BURDEN, SCREENING, AND TREATMENT OF DEPRESSIVE AND ANXIOUS SYMPTOMS AMONG WOMEN REFERRED TO CARDIAC REHABILITATION: A PROSPECTIVE STUDY

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THESIS SUBMITTED TO THE FACULTY OF GRADUATE STUDIES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF SCIENCE

GRADUATE PROGRAM IN KINESIOLOGY AND HEALTH SCIENCE
YORK UNIVERSITY
TORONTO, ONTARIO

AUGUST 2013

Abstract

Women with cardiovascular disease experience a significantly greater burden of psychosocial distress than men. Clinical practice guidelines promote screening in cardiac rehabilitation (CR).

The objectives of this thesis were to describe the burden of psychosocial distress, screening, forms of treatment, awareness of elevated symptoms, and whether receipt of treatment was related to subsequent psychosocial distress symptom severity, within women referred to CR.

This study presents a secondary analysis of a multi-centre trial of women outpatients randomized to 1 of 3 CR models. Consenting participants were asked to complete an initial and follow-up survey 6 months later, and clinical data were extracted from charts.

Findings reiterate that despite clinical recommendations, few women reported being screened for psychological distress, and when screened, only approximately 1/5th were informed of their results. When treated, most women were prescribed anti-depressants by their family doctor. Unfortunately therapy was not related to improvements in symptoms.

Acknowledgements

First and foremost, I would like to thank my supervisor Dr. Sherry Grace for all of her support and guidance over the past two years. I would not have gotten to where I am today and achieved my academic goals without her. She has truly been a wonderful mentor and I cannot thank her enough. I would also like to thank my committee members, Dr. Michael Rotondi for all of his detailed reviews and wonderful feedback, and Dr. Henny Westra for her time and participation. I would like to extend a huge thank you to all of my lab mates who I have had the pleasure of working with over the last two years: Tomasz Kowal, Sanam Pourhabib, Yongyao Tan, Shamila Shanmugasegaram, Liz Samayoa, Christine Andraos, Stephanie Bennett, Cassandra Collins, Golnoush Taherzadeh, Mary Attia, Shannon Gravely, Peter Polyzotis and Lori Van Langen. I would like to extend a special thank you to all of the members of the Toronto Western Hospital Cardiac Rehabilitation Team for their mentorship and the wonderful opportunities they have provided me with over the past two years: Caroline Chessex, Kelly Angevaare, Holly Wykes, Margaret Brum, Veola Caruso, Lucy Moniz, Valerie Skeffington, and Marion Ryujin. Finally, I would like to thank my Mom, Dad, and Adam Hurley for their continuous love and support and for putting up with me during the many times I was stressed over the past two years. Thank you to everyone for helping me along the way and making these last two years a great experience!

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Introduction

Globally, cardiovascular disease (CVD) is the leading cause of mortality. In 2008, an estimated 17.3 million people died as a result of CVD, which represents 30% of all global deaths[1]. Depression and anxiety are two of the most frequent co-morbidities of CVD. It has been estimated that approximately 30% of patients who have been hospitalized for a myocardial infarction (MI) display depressive symptoms, in which 15 to 20% suffer from major depression[2,3].The prevalence of anxiety has been less-studied than depression, but there is an understandable elevation of anxious symptoms in patients with CVD[4]. Lane et al.[5] found that 26% of patients who had been hospitalized for an MI, displayed elevated anxiety scores, and when revaluated at four and twelve months, the prevalence of anxious symptoms increased to 41.8% and 40.0%, respectively. Both depressive and anxious symptoms post-MI are associated with an increased risk of experiencing recurrent cardiac events[6]. Specifically, co-morbid depression is related to two-times the risk of mortality in patients with CVD[7]. Furthermore, co-morbid depression is inversely related to the adoption of secondary prevention behaviours, including smoking cessation and participation in cardiac rehabilitation (CR)[2].

The prevalence of major depression is greater in women with CVD compared to men. Specifically, the prevalence of depression in women with CVD is two-times greater than men[8]. Moreover, it has been reported that women also tend to be at a greater risk of experiencing anxiety after a cardiac event[9,10]. There are few reports of successful treatment of these co-morbid conditions among women in the literature.

Cardiac rehabilitation (CR) is a multidisciplinary outpatient program focused on improving and maintaining cardiovascular health through, exercise, education, and counselling[11]. The Canadian Association of Cardiac Rehabilitation (CACR) identifies exercise training as one of the core elements of CR[11]. Exercise training is a major component of CR that has been shown to significantly improve exercise capacity, plasma lipids, and overall quality of life[12]. Exercise-based CR has also been shown to have significant psychosocial benefits and CR practice guidelines promote depression and anxiety screening in CR[3,11,13–15]. The primary objective of this prospective study is to describe the burden, screening, and treatment of depressive and anxious symptoms among women participating in CR, as well as the effectiveness of treatment.

Literature Review

CVD is defined as a group of conditions that affect the function and structure of the heart and blood vessels[1,16]. Coronary artery disease (CAD) is one of the most common types of CVD. CAD is characterized by problems with the circulation of blood to the heart muscle[17]. The most common cause of this circulation problem is a build-up of fatty deposits on the inner walls of the coronary arteries[1]. Blockage of the coronary arteries can result in a lack of oxygenated blood being delivered to the heart, which can cause chest pain. A myocardial infarction, also known as a heart attack, occurs when there is a complete blockage of a coronary artery. This results in damage or death to part of the heart tissue[17].

Burden of Cardiovascular Disease in Women

Globally, CVD is the leading cause of morbidity and mortality in women, with 8.6 million lives lost every year[18,19]. In Canada, CVD is the number one killer of women[20]. In 2008, CVD accounted for 29.7% of all deaths in Canadian women[21]. With advances in treatment, mortality rates in men are on the decline in the developed world, while mortality rates in women remain stable[22].

In addition to this burden of morbidity, women with heart disease are at particular risk for several reasons. First, certain risk factors of CVD are more common in women than men. It has been reported that women are less active than men[22]. Certain barriers to physical activity, including family responsibilities, often affect women to a greater extent[22]. In addition, having a low socioeconomic status puts women at an even greater risk of developing CVD than men. Although low socioeconomic status puts both men and

women at an increased risk of CVD, it has been reported that women experience a 61% increased risk of CVD mortality, while men only experience a 29% increased risk[22]. Finally, the prevalence of psychosocial risk factors, such as depression, is higher in women compared to men. This discrepancy in prevalence begins at puberty and continues throughout adulthood, with depression being two-times greater in women[8,22,23].

Second, women experience CVD differently than men. There are sex differences in disease presentation between men and women, with women often experiencing atypical symptoms. Subsequently, women tend to be under-diagnosed[22,24,25]. It has been found that women often present to the hospital later after the onset of symptoms, wait longer for treatment, and are less likely to be admitted to intensive care settings[22]. When women receive treatment, they are less likely than men to undergo aggressive treatment such as revascularization[22,25].

Finally, research has shown that women may have a poorer prognosis after experiencing a cardiac event than men. It has been documented that women experience longer hospital stays, more discomfort, greater activity restriction, and disability[22]. In addition, women may have higher mortality rates compared to men. The Framingham study was initiated to identify factors associated with CVD by following their development over a long period, in a large group of participants[26]. Researchers found that initial and 1-year after infarction mortality rates were higher in women, with 44% mortality in women and only 27% in men[25]. Moreover, women have lower utilization rates of secondary prevention programs, such as CR[22,25]. In addition to low enrollment rates, women also have higher dropout rates[25].

Co-morbid Depression and Anxiety in Cardiovascular Disease

Depression and anxiety fall under the broad umbrella of mood disorders, which are characterized by having a disturbance in disposition as their prominent feature. The DSM-IV-TR[27] defines a major depressive episode as a period of at least two-weeks in which there is either depressed mood or the loss of interest or pleasure in nearly all activities. The individual also must experience at least four additional symptoms, including changes in weight or appetite, changes in sleep, decreased energy, feelings of worthlessness, difficulty concentrating, and suicidal ideation[27]. For an individual to be diagnosed with generalized anxiety disorder they must experience persistent and excessive worry in a variety of situations for a period of at least 6 months. They must also experience at least three additional symptoms on most days of the week, including constant worrying, inability to relax, difficulty concentrating, irritability, feeling tense, and trouble sleeping[27]. Note that there is a difference between clinical and non-clinical depression and anxiety. Clinical depression and anxiety are persistent, cause social and/or occupational impairment, and must be diagnosed through structured assessment by a trained clinician[27].

Co-morbid depression is related to twice the odds of mortality in patients with CVD[7]. A meta-analysis of 22 studies, which assessed the association between depression following an MI and cardiovascular prognosis found that post-MI depression was significantly associated with both all-cause and cardiac mortality[28]. Frasure-Smith et al.[29] found that in hospital depression was a significant predictor of one-year mortality post-MI, where the rate of cardiac death for depressed women was 8.3% compared to 2.7% in

non-depressed women. In addition, depression after a cardiac event is related to an increased risk for new cardiovascular events, rehospitalization, and decreased patient adherence to secondary prevention strategies, including smoking cessation and participation in CR[2,28]. Although anxiety is often one of the earliest psychological responses to a cardiac event, it tends to be less investigated[6,10,13]. Strik et al.[6] examined both depressive and anxious symptoms in patients following an MI. They found that both depressive and anxious symptoms post-MI were associated with an increased risk of experiencing recurrent cardiac events. Moreover, Rothenbacher et al.[30] found that CVD patients participating in an inpatient CR program with symptoms of anxiety had a statistically significant hazard ratio of 2.32 for experiencing recurrent fatal and non-fatal cardiovascular events compared to other patients, during a 3-year follow-up period.

Depression and anxiety are quite common in patients with CVD. Approximately 30% of patients display depressive symptoms, with 15-20% of patients suffering from major depression[2,3]. A review by Thombs et al.[31] reported that the prevalence of major depression in patients following an MI was 19.8%. Moreover, the prevalence of significant depressive symptoms based on Beck Depression Inventory-II (BDI-II) scores in post-MI patients was 31.1%. Women tend to be at a greater risk of experiencing depression after a cardiac event. Frasure-Smith et al.[32] reported that women are about twice as likely to be depressed following an MI than men. They found that 24.5 % of women experienced in-hospital depression following an MI, while only 13.3% of men experienced this outcome. A study, which examined the prevalence and persistence of anxious symptoms in post-MI patients, found that 26% of patients displayed elevated

anxiety scores, and when re-evaluated at four and twelve months, the prevalence rates of anxious symptoms increased to 41.8% and 40.0%, respectively[5]. Women also tend to be at a greater risk for developing anxious symptoms following a cardiac event compared to men. It has been reported that women are significantly more anxious upon entry to CR than men[9,10].

Since depression and anxiety are two of the most common co-morbidities of CVD, in-hospital screening of depressive and anxious symptoms is recommended to identify those patients who may require treatment[33]. In addition, CR guidelines recommend that all patients undergo screening at program intake and receive treatment, if required[11,14]. One core component of CR that is inconsistent across programs is psychosocial distress screening[34,35]. There tends to be controversy over the treatment of depression, as there is little capacity to do so. Many programs do not have qualified mental health professionals on staff[34]. Moreover, it has not been established that treatment can improve clinical outcomes[36], however, there is some preliminary evidence that depressive and anxious symptoms can be moderately alleviated[37,38].

As depression is related to increased morbidity and mortality in patients with CVD, number trials have been performed to assess whether treatment can alleviate this increased risk. Primary treatments for depression and anxiety include pharmacology and psychotherapy[39–46]. The majority of the major CVD and depression studies, found that anti-depressants, specifically selective serotonin reuptake inhibitors (SSRIs), psychotherapy, or a combination of the two, are safe to use in cardiac patients and improve psychological outcomes, however it is not well established if this translates into

improved cardiac outcomes[37,41,44,46]. There is emerging evidence that psychosocial treatment, including psychotherapy and a combination psychotherapy and pharmacology, not only reduce psychosocial distress, but may reduce the risk of recurrent MI's and improve overall prognosis[45,47].

Research in the area of CVD and depression has shown that treatment of depression in women with CVD may be hazardous. The Montreal Heart Attack Readjustment Trial[48] demonstrated that women randomized to a psychological nursing treatment displayed higher cardiac ($p=0.051$) and all cause mortality ($p=0.064$) compared to usual care. Furthermore, although not statistically significant, women in the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) trial, favoured usual care, which differs from men who favoured treatment in the form of psychotherapy, or a combination of psychotherapy and pharmocolgy[46]. Results of these studies suggest that there may be possible differential effects of psychosocial treatment between genders[46,48]. It is clear that further research examining treatment of psychosocial distress in women is needed.

Cardiac Rehabilitation in the Management of Cardiovascular Disease and Depression

The Canadian Association of Cardiac Rehabilitation[11] has defined CR as the enhancement and maintenance of cardiovascular health through individualized programs designed to optimize physical, psychological, social, vocational, and emotional status. This process includes the facilitation and delivery of secondary prevention through risk factor identification and modification in an effort to prevent disease progression and the recurrence of cardiac events. Exercise-based CR is an effective outpatient disease

management program[49], and there is a multitude of evidence based research that demonstrates the benefits of CR. Most notably, a systematic review and meta analysis of 34 exercise-based CR randomized control trials, found that compared to usual care, participation in exercise-based CR was associated with a 47% lower risk of reinfarction, 26% reduction in all cause mortality, and a 36% reduction in cardiac morality[50]. Additionally, participation in CR has been found to increase survival after cardiovascular hospitalization[51], improve exercise capacity, reduce cardiac risk factors, and have psychological benefits[52,53]. Moreover, CR is also beneficial to the healthcare system. It has been reported that participation in CR reduces healthcare costs[54,55], as it is associated with reduced hospital readmissions[54,56].

Physical activity is the central component of CR[11,14]. Numerous studies have demonstrated the beneficial effects that CR and specifically exercise have on an individual's cardiovascular and psychological health[3,9,52,53,57]. Lavie et al.[57] reported that individuals who participated in CR had significant reductions in body mass index, percent body fat, resting heart rate, and resting systolic blood pressure. Moreover, CR participants displayed increased high density lipoprotein (HDL), and peak maximum oxygen consumption. The same improvements were seen when specifically looking at women. In one study women had a 33% improvement in exercise capacity and a 7% reduction in percent body fat[52]. In addition, exercise has been shown to reduce the psychosocial distress among patients participating in CR[58]. In one study individuals showed marked improvements on both depression and anxiety scores on the Symptom Questionnaire (SQ), with reductions of 58.5% and 46.0%, respectively after attending

CR. Participants also experienced a 15.8% increase in overall quality of life, which was assessed by the Short Form Health Survey (SF-36)[57]. The same trend is seen when looking exclusively at women. Lavie et al.[3] reported that after attending CR, depressed women showed improvements on both depression and anxiety scores on the Symptom Questionnaire (SQ), with reduction of 55% and 54%, respectively. Women also displayed a 30% increase in overall quality of life, measured by the Sort Form Health Survey (SF-36). Following CR, the prevalence of depression in the study sample nearly dropped in half, from 23% to 12%.

As there is clear relationship between CVD and mood disorders[59], CACR[11] and American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)[15] recommend that all CR patients undergo screening for depression and anxiety. Moreover, The Canadian Network for Mood and Anxiety Treatments (CANMAT) state that co-morbidities, such as mood disorders must be properly diagnosed and treated to ensure optimal patient outcomes[59]. After such screening, any individuals who screen positive for depression or anxiety should be referred to a qualified professional, such as a psychologist or psychiatrist, for formal assessment and treatment, as necessary[11]. Furthermore, the guidelines recommend that any patients who report ongoing stress, but do not have active depression or anxiety should be offered a stress management program. Stress management programs or group sessions that focus on psychosocial issues may be beneficial, as psychosocial problems are common in the cardiac population and can have unfavorable effects[11].

Despite these recommendations, rates of psychosocial distress screening in CR programs are inconsistent. In a recent study evaluating the core components of CR programs in Ontario, 68.4% of programs screened patients for depressive symptoms[34]. In an earlier American study, only 36% of programs screened for depression[35]. Low rates of psychosocial distress screening in CR programs may be due to capacity issues[34]. Screening for and treatment of psychosocial issues are an important component of CR as patients with psychosocial distress may be more likely to drop out compared to patients without depression. Grace et al.[60] found a significant inverse relationship between depressive symptomatology and number CR exercise session attended. Furthermore, minimal psychosocial interventions were offered.

Objectives

The objectives of this thesis were to: (1) describe rates of psychosocial distress screening, as well as outcome of such screening; and (2) describe women's awareness of elevated depressive and/or anxious symptoms. In addition, (3) in women with elevated symptoms, the aim was to: (a) describe the proportion treated, (b) the types of treatments received, and (c) the type of provider from whom they received treatment. In the case of pharmacological treatment, the aim was to: (3d) describe the class of medication, (3e) patient adherence, and (3f) if the medication had been changed or titrated since pre-testing. Finally, the last objective was to: (4) to describe whether receipt of treatment was related to depressive/anxious symptom severity at post-test.

It is hoped the current study will inform clinical and scientific audiences on the importance of screening in the CR setting, how CR programs are performing in this regard, and the effects for patients.

Manuscript Preface

This thesis is prepared in manuscript style. Participants were recruits from a larger study involving six CR programs across Ontario, Canada (Appendix A). Participants were described based on chart-reported clinical characteristics (Appendix B and C) and self-reported sociodemographic characteristics (Appendix D). All objectives were assessed through self-report surveys, which consisted of investigator-generated and psychometrically-validated scales (Appendix E, F, G, H, I, K and L). The study was approved by the Research Ethics Boards of the participating hospitals, as well as York University's Office of Research Ethics (certificate #: 2009 - 323). The results of this study are presented in the manuscript which follows.

Certificate of Authentication

Re: Burden, Screening, and Treatment of Depressive and Anxious Symptoms among Women Referred to Cardiac Rehabilitation: A Prospective Study

I hereby confirm that the first author of this manuscript, Megan Cahill, was responsible the majority of data extraction from patient charts at two CR sites, mailing and entering post-test patient surveys, for all of the cleaning of post-test data, statistical analysis, and for the write-up of the first draft of the manuscript. As well, she revised the manuscript on a further 2 occasions following receipt of input from co-authors. Dr. Sherry L. Grace played an instrumental role in the conception and design, analysis and interpretation, as well as provided editorial feedback for the manuscript. The co-authors were co-investigators on the grant, who served on the steering committee for the trial. They provided editorial feedback on the drafted manuscript prior to submission to the journal *Psychosomatics*.

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Burden, Screening, and Treatment of Depressive and Anxious Symptoms among Women Referred To Cardiac Rehabilitation: A Prospective Study

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Abstract

Background: Cardiovascular disease (CVD) is one of the leading causes of morbidity and mortality among women. Women with CVD experience a greater burden of psychosocial distress than men, and practice guidelines promote screening in cardiac patients.

Objectives: To describe the burden of psychosocial distress, screening and forms of treatment among women cardiac patients. Also to describe awareness of elevated symptoms and whether receipt of treatment was related to post-test psychosocial distress symptom severity.

Methods: Within a multi-centre trial of women randomized to 1 of 3 cardiac rehabilitation models, consenting participants were asked to complete surveys upon consent and 6 months later. Clinical data were extracted from charts. This study presents a secondary analysis of the surveys, including the Hospital Anxiety and Depression Scale.

Results: Of the 111 (79.9%) participants retained, 44 (42.8%) self-reported that they recalled being screened, and of these, 8 (18.6%) reported discussing the results with a healthcare professional. Sixty-eight (48.9%) participants had elevated symptoms of psychosocial distress at pre-test, of which 18 (26.5%) appeared to be unaware. Twenty-one (42.9%) participants were receiving treatment. Regression analyses showed that treatment of psychosocial distress was not significantly associated with post-test depressive or anxious symptom severity.

Conclusions: Findings reiterate the great burden of psychosocial distress among women with CVD. Despite clinical recommendations, results suggest few women report being screened, and when screened, only approximately 1 in 5 women were informed of their results. Less than half of patients with elevated symptoms were treated, and the treatment approaches did not appear to reduce symptoms.

Introduction

Globally, cardiovascular disease (CVD) is the leading cause of morbidity and mortality in women and men, representing 30% of all deaths worldwide[1]. Depression and anxiety are two of the most frequent co-morbidities of CVD, increasing the overall impact of the disease. Approximately 30% of patients who have been hospitalized for a myocardial infarction experience depressive symptoms, of which 15 to 20% suffer from major depression[2]. The prevalence of anxiety has been less-studied, but there is an understandable elevation of anxious symptoms following an acute CVD event[3]. Moreover, both depressive and anxious symptoms post-myocardial infarction are associated with an increased risk of experiencing recurrent cardiac events[4]. Co-morbid depression is related to twice the risk of mortality in patients with CVD[5] and is inversely related to the adoption of secondary prevention behaviours, including smoking cessation and participation in cardiac rehabilitation (CR)[2]. Accordingly, cardiovascular clinical practice guidelines recommend routine screening for depression following a cardiovascular event[6,7].

The prevalence of major depression in women with CVD is twice that of men. Moreover, women also tend to experience greater anxiety after a cardiac event[8]. Evidence-based therapies for depression and anxiety are well-established[9,10], and have been tested in the CVD population[11–14]. There is some emerging evidence that treatment, including psychotherapy, pharmacology, and a combination of the two, not only reduce psychosocial distress[11–15], but also can reduce the risk of recurrent myocardial infarctions and improve overall prognosis[11,16]. However, there are some reports of unsuccessful

treatment of these co-morbid conditions among women, and in fact that psychosocial treatment may be associated with adverse outcomes. For instance, the results of The Montreal Heart Attack Readjustment Trial[17] demonstrated that women in the treatment arm displayed significantly higher cardiac and all-cause mortality compared to usual care. Moreover, minimal improvements in depressive and anxious symptom severity were reported. Furthermore, although not significant, results showed that outcomes for women in the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) trial appeared better under usual care, compared to men who favored treatment[12]. Results of these studies suggest that a better understanding is needed of effective psychological therapies for women with CVD[12,17].

Psychosocial distress screening is recommended in clinical practice guidelines for cardiac patients[18,19]. After such screening, it is recommended that any individuals who indicate a heightened level of symptoms of depression or anxiety be referred to a qualified professional, such as a psychologist, social worker or psychiatrist, for formal assessment and treatment, as necessary[18–20]. Accordingly, the objectives of this study were to: (1) describe rates of psychosocial distress screening, as well as outcome of such screening; and (2) describe women's awareness of elevated depressive and/or anxious symptoms. In addition, (3) in women with elevated symptoms of psychosocial distress, the aims were to: (a) describe the proportion treated, (b) the types of treatments received, and (c) the type of provider from whom they received treatment. In the case of pharmacological treatment, the aims were to: (3d) describe the class of medication, (3e) patient adherence, and (3f) if the medication had been changed or titrated between pre

and post-testing; and (4) describe whether receipt of treatment was related to depressive/anxious symptom severity at post-test.

Methods

Design and Procedure

This study presents a secondary analysis of an ongoing single-blind pragmatic randomized controlled trial of female CVD outpatients randomized to one of three types of CR, to understand the effects of program model on adherence[21]. The design herein is a prospective cohort.

In the original study, participants were recruited from six inpatient and outpatient cardiac units in the Greater Toronto Area of Ontario, Canada. Consenting and eligible patients were then randomized to one of three CR program models: (1) mixed-sex traditional hospital-based CR, (2) women-only hospital-based CR, and (3) monitored home-based CR (Appendix A). CR patients attending the women-only model who were not participating in the larger trial were also approached to participate in an observational sub-study, where the same assessments were administered. CR enrollment and participation was observed in all patients.

Clinical information was extracted from inpatient and/or outpatient medical charts (Appendix B and C). Prior to CR initiation, participants were asked to complete a self-report survey, which included a number of standardized and validated scales assessing socio-demographic characteristics (Appendix D), psychosocial distress (Appendix E, F, and G), medication adherence (Appendix H), medications (Appendix I), and exercise behaviour (Appendix J).

Post-test assessments occurred six months later by mail. The self-report survey assessed psychosocial distress (Appendix G, K and L), medication adherence (Appendix H), medication use (Appendix I), and exercise behaviour (Appendix J). Moreover, an audit of patient CR charts was undertaken to ascertain CR enrollment and completion (Appendix M). Response rate was optimized through repeated and personalized contacts[22]. This included a replacement survey mailing and telephone calls, if required.

Participants

Participants in this study were consenting women inpatients or outpatients with documented coronary artery disease (CAD), and/or acute coronary syndrome (ACS), and/or undergoing revascularization (percutaneous coronary intervention [PCI] or coronary artery bypass grafting [CABG]), and/or valve surgery. These chosen cardiac indications were based on CR referral recommendations[18–20].

Inclusion criteria were: patient resided in Toronto or Hamilton, within 45 minutes of CR site; proficiency in the English language, and eligibility for home-based CR. Exclusion criteria were: (1) musculoskeletal, neuromuscular, visual, cognitive or non-dysphoric serious psychiatric condition (e.g., schizophrenia), or any serious or terminal illness not otherwise specified which would preclude CR eligibility based on CR guidelines[18], (2) physician deemed patient not suitable for CR at time of intake exercise stress test, (3) patient planned to leave the region prior to the anticipated end of participation, (4) patient discharged to a long-term care facility, and (5) participation in another clinical trial with behavioural interventions.

Measures

Sociodemographic characteristics were assessed in the initial patient survey through forced-choice response options, including: age, ethnic background, marital status, education, income, work status and dependents (Appendix D). Clinical data extracted from medical charts included cardiac diagnoses, risk factors, and co-morbid conditions (Appendix B). Exercise behaviour was also measured in the final survey, considering its relation to mood[23,24] using the Godin Leisure-time Exercise Questionnaire[25]. This is a brief and reliable instrument that was used to assess usual leisure-time physical activity behaviour during a one-week period (Appendix J). Lastly, CR participation was verified via an audit of participants' CR charts (Appendix M).

Assessment of Depressive and Anxious Symptoms

Psychometrically-validated scales were administered in both the pre and post-test self-report surveys to assess psychosocial distress. First, the Beck Depression Inventory-II (BDI-II)[26] was administered to assess depressive symptoms in the pre-test survey (Appendix F). It is a reliable and well-validated 21-item scale that uses a 4-choice response format. It has been widely used in the general population and in populations with long-term illness, including cardiac disease. Higher scores reflect greater depressive symptomatology, with scores $\geq$14 reflecting "elevated" (i.e., mild to severe) symptomatology.

Second, the Patient Health Questionnaire-2 (PHQ-2)[27] was administered in both the initial and final surveys to assess the frequency of the two cardinal features of depression, namely depressed mood and anhedonia (Appendix G). The PHQ-2 total score

ranges from 0 to 6, with score of ≥ 3 indicating elevated symptoms[27]. Finally, The Hospital Anxiety Depression Scale (HADS)[28] was administered in the final survey, to additionally assess anxiety (Appendix L). The HADS is a 14-item questionnaire with seven items assessing anxiety and seven items assessing depressive symptoms. Each item is scored from 0 to 3, with each subscale scored out of 21. Scores ≥ 9 represented elevated symptoms of anxiety or depression[28,29].

Investigator-generated items assessing problems with, awareness of, and treatment for depression and anxiety were incorporated in both surveys (Appendix E and K). In the initial survey, participants were asked if they had current problems with depression and/or anxiety (yes/no). Participants who reported no problems, but scored above scale thresholds as per above, were considered "unaware". In both initial and final surveys, participants were also asked if they were receiving treatment (yes/no), the type of provider from whom they were receiving treatment, and finally the type of treatment they were receiving (i.e., pharmacotherapy, psychotherapy, or both). In the final survey, participants were asked whether they had been screened for depression and/or anxiety since they were referred to CR (yes/no), and the outcome of such screening.

Use of psychoactive medication was ascertained by reviewing self-reported medication lists (Appendix I). Participants were asked in both initial and final surveys to record all medications they were currently taking, and the dose per day. Psychoactive drugs were coded according to their drug class[30]. Whether the psychoactive medication(s) listed were different on the pre and post-test survey was also assessed, and where the same medication was reported at both assessment points, whether the dosage had been

changed. Finally, adherence to medication was assessed via Morisky's Medication Adherence Scale (MMAS-4)[31], which was administered in both pre and post-test surveys (Appendix H). It is a brief and reliable instrument to assess medication adherence. The MMAS-4 total score ranges from 0-4, with any score less than 4 indicating non-adherence.

Analysis

All statistical analyses were performed using SPSS version 20[32]. Comparisons of sociodemographic, clinical and psychosocial characteristics between participants retained and those lost-to-follow-up, as well as group differences (i.e., self-reported and/or elevated scores vs. no self-reported and/or elevated scores) were performed. Scores were compared using 2- tailed independent sample t-tests or 2-tailed chi-squared tests, as appropriate, with a significance cut-off value of $p<0.05$. The relationship between pre and post-test psychological distress was also explored.

To test the first objective, a descriptive analysis of the investigator-generated item in the final survey, which assessed self-reported screening of depression and anxiety and the outcome of such screening, was performed (Appendix K). To test the second objective, a descriptive analysis of the investigator-generated item in the initial survey which asked respondents if they were currently having problems with depression and/or anxiety (yes/no) was performed (Appendix E). Responses were cross-referenced to participant symptom scores on the scales (Appendix F and G). The number of participants who scored above thresholds, yet did not report depression and/or anxiety, was described.

To test the third objective, participants who self-reported currently experiencing psychosocial distress and/or scored above the thresholds indicating elevated distress on the BDI-II or PHQ-2 were first selected (Appendix N). Due to a change in survey scales after the study had begun, a small number of participants received the HADS scale instead of the BDI-II in their pre-test survey. In this case, those that scored above thresholds on the HADS-D were also selected (Appendix L). A descriptive analysis of treatment pre and post-test was performed (Appendix E and K). Among those receiving treatment, description of treatment and provider type was performed. To test objectives d-f, participants who were prescribed pharmacological therapy were selected. Next, a descriptive analysis of the drug classification, medication adherence, and the frequency of medication and/or dosage change from pre to post-test assessment was performed (Appendix H and I).

To test the final objective, a multiple linear regression was undertaken to examine whether receipt of any treatment post-test (yes/no) was associated with depressive and anxious symptom severity at post-test (Appendix L), in those with elevated symptoms of psychosocial distress at pre-testing. The model adjusted for sociodemographic and clinical variables shown to be associated with post-test depressive and anxious symptom severity in bivariate analyses.

Results

Respondent characteristics

Of the 139 participants included in this analysis, 111 (79.9%) participants were retained at the 6-month follow-up. **Table 1** displays the pre-test sociodemographic, clinical and psychosocial characteristics of the respondents and non-respondents. As shown, there were no significant differences in sociodemographic characteristics between groups. However, retained participants were more likely to have undergone a PCI compared to those lost to follow-up. No other clinical differences were found between retained participants and those lost to follow-up. Finally, there were no significant differences in depressive symptoms by retention status.

As shown in **Table 1**, 49 (44.1%) retained participants experienced elevated symptoms of psychosocial distress at baseline. As expected, there were significant differences in psychometrically-validated depression scales by categorization of evaluated symptoms of psychosocial distress versus no distress, suggesting the categorization was valid. Moreover, those with elevated distress symptoms were significantly more likely to have a self-reported history of depression or anxiety, as well as self-reported history of treatment for depression or anxiety than those without distress. Participants with elevated symptoms were also significantly younger, had a higher body mass index, and were more likely to have dyslipidemia than participants without elevated symptoms.

At post-test, 38 (34.5%) participants were considered to be experiencing elevated symptoms of psychosocial distress (no significant difference between the number of

women with elevated symptoms at pre and post-test; McNemar test= $p>0.05$; OR=4.92). A significant difference between pre and post-test PHQ-2 symptom scores was found for women with elevated symptoms at pre-test (mean difference= -0.76; paired t=3.27, p <0.01). **Table 2** displays post-test psychosocial indicators among women with elevated symptoms of psychosocial distress and those without at pre-test. At follow-up, those with elevated symptoms at pre-test still had significantly higher symptom scores on psychometrically-validated scales than participants without elevated symptoms, but their mean scores fell below the established cut-offs. No differences in exercise behaviour, medication adherence or CR use were observed.

Screening and Awareness

Thirty-seven (34.9%) participants self-reported that they recalled being asked about their mood and/or anxiety by any healthcare provider at post-test. Forty-four (42.8%) participants reported they recalled being formally screened for psychosocial distress, of which 32 (31.1%) reported completing a paper-and-pencil screen, 4 (3.9%) a structured interview, and 8 (7.8%) reported completing both. The number of participants who reported being asked about their mood and undergoing formal screening did not significantly differ in those who ultimately enrolled in CR following referral versus those who did not ($p=0.54$ and $p=0.59$, respectively).

Of those who reported being formally screened, 8 (18.6%) had their results discussed with them. The outcomes of formal screening were (participants were asked to check all that apply): appropriately nothing (n=17, 45.9%), pharmacology prescription (n=5; 13.5%), referral to a mental health professional (n=5; 13.5%), follow-up by a

healthcare provider (n=5; 13.5%), inappropriately nothing (n=4; 10.8%), referral for other mental health treatment (n=1; 2.7%), other (n=5; 13.5%), and unknown by patient (n=1; 2.7%).

Sixty-eight (48.9%) women were considered to be experiencing elevated psychosocial distress at the initial assessment (of which 49 participants were retained at follow-up). Of these, 18 (26.5%) reported they were not anxious or depressed, and thus could be considered unaware that they may have a psychological disorder.

Treatment of Distressed Women

Of the 49 distressed women retained at post-test, 21 (42.9%) were receiving some form of treatment at pre-test. Of these, 18 (85.7%) were still receiving treatment at post-test, and 3 (14.3%) were not. Of those 49 distressed women at pre-test, 23 (47.9%) were receiving some form of treatment at post-test (i.e., 18 patients + 5 new). The number of participants receiving treatment did not significantly differ between pre and post-test assessment (McNemar test=$p>0.05$; OR=27.60). **Table 3** displays the types of treatment, as well as who was providing it, at both assessment points. The number of distressed women receiving treatment, and type of treatment did not differ by CR enrollment ($p>0.05$ in all cases).

Of those receiving treatment, 17 (80.9%) were taking psychoactive medications at pre-test and 21 (91.3%) were taking them at post-test. Their overall mean medication adherence score was 3.81±0.40 at pre-test and 3.21±1.01 at post-test, with 3 (18.8%) and 9 (42.9%) considered "non-adherent", respectively. **Table 3** also displays the class of psychoactive medication taken at both time points. The same medication was reported at

both assessment points for 10 (83.4%) participants, for which 2 (16.7%) participants reported a change in dosage over time (one increased and one decreased). Two (16.7%) participants reported a change in psychoactive medication from pre to post-test: one from selective serotonin reuptake inhibitor to a serotonin norepinephrine reuptake inhibitor, and one switched medications within the atypical class.

Participants who were receiving any form of treatment at pre-test had significantly higher depressive (6.95±5.19 vs. 3.83±3.31) and anxious (10.38±4.61 vs. 5.89±3.68) symptom scores at post-test than those who were not receiving treatment ($p<0.001$ in both cases). Similarly, participants who were receiving any form of treatment at post-test had significantly higher depressive (7.13±4.98 vs. 3.40±3.08) and anxious (10.52±4.35 vs. 5.40±3.43) symptom scores at post-test than those who were not receiving treatment ($p<0.01$ and $p<0.001$, respectively). **Table 4** displays analysis of correlates of depressive and anxious symptoms at post-test. Unadjusted analyses showed that greater pre-test psychosocial distress symptom scores were significantly associated with greater depressive and anxious symptom scores at post-test. Moreover, greater post-test exercise behaviour was found to be significantly related to lower post-test depressive symptom severity.

Two multiple linear regressions were performed to ascertain whether receipt of any treatment (independent variable) was related to psychosocial distress scores at post-test (i.e., HADS-D and HADS-A; dependent variables). The model was adjusted for pre-test symptom scores and post-test exercise behaviour (i.e., significant differences identified in Table 5), as well as age and cardiac indication (i.e., primary significant

differences identified in Table 1). PHQ-2 scores were not included due to their correlation with BDI-II scores. The results are shown in **Table 5.** The models overall were significant ($F=5.68$, $p<0.01$; $F=5.20$, $p=<0.01$, respectively), and were amply powered (0.94 and 0.92, respectively). The effect of treatment on depressive or anxious symptom severity at post-test did not sustain adjustment, suggesting that pharmacologic or counseling treatments did not seem to lower symptom scores. As shown, psychosocial distress symptom scores at post-test were significantly related to psychosocial distress symptom scores at pre-test, but no other variables in the model were found to be significantly related.

Discussion

These findings reiterate the great burden of psychosocial distress among women with CVD[33], with approximately half of women displaying elevated symptoms. Of these, 25% were unaware or did not consider themselves to be experiencing elevated symptoms. Despite clinical recommendations, less than half of women cardiac patients recall being formally screened for depression and anxiety. Even when screened, only one in five recall being informed of the results. This clearly represents a gap in patient-provider communication. Finally, less than half of women with elevated symptoms were receiving treatment, but regardless, receiving treatment had no significant impact on their symptoms. While a structured clinical interview is needed to confirm a psychological disorder and whether treatment is warranted, these findings certainly corroborate previous reports of insufficient and even inappropriate (i.e., TCAs) treatment of this important co-morbidity.

Despite recommendations, depression is not routinely identified in cardiac patients[34], a finding which was reiterated in the current study. Shanmugasegaram et al.[35] found that only 28.7% of coronary artery disease patients reported being screened following a cardiac hospitalization, and 32.5% of patients enrolled in CR reported being screened. While the rates in our study were somewhat higher, given that less than half of women recall being screened, perhaps it is not surprising that so many women with elevated symptoms of distress were unaware.

Given CR-specific screening recommendations[18], it was surprising that patients who enrolled in CR following referral did not report greater rates of screening than patients who did not enroll. Given women's great burden of both psychosocial distress as well as heart disease, the CR context presents an important opportunity to screen and address these co-morbidities, to improve women's psychological and potentially physical well-being. It is hoped results from this study will raise awareness of the importance of screening in the CR setting, and how CR programs are under-performing in their patient communication regarding screening. It is postulated that CR staff who undertake intake assessments including depressive symptoms may need training to improve their patient communication skills regarding what can be a sensitive topic. It is also suggested that there is insufficient capacity to ensure effective treatment is available for all patients who screen positive, given the chronic under-funding of CR services, which may serve as a deterrent to screening.

A number of studies have examined the effect of in-hospital depression screening on patient outcomes[36–38]. Results suggest that when screening is combined with

"collaborative care", patients can achieve significant reductions in depressive symptoms[36–38]. Moreover, some studies have also reported significant improvements in mental health-related quality of life (HRQoL)[36,37], adherence to medical recommendations[36], physical function[37] and reductions in the number and intensity of cardiac symptoms[36] with this approach. Our results suggest that while few women cardiac patients recall being screened, even fewer recall being informed of the results, and for this reason, it is unknown if these benefits could be achieved. Given that less than half of the women in the study who were distressed received any form of treatment, it is unlikely that the above benefits could be achieved.

Our findings are not consistent with many of the major CVD and psychosocial distress trials, which showed that psychoactive drugs, psychotherapy, or a combination of the two, improve psychological outcomes[11–14]. Our data are pragmatic and observational, and suggest that distressed women patients are: (a) not getting sufficient therapy (b) may need to change or introduce additional therapeutic modalities to achieve symptom control and remission, or (c) have chronic treatment-resistant depression. In the case of pharmacological treatment, which was the primary form of treatment in this sample, it is known that individuals being treated with psychoactive drugs are not put on an full therapeutic dose right away, to reduce the chance of side effects[9]. Patients should be followed-up with by their physician to observe how they are tolerating the medication, whether they are experiencing side effects, and to up-titrate the dose if needed (to balance efficacy and safety)[9,39]. Our results suggest patients may not be receiving adequate follow-up, as only 1/3 of those treated pharmacologically reported any change in

medication (i.e. type or dose change; although we acknowledge that we do not have data on the frequency of follow-up visits to the treating healthcare professional). It has been reported that only 20-30% of patients undergoing depression treatment receive adequate care and follow-up in the primary care setting[6]. Given most patients were receiving therapy from primary care, and the CR setting was also shown to be ineffective, perhaps it is time to increase the capacity of cardiac psychologists and psychiatrists to address this burden.

Caution is warranted when interpreting these findings. First, the protocol did not include a structured clinical interview to formally diagnose depression or anxiety, so the number of participants with a major depressive disorder or anxiety disorder is unknown, as is the appropriateness of the rates of treatment. Indeed, self-report of depressive and anxiety symptoms is subject to under-reporting bias. Second, rates of distress screening and identification may be under-reported due to possible recall bias. Screening was only ascertained through self-report, and they may have forgotten screening that had occurred months prior. Indeed, the CR programs where patients were referred routinely administer a paper-and-pencil depression survey, however we did not verify this in CR charts. Third, due to the nature of the study design, causality in the relationship between the variables of interest and symptom control cannot be inferred. Fourth, the MMAS assesses adherence to medications broadly, and is not specific to psychoactive medications. Therefore, the degree of patient adherence to prescribed psychoactive medications cannot be known. Finally, results are limited by selection and retention bias. With regard to the former, it is not known how participants who consented to participate in this randomized

trial on CR differed from those who did not, however previous research has suggested that there are some important differences which may impact the generalizability of these findings[40]. While the only observed difference between those retained and lost to follow-up was in the rate of PCIs, there may be unmeasured factors which introduce a bias in our retained sample.

In conclusion, our findings reiterate the great burden of psychosocial distress in women cardiac outpatients. Despite guideline recommendations, screening rates are suboptimal, and communication of results to patients is minimal. Where treated, most women were often prescribed psychoactive medication from their family physicians, however substantive symptom reduction compared to those not receiving treatment was not achieved.

Acknowledgments

This research was funded by the Heart and Stoke Foundation of Ontario (HSFO), Grant-in-Aid #NA 6682. Other co-investigators are: Dr. Kenneth Melvin (University Health Network, Toronto Western Hospital), Dr. Louise Pilote (McGill University Health Centre and McGill University), and Dr. Stephanie Brister (University Health Network), and Dr. Tracey Colella (University Health Network, Toronto Rehabilitation Institute) was a collaborator. We gratefully acknowledge the efforts of Yongyao Tan, MSc, CCRP (University Health Network) in data management, and all the patients who volunteered their time to participate in this research study.

Disclosures

None.

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Table 1. Participant Characteristics at Pre-Test (N=139)

Characteristics	Retained Participants			Lost-to follow-up	Total
	Self-reported distress and/or elevated scores n=**49 (44.1%)**	No self-reported distress and/or elevated scores n=**62 (55.9%)**	Total N= **111**	n=**28**	N=**139**
Sociodemographic					
Age, years (mean ± SD)	62.95 ± 8.40	68.96 ± 10.90	66.38 ± 10.30**	61.73 ± 10.10	65.54 ± 10.38
Marital Status, n (% married)	23 (46.9)	34 (54.8)	57 (51.4)	13 (46.4)	70 (50.4)
Work Status, n (% retired)	23 (46.9)	39 (62.9)	62 (55.9)	14 (50.0)	76 (54.7)
Highest Education, n (% post-secondary)	13 (26.5)	24 (38.7)	37 (33.3)	9 (32.1)	46 (33.1)
Ethnicity, n (% white)	37 (75.5)	45 (72.6)	82 (73.9)	17 (60.7)	99 (71.2)
Annual Family Income, n (% $50,000CDN or greater)	25 (51.0)	40 (64.5)	65 (58.6)	16 (57.1)	81 (58.3)
Children, n (% yes)	39 (83.0)	49 (80.3)	88 (81.5)	23 (82.1)	111 (81.6)
Clinical					
Cardiac Indication					
PCI (% yes)	26 (57.8)	29 (50.9)	55 (53.9)	5 (21.7)	60 (48.0)††
Angina/ACS/CAD (% yes)	19 (43.2)	18 (32.1)	37 (37.0)	10 (43.5)	47 (38.2)
MI (% yes)	15 (33.3)	17 (30.4)	32 (31.7)	6 (26.1)	38 (30.6)
CABG (% yes)	8 (17.8)	20 (35.1)	28 (27.5)	5 (21.7)	33 (26.4)
Valve (% yes)	7 (15.6)	14 (25.0)	21 (20.8)	6 (26.1)	27 (21.8)
BMI (mean ± SD)	31.68 ± 7.82	27.86 ± 5.23	30.01 ± 7.07**	31.04 ± 9.28	30.24 ± 7.47
Diabetes, n (% yes)	13 (36.1)	8 (19.5)	21 (27.3)	7 (41.2)	28 (29.8)
Hypertension, n (% yes)	27 (73.0)	40 (81.6)	67 (77.9)	15 (78.9)	82 (78.1)
Dyslipidemia, n (%)	34 (97.1)	36 (80.0)	70 (87.5)*	18 (90.0)	88 (88.0)
Exercise Behavior (mean ± SD)	21.97 ± 20.35	19.51 ± 14.13	20.62 ± 17.19	17.77 ± 23.48	20.04 ± 18.60
Psychosocial					
Self-Reported History of Depression or	22 (45.8)	13 (22.8)	35 (33.3)*	13 (52.0)	48 (36.9)
Self-reported History of Pharmacological	11 (22.9)	7 (12.3)	18 (17.1)**	4 (16.0)	22 (16.9)
Self-reported History of Psychotherapy for	14 (29.2)	12 (20.7)	26 (24.5)**	10 (40.0)	36 (27.5)
BDI-II (mean ± SD)	17.73 ± 12.07	5.42 ± 3.73	10.57 ± 10.26***	10.94 ± 7.75	10.65 ± 9.75
PHQ-2 (mean ± SD)	2.11 ± 2.00	0.36 ± 0.62	1.17 ± 1.67***	1.17 ± 1.37	1.17 ± 1.62

PCI, Percutaneous Coronary Intervention; ACS, Acute Coronary Syndrome; CAD, Coronary Artery Disease; CDN, Canadian dollars; MI, Myocardial Infarction; CABG, Coronary Artery Bypass Graft; BMI, Body mass index; BDI, Beck Depression Inventory; PHQ, Patient Health Questionaire

Denotes difference between participants with elevated vs. no elevated symptoms ($p < .05$; **$p < .01$; ***$p < .001$).

†Denotes difference between participants who were retained vs. not retained at 6 month follow-up (†$p < .05$; ††$p < .01$; †††$p < .001$).

Table 2. Post-Test Psychosocial and Other Indicators among Women by Psychosocial Distress Status at Pre-Test (N=111)

Variable	Self-reported distress and/or elevated scores n=**49 (44.1%)**	No self-reported distress and/or elevated scores n=**62 (55.9%)**	Total
Psychosocial Symptoms†			
Depressive Symptoms (PHQ-2)	1.42 ± 1.88	0.37 ± 0.91	0.83 ± 1.50**
Depressive Symptoms (HADS-D)	5.19 ± 4.48	2.42 ± 2.18	3.63 ± 3.63***
Anxious Symptoms (HADS-A)	7.85 ± 6.65	3.65 ± 2.85	5.48 ± 4.27***
Psychosocial Distress Screening (% yes)	21 (44.7)	16 (27.1)	37 (34.9)
Exercise Behaviour (Godin)†	26.94 ± 17.92	29.32 ± 17.94	28.25 ± 17.89
Medication Adherence (MMAS)†	3.49 ± 0.79	3.69 ± 0.67	3.63 ± 0.73
Enrolled in CR (% yes)	43 (87.8)	59 (95.2)	102 (91.9)
Completed CR (% yes)	30 (69.8)	40 (85.1)	70 (77.8)

PHQ, Patient Health Questionnaire; HAD-A and HAD-D, Hospital Anxiety and Depression Scale, MMAS, Morisky's Medication Adherence Scale

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ for t-test or chi-square comparing indicators by psychosocial distress status, as appropriate.

†mean and standard deviation.

Table 3. Treatment of Patients who were Considered Distressed at Pre-Test, by Assessment Point

	Pre-Test **(n=21; 42.9% treated)**	Post-Test **(n=23; 47.9% treated)**
Treatment Type		
Medication	10 (46.7)	13 (56.5)
Combination	7 (33.3)	8 (34.8)
Counseling	4 (19.0)	2 (8.7)
Type of Provider*		
Family Doctor	13 (68.4)	18 (90.0)
Psychiatrist or Psychologist	7 (36.8)	5 (25.0)
Other	2 (10.5)	4 (20.0)
Nurse	1 (5.3)	2 (10.5)
Cardiologist	1 (5.3)	2 (10.0)
Class of Psychoactive Medication*†		
SSRI	5 (33.3)	4 (21.1)
Atypical antidepressant§	7 (46.7)	6 (31.6)
Benzodiazepines	5 (33.3)	10 (52.6)
SNRI	3 (20.0)	3 (15.8)
TCA	2 (13.3)	2 (10.5)

*Note that some women reported receiving treatment from more than one type of provider and taking more than one psychoactive medication.

SSRIs, Selective Serotonin Reuptake Inhibitors; SNRIs, Serotonin Norepinephrine Reuptake Inhibitors; TCA, Tricyclic Antidepressants.

† Includes those treated with medication (n=17 and n= 21, respectively)

§for example: Mirtazapine, Bupropion and Trazodone.

Table 4. Sociodemographic and Clinical Correlates of Depressive and Anxious Symptom Severity at Post-Test (N=49)

	Depression† t / r	Anxiety† t / r
Sociodemographic		
Age	-.263	-.281
Marital Status (married)	-.137	-.369
Work Status (retired)	-.020	-.845
Highest Education (post-secondary)	.139	.408
Ethnicity (white)	1.203	.160
Annual Family Income ($50,000CDN or greater)	-.032	.030
Children (yes)	-.416	-1.306
Clinical		
Cardiac Indication		
PCI (yes)	-1.549	-1.409
Angina/ACS/CAD (yes)	1.699	-1.364
MI (yes)	-.924	-.896
CABG (yes)	1.136	1.321
Valve (yes)	-.848	-.381
BMI	.189	.120
Exercise Behavior (Godin)†	-.302*	-.155
Diabetes (yes)	1.486	.231
Hypertension (yes)	.475	.295
Dyslipidemia (yes)	-.376	-1.443
CR Enrollment (yes)†	-1.468	-1.510
CR Completion (yes)†	-1.418	-.867
Psychosocial		
Treatment (yes)†	3.087**	4.539***
BDI-II	.626***	.567***
PHQ-2	.548***	.528***
PHQ-2†	.891***	.782***

PCI, Percutaneous Coronary Intervention; ACS, Acute Coronary Syndrome; CAD, Coronary Artery Disease; CDN, Canadian dollars; MI, Myocardial Infarction; CABG, Coronary Artery Bypass Graft; BMI, Body mass index; BDI, Beck Depression Inventory; PHQ, Patient Health Questionaire

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ for t-test and Pearson's correlation (r), as applicable.

† Assessed at post-test. All other variables assessed at pre-test.

Table 5. Adjusted Multiple Linear Regression Model Examining the Association of Treatment with Depressive and Anxious Symptom Severity at Follow-up (N=49)

	Depressive Symptoms					Anxiety Symptoms				
Variable	**β**	**SE**	**p**	**95% CI**		**β**	**SE**	**p**	**95% CI**	
				Lower Bound	Upper Bound				Lower Bound	Upper Bound
Treatment	-.443	1.483	.768	-3.498	2.612	-2.416	1.431	.104	-5.363	.531
Psychosocial Distress at Pre-Test (BDI-II)	.211	.061	.002	.086	.336	.167	.059	.009	.046	.288
Exercise Behavior Post-test (Godin)	-.022	.039	.581	-.103	.059	-.003	.038	.932	-.081	.075
Age	-.128	.081	.127	-.296	.039	-.098	.078	.221	-.260	.063
PCI	1.411	1.403	.324	-1.478	4.300	.536	1.353	.695	-2.251	3.323

PCI, Percutaneous Coronary Intervention; BDI, Beck Depression Inventory
CI, Confidence interval; SE Standard Error.

Extended Results and Discussion

Overall, we were not concerned about missing clinical data as it was only used to describe the sample. However, missing depression and anxiety data was examined. A total of 109 (78.4%) participants completed the BDI-II and 125 (89.9%) the PHQ-2. Of those participants who were retained at follow-up, 110 (99.1%) completed both HADS-D and HADS-A.

We originally proposed to handle missing data with the use of multiple imputation. After discussing this with a statistical consulting service consultant through the Institute for Social Research at York University, we decided to approach missing data using listwise deletion. Although this method decreases sample size and has the potential to create bias in the results when dealing with sensitive data, we perceived it was a preferable option to imputation which has the potential to create even greater bias. With regard to sample size, we had sufficient power to test the hypotheses proposed. Moreover, the reason for much of the missing data was a change in assessment tools by the investigators after the study had begun (i.e., 28 [21.1%] participants were not administered the BDI-II at pre-test). Therefore the reason for this missingness was not a patient-related bias. Although depression and anxiety could be considered as sensitive by patients, the rate of survey completion was high.

Clinical Implications

General principles for any kind of screening[61] specify that programs should be implemented if: (a) the condition is common and (b) associated with significant morbidity[7,28], (c) if screening is accurate[62,63], (d) low cost[64], and (e) there is effective

therapy available[37,41,44–46]. In the case of co-morbid depression, most of these elements appear to be satisfied. However, it suspected there in insufficient capacity to ensure that effective therapy is available for all patients who screen positive, especially in the context of CR.

Despite recommended guidelines, our data shows that less than half of women reported being screened. Moreover, screening rates did not differ between those who enrolled in CR and those who did not. At this time, little is known about screening rates in the CR context. A literature search carried out pertaining to depression screening and treatment in the cardiac setting identified no information available in the CR context, suggesting a gap in this area of research[65]. An abstract prepared in the Grace lab suggested that 28.7% of patients recalled being screened for depression since their cardiac diagnosis, while 32.5% of those enrolled in CR recalled screening[66]. This is fairly-consistent but somewhat lower than the results reported herein (34.9%).

Although it has been reported that depression screening alone does not improve cardiac patient outcomes[66], when screening is combined with adequate follow-up (i.e. communication between healthcare providers, frequent check-ins, medication adjustments, promotion of treatment adherence, etc) significant improvements can be achieved[64,67,68]. A number of studies have shown the effectiveness of screening in combination with adequate follow-up care in improving depressive symptoms[64,67,68], quality of life[67,68], and physical function[68]. These studies suggest that while screening for depression on its own is not sufficient to obtain substantive improvements in patient

outcomes, it is important to provide patients with a system of care which will assist them in achieving significant improvements throughout their rehabilitative process.

Future Directions

Unfortunately, there continues to be a lack of evidence for the efficacy of screening, and some have suggested that the American Heart Association should reconsider their advisory to screen[69]. However, given the high co-morbidity of CVD and depression, as well as the association between depression and adverse outcomes in cardiac patients, there appears to be consensus that screening should be undertaken if and only if it can be combined with effective and appropriate care.

Future research is needed to examine screening and treatment of psychosocial distress in the CR setting in jurisdictions other than Ontario. These studies should not only observe rates of screening in CR, but also the rates of referrals to internal and external sources for all patients who screen positive, and the number of follow-up visits over time. As stated above, sufficient follow-up appears to be crucial for patients to achieve remission. It is not clear what role the CR team plays in follow-up care for depressed patients, and how this differs in programs where their staffing complement includes a psychologist or psychiatrist. It is important to outline how the CR team could be utilized in follow-up for patients who are identified as distressed, as patients have repeated contacts with staff on a weekly basis, and there is communication between the CR program and other members of the patients' circle of care.

Moreover, although adequate follow-up seems to be essential for effective treatment, it may also be imperative to catch inappropriate treatment. Past research has

reported that there is little difference in the efficacy of psychoactive medications in treating mild to moderate depression, but differences in adverse effects among the medications are significant[70]. Over the past two decades, SSRIs have become known as a first-line pharmacological treatment for depression in cardiac patients, given they are shown as both safe and effective in cardiac patients[70]. In the past, TCAs were shown to successfully treat depression in cardiac patients[71]. Unfortunately, it has been identified that TCAs can have negative effects on the cardiovascular system, including hypotension, pro-arrhythmic effects, cardiac conduction problems and significant drug interactions[70,71]. Despite the fact that TCAs are accordingly contraindicated for cardiac patients, our results revealed that over 10% of the women who were taking a psychoactive medication were taking TCAs at pre-test and rates of those on TCAs remained stable at post-test. Our results suggest there has been little reduction in the rates of use of these contraindicated medications. Benazon et al.[72] examined trends in anti-depressant prescription for post-MI patients over a decade. It was found that rates of TCA anti-depressant prescriptions decreased, but the proportion of post-MI patients receiving TCAs remained stable at 6%. Another study examining anti-depressant use in cardiac patients found that 12.5% of patients reported taking TCAs[73]. It would be interesting to see if adequate screening rates and follow-up in the CR context would have an effect on the number of patients treated with contraindicated medications.

Conclusion

Rates of psychosocial distress screening in the CR context are low, despite clinical recommendations. Given the high co-morbidity of CVD and depression,

screening and treatment are important, but sufficient follow-up care seems to be imperative for patients to achieve substantive improvements. Little is known regarding screening, treatment and follow-up care of depression in the CR setting. It is hoped that these preliminary findings spur future research, as well as implementation of more systematic processes of CR care to address the mental health needs of cardiac patients.

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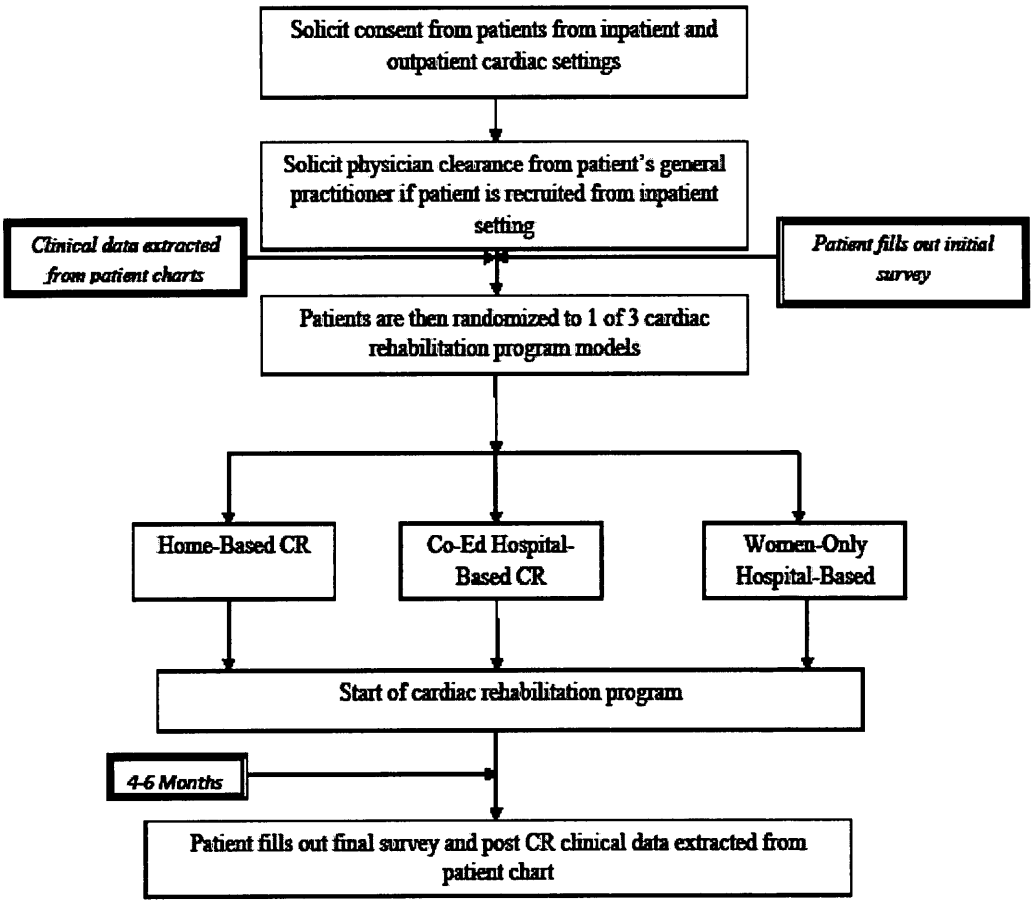
Appendix A: Study Design

Pictorial Flow Diagram: Cardiac Rehabilitation for Heart Event Recovery



Appendix B: Case Report Form

CR4HER Case Report Form (CRF)

1. Study ID #: _____

2. Today's Date [dd] [mmm] [yyyy]

3. Index Cardiac Condition and/or Procedure *(check all that apply)*:

- ☐ PCI
- ☐ CABG
- ☐ Unstable Angina / ACS
- ☐ MI

4. Patient Ineligible for Study: ☐ Yes (if yes, specify below) ☐ No

- ☐ Musculoskeletal, neuromuscular, vision, cognitive or non-dysphoric psychiatric condition which precludes CR eligibility, specify: _____
- ☐ Does not speak/read English proficiently
- ☐ Lives and works too far from CR sites (Hwy 427, across Hwy 7 to far end of Scarborough)
- ☐ Planning to leave the province or region in the next 9 months
- ☐ Not eligible for home-based CR, specify:
  - ☐ Complex ventricular dysrhythmia
  - ☐ Ejection fraction <40% and/or NYHA Class > 2
  - ☐ CCS Class 4
  - ☐ Didn't pass GXT at CR intake (< 3 min tolerated of modified Bruce Treadmill Protocol)
- ☐ Enrolled in other study with behavioural intervention
- ☐ Referral to CR program prior to study randomization
- ☐ Terminal illness or life-threatening condition
- ☐ Being discharged to long-term care
- ☐ Previous participation in CR, so recent that CR program deems pt not eligible to re-enroll at this time
- ☐ Patient does not have cardiac diagnosis or procedure meeting inclusion criteria (e.g., angiogram results negative, review of discharge note)
- ☐ Physician clearance not received
- ☐ Physician does not deem patient eligible (clearance received, negative response)
- ☐ Other, please specify: _____

5. Patient Decline to Participate:
   ☐ No ☐ Yes -Reason, if willing: _____

6. PI / Investigator confirm patient eligible:

   ☐ Eligible ☐ Ineligible, Reason: _____

_____ _____
P.I. Signature **Date**

Stop here if patient is ineligible or declined.

CRF Completed By: _____	CRF Entered By: _____
Date: _____	Date: _____

Study ID#: _____

7. Age [ ] yrs

8. Admission Date [ ] [ ] [ ] (dd mmm yyyy)

9. Discharge Date [ ] [ ] [ ] (dd mmm yyyy)

10. Index Cardiac Condition and/or Procedure:

☐ PCI Date: _____

Procedure:	Vessel(s):
☐ Primary	☐ LM
☐ Non-Primary	☐ RCA
☐ Unknown	☐ LAD (circle: prox / med / dist)
	☐ Circ
	☐ Ramus

☐ CABG Date: _____

Vessel(s):

- ☐ LM
- ☐ RCA
- ☐ LAD (circle: prox / med / dist)
- ☐ Circ
- ☐ Ramus

☐ Concurrent heart valve Date: _____

Surgery:	Valve(s):
☐ Repair	☐ Aortic
☐ Replace	☐ Tricuspid
	☐ Bicuspid
	☐ Pulmonary

☐ MI Date: _____

Location(s):	Type:
☐ Anterior	☐ STEMI
☐ Inferior	☐ NSTEMI
☐ Lateral	☐ Q-Wave
☐ Posterior	☐ BBB
☐ Septal	☐ NON-Q-Wave
☐ Rt Ventricular	☐ Unstable Angina

☐ ACS Confirmation Date: _____

☐ ECG ☐ Angiogram ☐ Enzymes ☐ Symptoms

☐ Other cardiac cond(s) Date: _____

☐ CHF	☐ Arrhythmia
☐ Infection	☐ Congenital HD
☐ Valve Condition	☐ Cardiomyopathy
☐ Infection	☐ Aneurysm

11. Current Medications (*check all*):

☐ ACE Inhibitors	☐ Anti-arrhythmic
☐ Anti-coagulants	☐ Anti-platelets
☐ ASA	☐ Beta-blockers
☐ Ca^{2+} antagonists	☐ Digoxin
☐ Statin	☐ Nitrates (not PRN)
☐ LL – fibrate	☐ ARBs
☐ LL – nicotinic acid	☐ Anti-depressant
☐ LL – resin drugs	☐ Coumadin
☐ Diuretics	☐ Heparin
☐ Clopidogrel or ticlopidine	☐ HRT
☐ Other anti-platelet	☐ Insulin
☐ Nicotine Replacement	☐ Oral hypoglycemics

☐ Other: _____

12. CCS Angina Class:

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

→ ☐ IV-a ☐ IV-b ☐ IV-c ☐ IV-d

13. NYHA Functional Class:

☐ 1 ☐ 2 ☐ 3 ☐ 4

14. LV Function:

☐ Nuclear ☐ Echo ☐ Angiogram

☐ LVEF %: _____

☐ Narrative: _____

_____

☐ Normal ☐ Mild ☐ Moderate ☐ Severe

☐ Date assessed: _____

15. Complications during stay:

☐ Arrhythmia	☐ Cardiac Arrest
☐ Recurrent Angina / ischemia	☐ Pericarditis
☐ Cardiogenic shock	☐ Pneumonia
☐ Cerebrovascular Accident	☐ Acute Renal Fail
☐ Readmit (ICU / CCU)	☐ DVThrombosis
☐ Infection	☐ MI
	☐ Cardioversion
	☐ Cardiac Tamponade
	☐ Other: specify:

Study ID#: _____

16. Risk Factors:

Y	N	
☐	☐	Diabetes: ☐ Type I ☐ Type II HbA1c%: _____ Date assessed: _____
☐	☐	Obesity (BMI>30) BMI (kg/m^2): _____ Waist circ (cm): _____ Date assessed: _____
☐	☐	Hypertension BP: syst: _____ / diast: _____ Date assessed: _____
☐	☐	Dyslipidemia Total Cholesterol: _____ HDL: _____ LDL: _____ Triglycerides: _____ Date assessed: _____

17. CRP: _____
Date assessed: _____

18. Heart rate: _____
Date assessed: _____

19. Previous cardiac diagnosis?

☐ CAD	☐ Infection
☐ CHF	☐ Valve condition
☐ Arrhythmia	☐ Cardiomyopathy
☐ Congenital HD	☐ Other: _____
☐ ACS/MI	☐ None

20. Comorbid Conditions

- ☐ Cancer
- ☐ Hyperthyroid
- ☐ Liver Disease
- ☐ PAD/PVD
- ☐ Depression
- ☐ Renal Disease
- ☐ MSK / Joint Replacement, specify: _____
- ☐ Other: _____

21. Family physician:
_____
Phone number:
_____

22. Cardiac specialist(s):
_____
Phone number:
_____

23. Clearance Received:
☐ Yes ☐ No

24. Received By:
☐ Family Physician ☐ Cardiac Specialist
☐ Both

25. Cleared for CR referral:
☐ Yes ☐ No

26. Randomized to:
- ☐ Home based
- ☐ Co-ed hospital based
- ☐ Women only

27. Site referred to: ☐ TRI ☐ TWH

28. Referral Date: | | | | (dd mmm yyyy)

29. Call to patient re: program site & model:
☐ Yes ☐ No
Date: | | | | (dd mmm yyyy)

Notes:
_____
_____

30. Did patient go off-study?
☐ Yes ☐ No
If yes, specify: _____

Study ID#: _____

1. Patient's First Name:

2. Patient's Last Name:

3. Preferred Salutation:

- ☐ Ms.
- ☐ Mrs.
- ☐ Dr.

4. Patient's Telephone Number:

(Area code)

5. Patient's Address:

Street Address			
City			
Province	ON	Postal Code	

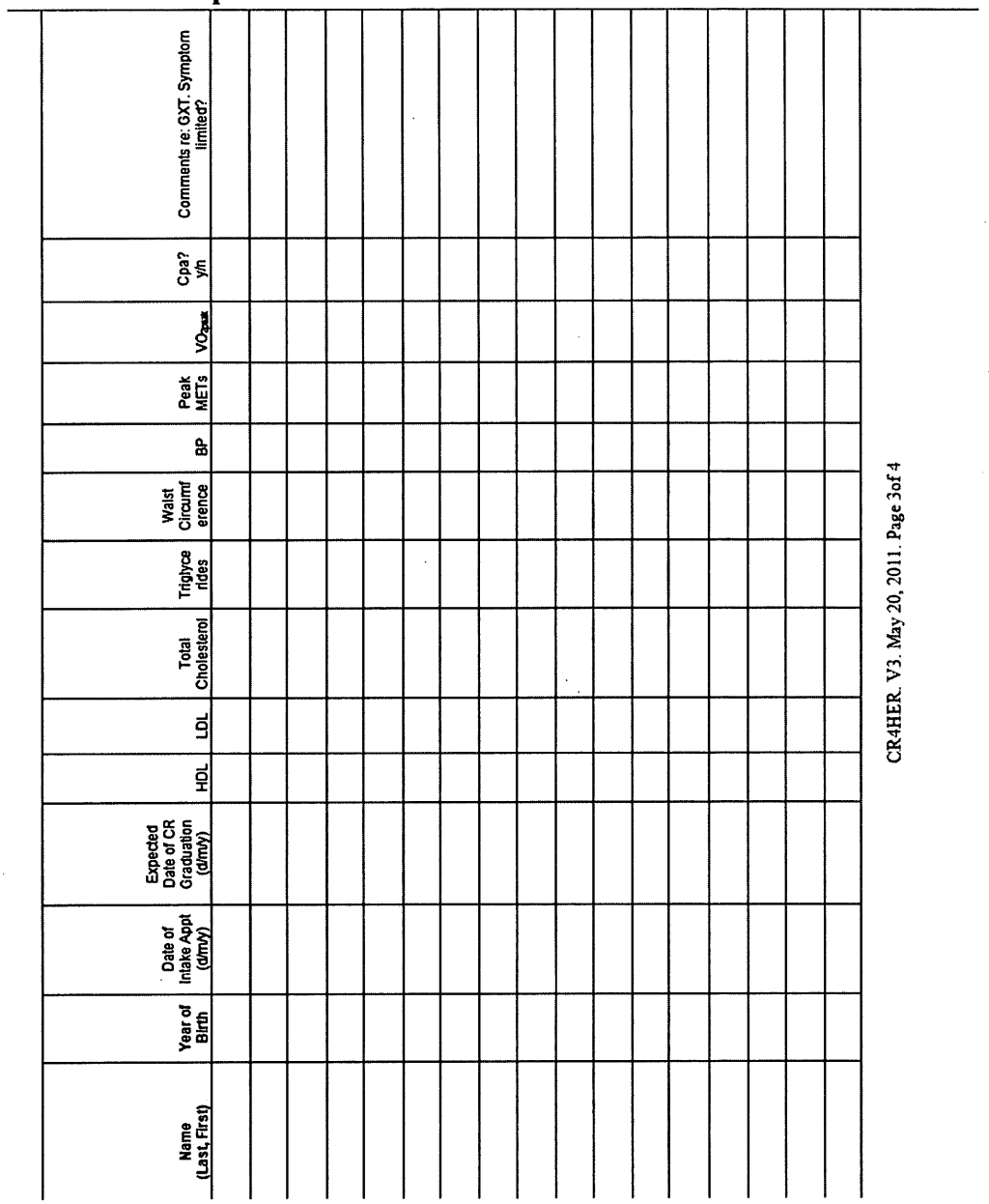
6. Patient's email address: _____

7. Alternate Contact Information (*if willing*):

Name	
Relationship	
Telephone	

8. If patient works rather than lives close to the CR programs, record office postal code:_____

Appendix C: Intake Report Form



Name (Last, First)	Year of Birth	Date of Intake Appt (d/m/y)	Expected Date of CR Graduation (d/m/y)	HDL	LDL	Total Cholesterol	Triglycerides	Waist Circumference	BP	Peak METs	VO_{2peak}	Cpa? y/n	Comments re: GXT: Symptom limited?

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Appendix D: Assessment of Sociodemographic Characteristics

SECTION N: DEMOGRAPHICS and CARDIAC RISK FACTORS

1. What do you consider to be your racial/ethnic background? Please check ☑ one (1) of the following boxes:

   - ☐ White (Caucasian)
   - ☐ French-Canadian
   - ☐ Jewish
   - ☐ Arab / West Asian (e.g., Afghan, Armenian, Iranian, Egyption, Lebanese, Morrocan)
   - ☐ South Asian (e.g., East Indian, Punjabi, Pakistani, Bengali, Nepali, Sri Lankan)
   - ☐ South East Asian (e.g., Cambodian, Indonesian, Malaysian, Singaporean, Vietnamese, Thai)
   - ☐ Chinese
   - ☐ Japanese
   - ☐ Filipino
   - ☐ Korean
   - ☐ Black (e.g., African, Haitian, Jamaican, Somali)
   - ☐ Latin American
   - ☐ Aboriginal (e.g., Métis, Inuit)
   - ☐ Other (specify: _____)

   ☐ Multiple cultural backgrounds (specify: _____)

2a) Who do you live with?
   - ☐ Family (spouse, children, etc.)
   - ☐ Alone (skip to question #3)
   - ☐ Other (specify:_____)

b) If you do not live alone, how many other people do you live with? (not including yourself):_____

c) Do you live with someone who requires caregiving (e.g., ill spouse, grandchildren)?
   - ☐ Yes
   - ☐ No

d) If yes you live with someone who requires care giving, please describe 1) for whom you provide care, 2) the type of care giving you do, 3) the number of hours in an average week you spend care giving:

1._____

2._____

3._____

e) If you have a spouse or partner, would you say his/her health is (please ✓ one):

☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

3a) Do you have children?
- ❑ Yes
- ❑ No

b) If 'Yes' how many children do you have? _____ #

4. On average, how many hours a week do you usually spend doing housework (e.g., cooking, cleaning, washing)?

_____ hours per week

5. What is your marital status:
- ❑ Married/common-law
- ❑ Separated/divorced
- ❑ Single
- ❑ Widow/Widower

6. What is the highest level of education you have completed?
- ❑ less than grade 9
- ❑ less than high school
- ❑ completed high school
- ❑ some college or university courses
- ❑ completed college or university degree
- ❑ Graduate School/Professional Program

7. What is your gross annual family income?
- ❑ $19,999 or less
- ❑ $20,000 – $29,999
- ❑ $30,000 – $39,999
- ❑ $40,000 – $49,999
- ❑ $50,000 - $59,999
- ❑ $60,000 - $69,999
- ❑ $70,000 or greater

8. Which option best matches your work status?
- ❑ full-time work
- ❑ part-time work
- ❑ full-time caregiver or homemaker (inside your home)
- ❑ unemployed
- ❑ receiving disability
- ❑ retired
- ❑ other: _____

9a) What is your height? _____ feet and _____ inches or (_____ cm)

b) What is your weight? _____ pounds or (_____ kgs)

10. Please describe your smoking status:
    - ☐ I have never smoked
    - ☐ I currently smoke
        - How many cigarettes per day on average? _____ cigarettes per day
        - For how many years have you smoked? _____ years
    - ☐ I quit smoking
        - When did you quit? Month _____ year_____
        - How many cigarettes per day did you smoke on average? _____ cigarettes per day
        - For how many years did you smoke? _____ years

11. Do you have a history of heart disease in your family?
    - ☐ Yes
    - ☐ No

12. Do you have high cholesterol, or take cholesterol-lowering medication?
    - ☐ Yes
    - ☐ No

13. Do you have high blood pressure, or take blood pressure medication?
    - ☐ Yes
    - ☐ No

14. Did you exercise to the point of getting short of breath on a regular basis (as an adult) <u>prior</u> to your cardiac event?
    - ☐ Yes
    - ☐ No

15. Did a doctor tell you that you were diagnosed with heart disease <u>before</u> this hospitalization?
    - ☐ Yes
    - ☐ No

    If yes, approximately when were you diagnosed? _____/_____
    (Month) (Year)

16. Have you <u>previously</u> experienced any of the following health problems? Please ✓ all that apply:
    - ☐ Heart Attack
    - ☐ Angina
    - ☐ Angioplasty (stent)
    - ☐ Bypass Surgery
    - ☐ Valve Surgery
    - ☐ Heart Failure
    - ☐ Arrhythmia (irregular heart rhythm)
    - ☐ Heart transplant
    - ☐ Cardiac device: pacemaker or implantable cardioverter defibrillator
    - ☐ Stroke / TIA (i.e., blocked arteries in neck or brain)
    - ☐ Peripheral Vascular Disease (e.g., blockages in legs)
    - ☐ None of the above

Appendix E: Pre-test Depression and Anxiety Assessment

SECTION M: TALKING WITH HEALTH CARE PROVIDERS ABOUT MOOD & ANXIETY

(I) History of Depressed Mood

1. Have you ever had problems with depressed mood? ☐ YES ☐ NO

1b. If yes, how many years has it been since you first had problems with depressed mood? _____(yrs)
1c. If yes, how many times in your life have you had problems with depressed mood? _____ (times)

2. Has a health care provider ever diagnosed you with depression? ☐ YES ☐ NO

2b. If yes, how many years ago were you first given the diagnosis? _____ (yrs)
2c. If yes, who diagnosed you with depression?
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other: _____

(II) History of Anxiety

3. Have you ever had problems with anxiety? ☐ YES ☐ NO

3b. If yes, how many years has it been since you first had problems with anxiety? _____ (yrs)

4. Has a health care provider ever diagnosed you with an anxiety disorder? ☐ YES ☐ NO

4b. If yes, how many years ago were you first given the diagnosis? _____ (yrs)
4c. If yes, who diagnosed you with anxiety?
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other: _____

(III) Current Depression or Anxiety

5. Are you currently having problems with depressed mood or anxiety? ☐ YES ☐ NO

5b. If yes, are you having problems with:
☐ Depressed mood
☐ Anxiety
☐ Both depressed mood and anxiety

5c. If yes, who is treating you for these problems? (check all that apply)
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other: _____
☐ Not being treated by health care provider

5d. If yes, what treatments are you using: (check all that apply)
☐ Medication (antidepressant or anti-anxiety pills)
☐ Counseling/Talk therapy
☐ Exercise
☐ Other: _____
☐ My depression/anxiety is not being treated

(IV) Treatment for Depression or Anxiety

6. Have you ever taken anti-depressant or anti-anxiety medications?
☐ Never taken ☐ I took them in the past ☐ I take them now: (name: _____)

7. Have you ever had counseling or 'talk therapy' for depression or anxiety?
☐ Never had ☐ I had it in the past ☐ I'm in counseling/therapy now

(V) Mood and Anxiety Since Start of Heart Problems

8. How often do you feel down or blue because of your heart condition?
☐ Never ☐ Sometimes ☐ A lot of the time

8b. If you answered Sometimes or A lot of the time, what is your main concern?
_____
_____
_____

9. Since being diagnosed with a heart problem, have any health care providers asked about your mood or anxiety? ☐ YES ☐ NO

9b. If yes, who asked about your mood or anxiety? (check all that apply)
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other: _____

10. Since being diagnosed with a heart problem, have you ever been asked to fill in a survey or had an interview with questions about your mood or anxiety?
☐ Survey ☐ Interview ☐ Both ☐ Neither

If yes to either survey or interview:

10b. Please describe the survey or interview:
_____
_____

10c. Did anyone talk to you about the results? ☐ YES ☐ NO

10d. What happened next (check all that apply)?
☐ I was prescribed medicine for my mood or anxiety
☐ I was referred to a psychiatrist, psychologist or counselor
☐ I was referred for other mental health treatment – please specify: _____
☐ My healthcare provider is going to follow-up with me about this
☐ Nothing (and I do have problems with mood or anxiety)
☐ Nothing (and I do not have problems with mood or anxiety)
☐ Other, please specify: _____
☐ I don't know

Appendix F: The Beck Depression Inventory-II

SECTION F: MOOD

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Mark (X) in the box beside the statement that you have picked. Be sure that you do not choose more than one statement for any group.

1. Sadness
- ☐ I do not feel sad.
- ☐ I feel sad much of the time.
- ☐ I am sad all the time.
- ☐ I am so sad or unhappy that I can't stand it.

2. Pessimism
- ☐ I am not discouraged about my future.
- ☐ I feel more discouraged about my future that I used to be.
- ☐ I do not expect things to work out for me.
- ☐ I feel that my future is hopeless and will only get worse.

3. Past Failure
- ☐ I do not feel like a failure.
- ☐ I have failed more than I should have.
- ☐ As I look back on my life, I see a lot of failures.
- ☐ I feel I am a complete failure as a person.

4. Loss of Pleasure
- ☐ I get as much pleasure as I ever did from the things I enjoy.
- ☐ I don't enjoy things the way I used to.
- ☐ I get very little pleasure from the things that I used to enjoy.
- ☐ I can't get any pleasure from the things that I used to enjoy.

5. Guilty Feelings
- ☐ I don't feel particularly guilty
- ☐ I feel guilty over many things I have done or should have done.
- ☐ I feel quite guilty most of the time.
- ☐ I feel guilty all the time.

6. Punishment Feelings
- ☐ I don't feel I am being punished.
- ☐ I feel I may be punished.
- ☐ I expect to be punished.
- ☐ I feel I am being punished.

7. Self-Dislike
- ☐ I feel the same about myself as ever.
- ☐ I have lost confidence in myself.
- ☐ I am disappointed in myself.
- ☐ I dislike myself.

8. Self-Criticalness
- ☐ I don't criticize myself more than usual.
- ☐ I am more critical of myself than I used to be.
- ☐ I criticize myself for all of my faults.
- ☐ I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
- ☐ I don't have any thoughts of killing myself.
- ☐ I have thoughts of killing myself, but I would not carry them out.
- ☐ I would like to kill myself.
- ☐ I would kill myself if I had the chance.

10. Crying
- ☐ I don't cry any more than I used to.
- ☐ I cry more than I used to.
- ☐ I cry over every little thing.
- ☐ I feel like crying.

11. Agitation
- ☐ I am no more restless or wound up than usual.
- ☐ I feel more restless or wound up than usual.
- ☐ I am so restless or agitated that it is hard to stay still.
- ☐ I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest
- ☐ I have not lost interest in other people or activities.
- ☐ I am less interested in other people or things than before.
- ☐ I have lost most of my interest in other people or things.
- ☐ It is hard to get interested in anything.

13. Indecisiveness
- ☐ I make decisions about as well as ever.
- ☐ I find it more difficult to make decisions than usual.
- ☐ I have much greater difficulty in making decisions than I used to.
- ☐ I have trouble making decisions.

14. Worthlessness
- ☐ I do not feel I am worthless.
- ☐ I don't consider myself as worthwhile and useful as I used to.
- ☐ I feel more worthless than other people.
- ☐ I feel utterly useless.
- ☐

15. Loss of Energy
- ☐ I have as much energy as ever.
- ☐ I have less energy than I used to have.
- ☐ I don't have enough energy to do very much.
- ☐ I don't have enough energy to do anything.

16. Changes in Sleeping Pattern
- ☐ I have not experienced any change in my sleeping pattern.
- ☐ I sleep somewhat more than usual.
- ☐ I sleep somewhat less than usual.
- ☐ I sleep a lot more than usual.
- ☐ I sleep a lot less than usual.
- ☐ I sleep most of the day.
- ☐ I wake up 1-2 hours early and can't get back to sleep.

17. Irritability
- ☐ I am no more irritable than usual.
- ☐ I am more irritable than usual.
- ☐ I am much more irritable than usual.
- ☐ I am irritable all the time.

18. Changes in Appetite
- ☐ I have not experienced any changes in my appetite.
- ☐ My appetite is somewhat less than usual.
- ☐ My appetite is somewhat greater than usual.
- ☐ My appetite is much less than before.
- ☐ My appetite is much greater than usual.
- ☐ I have no appetite at all.
- ☐ I crave food all of the time.

19. Concentration Difficulty
- ☐ I can concentrate as well as ever.
- ☐ I can't concentrate as well as usual.
- ☐ It is hard to keep my mind on anything for very long.
- ☐ I can't concentrate on anything.

20. Tiredness or Fatigue
- ☐ I am no more tired or fatigued than usual.
- ☐ I get more tired or fatigued more easily than usual.
- ☐ I am too tired or fatigued to do a lot of the things I used to do.
- ☐ I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex
- ☐ I have not noticed any recent changes in my interest in sex.
- ☐ I am less interested in sex than I used to be.
- ☐ I am much less interested in sex now.
- ☐ I have lost interest in sex completely.

Appendix G: The Patient Health Questionnaire-2

SECTION G: MOOD CONTINUED

Over the past 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

Appendix H: Morisky's Medication Adherence Scale

SECTION H: PILL TAKING

Thinking of the medications PRESCRIBED to you by your doctor(s), please answer the following questions:

1. Do you ever forget to take your medication?
   - ☐ Yes
   - ☐ No

2. Are you careless at times about taking your medication?
   - ☐ Yes
   - ☐ No

3. When you feel better, do you sometimes stop taking your medication?
   - ☐ Yes
   - ☐ No

4. Sometimes, if you feel worse when you take your medicine, do you stop taking it?
   - ☐ Yes
   - ☐ No

5. What percentage of the time would you say you take your pills as prescribed by your doctors? (0% would be not taking as prescribed at any time, to 100% taking as prescribed all the time).

   _____%

Appendix I: Self-Reported Medication List

11. Please check your medication bottles. Please list below the names of all of the medications you are currently taking and the dose per day.

a. _____ f. _____

b. _____ g. _____

c. _____ h. _____

d. _____ i. _____

e. _____ j. _____

Other medications _____

Appendix J: Godin Leisure-time Exercise Questionnaire

SECTION E: EXERCISE

1. During a typical 7-Day period (a week), how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

	Times Per Week
a) STRENUOUS EXERCISE **(heart beats rapidly)** (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	_____
b) MODERATE EXERCISE **(not exhausting)** (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	_____
c) MILD EXERCISE **(minimal effort)** (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	_____

2. During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
1. ☐	2. ☐	3. ☐

Appendix K: Post-test Depression and Anxiety Assessment

SECTION R: TALKING WITH HEALTH CARE PROVIDERS ABOUT MOOD & ANXIETY

1. Since being referred to cardiac rehab, have you had problems with depressed mood or anxiety?

☐ YES ☐ NO

1b. If yes, have you had problems with:
- ☐ Depressed mood
- ☐ Anxiety
- ☐ Both depressed mood and anxiety

1c. If yes, who has treated you for these problems? (check all that apply)
- ☐ Family doctor
- ☐ Heart doctor (cardiologist)
- ☐ Psychiatrist or psychologist
- ☐ Nurse
- ☐ Other: _____
- ☐ Not being treated by health care provider

1d. If yes, what treatments have you used: (check all that apply)
- ☐ Medication (antidepressant or anti-anxiety pills)
- ☐ Counseling/Talk therapy
- ☐ Exercise
- ☐ Other: _____
- ☐ My depression/anxiety is not being treated

2. Since you were referred to cardiac rehab, have any health care providers asked about your mood or anxiety? ☐ YES ☐ NO

2b. If yes, who asked about your mood or anxiety? (check all that apply)
- ☐ Family doctor
- ☐ Heart doctor (cardiologist)
- ☐ Psychiatrist or psychologist
- ☐ Nurse
- ☐ Other: _____

3. Since you were referred to cardiac rehab, have you ever been asked to fill in a survey or to have an interview with questions about your mood or anxiety?

☐ Survey ☐ Interview ☐ Both ☐ Neither

If yes to either survey or interview:

10b. Please describe the survey or interview:

_____

_____

10c. Did anyone talk to you about the results? ☐ YES ☐ NO

10d. What happened next (check all that apply)?
- ☐ I was prescribed medicine for my mood or anxiety
- ☐ I was referred to a psychiatrist, psychologist or counselor
- ☐ I was referred for other mental health treatment – please specify: _____
- ☐ My healthcare provider is going to follow-up with me about this
- ☐ Nothing (and I do have problems with mood or anxiety)
- ☐ Nothing (and I do not have problems with mood or anxiety)
- ☐ Other, please specify: _____
- ☐ I don't know

Appendix L: The Hospital Anxiety Depression Scale

SECTION J: YOUR EMOTIONS

Instructions: Read each item below and put an x in one box for each question which comes closest to how you have been feeling in the past week.

I feel tense or 'wound up' ❑ Most of the time ❑ A lot of the time ❑ From time to time, occasionally ❑ Not at all	**I feel as if I am slowed down** ❑ Nearly all the time ❑ Very often ❑ Sometimes ❑ Not at all
I still enjoy the things I used to enjoy ❑ Definitely as much ❑ Not quite as much ❑ Only a little ❑ Hardly at all	**I get a sort of frightened feeling like 'butterflies' in the stomach** ❑ Not at all ❑ Occasionally ❑ Quite often ❑ Very often
I get a sort of frightened feeling as if something awful is about the happen ❑ Very definitely and quite badly ❑ Yes, but not too badly ❑ A little, but it doesn't worry me ❑ Not at all	**I have lost interest in my appearance** ❑ Definitely ❑ I don't take as much care as I should ❑ I may not take quite as much care ❑ I take just as much care as ever
I can laugh and see the funny side of things ❑ As much as I always could ❑ Not quite as much now ❑ Definitely not so much now ❑ Not at all	**I feel restless as if I have to be on the move** ❑ Very much indeed ❑ Quite a lot ❑ Not very much ❑ Not at all
Worrying thoughts go through my mind ❑ A great deal of the time ❑ A lot of the time ❑ Not too often ❑ Very little	**I look forward with enjoyment to things** ❑ As much as I ever did ❑ Rather less than I used to ❑ Definitely less than I used to ❑ Hardly at all
I feel cheerful ❑ Never ❑ Not often ❑ Sometimes ❑ Most of the time	**I get sudden feelings of panic** ❑ Very often indeed ❑ Quite often ❑ Not very often ❑ Not at all
I can sit at ease and feel relaxed ❑ Definitely ❑ Usually ❑ Not often ❑ Not at all	**I can enjoy a good book or radio or television programme** ❑ Often ❑ Sometimes ❑ Not often ❑ Very seldom

Appendix M: Discharge Report Form

CR4HER Discharge Data Extraction Form

1. Participant ID#: _____
2. Date of data extraction: | | | | dd | mmm | yyyy |
3. Did the patient complete the program (circle one)? Yes No

   2b. If yes: Date of discharge: | | | | dd | mmm | yyyy |

   2c. If no, Date last attended rehab: | | | | dd | mmm | yyyy |

   2d. If no, specify whether (circle one): Medical Non-Medical

   2e. Describe:

_____

_____

4. Number of Sessions prescribed (on site or via telephone): _____
5. Number of sessions completed (on site or via telephone): _____
6. Number of Sessions prescribed to drop out for medical reason (if applicable):_____
7. Number of Sessions completed to drop out for medical reason (if applicable):_____
8. Blood lipid profile:

Total Cholesterol		mmol/L
HDL		mmol/L
LDL		mmol/L
Triglycerides		mmol/L

9. Waist Circumference (cm): _____

10. Discharge Exercise Stress Test:

    a. Resting blood pressure:_____

    b. Peak METs: _____

    c. Peak VO_2: _____

    d. CPA Completed: Yes No

11. Other comments:

    _____

    _____

Appendix N: Psychosocial Distress Categorization