size and non-normality of the data, nonparametric statistics were used to analyze the data.

Descriptive statistics were calculated summarizing the baseline demographics of patients and partners in the PaTH and usual care CR groups. Chi-square (for nominal data) and Mann-Whitney U tests (for ordinal data) tests were performed to determine significant differences between patients and partners in the PaTH and usual care CR groups for: age, sex, marital status, ethnicity, education level, household income, patients' number of days since CAB surgery event to the start of CR, number of grafts, number of CR session, number of educational sessions, and patients' and partners'

comorbidities. Internal consistency for the dependent variables (physical function, depression, and dyadic adjustment) were calculated with Cronbach's alpha coefficients, separately for patients and partners at all 3 time points.

The following data analyses for dependent variables were performed at the .05 level of significance and with two-tailed direction. The following series of data analyses were performed for Aim One and Aim Two:

- (a) Wilcoxon Signed Ranks tests were used to examine changes over time in each dependent variable for patients (Aim One) and partners (Aim Two).
- (b) Mann Whitney U test statistics were used to compare differences between groups (PaTH versus usual care) by first computing a change score for each dependent variable by subtracting T1 from T2, and T2 from T3, for patients (Aim One) and partners (Aim Two).
- (c) Mann Whitney U statistics were used to examine differences between patients (Aim One) and partners (Aim Two) by CR site, at each time point (T1, T2, and T3) for each dependent variable.
- (d) Mann Whitney U statistics were used to examine differences between patients (Aim One) and partners (Aim Two) in each group (PaTH versus usual care) by site (NMC versus Methodist Hospital) between T1 and T2, and between T2 and T3)

These non-parametric tests (Wilcoxon signed ranks and the Mann-Whitney U) examine differences between medians. Critical assumptions for the Wilcoxon signed ranks test are: (a) the data are paired observations, (b) the dependent variable is continuous and at least at the ordinal level of measurement, (c) the computed difference

scores are symmetrical about the true median for the population (Pett, 1997). Critical assumptions for the Mann-Whitney U test are: (a) the independent variable is dichotomous (e.g. two groups), (b) the dependent variable is at least at the ordinal level of measurement, (c) the data are randomly selected from two independent groups, and (d) the population distributions of the dependent variables of the two independent groups share similar shapes; but this shape does not need to be normal (Pett, 1997).

To analyze the couple data for Aim Three, a difference score within the couple was first computed for each dependent variable. Then, Wilcoxon signed ranks test for paired data were used to examine the differences in HRQOL outcomes between patients and partners in the PaTH intervention, and between patients and partners in the usual care group. Analyses were conducted over time, between T1 and T2, and between T2 and T3.

For Aim Four, descriptive statistics were examined for the treadmill exercise performance data using the calculated METs achieved during CR sessions numbered 4-6 (baseline) and the last 3 exercise sessions (end of CR). Wilcoxon signed rank test statistics were used to analyze the paired data for exercise performance from baseline to the end of CR in the PaTH and usual care groups. Finally, a Mann Whitney U test was performed to examine the difference in exercise performance between patients in the PaTH and usual care groups between baseline and the end of CR.

Chapter Four

This chapter includes how the data were screened, reliability analyses, demographic characteristics of the sample, and data analyses of the aims.

Data Screening

Data entry was confirmed through double entry. Data were inspected for missing data, outliers, normality, skewness and kurtosis at all three time points (at the start of CR [T1], the end of CR [T2], and 3 months after the end of CR [T3]).

Missing data.

Missing SF-36 PF subscale data were imputed for four subjects according to the recommended method by Ware, Kosinski, and Dewey (2000). The average score for each respondent across the PF scale was imputed for the missing item. The missing items were randomly distributed across subjects and times of data collection: one item at T1, one item at T2, and 2 items at T3.

For Aim One, 3% (n=1) of patients were excluded from the PHQ-9 analysis due to one item missing. For Aim Two, 3% (n=1) of partners were excluded from the PHQ-9 analysis and 6% (n=2) were excluded from the DAS-7 analysis. For Aim Three, one PaTH pair (3%) was excluded from the DAS-7 analysis. For Aim Three, two usual care patient-partner pairs (6%) were excluded from the PHQ-9 analysis, and one pair (3%) was excluded from the DAS-7 analysis due to missing data of one item each (see Table 1). For Aim Four, one usual care patients' exercise performance was missing between T1 and T2, as this patient did not use the treadmill in the CR program. Missing data were not imputed for the PHQ-9 or DAS-7 surveys, as no imputing recommendations were found for these scales. Due to the small sample size and very small amount of missing data, analyses were performed on the variables with complete data only.

Table 1. Number of Subjects in Each Data Analysis by Aims

	PF	PHQ	DAS
Aim One (Patients)	34	33	34
Aim Two (Partners)	34	33	32
Aim Three (Couples)			
PaTH	34	34	33
Usual Care	34	32	33

Note: total possible subjects in each cell = 34.

Outliers.

Box plots and z-scores were examined to identify univariate extreme values at each time point for patients and partners. A z-score of $> |3|$ was used to identify outliers. One patient in the usual care CR group had high z-scores for depression at baseline and T2 (3.35 and 5.74); and one patient had a high z-score (3.54) for depression at T3. One usual care partner reported high depression and low dyadic adjustment z-scores (3.5 and -3.28 respectively) at baseline. One usual care couple reported the lowest physical function z-scores: for the patient (-4.18) at T3 and for the partner (-3.05) at T2. This couple did not show extreme values for the other two HRQOL variables. No other extreme values were identified by z-score analyses.

Multi-variate outliers were examined by calculating Mahanlanobis Distances for the three subscales using the test statistic: $\chi^2 = 16.27$ ($df = 3$, $p < .001$). For patients, one usual care patient exhibited extreme values for the PF subscales ($\chi^2 = 21.02$) and one PaTH patient showed a high extreme value for the DAS subscales ($\chi^2 = 18.54$). There were no extreme outliers noted in patients for the PHQ-9 subscales when Mahanlanobis Distances were examined. For partners, one control subject exhibited an extreme value for the PF subscales ($\chi^2 = 29.01$) and one control subject had an extreme value ($\chi^2 =$

17.24) for the DAS subscales. No extreme outliers were detected for the PHQ-9 subscales in partners via the Mahalanobis Distances method for multi-variate outliers.

Normality.

Data were examined for normality by analyzing histograms, p-p plots, the Kolmogorov-Smirnov and Shapiro-Wilk tests, skewness, and kurtosis. All subscales (PF, PHQ-9, and DAS-7) were non-normal at all time points except for the patients' baseline (T1) PF subscale z-score (Shapiro-Wilk test, $p = 0.522$). Square root and log10 transformations did not improve normality. Skewness was visually examined and calculated. The PHQ-9 subscales at all three time points exhibited positive skewness; while the PF and DAS-7 subscales primarily exhibited negative skewness. Due to apparent non-normality and skewness of the distributions, kurtosis was not examined in depth. Subsequent data analyses were performed using non-parametric statistics.

Reliability.

Reliability of the three dependent variables was satisfactory (Burns & Grove, 2005) over the three time points as analyzed by Cronbach's alpha test statistics (see Table 2).

Table 2. Reliability: Cronbach's Alpha Coefficients of Dependent Variables over Time.

Dependent Variables	Full Sample	Patients	Partners
Physical Function^a			
Time 1 (baseline start of CR)	.91	.88	.88
Time 2 (end of CR)	.80	.80	.80
Time 3 (3 months after CR)	.90	.93	.81
Depression^b			
Time 1 (baseline start of CR)	.87	.84	.90
Time 2 (end of CR)	.83	.83	.86
Time 3 (3 months after CR)	.67	.65	.70
Dyadic Adjustment^c			
Time 1 (baseline start of CR)	.84	.79	.88
Time 2 (end of CR)	.80	.79	.81
Time 3 (3 months after CR)	.84	.82	.87

Note: ^a Physical Function subscale of the SF-36; ^b PHQ-9; ^c DAS-7.

The Sample

Demographic characteristics.

The final sample consisted of 34 patient-partner pairs (N=68) randomly assigned to the PaTH (n = 17 pairs) or usual care (n = 17 pairs) CR groups. As expected, a majority of CAB surgery patients were White males (see Table 3). Only two patients and two partners indicated Hispanic ethnicity. Patients and partners were more likely to be employed outside the home than being retired or unemployed. Patients and partners reported relatively high household incomes. Patients in both groups attended the same median number of CR sessions (18) with a range of 11-36 sessions for the PaTH group and 12-36 sessions for the usual care group. This indicated that the length of the CR program varied between 6 and 12 weeks, and was largely dependent upon insurance benefits. There was no evidence of a difference in number of CR sessions between groups.

The data were also examined for comorbidities that may have negatively impacted HRQOL such as COPD, asthma, peripheral vascular disease (PVD), and arthritis. Forty-one percent (n=14) of patients and 44% (n=15) of partners reported having arthritis. Although 17.8 % (n=3) of patients reported COPD and 17.8% (n=3) reported PVD; no partners indicated having these comorbidities. Comparisons between patients in both groups and between partners in both groups were analyzed by Mann-Whitney U tests for ordinal data and by Chi-square statistics for nominal data. There was no evidence of a difference ($\alpha = .05$) between the demographic characteristics of patients (see Table 3) in the intervention and control groups or between partners (see Table 4) in

the intervention and control groups. Median age and age range were reported in accordance with choosing non-parametric statistics for data analyses.

Table 3. Comparisons of **Patients'** Baseline Demographic Characteristics by Group

Patients (n= 34)	PaTH		Usual Care CR		Mann-Whitney	
	Median	Range	Median	Range	z	p
Age	64	33-77	66	40-77	-0.99	.34
# of grafts	4	1-5	3	2-5	-0.76	.45
# CR sessions	18	11-36	18	12-36	-1.27	.20
# CR planned	18	18-36	18	12-36	-0.44	.66
# Education sessions	18	7-19	14	9-18	-0.53	.60
	N	%	N	%	χ^2	p
Gender						
Male	15	88.2	13	76.5	0.81	.37
Female	2	11.8	4	23.5		
Race and Ethnicity						
White	15	88.2	17	100	2.13	.14
Hispanic	2	11.8	0	0		
Education Level						
High school or less	7	41.2	5	29.4	2.22	.33
Some college	3	17.6	1	5.9		
College degree or post-graduate	7	41.2	11	64.7		
Employment Status						
Employed	14	82.3	10	58.9	2.67	.26
Not employed	1	5.9	1	5.9		
Retired	2	11.8	6	35.2		
Household Income						
Below \$40,000	3	17.6	3	17.6	0.15	.93
\$40,000 – 79,999	9	53.0	8	47.1		
\$80,000 or more	5	29.4	6	35.3		
Marital Status						
Married	17	100	15	88.2	2.13	.14
Co-habiting	0	0	2	11.8		
Site						
NMC	4	44	5	56	0.15	.70
Methodist	13	52	12	48		
Comorbidities						
Arthritis	7	41.0	7	41.0	0.00	1.00
Asthma	1	5.9	0	0	1.03	.31
COPD	3	17.6	0	0	3.29	.07
PVD	2	11.8	1	5.8	0.37	.54

Note: COPD = chronic obstructive pulmonary disease, PVD = peripheral vascular disease.

Table 4. Comparisons of **Partners'** Baseline Demographic Characteristics by Group

Partners (n = 34)	PaTH		Usual Care CR		Mann-Whitney	
	Median	Range	Median	Range	z	p
Age	62	33 - 76	63	29 - 76	-0.83	.41
# CR sessions	18	9-36	18	0-34	-1.42	.16
# Education sessions	14	7-18	15	7-19	-0.10	.92
	N	%	N	%	χ^2	p
Gender						
Male	2	11.8	3	17.6	0.23	.63
Female	15	88.2	14	82.4		
Race and Ethnicity						
White	16	94.1	16	94.1	0.00	1.00
Hispanic	1	5.9	1	5.9		
Education Level						
High school or less	7	41.2	6	35.3	4.00	.13
Some college	6	35.3	2	11.8		
College degree or post -graduate	4	23.5	9	52.9		
Employment Status						
Employed	10	58.8	10	58.9	2.33	.31
Not employed	2	11.8	0	0		
Retired	5	29.4	7	41.1		
Comorbidities						
Arthritis	10	58.9	5	29.4	2.98	.08
Asthma	4	23.5	3	17.6		

Note: COPD = chronic obstructive pulmonary disease.

Comparisons by CR site.

Patients' demographic characteristics were compared between the two clinical sites and significant differences were found in the median number of days between the patients' surgery date and the first CR session ($z = -3.85$, $p = .000$). Nebraska Medical Center (NMC) patients began the CR program a median of 21 days from the date of surgery (range 15 – 27 days) compared to those at Methodist Hospital who entered the CR program at a median of 11 days (range 7 – 26 days). Both the ACSM (2010) and the AACVPR (2004) recommend that CHD and CAB surgery patients begin CR within 1-2

weeks of hospital discharge. Because starting CR earlier or later may impact outcomes for patients and partners, Aims One and Two were also analyzed by comparing patient and partner differences between clinical sites.

Results: Aim One

The first aim of this study was to examine the differences between patients in the PaTH intervention and usual care CR groups in changes over time in physical, psychological, and relational HRQOL outcomes. The descriptive results for patients' HRQOL scores are in Table 5.

Physical function.

The SF-36 PF subscale scores can range from 0 to 100 with higher scores indicating greater physical function (Ware & Sherbourne, 1992; Ware, Snow, Kosinski, & Gandek, 1993). Patients in both the PaTH and usual care groups reported moderate levels of physical function at T1 (close to the start of CR) (see Table 5). The results of the Wilcoxon signed ranks test indicated that patients in the PaTH group significantly improved their physical function from T1 (median = 55.0) to T2 (median = 85.0) ($z = -3.52, p = .000$); and patients in the usual care group also significantly improved their physical function from T1 (median = 55.0) to T2 (median = 90.0) ($z = -3.23, p = .001$) (See table 5). There was no evidence of a difference in physical function between T2 and T3 for patients in either group by Wilcoxon signed rank test statistics.

Depression.

Patients' median PHQ-9 subscale scores indicated very low levels of depression over time (see Table 5). PHQ-9 scores may be categorized as minimal (0-4), mild (5-9), moderate (10-14), moderate-severe (15-19), and severe (20-27) symptoms (Kroenke et

al., 2001). The results of the Wilcoxon signed ranks tests indicated that patients in the PaTH group showed a significant improvement in depression from T1 to T2 ($z = -2.85$, $p=.004$); and patients in the usual care group also experienced a significant improvement in depression from T1 to T2 ($z = -2.56$, $p=.01$). There was no evidence of a difference in patients' depression from T2 to T3. The majority of patients in both groups (91.2%, $n=31$) reported minimal symptoms of depression at T1. A cut-point of ≥ 10 has been recommended for depression screening and indicates that further clinical assessment is needed (Gilbody, Richards, Brealey, & Hewitt, 2007; Kroenke et al., 2001; Kroenke et al., 2010). Six patients (18%) reported symptoms at the cut point or above (PHQ-9 ≥ 10) at T1 (PaTH $n=2$, usual care $n=4$). By T2 and T3, only 1 (3%) patient reached the depression threshold (PHQ-9 ≥ 10) at those follow-up time points.

Dyadic adjustment.

Dyadic adjustment scores can range between 0 to 36, with higher scores indicating better marital adjustment (Hunsely et al., 2001). Patients' mean and median DAS-7 scores showed moderately high marital adjustment at all time points with little change over time (see Table 5). Results of Wilcoxon signed ranks tests did not show evidence of a difference in dyadic adjustment from T1 to T2 or from T2 to T3 for patients in either the PaTH or usual care groups (see Table 5).

Comparisons between patients by group.

The next step was to compare patients in the PaTH versus usual care groups for differences in HRQOL outcomes. Change scores were computed for each of the dependent variables between T1 and T2 and between T2 and T3 so that group (PaTH or usual care) differences could be examined using Mann-Whitney U tests. There was no

evidence of a difference between patients in the PaTH group versus the usual care group on the three HRQOL variables over time (see Table 6).

Table 5. Changes in Patients' HRQOL Subscale Scores over Three Time Points Using Wilcoxon Signed Ranks Tests

	T1	T2	z	p	T2	T3	z	p
PaTH (n = 17)								
PF								
Mean	53.5	84.7			84.7	85.0		
SD	23.2	12.4			12.4	15.8		
Median	55	85	-3.52	<.001	85	90	-0.04	.97
Range	15-95	50-100			50-100	40-100		
PHQ-9								
Mean	4.1	1.6			1.6	1.6		
SD	3.8	1.2			1.2	1.5		
Median	4	2	-2.85	.004	2	1	-0.05	.96
Range	0-15	0-3			0-3	0-4		
DAS-7								
Mean	27.4	27.2			27.2	27.5		
SD	5.7	4.2			4.2	5.5		
Median	28	28	-0.60	.55	28	28	-0.97	.33
Range	11-33	17-33			17-33	17-32		
	T1	T2	z	p	T2	T3	z	p
Usual Care (n = 17)								
PF								
Mean	53.5	82.6			82.6	81.2		
SD	27.3	17.7			17.7	24.1		
Median	55	90	-3.23	.001	90	95	-0.44	.66
Range	10-100	50-100			50-100	40-100		
PHQ-9								
Mean	5.0	2.8			2.8	2.8		
SD	5.9	4.7			4.7	3.3		
Median	2	1	-2.56	.01	1	2	-1.19	.23
Range	0-19	0-19			0-19	0-10		
DAS-7								
Mean	25.6	27.2			27.2	26.3		
SD	3.7	4.2			4.2	4.1		
Median	26	28	-1.55	.12	28	28	-0.95	.34
Range	19-32	18-34			18-34	16-35		

Note: SD = Standard Deviation, T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ = Patient Health Questionnaire (9-item), DAS= Dyadic Adjustment Scale (7-item), PaTH = Partners Together in Health group.

Table 6. Comparisons of Patients in the PaTH versus the Usual Care Groups on the HRQOL Variables.

Aim One: Patients	n	Mean Rank	Mann- Whitney z	p	Mean Rank	Mann- Whitney z	p
			T1 - T2			T2 - T3	
PF							
PaTH	17	17.68	-0.10	.92	17.09	-0.24	.81
Usual care	17	17.32			17.91		
PHQ-9							
PaTH	17	17.91	-0.53	.60	17.80	-0.75	.45
Usual care	16	16.15			15.35		
DAS-7							
PaTH	17	20.18	-1.58	.12	19.97	-1.46	.14
Usual Care	17	14.82			15.03		

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item). PaTH = Partners Together in Health group.

Patients' HRQOL by CR site.

Additional analyses were examined by site because a significant difference ($z = -3.85$, $p = .000$) was found between the CR sites for the median number of days between the patients' date of surgery and the first CR session. The descriptive and comparative results for patients' HRQOL scores at the two CR sites are found in Table 7. On average, patients at Methodist, who started CR earlier, had worse (mean and median) physical function and depression scores at baseline than patients at NMC. However, at each time point there was no evidence of a difference between groups at NMC and Methodist Hospital on any of the HRQOL variables by Mann-Whitney U test statistics for independent samples (see Table 7). By 3 and 6 months, patients at Methodist had similar scores for physical function and depression as patients at NMC.

Table 7. Comparisons of Patients' HRQOL Subscale Scores by CR Site at the Three Time Points Using Mann-Whitney Tests

Patients by Site	n	Mean	SD	Median	Range	z	p
Time 1							
PF							
NMC	9	63.3	23.3	65.0	25-100	-1.47	.14
Methodist	25	50.0	25.0	45.0	10-95		
PHQ-9							
NMC	9	2.1	2.1	1.0	0-6	-1.83	.07
Methodist	25	5.8	5.5	4.0	0-19		
DAS-7							
NMC	9	25.8	6.9	28.0	11-33	-0.08	.94
Methodist	25	26.8	3.9	27.0	19-33		
Time 2							
PF							
NMC	9	85.6	14.9	90.0	55-100	-0.57	.57
Methodist	25	83.0	15.4	90.0	50-100		
PHQ-9							
NMC	9	1.2	1.4	1.0	0-4	-0.98	.33
Methodist	24	2.5	4.1	2.0	0-19		
DAS-7							
NMC	9	27.4	4.7	29.0	17-33	-0.53	.62
Methodist	24	27.1	4.0	27.0	18-34		
Time 3							
PF							
NMC	9	80.0	28.2	90.0	15-100	-0.36	.72
Methodist	25	84.2	17.1	90.0	40-100		
PHQ-9							
NMC	9	2.8	2.8	3.0	0-8	-0.77	.44
Methodist	24	2.0	2.6	1.0	0-10		
DAS-7							
NMC	9	25.0	6.2	28.0	17-35	-0.92	.38
Methodist	25	27.6	4.1	28.0	16-33		

Note: SD = Standard Deviation, Time 1 = close to start of CR, Time 2 = end of CR, and Time 3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), NMC = Nebraska Medical Center.

The next step was to compare differences between the PaTH patients at the two sites and between the usual care CR patients at the two sites on changes over time in HRQOL outcomes. There was no evidence of a difference, using Mann Whitney U statistics, between patients in the PaTH group at either site, or for patients in the usual

care group at either site for changes between T1 and T2 or changes between T2 and T3 in physical, psychological, or relational HRQOL outcomes (see Table 8).

Table 8. Comparisons of Patients by Group and Site on HRQOL Variables

Patients	n	Scale	Mean Ranks	Mann- Whitney z	p	Mean Ranks	Mann- Whitney z	p
			T1 – T2	T2 – T3				
PaTH								
NMC	5	PF	13.0	-1.83	.07	12.1	-1.45	.15
Methodist	12		7.8			8.0		
NMC	5	PHQ-9	7.9	-0.31	.76	6.3	-0.94	.35
Methodist	12		8.7			8.6		
NMC	5	DAS-7	6.1	-1.32	.19	9.0	.00	1.0
Methodist	12		9.9			9.0		
Usual Care								
NMC	4	PF	9.7	-0.37	.71	9.4	-0.21	.83
Methodist	13		8.7			8.8		
NMC	4	PHQ-9	6.2	-1.49	.14	7.0	-1.07	.28
Methodist	12		10.2			9.8		
NMC	4	DAS-7	8.8	-0.11	.92	10.7	-0.91	.36
Methodist	13		9.1			8.3		

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), NMC = Nebraska Medical Center.

Results: Aim Two

The second aim was to examine the differences between partners in the PaTH and usual care CR groups in changes over time in physical, psychological, and relational HRQOL. The descriptive and comparative results of partners' HRQOL subscale scores are displayed in Table 9. Subscale scores and data analyses for Aim Two were computed in the same manner as described in Aim One analyses, except using partner data.

Physical function.

Partners in both groups reported high levels of physical function at all three time points (see Table 9). The results of the Wilcoxon signed ranks tests indicated that partners in the PaTH group had significant improvement in physical function between T1 (median = 85.0) and T2 (median = 95.0) ($z = -1.99$, $p = .046$); and there was no evidence of a difference in physical function for partners in the usual care group between T1 and T2. In addition, there was no evidence of a difference in physical function for partners in either group between T2 and T3, using Wilcoxon signed rank tests (see Table 9).

Depression.

Partners' depression scores indicated relatively low levels of depression across the three time points (see Table 9). Mean and median subscale scores were remarkably low, indicating minimal depressive symptoms (subscale scores 0-4 range) (Kroenke et al., 2001). There was no evidence of a difference between the PaTH and usual care partners' depression scores between T1 and T2, or between T2 and T3, by Wilcoxon signed rank test analyses for two related samples (see Table 9). Only two partners (12%) in the usual care group reported depression scores above the PHQ-9 cut-off point (PHQ-9 score ≥ 10) (Gilbody et al., 2007; Kroenke et al., 2001; Kroenke et al., 2010) at T1. There were no partners above this depression cut-off point at T2 or T3.

Dyadic adjustment.

Partners' mean and median dyadic adjustment scores indicated moderately high marital adjustment for all three data collection times (see Table 9). The results of the Wilcoxon signed rank tests indicated that there was no evidence of a difference in dyadic

adjustment from T1 to T2 or from T2 to T3 for partners in either the PaTH or usual care groups (see Table 9).

Table 9. Changes in Partners' HRQOL Subscale Scores between Time Points Using Wilcoxon Signed Ranks Tests

Partners	T1	T2	z	p	T2	T3	z	p
PaTH (n = 17)								
PF								
Mean	85.3	90.5			90.5	91.4		
SD	14.8	11.3			11.3	9.8		
Median	85	95	-1.99	.046	95	95	-0.59	.56
Range	50-100	65-100			65-100	70-100		
PHQ-9								
Mean	1.8	0.9			0.9	1.4		
SD	2.6	1.4			1.4	1.6		
Median	0	0	-1.37	.17	0	2	-1.22	.22
Range	0-9	0-5			0-5	0-6		
DAS-7								
Mean	26.4	27.2			27.2	26.2		
SD	6.5	5.6			5.6	5.2		
Median	28.5	29	-1.27	.21	29	29	-0.86	.39
Range	13-34	17-33			17-33	17-33		
	T1	T2	z	p	T2	T3	z	p
Usual Care (n = 17)								
PF								
Mean	84.1	86.2			86.2	89.4		
SD	22.7	17.5			17.5	14.3		
Median	95	90	-0.63	.53	90	95	-0.98	.32
Range	15-100	40-100			40-100	45-100		
PHQ-9								
Mean	2.9	2.0			2.0	2.0		
SD	5.2	3.1			3.1	2.2		
Median	1	0.5	-1.28	.20	0.5	1	-0.42	.67
Range	0-20	0-9			0-9	0-6		
DAS-7								
Mean	25.7	26.2			26.2	27.6		
SD	5.2	3.6			3.6	5.0		
Median	26.5	26.5	-0.09	.93	26.5	28	-0.60	.55
Range	9-32	19-31			19-31	15-33		

Note: SD = Standard Deviation, T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), PaTH = Partners Together in Health group.

Comparisons between partners by group.

The next step was to compare the partners in PaTH and partners in usual care CR groups for differences in HRQOL outcomes over time. Change scores were computed for each of the dependent variables between T1 and T2 and between T2 and T3 so that group (PaTH or usual care CR) differences could be examined using Mann-Whitney U tests. There was no evidence of a difference between partners in the PaTH or usual care groups on the three HRQOL variables over time (see Table 10).

Table 10. Comparisons of Partners in the PaTH versus the Usual Care Groups on the HRQOL Variables

Aim Two: Partners		Mean Rank	Mann- Whitney		Mean Rank	Mann- Whitney	
	n		<i>z</i>	<i>p</i>		<i>z</i>	<i>p</i>
			T1 – T2		T2 – T3		
PF							
PaTH	17	16.21	-0.77	.44	18.24	-0.46	.65
Usual care	17	18.79			16.76		
PHQ-9							
PaTH	16	17.38	-0.24	.81	19.26	-1.09	.28
Usual care	17	16.59			15.74		
DAS-7							
PaTH	16	15.16	-0.82	.41	17.38	-0.07	.94
Usual Care	16	17.84			17.62		

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item).

Partners' HRQOL by CR site.

Although partners were randomly assigned to the PaTH or usual care CR groups (along with their patient-spouses), they were not randomly assigned to the site of the CR intervention. It was previously established that patients entered the Methodist Hospital site significantly ($z = -3.85$, $p = .000$) earlier than patients at NMC ($M = 11$ days vs. 21

days post-CAB surgery). In addition, the Methodist CR program had an established 'partner program' which allowed all partners to exercise in the facility. Although partners in the usual care Methodist CR group did not receive individual counseling, exercise prescription, and monitoring, this variation on the planned intervention and usual care methods of the parent study may have impacted outcomes also. Therefore, data analyses were performed comparing partners in the NMC and Methodist cohorts. The descriptive results of partners' HRQOL scores at each CR site are described in Table 11.

Partners at NMC and Methodist Hospital CR sites had fairly high physical function scores at all three time points (see Table 11). Similarly, depression scores were low at all three time points for partners at both clinical sites. For dyadic adjustment, partners at both clinical sites reported fairly high marital adjustment at all three time points. There was no evidence of a difference between partners at NMC or Methodist Hospital at any time point for any of the HRQOL variables using Mann-Whitney U test statistics for independent samples (see Table 11).

Comparisons of Partners in PaTH and Usual Care CR by site.

The next step was to compare differences between the partners in the PaTH group at the two sites (see Table 12) and between the partners in the usual care group at the two sites (see Table 13) on changes in the HRQOL outcomes between T1 and T2 and between T2 and T3. Using Mann-Whitney U tests, there was no evidence of differences between partners in the Path group at either site for physical function, depression, or dyadic adjustment (see Table 12).

However, there was evidence of differences between partners in the usual care group at NMC and Methodist sites for physical function and depression between T2 and

T3 (see Table 13). Partners in the usual care group at NMC reported greater physical function mean and median difference scores than partners in usual care at Methodist Hospital ($M = -14$ vs. 1.3 ; $Median = -10$ vs. 0) ($z = -2.47$, $p = .013$) (see Table 13).

Partners in the usual care group at NMC reported greater depression change scores ($Mean = 1.4$, $Median = 0$) between T2 and T3 compared to usual care partners at Methodist ($Mean = -0.3$, $Median = 0$) ($z = -2.0$, $p = .045$) (see Table 13). This indicates that the partners in the usual care group at NMC reported a greater amount of change between T2 and T3 for physical function and depression than partners in usual care at Methodist. To further analyze these differences between partners in the usual care group, descriptive data for subscale scores were examined (see Table 14). This showed that while partners in usual care at NMC made greater improvement in change scores from T2 to T3 for physical function and depression (see Table 13), their scores were worse (lower physical function scores and higher depression scores) at all three time points compared to partners in usual care at Methodist (see Table 14). There was no evidence of a difference between sites for usual care partners' dyadic adjustment from T1 and T2 or from T2 and T3 (see Table 12).

Table 11. Comparisons of Partners' HRQOL Subscale Scores by CR Site at the Three Time Points Using Mann-Whitney Tests

Partners by Site	n	Mean	SD	Median	Range	z	p
Time 1							
PF							
NMC	9	77.2	29.2	90.0	15-100	-0.52	.60
Methodist	25	87.4	13.4	95.0	50-100		
PHQ-9							
NMC	9	3.0	6.5	.00	0-20	-0.49	.62
Methodist	24	2.1	2.9	1.0	0-10		
DAS-7							
NMC	8	24.6	8.7	28.0	9-32	-0.22	.83
Methodist	24	26.5	4.6	26.5	13-34		
Time 2							
PF							
NMC	9	77.8	22.4	85.0	40-100	-1.86	.06
Methodist	25	92.0	8.5	95.0	70-100		
PHQ-9							
NMC	9	2.0	4.0	.00	0-9	-1.02	.31
Methodist	25	1.2	1.6	1.0	0-6		
DAS-7							
NMC	9	25.9	5.5	26.5	18-33	-0.35	.72
Methodist	25	26.9	4.4	27.0	17-33		
Time 3							
PF							
NMC	9	85.6	17.4	90.0	45-100	-1.07	.29
Methodist	25	92.2	9.5	95.0	65-100		
PHQ-9							
NMC	9	1.3	2.4	.00	0-6	-1.31	.19
Methodist	25	1.8	1.7	.20	0-6		
DAS-7							
NMC	9	25.0	6.1	28.5	15-30	-1.14	.25
Methodist	25	27.5	4.6	28.5	17-33		

Note: SD = Standard Deviation, Time 1 = close to start of CR, Time 2 = end of CR, and Time 3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), NMC = Nebraska Medical Center.

Table 12. Differences between Partners in PaTH Group by Site between Time 1 and Time 2 and Time 2 and Time 3

Partners in PaTH	n	Mean	SD	Median	Mean Ranks	Mann- Whitney z	p
T1-T2							
PF							
NMC	5	-2.5	6.5	-2.5	9.5	-0.24	.81
Methodist	12	-6.2	13.1	0.0	8.9		
PHQ-9							
NMC	5	0.5	1.0	0.0	8.8	-0.12	.90
Methodist	11	1.1	3.3	0.0	9.1		
DAS-7							
NMC	5	-1.8	2.5	-1.5	6.7	-0.92	.36
Methodist	12	-1.4	4.0	0.0	9.1		
T2-T3							
PF							
NMC	5	0.0	7.1	2.3	10.5	-0.74	.46
Methodist	12	-1.2	5.1	0.0	8.5		
PHQ-9							
NMC	5	-0.3	0.5	0.0	10.4	-0.64	.52
Methodist	12	-0.6	1.9	-1.0	8.6		
DAS-7							
NMC	5	-0.3	3.3	0.5	10.9	-0.86	.39
Methodist	12	-0.5	2.3	0.8	8.4		

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), NMC = Nebraska Medical Center.

Table 13. Differences between Partners in the Usual Care Group by Site between Time 1 and Time 2 and Time 2 and Time 3

Partners in Usual Care		n	Mean	SD	Median	Mean Ranks	Mann-Whitney	p
							z	
T1-T2								
PF								
NMC	4	1.0	35.2	0.0	9.1	-0.05	.96	
Methodist	13	-3.3	12.9	0.0	9.0			
PHQ-9								
NMC	4	1.4	6.1	0.0	8.9	-0.23	.81	
Methodist	13	0.6	1.7	0.0	8.3			
DAS-7								
NMC	4	-0.8	8.3	2.0	10.3	-0.85	.39	
Methodist	12	-0.4	-0.5	2.5	7.9			
T2-T3								
PF								
NMC	4	-14.0	17.8	-10.0	4.5	-2.47	.013	
Methodist	13	1.3	6.1	0.0	10.9			
PHQ-9								
NMC	4	1.4	1.9	0.0	12.5	-2.00	.045	
Methodist	13	-0.3	1.3	0.0	7.5			
DAS-7								
NMC	4	1.0	4.0	-1.0	9.9	-0.48	.63	
Methodist	13	-0.6	1.8	-0.5	8.6			

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), NMC = Nebraska Medical Center.

Table 14. Mean and Median HRQOL Subscale Scores for Usual Care Partners by Site

Partners Usual Care	T1			T2			T3		
	n	Mean	Median	n	Mean	Median	n	Mean	Median
NMC									
PF	4	72.0	95.0	4	71.0	85.0	4	85.0	95.0
PHQ-9	4	5.0	2.0	4	3.6	0.0	4	2.2	0.0
DAS-7	4	23.0	26.5	4	24.2	25.0	4	23.2	27.0
Methodist									
PF	13	89.1	95.0	13	92.5	92.5	13	91.2	95.0
PHQ-9	13	2.0	1.0	13	1.4	1.0	13	1.8	1.0
DAS-7	12	26.5	26.5	13	27.0	27.0	13	27.6	28.5

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item), NMC = Nebraska Medical Center.

Results: Aim Three

The third aim was to examine the differences in physical, psychological, and relational HRQOL between patients and partners as couples, separately by group: (a) PaTH intervention and (b) usual care CR. Descriptive data for patients are displayed in Table 5 and in Table 9 for partners, and therefore these data were not repeated here. To analyze the couple data, a difference score was computed for each variable within the couple. Wilcoxon signed rank tests for two related samples were run to compare the couples in the PaTH (see Table 15) and usual care (see Table 16) groups.

Couples in the PaTH Group.

There was evidence of a difference between couples for physical function at T1 in the PaTH group ($z = -3.2, p = .001$) (see Table 15). The physical function subscale scores for PaTH couples indicated that the partners' physical function score (median = 85) (see Table 9) was higher than the patients' physical function score (median = 55) (see Table 5) at T1, accounting for the significant finding (see Table 15). There was no evidence of

a difference for couples in the PaTH group for any other HRQOL variable at each time point (see Table 15).

Table 15. Comparisons of Couples in the PaTH Group Using Wilcoxon Signed Ranks Tests

Couples in PaTH	n	Negative Sum of Ranks	Positive Sum of Ranks	z	p
Time 1					
PF	34	6.0	130.0	-3.2	.001
PHQ-9	34	103.5	32.5	-1.84	.07
DAS-7	33	81.0	39.0	-1.21	.23
Time 2					
PF	34	32.5	87.5	-1.58	.12
PHQ-9	34	61.0	17.0	-1.75	.08
DAS-7	33	46.5	44.5	-0.07	.94
Time 3					
PF	34	26.0	79.0	-1.69	.09
PHQ-9	34	44.5	33.5	-0.44	.66
DAS-7	33	39.0	39.0	0	1.00

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item).

Couples in the Usual Care Group.

There was evidence of a difference between couples for physical function at T1 in the usual care CR group ($z = -2.7$, $p = .006$) (see Table 16). The physical function subscale scores for couples in the usual care group indicated that the partners' physical function score (median = 95) (see Table 9) was higher than the patients' physical function score (median = 55) (see Table 5) at T1, accounting for the significant finding. There was no evidence of a difference for couples in the usual care group with any other HRQOL variable at each time point (see Table 16).

Table 16. Comparisons Couples in the Usual Care Group Using Wilcoxon Signed Ranks Tests

Couples in Usual Care	n	Negative Sum of Ranks	Positive Sum of Ranks	z	p
Time 1					
PF	34	18.5	134.5	-2.7	.006
PHQ-9	32	58.0	33.0	-0.89	.38
DAS-7	33	59.0	61.0	-0.06	.96
Time 2					
PF	34	39.0	66.0	-0.86	.39
PHQ-9	32	45.5	32.5	-0.51	.61
DAS-7	33	93.0	27.0	-1.90	.06
Time 3					
PF	34	16.0	62.0	-1.84	.06
PHQ-9	32	67.5	37.5	-0.95	.35
DAS-7	33	50.5	27.5	-0.93	.35

Note: T1 = close to start of CR, T2 = end of CR, and T3 = 3 months after CR. PF = Physical Function subscale (SF-36), PHQ-9 = Patient Health Questionnaire (9-item), DAS-7 = Dyadic Adjustment Scale (7-item).

Results: Aim Four

The final aim of this study was to examine differences between PaTH and usual care CR patients' exercise performance as measured by submaximal treadmill exercise performance from baseline to end of the CR program. The mean and median treadmill METs were calculated for sessions numbered 4, 5, and 6 and for the last three CR sessions (see Table 17). Wilcoxon signed ranks tests were computed for two related samples, to examine the paired data in the PaTH patients and then in the usual care patients (see Table 17). Patients in both the PaTH and usual care groups showed significant improvements in exercise performance from the start to finish of the CR program (see Table 17).

Table 17. Comparisons of Patients' Submaximal Treadmill Exercise Performance from Baseline to Final Three Exercise Sessions by Group Using Wilcoxon Signed Ranks

Patients	Mean METS	Median METS	Range	Negative Sum of Ranks	Positive Sum of Ranks	z	p
PaTH (n=17)							
Sessions 4-6	2.9	2.8	2.0 - 4.1	0	136	-3.52	<.001
Final 3 sessions	4.5	4.6	2.6 - 6.5				
Difference Score	1.6	1.4					
Usual Care (n=16)							
Sessions 4-6	3.0	3.0	2.1 - 4.6	0	136	-3.52	<.001
Final 3 sessions	4.3	4.1	2.7 - 5.8				
Difference Score	1.3	1.4					

Note: CR Sessions number 4-6 and last 3 CR sessions. METs = metabolic equivalents. Difference score = computed difference of treadmill exercise performance for the final 3 sessions minus sessions #4-6.

Next, the results of Mann-Whitney U tests for independent samples indicated there was no evidence of differences between patients in the PaTH and usual care CR groups for submaximal exercise performance at baseline ($z = -0.18$, $p = .86$) or the final 3 sessions ($z = -0.56$, $p = .58$) (see Table 18). Also, there was no evidence of a difference between patients in either group using the difference score for exercise performance from baseline to the end of CR. Examining the mean scores overtime, there was a 55% improvement in treadmill exercise performance for patients in the PaTH group from baseline to the end of CR, compared with a 43% improvement for patients in the usual care group (1.6 vs. 1.3 METs).

Table 18. Comparisons of Patients' Submaximal Treadmill Exercise Performance from Baseline to Final Three Exercise Sessions between Groups

	Mann-Whitney			
	n	Mean Ranks	z	p
Sessions # 4-6				
PaTH	17	16.71	-0.18	.86
Usual Care	16	17.31		
Last 3 sessions				
PaTH	16	17.91	-0.56	.58
Usual Care		16.03		
Difference between final & baseline				
PaTH	17	18.09	-0.67	.51
Usual Care	16	15.84		

Key: CR Sessions number 4-6 and last 3 CR sessions. METs = metabolic equivalents.

Chapter Five

This chapter will discuss the major findings of each aim relative to published literature. In addition, the study's strengths and limitations will be identified; and also recommendations for future research and clinical practice. This study was an analysis of the secondary outcomes for the PaTH intervention primary study by Yates (2009).

Aim One

The first aim of this study was to examine the differences between patients in two groups (PaTH intervention vs. usual care groups) in changes overtime from T1 to T2, and from T2 to T3 in physical, psychological, and relational HRQOL outcomes.

Patients' Physical Function.

Physical function for patients in both groups was found to significantly improve from the beginning to the end of the CR program. Similar findings of early improvement in physical functioning occurring in the first weeks through 3 months have been reported in patients with CHD (Kristofferzon et al., 2005a), CAB surgery (Barnason et al., 2000, DiMattio & Tulman, 2003; Rantanen et al., 2009), and for those patients enrolled in CR programs (Hsu et al., 2011; McKee, 2009; Morrin et al., 2000).

In our study, baseline PF scores indicated moderate levels of physical functioning at the start of CR (PaTH: $M = 53.5$, Usual Care: $M = 53.5$). Comparing our results to those of other studies that used the PF subscale, Muller-Nordhorn et al. (2004) reported very similar PF scores ($M = 54$) in patients who entered CR programs about three weeks after CAB surgery. Two other studies found slightly higher, but still moderate levels of physical functioning in CAB surgery patients at baseline. A mean PF mean score of 60.0 was reported by Hsu et al. (2011) for CAB surgery patients at the start of a 6-week CR

program. Patients with CHD, including MI, CAB surgery and PCI, began CR with a mean PF score of 67.5 (McKee, 2009), and 62.7 (Morrin et al., 2000). One study reported that pre-operative physical functioning, measured in the hospital after CAB surgery, was also reduced ($M = 63.1$) (Barnason et al., 2000). Therefore our patients began the CR program with somewhat lower physical functioning levels than other published findings, despite similar age and gender demographics.

Barnason et al. (2000) found that CAB surgery patients with two or more comorbidities had significantly lower levels of physical functioning pre-operatively, but comorbidities did not impact physical function over time. In our study, the most prevalent comorbidity was arthritis, affecting 41% ($n = 14$) of patients, which may have influenced physical function. Few patients in our study reported other comorbidities, with 18% ($n=3$) reporting COPD and 18% ($n=3$) reporting PVD, that may have impacted physical function. Specific comorbidities were not reported in the studies by Muller-Nordhorn et al. (2004), McKee (2009), and Hsu et al. (2011).

Comparing this study with other studies from baseline to 3 months post CHD event, patients in this study achieved a high level of physical function (PaTH: $M = 84.7$; Usual Care: $M = 82.6$) at the completion of the CR program. McKee (2009) reported a PF mean score of 74.4 for CHD patients after a 6-week CR program (approximately 10-12 weeks post-CHD event). A mean PF score of 78.7 was reported for CHD patients following a 3-month CR program (Morrin et al., 2000). Similar results were reported by Hsu et al. (2011) with mean PF scores of 73.4 ($SD = 18.0$) in CAB surgery patients after a 12-week CR program. Therefore patients in our study had slightly higher levels of physical function following CR compared to patients in these two studies. In the study

by Barnason et al. (2000), a mean PF score of 80.7 ($SD = 15.0$) was reported at 3 months after hospitalization for CAB surgery. Patients in our study and the Barnason et al. (2000) study were both from Midwestern U.S. hospitals and cardiac referral centers, and the mean PF scores at 3 months were more similar than the other three studies conducted in Canada (Morrin et al., 2000), the U.K. (McKee, 2009) and Taiwan (Hsu et al., 2011). Overall, these studies reported that patients typically improved their physical function in the first 3 months following a CHD event, or CAB surgery. This same finding of physical function improvement during the first 3 months was recently summarized in an integrative literature review that examined the trajectory of recovery for cardiac patients (Barnason et al., 2012).

There were less consistent findings for improvement in physical function 6 months following the CHD event. In our study, there was no evidence of improvement in physical function in patients in both groups between the end of CR and 3 months after CR was completed. Three months after the CR program (T3), patients in the PaTH group reported a mean PF score of 85.0 and the usual care mean PF score was 81.2 in this study. Compared to our study, Morrin et al. (2000) reported mean PF score of 80.1 at 6 months. Similarly, there was no significant improvement in physical function from 3 months to 6 months in these patients with CHD. Patients in our study were found to have relatively higher levels of physical function at 6 months (T3), compared to several other studies. Muller-Nordhorn et al. (2004) reported mean PF score of 66.0 at 6 months following CAB surgery and a 3-week CR program. Barnason et al. (2000) reported CAB surgery patients' mean PF score of 89.0 at 6 months post-surgery, compared to 80.7 at 3

months; with follow-up repeated measures indicating lower scores at 3 months compared to the 6 month functional level.

Although this study did not examine changes in physical function beyond 6 months after CAB surgery, several studies report conflicting findings over time from baseline to 6 and 12 months following a CHD event (Barnason et al., 2000; Grady et al., 2011; Muller-Nordhorn et al., 2004). The majority of studies suggest that patients' physical function tends to peak at 3 months and is generally maintained at 6 months. However, because there are conflicting findings about significant improvements in physical function between 3 and 6 months and beyond, future studies are needed to continue to follow patients through 12 months to determine whether improvements in physical function are maintained.

Patients' Depression.

Patients in both groups showed evidence of improvement in depression from the start to end of CR. However, the PHQ-9 subscale scores indicated very minimal levels of depression (score 0-4) (Kroenke et al., 2001). Depression has been found to be a barrier to CR participation (Ades, Waldmann, McCann, & Weaver, 1992) and in this study may have resulted in fewer depressed patients being recruited at baseline. When PHQ-9 descriptive data were examined at baseline, 18% (n = 6) of patients were categorized at the depression cut-off point (PHQ-9 score ≥ 10) (Gilbody et al., 2007; Kroenke et al., 2001; Kroenke et al., 2010). Using this PHQ-9 cut-off, Ruo et al. (2003) found 20% of patients with stable CAD in outpatient clinics were classified as *depressed*; and the 12-month depression prevalence in cardiac patients was reported to be 9.3% (Lichtman et al., 2008). For CAB surgery patients specifically, a literature review by Pignay-Demaria et

al. (2003) reported that pre-operative depression prevalence was 27% to 47%, and post-CAB surgery prevalence was 19 to 61%. One month post CAB surgery, 13% to 53% of patients were depressed, depending on if they were not depressed or they were depressed pre-operatively (McKhann, Borowicz, Goldsborough, Enger & Selnes, 1997). In another study, 23% of patients were depressed when measured with the CES-D at 6 months post-CAB surgery (Pirraglia, Peterson, Williams-Russo, Gorkin, & Charlson, 1999).

Predictors of major depression and depressive symptoms post-CAB surgery include lack of social support, at least one stressful life event, low education level, and greater than moderate dyspnea (Pignay-Demaria et al., 2003; Pirraglia et al., 1999). Therefore, the prevalence of depression in our study was comparable to the low range identified by Pignay-Demaria et al. (2003), and comparable to outpatients with stable CAD (Ruo et al., 2003).

Our study found no evidence of a difference in patients' depression between the PaTH and usual care groups from the start to the end of CR, and between the completion of CR to 3 months following the CR program. Subsequent examination of PHQ-9 descriptive data showed that only one (3%) patient remained in the *moderately-severe* category (score 19) at the end of CR but reduced to minimal depression at 3 months after CR. Three months' after CR, only one (3%) patient remained at a *moderate* level of depression. Once depression has been identified, the cut-point is used to refer patients to treatment, including medical referrals, medication, and/or counseling (Lichtman et al., 2008). Treatment interventions for patients who screened positive for depression in our study were not identified, and somewhat limits the interpretation of changes in depression over the course of the study.

The PHQ-9 survey was recommended for screening depression in patients with CHD in primary care settings such as physician offices, outpatient clinics, and cardiac rehabilitation programs (Lichtman et al., 2008). When using the cut-off point (PHQ-9 ≥ 10) (Gilbody et al., 2007; Kroenke et al., 2001; Kroenke et al., 2010), the PHQ-9 has been found to have an 88% specificity and 88% sensitivity (likelihood ratio = 7.1) for major depressive disorder (Kroenke et al., 2001); and satisfactory sensitivity to change over time when used to monitor treatment (Kroenke et al., 2010). Because PHQ-9 scores between 10 and 15 “represent a gray zone” (Kroenke et al., 2001, p. 608) in the categorization of major depression, the authors examined the sensitivity, specificity, and likelihood ratios of various cut-points. Thus, a PHQ-9 cut-point of 9 yielded a 31% positive predictive value; while a PHQ-9 cut-point of 15 resulted in a 51% predictive value (Kroenke et al., 2001). In a recent meta-analysis of 17 validation studies, Gilbody et al. (2007) found that the PHQ-9 had good diagnostic properties for major depressive disorder in most medical populations except for cardiac patients. The one study (McManus et al., 2005) examined by Gilbody et al. (2007) found that the PHQ-9 had only 54% sensitivity and 90% specificity with a likelihood ratio of 5.4. That study by McManus et al. (2005) examined the test characteristics of 1024 patients with a history of MI or CAD being seen in outpatient clinics. In future studies, the PHQ-9 may need to be supplemented with other measures of depression to capture these patients’ depressive symptoms.

Many studies measure psychological HRQOL with other instruments. Rantanen et al. (2009) reported that CAB surgery patients’ depression improved from 1 to 6 months post-event using the “15 D” measure of HRQOL. Penckofer et al. (2005) found no

significant change in patients' depression from pre-CAB surgery to 3 months after surgery using the Quality of Life Index. Penckofer et al. (2005) noted that 53% of the sample continued to experience dyspnea, and 84% reported fatigue at 3 months; which they postulated may have been related to a fairly high incidence of diabetes (33%) and redo cardiac surgery (15%) in this sample of women. Kroenke et al. (2001) reported that the PHQ-9 survey correlated ($r = .73$) most highly with the Mental Health subscale of the SF-20. Although no studies were found using the SF-20, several studies used the Mental Health subscale of the SF-36 to detect change in mental HRQOL. While our study showed a significant change in depression from baseline to 3 months, Morrin et al. (2000) and Hsu et al. (2011) reported no significant differences in mental HRQOL over this time period. Many authors reported that psychological changes tended to improve later than physical changes after a cardiac event (Apostolakis et al., 2006; Morrin et al., 2000; Muller-Nordhorn et al., 2004). Because psychological variables have been operationalized to include emotional and psychological distress, well-being, anxiety, depression, and other forms of mental health status, comparisons of changes in depression across studies are limited.

Patients' Dyadic Adjustment.

In our study, patients in both groups rated their marital adjustment as *satisfactory* as described by Hunsley, Pinsent, Lefebvre, Janes-Tanner, & Vito (1995), in which the cut-off score of one standard deviation below the mean ($M = 25.6$, $SD = 4.8$) was used to classify subjects as *maritally distressed*. These cut-points were originally established by Spanier in 1976 during testing of the psychometric properties of the full length DAS (Hunsely et al., 1995). In a sample of 196 community dwelling married or co-habiting

adults, Hunsely et al. (1995) compared the construct validity of the DAS-7 with the full length DAS and three other short forms of marital adjustment. The DAS-7 was found to have satisfactory correlations with the full length DAS form, and used the previously established cut-points for *distressed* or *adjusted* relationships.

Patients' marital adjustment in our study showed very little change over time; with median DAS-7 scores ranging from 26 to 28, and mean scores ranging from 25.6 to 27.5 over the 3 time points. There was no evidence of a difference in dyadic adjustment between patients in both groups from the start to end of CR, or from the end of the CR program to 3 months later. When descriptive data were examined, 12% ($n=4$) of patients fell below the cut-point ($20.1 = 1\ SD$ below the M of 25.6) indicating *distressed* marital quality at all 3 time points of the study. The scores in the *distressed* category ranged from 11 to 20 for these four patients over time. The proportion of patients with *distressed* or *adjusted* marriages was not found in the literature that was reviewed for this paper; and therefore our findings add to the understanding of marital adjustment following CAB surgery. Future studies are needed to establish the validity of the *distressed* versus *adjusted* scores of the DAS-7 in CAB surgery patients and partners.

Dyadic adjustment was an especially important variable in this study because the intervention was couple-focused. Few studies of CHD or CAB surgery patients measure marital satisfaction or dyadic adjustment (Van Horn et al., 2002). The literature review investigating the trajectory of recovery from cardiac illness with couple-centered interventions by Van Horn et al. (2002) did not find improvements in family functioning and marital satisfaction overall. However, one of the studies reported in the Van Horn et al. (2002) review did report that marital adjustment for CAB surgery patients improved

from baseline to 6 months (Gilliss et al., 1990). Marital adjustment was measured with the Marital Adjustment Scale, and does not allow for comparisons of scores with our patients. The authors noted that family functioning decreased at 3 months post cardiac event, but had regained stability by 6 months.

Two studies that used the full length DAS in patients with CHD reported that better marital adjustment is associated with better psychological adjustment (Brecht et al., 1994; Moser & Dracup, 2004). Similarly, patients in our study were found to report good levels of marital adjustment and minimal depression. Often, relational HRQOL has been operationalized in a variety of ways such as family functioning, coping, social support, and marital adjustment or satisfaction (Kulik & Mahler, 1993; Mahrer-Imhoff et al., 2007). Thus, comparing the results of this study with other couple-centered intervention studies in terms of relational HRQOL was also limited.

Aim Two

The second aim of this study was to examine the differences between partners in two groups (PaTH intervention vs. usual care groups) in changes overtime from T1 to T2, and from T2 to T3 in physical, psychological, and relational HRQOL outcomes.

Partners' Physical Function.

Despite documented increases in physical burdens taken on by spouses and family members (Halm et al., 2006; Stewart et al., 2001), very few studies investigate physical function in the partners of CHD or CAB surgery patients. It was hypothesized for this study that partners in the PaTH intervention group would show greater levels of physical function than the usual care partners. Partners in the PaTH group showed evidence of significant improvement ($p = .046$) in physical function from T1 to T2. In contrast,

partners in the usual care group did not show evidence of a difference in physical function from T1 to T2.

Eighty-eight percent ($n = 15$) of partners in the PaTH group and 82% ($n = 14$) of partners in the usual care group were female. Findings from the Nurses' Health Study (NHS), which examined the HRQOL of over 54,000 women, indicated that increased physical activity was significantly associated with better PF scores on the SF-36 survey than those women who were not physically active, as measured in MET-hours per week (Michael, Colditz, Coakely, & Kawachi, 1999). Thus, one possibility that supports our finding that partners in the PaTH group showed a significant improvement from T1 to T2 was the addition of exercise that partners in the PaTH group received as part of the intervention. Physical function scores at baseline in this study were comparable to those in the NHS for women aged 60 to 64 years (PaTH: $M = 85.3$, usual care $M = 84.1$, NHS: 85.2) (Michael et al., 1999). In addition to physical activity, close personal relationships and group participation in the NHS were also related to better physical function (Michael et al., 1999); thus lending support to the improvement in PF scores between T1 and T2 for partners in the PaTH group who participated in CR with the patient-spouses. Despite improvements between T1 and T2 for partners in the PaTH group, there was no evidence of a difference in the median physical function scores between PaTH and usual care partners from T1 to T2.

Few studies were found that reported the PF scores of partners or caregivers. Often studies of caregivers of patients with other medical conditions such as stroke, cancer, and dementia focus on family-centered, versus couple-centered, interventions, because the caregiver may not be the spouse (Van Horn et al., 2002). Therefore even

fewer studies of partners' physical function were found. However one randomized trial of a family support intervention in the U.K did measure SF-36 subscales of stroke patients and their immediate caregivers 6 months after the patients' hospitalization (Mant, Carter, Wade, & Winner, 2000). Sixty-six percent (n=174) of these caregivers were female, compared to 85% in our study; and caregivers' mean age was 64.4 years, compared to 62.5 years in our study. Six months after the patient's stroke, caregivers in the intervention group had significantly better median PF scores than caregivers in the usual care group (90 vs. 80, $p<.025$). Although the authors stated that what caused the differences between the intervention and usual care groups was not clear, it was noted that caregivers in the intervention group had significantly higher median mental health scores than the control group, and they were more satisfied with knowledge about risk factors and stroke care. The median PF scores in this group of caregivers were lower than those found in our study at 6 months after CAB surgery (*Median* = 95). In addition this family-support intervention did not include a physical activity or exercise component as our study did. However the comparison of these findings in PF scores in couple-centered and family-centered interventions adds to our understanding of changes in the partners' and caregivers' physical function at 6 months.

Partners were compared with the SF-36 physical function U.S. normative values for healthy men and women between the ages of 55 and 64 years, because the median age of partners in the study sample was similar. The standardized 50th percentile (median) for this age group is a score of 85 (Ware et al., 1993). In this study, 35% (n = 12) of all partners fell below the U.S. physical function norm at T1, but improved to only 21% (n = 7) of partners scoring below the U.S. median at both T1 and T2.

Partners' Depression.

It was hypothesized for this study that partners in the PaTH intervention group would show better (lower) levels of depression than the usual care partners. Possible mechanisms for improved psychosocial HRQOL in the intervention group included increased social support and working together as a couple through the CAB surgery recovery (Brecht et al., 1994; Dracup et al., 1984; Rantanen et al., 2008, 2009).

However, partners' median PHQ-9 scores indicated very minimal levels of depression throughout the study time period; which, like patients, may have resulted from fewer partners with depressive symptoms agreeing to participate in the study. There was no evidence of differences in levels of depression between partners in the PaTH and usual care groups over time. In the general population, only 4.8% of people who do not have a comorbid illness were found to have major depression; compared to a prevalence range of 8% to 17% for those people with a chronic illness (Lichtman et al., 2008). In our study, less than 6% ($n = 2$) of partners were classified as having depression at baseline, which is comparable to Lichtman's (2008) findings; no partners scored above the PHQ-9 cut-off for depression at T2 or T3. The sensitivity of the PHQ-9 instrument may have limited the findings for depression in this study; and while it may be useful as an initial screening tool, other instruments for measuring psychological HRQOL may be more useful in this essentially healthy, adult sample.

In the few studies that were found that included levels of depression in partners of CHD patients, O'Farrell et al. (2000) reported that 66% of CAB surgery spouses were psychologically distressed in a cross-sectional study of CR patients and their partners. In that study the authors found that psychologically distressed spouses were more likely to

be younger ($M = 52$ years), used “disengaged coping strategies” such as withdrawal and avoidance, and had less intimacy in their marriages than spouses with better psychological HRQOL (O’Farrell et al., 2000, p. 101). In a longitudinal study of patient-family member dyads, Lenz and Perkins (2000) reported that 44% of caregivers were depressed at baseline, and 19% remained depressed 3 months later as measured with the CES-D. A significant increase in cardiac complications and the continued problems with sleep and pain in the patients in the study sample were believed to influence these results, and may have influenced the partners’ depressive outcomes as well. Rantanen et al. (2008; 2009) reported that CAB surgery significant others had the highest levels of depression at 1 month, with improvement in depression at 6 and 12 months following the cardiac event; proportions of depressed versus not depressed subjects were not reported. Rantanen et al. (2009) did not find that support from social networks was associated with changes in HRQOL from baseline to 12 months after CAB surgery. However, that study did not indicate who the members of the social network included; and one aspect focused on the level and type of support from nurses on the ward at the time of hospitalization. Thus, comparisons with our study are limited by the differences in instruments used to examine psychological HRQOL, particularly depression, the type and quality of the patient-partner dyads, and the minimal level of depression found in partners in our study at baseline and beyond.

Partners’ Dyadic Adjustment.

There was no evidence of a difference in dyadic adjustment over time for partners in either group. Partners’ mean and median dyadic adjustment scores were within the *adjusted* category ($M > 20.8$) (Hunsley et al., 1995) for all 3 data collection times.

However, 11.8% (n=4) of all partners rated their marriages as *distressed* ($M \leq 20.8$) at T1, and 14.7% (n=5) at T2 and T3. Hunsley et al. (1995) reported that 16% of a community sample was found to be maritally *distressed* when using the cut-off point of one standard deviation below the mean. That Canadian community sample was younger ($M = 29.3$, *Range* 18-57 years) than partners in our study, but had similarly high levels of education. Typically, marital adjustment tends to stabilize in older subjects; but a subset of maritally distressed couples was reported in a literature review of marital dissatisfaction (Gagnon, Hersen, Kabacoff, & Van Hasselt, 1999). Although representing a small segment of the total sample, a subset of maritally distressed partners was identified in our study and future research examining this subgroup may be beneficial to understanding HRQOL outcomes in patient-partner dyads.

Few studies were found that measured CHD partners' marital quality. Typically, couple-oriented interventions measured dyadic adjustment only from the patients' point of view (Brecht et al., 1994; Kulik & Mahler, 1993). One study that investigated marital adjustment in both patients with cardiac surgery (CAB, heart valve, or combination surgery) and spouses, found that patients' scores improved while spouses' scores worsened from baseline (preoperative) to 6 months following surgery (Gilliss et al., 1990). The authors postulated that worsening mood states such as depression may be responsible for these findings, although psychological HRQOL was not measured in their study. Two qualitative studies investigated the impact of cardiac events upon marital quality and satisfaction for both the patient and the partner (Mahrer-Imhoff et al., 2007; Panagopoulou et al., 2009). However, these studies focused on the meanings that couples

attached to the cardiac events in relation to their marital satisfaction, making comparisons with this study difficult.

Partners HRQOL Differences by CR Site

In this study, there was no evidence of a difference between partners in the PaTH group at NMC and Methodist Hospital CR sites for any of the HRQOL variables between T1 and T2 or between T2 and T3. However, there was a significant difference in change scores for physical function between partners in usual care at NMC and Methodist Hospital. Examination of the descriptive data found that partners in usual care at NMC had worse mean and median PF scores at all 3 time points than partners at Methodist. There was a trend for partners in both groups to decrease PF scores at T2, and then improve at T3. However, since the difference in physical function was noted to occur from the end of CR to 3 months later, one explanation would be that the partners at Methodist were more likely to be active than those at NMC, following some exposure to exercise at the Methodist CR program., especially since their baseline PF tended to be better.

There was also a significant difference in depression change scores between partners at NMC and Methodist between T2 and T3. Further examination of mean depression scores showed that partners in usual care at NMC had higher (worse) PHQ-9 scores than partners in usual care at Methodist at all time points. One possible explanation for this finding may be the associated lower physical HRQOL reported by the partners in usual care at NMC. However, these data of comparisons between partners by site need to be interpreted with caution, as the number of partner subjects at NMC (n=4) and at Methodist Hospital (n=13) was very small.

Aim Three

The third aim of this study was to examine the differences in physical, psychological, and relational HRQOL between patients and partners from T1 to T2 and from T2 to T3, separately by group: (a) PaTH intervention group and (b) the usual care group.

Couples' Physical Function.

In this study, there was evidence of differences in couples' level of physical function in the both groups at baseline. The partners' median physical function scores were higher in both groups than those of the patients at T1, contributing to this difference. This finding was expected in view of the patients' physical limitations within the first month following CAB surgery. Numerous studies have found decreased levels of physical function within the first month of recovery from CAB surgery (Barnason et al., 2000; Cohen et al., 2011; Hsu et al., 2011; Lie, Bunch, Smeby, & Arnesen, 2012). Rantanen et al. (2008; 2009) documented similar findings that significant others had greater physical function (measured with the 15D survey) than patients at 1, 6, and 12 months following CAB surgery. Similarly, partners in this study had higher median PF scores than patients' median PF scores at all three time points (92.5, 92.5, 95 vs. 55, 90, 90). While these scores indicated very high levels of physical functioning, they are comparable with CAB surgery patients (Barnason et al., 2000) and with healthy adult females in the U.S. (Michael et al, 1999).

Couples' Depression.

There was no evidence of a difference in depression between couples in either group over time. As previously noted, both patients and partners reported very minimal

levels of depression as measured with the PHQ-9 questionnaire; which again may be an indication of the lack of sensitivity of the instrument, or the tendency for couples with low levels of depression to enroll in research studies. Rantanen et al. (2008) reported that patients had worse levels of depression than significant others at 1 month post-CAB surgery; and that depression improved for both patients and significant others at 3 and 6 months following surgery (Rantanen et al., 2009). Similarly, patients in this study had worse (higher) median PHQ-9 scores than partners at each time point (3, 2, 2 vs. 1, 0, 1); and mean PHQ-9 scores showed a similar pattern. Also, there was a greater proportion of patients compared to partners who were classified as *depressed* at each time point (18%, 3%, 3% vs. 6%, 0%, 0%).

Couples' Dyadic Adjustment.

There was no evidence of a difference in dyadic adjustment between couples in either group. Dyadic adjustment median scores indicated relatively *adjusted* patients and partners in both groups. Median DAS-7 scores were virtually stable in our study for patients and partners over time (27, 28, 28 vs. 27, 27, 28.5); mean scores followed a similar pattern. One possible reason for such stable scores may be that only couples who were in a stable and adjusted relationship were interested in participating in a couple-oriented intervention study, that ultimately required a good deal of time and commitment from both members of the couple. Our findings were in contrast to the one study by Gilliss et al. (1990) in which partners marital adjustment scores decreased. Van Horn et al. (2002) recommended that studies of family interventions are needed that investigate marital quality. Due to the paucity of data examining marital satisfaction in CAB surgery

patient-partner dyads, this study adds to our understanding by providing longitudinal data with a well-accepted marital adjustment tool.

Aim Four

The final aim for this study was to examine the differences between CAB surgery patients in the PaTH intervention group versus the usual care group, in changes in exercise performance (treadmill submaximal MET level) from T1 to T2.

Submaximal treadmill exercise performance was found to significantly improve for patients in both groups. This finding lends support to the similar finding that patients in both groups also improved their physical HRQOL as measured with the SF-36 PF subscale from the start of CR to the end of CR. While each group was found to improve exercise performance from T1 to T2, there was no evidence of a difference in exercise performance between patients in the PaTH and usual care groups. Although the original hypothesis was that exercising together as a couple would enhance exercise performance, the results of this aim may actually reflect the well-documented improvement in exercise performance as a result of usual care CR (AACVPR, 2004). However, there was a trend for patients in the PaTH group to have greater improvement in submaximal treadmill exercise performance than patients in the usual care group from the start of CR to the end of CR (55 % vs. 43%).

Strengths and Limitations

One of the strengths of this study design was the randomization to intervention and usual care groups in the primary study (Yates, 2009). Also, the study was based in social support theory that posits improved outcomes when family members work together versus individual efforts (Kulik & Mahler, 1993; Rantanen et al., 2008; Yates, 1995).

The outcome variables were consistent with the physical and psychosocial domains found in HRQOL theories (Ferrans et al., 2005; WHO, 1998). Another important strength was the study's methods in which both patients and partners were measured on the same HRQOL variables. Because the framework for the study emphasized the couple-centered intervention versus usual care CR, it was essential to collect data on the same HRQOL outcomes for both the patients and the partners. Very few couple-centered studies have collected data on both the patient and the partner (Rantanen et al., 2008; 2009).

Measuring dyadic adjustment in both patients and partners added to the understanding of this couple-centered intervention. Although marital satisfaction has been investigated in other chronic diseases such as cancer, arthritis and dementia, very few studies have considered marital adjustment in patient-partner couples with cardiac illness (Martire et al., 2010). Furthermore, the longitudinal design allowed for some comparisons with other studies on several of the dependent variables. Another strength of this study was the use of established, community CR sites to deliver the intervention, thus lending to the translational focus of the study.

Generalizability was limited due to the convenience sample in two mid-western hospitals and CR sites. Also, a threat to external validity may exist in settings that agree to be in research studies versus non-research settings, thus affecting generalizability to non-research based settings. Selection bias may have occurred in terms of patients and partners who were willing to participate versus those who refused to be part of the study. This pilot study was not adequately powered to detect statistical differences; and the small sample size with multiple comparisons limits our analysis. There was also limited diversity in the sample, and possibly low sensitivity of the depression instrument.

Another limitation occurred because one CR site (Methodist Hospital) had an established “partner program” that allowed partners to exercise in the facility. However, this limitation was minimized because usual care partners at Methodist Hospital did not receive the full intervention which included individualized exercise prescription and regular counseling that the PaTH intervention partners received.

Clinical Implications

Although the majority of patients who enter CR are in dyadic relationships, few CR programs actively involve partners or family members in adopting lifestyle behaviors or addressing psychosocial needs of the family. This study emphasized the fact that patients are not alone in their recovery process and that the HRQOL of both patients and partners is impacted by the CAB surgery and the CR process. While some CR programs have implemented some form of partner participation, investigating the HRQOL outcomes that occur when patients and partners work together in the CR setting was unique to this study. In addition, this study emphasized the trajectory and importance of HRQOL outcomes for both patients and partners in the CR setting. Often HRQOL outcomes may be less apparent during the CR experience, which often emphasizes physical activity and exercise behaviors. Nurses in these settings are in unique positions to assess and intervene with patients, and also partners, who present with poor levels of HRQOL. This study lends support to nurses to include family-centered interventions in CR programs.

Future Research.

The HRQOL variables in this study were the secondary outcomes of the primary PaTH study (Yates, 2009). One suggestion for future research investigating the HRQOL

outcomes in patients and partners in a couple-centered intervention would be to include an overall or global HRQOL outcome measure to establish an over-arching HRQOL framework. While attempting to balance subject burden with data collection needs, the use of the full SF-36 would allow for a more comprehensive and comparable set of HRQOL data. The addition of an instrument to measure symptoms, particularly in the CAB surgery patients, would add another explanatory element to this study. Also, controlling the CR site for an existing ‘partner program’ would be preferable; thus providing for a true control group comparison.

In regards to each dependent variable, future research considerations could include the addition of some form of physical activity monitor (e.g. accelerometers) to both the patients and partners, so the PF scores and actual activity may be compared. PHQ-9 may be used for initial screening, but follow-up with a more sensitive instrument may be considered. A similar method was adopted in the *Bypassing the Blues* trial (Rollman & Belnap, 2011) in which the PHQ-9 was initially used to screen and categorize CAB surgery patients on levels of depression; but the Hamilton Rating Scale of Depression was used for subsequent depression outcome analysis. The addition of other psychosocial outcomes such as anxiety may also warrant investigation, as several studies noted the existence of either depression or anxiety or a combination of both emotional variables (Brecht et al., 1994; Buls, 1995; Pignay-Demaria et al., 2003; Tully et al, 2009). In addition, examining treatment interventions (e.g. medications, counseling, or a combination of the two) that may have occurred with patients or partners who scored in the *depressed* category, would assist with the interpretation of changes over time in depression scores. While examination of dyadic adjustment in this study

elicited preliminary results over time following CAB surgery, further examination of couples who are maritally *distressed* versus *adjusted* may yield important differences in HRQOL outcomes. Subsequently, if the recruited sample size was large enough, subgroup analyses could be performed to detect differences by age, sex, comorbidities, and differences in subjects with low physical function, high levels of depression, and poor marital quality.

In conclusion, this study adds to our understanding of some basic HRQOL outcomes for both patients and partners following CAB surgery. The lack of HRQOL data for partners of patients with CHD has been noted previously. Although researchers often acknowledge the role of the family in recovery from acute and chronic illness, partners are rarely included in outcomes research. This study contributes to our understanding of patients' and partners' HRQOL following CAB surgery.

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Appendix A

Patient Health Questionnaire (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people would have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or hurting yourself in some way	0	1	2	3
PHQ-9 Score	=	+	+	
10. If you checked off any problems on this questionnaire, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult

From: Kroenke, K., Spitzer, R.L., Williams, D.S.W., & Lowe, B. (2010). The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptoms Scales: A systematic review. *General Hospital Psychiatry*, 32, 345-359.

Appendix B

DAS-7

Most persons have disagreements in their relationships. Please indicate below the approximate extent of agreement or disagreement between you and your partner on the following list.

1. Philosophy of life _____
2. Aims, goals, and things believed important _____
3. Amount of time spent together _____

5	4	3	2	1	0
Always Agree	Almost Always	Occasionally Disagree	Frequently Disagree	Almost Always Disagree	Always Disagree

How often would you say the following events occur between you and your mate?

4. Have a stimulating exchange of ideas _____
5. Calmly discuss something together _____
6. Work together on a project _____

0	1	2	3	4	5
Never	Less than once a month	Once or twice a month	Once or twice a week	Once a day	More often

7. The dots on the following line represent different degrees of happiness in your relationship. The middle point, "happy," represents the degree of happiness of most relationships. Please circle the dot which best describes the degree of happiness, all things considered, of your relationship.

•0	•1	•2	•3	•4	•5	• 6
Extremely Unhappy	Fairly Unhappy	A little Unhappy	Happy	Very Happy	Extremely Happy	Perfect

Note: the total score for the DAS-7 is the sum of the responses to the seven items.

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Appendix C

Key Intervention Components

Comprehensive risk reduction		
Exercise prescription (Exercise specialist)	Patients only (partners are not present)	Patients and partners each receive
Based on symptom-limited exercise test	X	X
Discuss results with participant	X	X
Target HR range is 60-85% of heart rate reserve	X	X
Rated perceived exertion of 14-16 on Borg scale	X	X
Safety tips about exercise	X	X
Signs and symptoms to watch for and report	X	X
Individualized for subjects' needs (eg, arm work)	X	X
Increase exercise intensity every 2-3 weeks	8-12 weeks	8-12 weeks
Length of CR program	24-36 sessions	24-36 sessions
# of total exercise sessions over 8 wks of CR		
Monitoring during exercise by CR staff	ECG, HR, and BP monitored in patients only	ECG, HR, and BP monitored in patients and partners
Dietary recommendations* (Dietitian)	Patients only; optional for partners	Patients and partners
Saturated fat intake	< 7% of total calories	< 7% of total calories
Total fat intake	≤ 30% of total calories	≤ 30% of total calories
Cholesterol intake	< 200 mg/day	< 200 mg/day
Soluble fiber	10-25 g/day	10-25 g/day
Risk factor counseling (RN)	Patients only (partners are not present)	Patients and partners
Goal setting with RN (exercise, diet, lipids)	X	X
Target goals** for:		
Exercise amount	≥ 150 min/wk of ≥ moderate intensity aerobic exercise	≥ 150 min/wk of ≥ moderate intensity aerobic exercise
Energy expenditure in exercise/physical activity	moderate intensity aerobic exercise	moderate intensity aerobic exercise
Lipid profile		
Total cholesterol	< 200 mg/dL	< 200 mg/dL
Low density lipoprotein cholesterol	< 70 mg/dL for patient***	< 70 mg/dL for patient*** < 130 mg/dL for partner*
High density lipoprotein cholesterol	> 40 mg/dL X	> 40 mg/dL X
Lipid medication adherence/ changes in dose		
Educational topics	Patients only; optional for partners	Patients and partners
Treatment for coronary heart disease	X	X
Modifiable and nonmodifiable risk factors	X	X
Exercise/Physical activity	X	X
Heart healthy fitness	X	X
Exercising safely	X	X
Nutrition and TLC diet	X	X
Psychosocial concerns	X	X

Dyslipidemia	X	X
Emphasis on individual's unique risk factors	X	X
Obesity (if relevant)	X	X
Diabetes (if relevant)	X	X
High blood pressure (if relevant)	X	X
Smoking cessation (if relevant)	X	X
Format of educational sessions	Group format	Group format
Location of sessions	Outpatient setting	Outpatient setting
	Attendance is required for patients; optional for partners	Attendance is required for patients and partners
Feedback about progress (verbal and written)	Patients only	Patients only
Lipid profile (total cholesterol, HDL, LDL)	X	X
Exercise levels (sessions/wk, intensity) from log	X	X

Note: Appendix C: Key Intervention Components (continued).

Appendix D



NEBRASKA'S HEALTH SCIENCE CENTER

Office of Regulatory Affairs (ORA)
Institutional Review Board (IRB)

February 24, 2012

Lynda Macken, MSN, RN
CON-Omaha
UNMC - 5330

IRB#: 080-12-EX

TITLE OF PROTOCOL: Partners Together in Health: Health-related Quality of Life Outcomes in Coronary Artery Bypass Surgery Patients and Partners

Dear Ms. Macken:

The Office of Regulatory Affairs (ORA) has reviewed your application for ***Educational, Behavioral, and Social Science Research*** on the above-titled research project. According to the information provided, this project is exempt under 45 CFR 46:101b, category 4. You are therefore authorized to begin the research.

It is understood this project will be conducted in full accordance with all applicable HRPP Policies. It is also understood that the ORA will be immediately notified of any proposed changes that may affect the exempt status of your research project.

Please be advised that this research has a maximum **approval period of 5 years** from the original date of approval and release. If this study continues beyond the five year approval period, the project must be resubmitted in order to maintain an active approval status.

Sincerely,

Gail Kotulak, CIP
IRB Administrator
Office of Regulatory Affairs (ORA)

gdk

