WOMEN'S PREFERENCES FOR CARDIAC REHABILITATION:

DO HOME-BASED AND WOMEN-ONLY PROGRAMS BETTER MEET THEIR NEEDS?

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Abstract

Background: Although cardiac rehabilitation (CR) is effective, women report programs do not meet their needs. The objectives of the study were to describe: (1) adherence to allocation, (2) CR satisfaction, (3) CR preferences, and (4) barriers.

Methods: A randomized controlled trial (RCT) of females allocated to: (a)mixed-sex, (b)women-only, or (c)home-based CR. Participants were randomized and asked to complete a baseline and follow-up survey.

Results: Overall**,** 265 patients consented (13.1%). Forty-five (26.6%) RCT participants did not receive the allocated model. Satisfaction, rated one to five, was high across all models (mean=4.24±1.16; p=0.83); women-only participants felt more comfortable in their workout attire (p=0.001), and perceived the environment as less competitive (p=0.02). Patients most-frequently preferred women-only CR (49.7%), and CRPF-R scores differed based on preferred model (p=0.02). Barriers differed significantly by model attended (p=0.03)

Conclusion: Females were satisfied, but preferred women-only programs. Females attending women-only CR were more comfortable in their environment.

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Chapter One: Introduction

Cardiovascular disease (CVD) is the leading cause of mortality worldwide. It was estimated that 17.3 million people died due to CVD in 2008, representing 30% of all global deaths[1]. More than half a million North American women die each year due to CVD—translating to approximately one death per minute[2]. These reported mortality rates are mainly attributed to modifiable risk factors such as hypertension, dyslipidemia, obesity, smoking, unhealthy diet, and a sedentary lifestyle[3]. In 2005, the costs of CVD were estimated to be approximately $20.9 billion; by 2020, cost estimates are expected to rise to $28.3 billion[4]. Death rates among men with CVD have declined progressively over the past 25 years; unfortunately, women have not reaped the same benefits and CVD-related deaths among women have fallen at slower rates[5].

Cardiac Rehabilitation (CR) is a multidisciplinary outpatient program focused on improving and maintaining cardiovascular health through, exercise, education, and counselling[6]. The literature has shown that CR can reduce overall and cardiovascular related mortality by 13% and 26% respectively[7]. In addition, CR has been shown to be as effective as statins, beta-blockers and aspirin in reducing morbidity and mortality in patients with heart disease[8,9]. The Canadian Association of Cardiac Rehabilitation (CACR) recognizes the importance of exercise training as one of the core elements of CR[6]. Exercise training has been shown to have significant positive effects on exercise capacity, plasma lipids, and overall quality of life[10].

Despite these benefits, CR is grossly underutilized. In Canada and the United States, approximately 25–31%[11,12] of eligible patients participate in CR; the participation of women is estimated to be even lower[13]. Given that patient preference is an important factor influencing

CR attendance, innovative models of CR care (e.g., women-only CR) have been developed to better suit the needs of women. The objectives of this thesis are to describe women's satisfaction with, preferences for, and barriers to participation in, the following three program models: traditional co-ed CR, women`s-only CR, and home-based CR.

Chapter Two: Literature Review

CVD is defined as a group of conditions that involve the function and structure of the heart and blood vessels[1]. Coronary artery disease (CAD) is one of the most common types of CVD; it is characterized by insufficient circulation of blood to the heart muscle[14]. The most common cause of CAD is a build-up of fatty deposits on the inner walls of the coronary arteries, resulting in a blockage[1]. Fatty deposits or blockages prevent adequate oxygenated blood delivery to the heart, which can cause chest pain. A myocardial infarction (MI), commonly known as a heart attack can occur due to a complete blockage of a coronary artery. This can result in permanent damage or death to part of the heart tissue if not treated immediately[14].

Burden of Cardiovascular Disease in Women

CVD is the leading cause of morbidity and mortality in women, accounting for approximately nine million fatalities each year worldwide[15,16]. In 2008, CVD accounted for nearly 30% of all deaths in Canadian women[17]. Moreover, women are 16% more likely to die after suffering a heart attack than men[18]. As medical treatments continue to progress, mortality rates among men continue to decline in the developed world; mortality rates among women however, remain stable[19].

The absence of improvement among women living with heart disease may be attributed to multiple factors. First, there are a number of CVD risk factors that affect women to a greater degree. It has been reported that women are less active than men, and barriers to physical activity (e.g., family obligations) are often greater in women compared to men[19]. Moreover, low socioeconomic status (SES) puts people at greater risk of developing CVD, and women are generally of much lower SES than men**.** In fact, women with low SES experience twice the risk of CVD mortality compared to men (61% vs. 29%)[19]. Finally, the prevalence of psychosocial

risk factors, such as depression, is greater in women. Starting from puberty, this trend continues throughout adulthood. The literature reported that depression is twice as prevalent in women than in men[19–21]. In addition, there is a two times greater risk of mortality when CVD is accompanied by depression and anxiety, compared to those with CVD alone[22].

Furthermore, it is evident that there are sex differences in disease presentation such as atypical symptoms[19,23,24]. Women tend to present to the hospital later after symptom onset, wait longer for treatment, and be less likely admitted to intensive care settings[19]. Even among those who receive treatment, women are less likely than men to undergo aggressive treatment such as revascularization[19,23].

Finally, research has shown that women may also have a poorer prognosis after experiencing a cardiac event compared to men: women experience longer hospital stays, greater degree of activity restriction, and greater disability[19]. In addition, researchers found that one year mortality rates of women with MI are significantly higher than the mortality rates among men (44% vs. 27%)[23].

Cardiac Rehabilitation

The CACR has defined CR as the enhancement and maintenance of cardiovascular health through individualized programs designed to optimize physical, psychological, social, vocational, and emotional status[6]. The British Association for Cardiovascular Prevention and Rehabilitation states that CR consists of seven core components: long-term management, lifestyle risk factor management, psychological health, cardio-protective therapies, health behaviour and change education, medical risk factor managements, as well as audit and evaluation[25]. CR programs are designed to aid patient recovery following a cardiac event or procedure, and prevent subsequent events[26].

A meta-analysis of 34 randomized controlled trials (RCT) reported significant benefits of exercise-based CR. Compared to usual care, patients participating in exercise-based CR had a 47% lower risk of re-infarction and a significant reduction in overall and cardiac-related mortality (36% and 26% respectively)[27]. Participation in CR has also been shown to improve exercise capacity, reduce cardiac risk factors, and have multiple psychological benefits[28,29]. For example, Lavie et al. (2006) showed a significant reduction of body mass index (BMI), percent body fat, resting heart rate, and resting systolic blood pressure in individuals who participated in CR. Research also showed significant improvements in both depression and anxiety. One study reported a 58.5% and 46.0% reduction in depression and anxiety scores in patients who participated in CR, respectively[30]. Moreover, CR has been reported to increase quality of life by 15.8% [30]. Finally, CR programs are effective in cutting healthcare costs (Ades, Huang, 1992; Dendale, Hansen, Berger, & Lamotte, 2008) and reducing hospital readmission[7,32,33].

Studies reporting the effectiveness of CR have generally revealed no major differences between men and women in terms of changes in risk factors, functional capacity and quality of life[28,34–37]— although sex differences for quality of life have been reported in some studies[38]. However, sex-specific data are lacking with regard to mortality and morbidity in particular[39]. Two RCTs reported no sex differences in morbidity or mortality; women in these two studies represented a minority of the total sample: 15% [40] and 20%[41]. It has also suggested that reduction in cardiovascular-related death among women has not yet been established due to the limited number and size of existing studies of women[42]. However, the literature has showed that women derive benefits from CR[39,43]. In fact, women often present with lower physical fitness and as such have greater potential benefit from CR[36]. The limited number of studies of women's outcomes post-CR has also been positive[43–46], however the literature suffered from small sample

sizes, a lack of randomization and lack of control groups. In light of the research as discussed above, guidelines on the management of CVD in women recommend they are referred to CR *(Class I; Level of Evidence A)*[47].

Women in Cardiac Rehabilitation

Unfortunately, there is gross under-representation of women in CR. In the United States and Canada,[48] approximately 15-30% of eligible patients participate in CR, while the rate of participation for women has been reported at 11-20%[49]. Despite clinical practice guidelines [50,51], the percentage of women in CR is 20% lower than what would be expected based on the coronary morbidity data[11,52]. A recent meta-analysis showed that rates of CR enrollment among women (38.5%) are significantly lower compared to men (45%); women were 36% less likely to enroll in a CR program[53].

Barriers to Women's Participation

The reasons women are missing from CR programs are multifactorial and are evident on a number of levels. Existing literature reported that physician referral patterns, program structure and patient-centred factors influence the degree of CR participation among women[54,55]. Women share a number of barriers with men, in addition to the barriers that are unique to their gender[56]. Although research is still required to overcome female-specific barriers, there are a number of factors reported in the literature across all three levels mentioned above.

Physician Referral Patterns. Women are indeed less likely to be referred to CR[54,56], and the strength of physicians recommendation and/or support was more apparent among men compared to women[11,57–59]. The importance of physician recommendation was reported in a number of studies to be the most significant predictor of enrollment/participation[11,12,60–63].

Therefore, physician bias may be one of the underlying factors accounting for the low rates of CR utilization among women[61].

Program Structure. Barriers within CR programs have been reported in a number of studies[54,56]. Factors that have been shown to affect the participation of women include travel issues[11,54,58,63–65], cost[58,63], inconvenient program time[62], and perception that CR programs are male-oriented [66,67]. It has been reported that the preferences of women are not met during exercise sessions[67]. A number of studies have also demonstrated that there is a general lack of awareness among women regarding the importance and/or health benefits of CR programs[54,65].

Patient-centred Factors. Studies investigating the barriers to CR participation have revealed older age, low self-efficacy, poor spousal support and/or unmarried status, low SES, family responsibilities, and concomitant illness as barriers specific to women[58,61,67,69,70]. Missik[69] also reported that women who participated in CR had a significantly higher level of education than those who did not participate. Two additional studies showed that women experience more stress due to caregiving roles, lower exercise tolerance and more pain during exercise compared to men and therefore are less likely to enrol in CR[37,70].

Women's Preferences in CR

The low rates of CR participation among women have led to the awareness that CR programs may not be equally appealing to both sexes[71]. CR programs were originally developed in the 1970s to address the needs of middle-aged men in order to facilitate their return to work post-MI[71,72].

Women typically have a different experience from men at the time of a cardiac event and/or procedure. For example, women are approximately ten years older, more likely to be widowed and living alone, and of lower socioeconomic status than men[73]. They often have

greater household and caregiving responsibilities[49,74], report suboptimal social supports and more psychosocial distress[49,63,75]. In addition, women are more likely to suffer from comorbid conditions (e.g. arthritis, osteoporosis, urinary incontinence)[62], and lower functional capacity[34,39]. These differences suggest that women may have dissimilar needs and preferences for CR programs. Indeed, upon examination of CR preferences, it was reveal that women's needs were not always met by traditional CR[56,71].

While the traditional model of CR is a mixed-gender program, women are often a minority. Women report perceiving these programs as male-oriented and failing to meet their care preferences[67,76]. A female hospital-based CR program reported the likes and dislikes of women for the traditional program model. Women 'liked' being monitored during exercise, receiving nutrition information, and being part of a group. They 'disliked' the lack of exercise alternatives, emotional support from staff, and socialization opportunities, being weighed, being in a crowded physical space; women perceived the program as a "men's club"(p.126)[67]. Women may find a CR program more appealing if there is a psychological component[77],variety of exercise options, and greater presence of female participants within CR programs[67].

In a study conducted by Moore[70], patients were queried regarding their experience with program elements. Both men and women rated discussions of progress and encouragement from staff as most important. Women, however, were more likely to rate the importance of not tiring while exercising. This is significant since women were also more likely to report pain during exercise, possibly due to lower exercise self-efficacy and tolerance to physical activity compared to men[63]. Features for which women claimed were not well-met included the following: ability to choose their own exercises, additional preferences of discussing progress, not tiring, flexible hours, and goal setting. Women's preference for pain or fatigue reduction during exercise was

significantly less 'well met' compared to men. Overall, women may be less likely to participate as they do not perceive the programs as meeting their specific needs[78]. The evidence in the literature suggests that women may benefit from alternative CR approaches[39,71], although much research is required to confirm this contention.

Alternate models of CR

In response to low utilization rates and patient preferences, home-based and women's only CR models have been developed.

Home-Based CR

To date, there is no universally recognized definition of what constitutes a home-based program[79]. A meta-analysis conducted by Jolly[79], reported varying program structures that ranged from exercise-based interventions with telemetrically-monitored sessions by a nurse to supportive telephone interventions. Home-based CR programs have been implemented to overcome distance and transportation barriers, as well as time constraints— barriers commonly reported by women[38,67].

Research has shown that home-based programs share similar benefits to hospital-based CR programs; improvements in morbidity rates, exercise capacity, cardiac risk reduction and health behaviour changes are comparable across the two program models[80,81]. In a meta-analysis[79], home-based CR outcomes were compared to hospital-based CR. Results revealed no significant differences in exercise capacity, systolic blood pressure and total cholesterol. Evidence also suggests that home-based CR can be more cost-effective than hospital-based CR[82–84], and that there are no differences in patient healthcare costs following hospital or home-based CR participation[85]. Such programs are considered safe only for low to moderate risk patients[79].

Evidence suggests that hospital-based mixed-sex CR programs may not meet women's needs; however, are alternative program models, such as home-based CR, preferred? A few studies reported higher patient preference for home-based CR[80,86], in addition to higher rates of program completion compared to those who attended hospital-based CR[80,81]. Program adherence, however, was not analyzed by sex.

Women's only CR

There is a dire need to adapt CR services to suit the need of women. Women-only programs do not merely exclude men, but target social and psychological needs that are specific to women[87,88]. Beswick et al.[88] reported five publications which advocate women-specific interventions to increase CR uptake[38,67,77,89,90], however few have been tested empirically in a controlled study. There are only three women-only CR programs in Canada to date that attempt to overcome these barriers specific to women. Canada's first women-only program was developed in 1996 to address women's needs and preferences[67,91,92]. These sessions are offered in a gender-sensitive manner, with female-focused content and delivery[93]. Individual interviews and focus groups of 100 female patients were used to develop the program. A retrospective review of 315 participants revealed 85% program adherence[94]. A second CR program in Hamilton, Ontario which recently instituted women-only exercise and education sessions revealed significant increases in self-efficacy and emotional well-being, with 75.71% program adherence[95]. Finally, the University Health Network has developed a women-only CR program. It is being evaluated through the current proposed study.

Although a review questioned whether traditional CR programs are equally suited to men and women,[71] only a few gender-specific behaviour change programs have been developed and evaluated to date[96–98]. A women-only lower-intensity exercise CR program established in

Glasgow, Scotland revealed a 74% uptake by women post-MI (vs. 6% prior to program)[99]. The increase in uptake may be explained by the low-intensity exercise program which does not cause pain or fatigue experienced by women due to low exercise tolerance and/or co-morbidities. Most recently, Beckie et al.[100] undertook an RCT of gender-tailored compared to tradition CR programs. Results favoured the gender-tailored model in terms of adherence[100–102], general health[101], mental health[100,101], social function[101], vitality[101] and quality of life[100,101]. This is the only RCT on women's only CR.

Rationale

There is an assumption that women-only CR programs will resolve many of the barriers encountered by women; however there have not been direct investigations to confirm or reject this hypothesis[71]. It is unclear if these types of programs should be offered more broadly until this is tested. We are undertaking a randomized controlled trial of three models of CR. One of the pre-specified secondary hypotheses was to compare women's satisfaction and preference with the three models. It will also be determined whether the participation in each of the three models is related to differences in the barriers which women may encounter.

There are four objectives for this thesis: 1) to report women's satisfaction with CR overall, and by model they attended; 2) to describe women's preference for CR model overall, and by model attended; 3) to describe the rate of post-randomization model switching, and women's reasons for switching; and 4) to describe CR barriers by model attended and specific CR preferences by CR model preferred.

No Canadian studies have yet evaluated the preference to, or effect of, a women-only program in a controlled study. Only one randomized study to date has evaluated the effect of a women-only program[100]. While results were positive, this study was conducted in the United

States where the CR reimbursement system and model of care delivery is quite different. For example, CR is not covered by the American government[103] and therefore only the affluent can participate. This is a problem since the results of such studies only applies to those belonging to a certain level of SES and not the general population. Another limitation of this trial was that there were many differences in the women-only program when compared to the traditional program in addition to the sex composition. For example, motivational interviewing was applied in the women-only arm but not in the traditional arm. Moreover, a home-based arm was not incorporated into the trial as it is herein.

Chapter Three: Hypotheses

It is hypothesized that 1) women will be significantly more satisfied with the women-only and home-based CR program models compared to the traditional CR program model; 2) women will more likely prefer the women-only and home-based CR program models compared to the traditional CR program model; 3) participants will rate the "gender-tailored" nature of the women-only program significantly higher than the other two models and 4) participants will report significantly greater barriers to the traditional model when compared to the other two models.

Chapter Four: Candidate's Role

The candidate was responsible for patient recruitment at 3 sites (Toronto General Hospital, Toronto Western Hospital and Mount Sinai Hospital) for 6-12 months. This involved determining patient eligibility and obtaining informed consent forms (ICF); securing completed baseline assessments; communication of patient referrals and CR program dates following randomization; and clinical data extraction for the case report form. The candidate also performed the statistical analyses for the objectives herein.

Chapter Five: Manuscript

Cardiovascular disease (CVD) is the leading cause of mortality worldwide[1]. It accounts for 54% of deaths among women in Europe[104]. While mortality rates among men with CVD have declined progressively over the past 25 years in high-income countries, unfortunately deaths among women have been declining at much slower rates[5].

Cardiac Rehabilitation (CR) is a multidisciplinary outpatient program focused on improving cardiovascular health through exercise, education, and counselling[6,105]. CR reduces overall and cardiovascular-related mortality by 13% and 26% respectively, when compared to usual care[7]. Despite these benefits, and women-specific clinical practice guideline recommendations for CR referral as a Class 1, Level A indication[47], a recent meta-analysis showed that rates of CR enrollment among women (38.5%) remain significantly lower than men (45%; OR=0.55, CI=0.43-0.72)[53].

The reasons women are under-represented in CR programs are multifactorial. Existing literature demonstrates that physician referral patterns, program structure, and patient preferences influence the degree of CR participation among women[54,55]. While women report some common CR preferences with men, in addition they report preferences that are unique to their gender[56]. Women-only CR programs have been developed[106], and evidence from a randomized trial found that these programs are associated with greater adherence and improved physiological and psychosocial outcomes[100–102].

Overall however, there is a dearth of investigations to ascertain whether women-only programming can better meet women's needs, and thus warrant widespread implementation[71].

The objectives of this study were to describe women's: (1) enrollment in CR; (2) satisfaction; and (3) preference for CR, by program model.

Methods

Design and Procedure

This was a single-blind, pragmatic[107,108], allocation-concealed randomized controlled trial (RCT) of female outpatients randomized to one of three parallel arms: (1) supervised mixed-sex; (2) supervised women-only; or (3) home-based CR. The RCT was registered with clinicaltrials.gov (NCT01019135). Research ethics approval was obtained from all participating institutions. This manuscript presents analysis of pre-specified tertiary objectives for the trial.

Patients were recruited from six inpatient and outpatient cardiac settings in the Greater Toronto Area of Ontario, Canada between September 2009 and July 2013. Female patients were identified through ward/program censuses, or upon CR referral receipt respectively, and approached first by someone in the circle of care. Interested participants were explained the study in full by a site-specific study coordinator or graduate student, at which point some screening for trial eligibility was undertaken. If the patient was recruited from an inpatient unit, physician clearance for CR participation was solicited, and patients were only enrolled if a positive response was received.

Consenting patients were asked to complete a baseline self-report survey including sociodemographic characteristics, and to undergo their CR intake assessment. Recruited outpatients attended the program at the site where they were recruited, and outpatients were referred to the CR facility involved in the study that was closest to their home or work. Clinical information was also extracted from patient charts to ascertain eligibility. Eligible patients were

then randomized to one of three CR models. The randomization sequence was computer-generated, in block sizes of 6 through randomize.net, with an equal treatment allocation ratio.

There were 3 CR programs involved in the trial, which all offered services consistent with Canadian CR guidelines[6]. The programs lasted four to six months. Participants attending on-site CR programs exercised in the facility 1-2 times per week. Home-based participants exercised at home and were phoned at varying intervals, depending on CR site. CR personnel at all sites included a physician, dietitian, exercise physiologists, and a nurse.

Six months following the date of the CR referral, participants were mailed a self-report survey. The survey included assessment of satisfaction and preferences. Non-responders were sent a replacement survey and were phoned to optimize retention rate.

As a manipulation check, a masked research assistant checked CR charts to confirm the program model attended. Patients who did not attend their allocated program model were contacted to complete a short phone survey, which captured reasons for switching CR models.

Participants

Female patients with documented coronary artery disease, and/or acute coronary syndrome, and/or undergoing revascularization (e.g., coronary artery bypass graft surgery or percutaneous coronary intervention), and/or valve surgery, who were eligible for CR were approached. The inclusion criteria were: residency in the city where the CR programs were offered, proficiency in the English language, and eligibility for home-based CR (i.e., low to moderate-risk as demonstrated by: [1] lack of complex ventricular dysrhythmia, [2] New York Heart Association[109] Class 1 or 2, and left ventricular ejection fraction >40%, or [3] Canadian Cardiovascular Society[110] Class 1 or 2). Exclusion criteria were: musculoskeletal,

neuromuscular, visual, cognitive or serious mental illness, or any serious or terminal illness not otherwise specified which would preclude CR eligibility based on CR guidelines[6] physician deemed patient not suitable for CR at time of intake exercise stress test; patient planned to leave the area in the next 6 months; patient was discharged to a long-term care facility; previous participation in CR; participation in another clinical trial with behavioural interventions; and referral to a non-study CR program by a healthcare provider before study randomization completed.

Measures

Clinical data extracted from charts included diagnosis, comorbid conditions, prescribed cardiac medications, risk factors, as well as indicators of disease severity. Patient sociodemographic characteristics such as income, education, age, number of children, and caregiving responsibilities was assessed through forced-choice items in the baseline survey.

CR Model. The model to which patients were randomized was entered in a separate data file for the purposes of blinding. A masked chart review was performed to ascertain into which model patients enrolled. A variable was then created to denote if the patient enrolled in the allocated model, did not enroll, or enrolled in another program model.

A semi-structured telephone interview was conducted with those who attended a different CR model. The items assessed reasons for switching from the model to which they were initially randomized, through a series of closed and open-ended questions.

Post-Test Survey. The post-test survey included assessment of CR satisfaction (objective 2), and preferences (objective 3). Overall patient satisfaction ("Please indicate your degree of satisfaction with the CR program to which you were referred") was assessed through a forced-choice (5-point Likert-type scale from "very unsatisfied" to "very satisfied") and an open-ended

question ("why?"). An additional seven items were generated by the investigators to assess the degree to which participants perceived the program they attended as "gender-tailored". Participants were asked to rate their degree of agreement to each item on a 5-point Likert-type scale from "strongly disagree" to "strongly agree". Cronbach's alpha was 0.77, showing good internal consistency.

With regard to the third objective, the preferred CR model and reason for preference were assessed through a forced-choice (i.e., "If you were given a choice, which CR program type would you prefer to attend?") and an open-ended item ("why?"). Moreover, the psychometrically-validated CR Preference Form-Revised (CRPF-R) was administered.[111] It is a self-report questionnaire, where participants are asked to rate the importance of 15 CR program features, on a 3-point scale from "little important" to "very important". Cronbach's alpha was 0.87.

Statistical Analyses

All analyses were performed using SPSS version 21.0[112]. Sociodemographic and clinical characteristics of retained participants versus those lost to follow-up were compared to detect retention bias, using t-tests and chi-square as appropriate.

To test the first objective, patient adherence to randomization was described. A descriptive analysis of randomized participant disposition at post-test was also performed, overall and by randomly-allocated model. Next, results of the telephone survey of patients who switched models were summarized. A descriptive examination of quantitative responses was performed; valid percentages were reported as some items were model-specific. The open-ended responses were coded using an interpretive-descriptive approach[113]. Patient responses were reviewed to detect emerging themes and categories were developed. Responses were coded

under the applicable category and the frequencies of each category as well as "other" responses were analyzed.

To assess patient satisfaction, only participants who enrolled were selected. Enrolled patients were those who attended an at least one CR session. To test the second objective, a descriptive analysis was performed on patient satisfaction. Differences in satisfaction were tested by model attended, and between those who attended the model to which they were referred versus those who did not. The open-ended satisfaction question was also coded using an interpretive-descriptive approach[113]. Differences in overall and "gender-tailored" satisfaction by model were analyzed using analysis of variance (ANOVA). If significance was detected, post-hoc least significant difference tests were used for multiple comparisons. This was then computed on an "intention-to-treat" and then "as-treated" basis.

To test the third objective, a frequency analysis was performed to describe participants' preferred CR model. The open-ended preference question was coded using an interpretive-descriptive approach[113]. Next, a chi-square test was performed to detect significant differences between the model attended and the model preferred. The latter two tests were computed in the total sample, and among those who enrolled in CR. Patients were analyzed on an "intent-to-treat" and "as-treated" basis for their preferences as above.

The relationship between overall satisfaction and model preference was considered. Specifically, a variable was created to denote whether patients did versus did not attend the CR model of preference. A student's t-test was used to examine difference in satisfaction among the groups. Finally, a descriptive analysis of the CRPF-R Scale[111] was performed. Overall and item-

specific differences by program randomized model, model attended and preferred were tested using ANOVA.

Results

Respondent Characteristics

A diagram of study flow is shown in Figure 1. A total of 2016 patients were approached, of which 1108 (55.0%) participants were deemed ineligible. Reasons for ineligibility are outlined in Figure 1. Of the 908 eligible patients, 169 (18.6%) consented to participate and were randomized. Of these, 144 (85.2%) completed the pre-CR survey.

Table 1 displays the sociodemographic and clinical characteristics of participants by randomized model. As shown, there were no significant differences among participants randomized to the three CR models.

As per Figure 1, a total of 116 (/169; 68.6%) participants were retained at follow-up (i.e., completed a post-test survey). With regard to retention bias, retained participants (n=5, 8.5%) were significantly less likely to live with someone requiring caregiving than non-retained participants (n=8, 33.3%; $\chi^2(2)=7.98$ p=<0.01). No other differences in sociodemographic or clinical characteristics were observed between retained and non-retained participants (data not shown).

Figure 1: Participant Flow Diagram

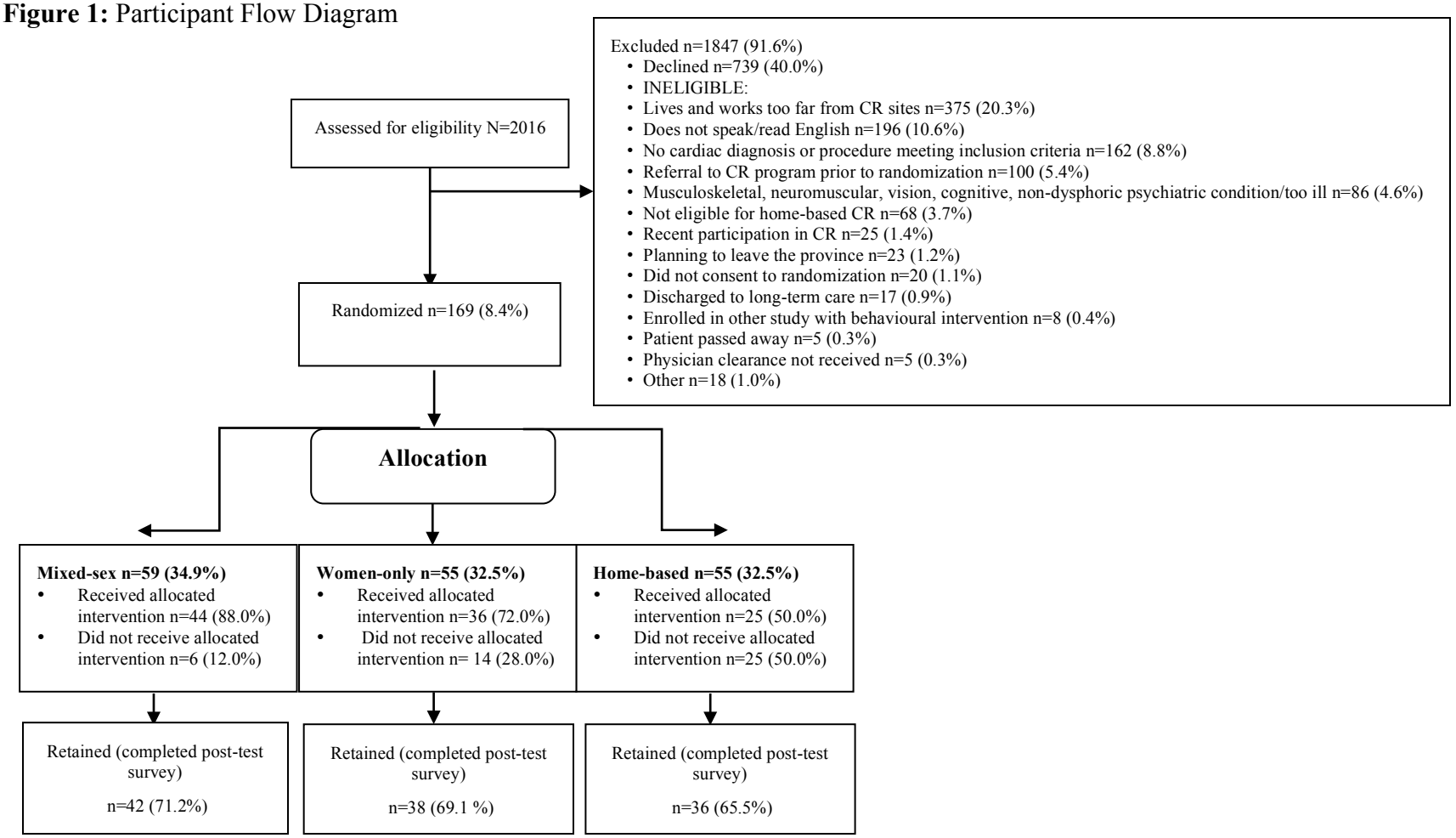


Table 1: Baseline sociodemographic and clinical characteristics of participants by randomized model

	Randomized Model			Total
Characteristics	**Women-Only n=55 (32.5%)**	**Mixed-Sex n=59 (34.9%)**	**Home-Based n=55 (32.5%)**	**N=169**
Sociodemographic§				
Age (mean ± SD)	66.22±10.21	61.56±9.73	63.13±10.94	63.64±10.42
Income/year (%<$50 000)	15 (39.5%)	23 (51.1%)	20 (47.6%)	58 (46.4%)
Education (%≤some college/university)	17 (38.6%)	25 (50.0%)	25 (51.0%)	67 (46.9%)
Marital Status (% married)	28 (63.6%)	20 (39.2%)	24 (49.0%)	72 (50.0%)
Work Status (% retired)	26 (59.1%)	24 (47.1%)	22 (44.9%)	72 (50.0%)
Ethnicity (% white)	26 (59.1%)	32 (62.7%)	32 (65.3%)	90 (62.5%)
Living with someone (% yes)	32 (72.7%)	33 (66.0%)	32 (65.3%)	97 (67.8 %)
Living with someone requiring care (% yes)	6 (20.0%)	5 (15.2%)	5 (16.7%)	16 (17.2%)
Number of children (mean ± SD)	2.46±0.97	2.10±0.97	2.27±0.98	2.28±0.97
Hours housework / week (mean ± SD)	15.61±10.35	13.47±13.62	11.54±8.27	13.45±11.06
Clinical				
Heart diagnosis before hospitalization n (% yes)	23 (54.8%)	20 (40.8%)	18 (38.3%)	61 (44.2%)
DASI (mean ± SD)	28.92±15.30	24.40±13.91	30.26±16.88	27.80±15.50
Post-menopausal (% yes)	36 (92.3%)	37 (80.4%)	35 (76.1%)	108 (82.4%)
Indication for CR†				
PCI (% yes)	26 (47.3%)	28 (50.0%)	27 (50.0%)	81 (49.1%)
Angina/CAD (% yes)	20 (36.4%)	20 (36.4%)	19 (35.8%)	59 (36.2%)
MI (% yes)	19 (34.5%)	22 (38.6%)	18 (34.0%)	59 (35.8%)
CABG (% yes)	16 (29.1%)	12 (21.4%)	14 (25.9%)	42 (25.5%)
Valve (% yes)	10 (18.5%)	11 (19.3%)	11 (20.4%)	32 (19.4%)
Risk Factors				
Family history of heart disease (% yes)	33 (78.6%)	32 (66.7%)	34 (73.9%)	99 (72.8%)
Hypertension (% yes)	26 (63.4%)	35 (71.4%)	37 (80.4%)	98 (72.1%)
Dyslipidemia (% yes)	33 (80.5%)	38 (77.6%)	38 (80.9%)	109 (79.6%)
BMI (mean ± SD)	29.62±8.02	29.26±6.61	28.61±5.44	29.19±6.78
Smoking history (% never smoked)	21 (51.2%)	19 (38.8%)	24 (50.0%)	64 (46.4%)

§Note: only 144 participants completed the pre-CR survey. †ascertained from clinical charts.
*Note: percentages take into consideration missing responses. BMI, Body mass index; PCI, Percutaneous Coronary Intervention; CAD, Coronary Artery Disease; DASI, Duke Activity Standard Index; MI, Myocardial Infarction; CABG, Coronary Artery Bypass Graft surgery; SD, Standard Deviation.

Model Allocation Adherence

The chart audit of CR enrollment and model attended demonstrated that, among the 169 patients, 19 (11.2%) did not enroll in CR, and 45 (26.6%) attended a different model than the program to which they were randomly-allocated (Table 2). As shown, patients randomized to the home-based model most frequently did not receive the allocated intervention, and these patients most often attended mixed-sex CR.

Of those 45 who switched CR models post-randomization, 18 (40.0%) were successfully reached, of whom 11 (61.1%) participants completed the semi-structured phone interview. Participants most frequently switched to a supervised CR model due to the preference for the on-site facilities (n=10, 90.9%). In addition, 8 (72.7%) reported a preference for supervised programs due to their perception they could reap greater health benefits. Coding of responses to the open-ended question revealed that patients most frequently reported 'time/transportation conflict' (n=5, 45.4%) and the need for 'facilities/equipment' (n=5, 45.4%) as the main reason for switching CR models. Finally, of the 11 respondents, four (36.4%) switched from women-only to mixed-sex CR. All four (100.0%) participants reported time conflict as the reason for switching.

CR satisfaction

Satisfaction was only considered among CR enrollees, and was assessed in the post-test survey. Among the 116 retained participants, 106 (91.4%) enrolled in CR. Among these participants, CR satisfaction was 4.23±1.16 (mean ± standard deviation). There was no significant difference in patient satisfaction by program model whether it was calculated on the basis of "intention-to-treat" (randomized model; $F(2,99)=2.22$, $p=0.11$) or "as-treated" (model attended; $F(2,93)=0.45$,

p=0.85). Satisfaction did not significantly between participants who attended their randomized model and those who did not (4.28±1.07 versus 4.08±1.38, F(2,94)=0.24, p=0.46).

Table 2: Disposition of Participants at Post-Test

Random Allocation	n (%)	Did not enroll	Model Attended			
			Home-Based	Mixed-Sex	Women-Only	Total
Home-Based	55 (32.5%)	5 (9.1%)	-	20 (36.4%)	5 (9.1%)	25 (45.4%)
Mixed-Sex	59 (34.9%)	9 (15.3%)	1 (1.7%)	-	5 (8.5%)	6 (10.2%)
Women-Only	55 (32.5%)	5 (9.1%)	2 (3.6%)	12 (21.8%)	-	14 (25.4%)
Total	**169**	**19 (11.2%)**	**3 (6.8%)**	**32 (71.1%)**	**10 (22.2%)**	**45 (26.6%)**

Eighty-three (/106=78.3%) patients answered the open-ended question regarding why they were satisfied or dissatisfied. Patients most-often reported 'positive staff' (n=28, 33.7%), followed by 'education' (n=23, 27.7%), and 'motivating environment' (n=14, 16.9%) as reasons for satisfaction. Patients most-frequently reported dissatisfaction with 'barriers' that hindered attendance (n=7, 8.4%).

Table 3 displays patients' mean scores to the "gender-tailored" satisfaction items among all enrollees. The "intent-to-treat" analysis showed that there was a significant difference in satisfaction with behaviour change counselling by model [$F(2,94)=3.78$, $p=0.4$]; post-hoc tests revealed participants randomized to women-only were significantly more satisfied than participants randomized to mixed-sex CR (3.69±1.07 versus 3.00±1.11, $p=0.01$). No other differences were observed. As shown in the "as-treated" analysis (Table 3), patients who attended the women-only model were significantly more comfortable in their workout attire compared to patients who attended the mixed-sex CR model [$F(2,94)=6.26$, $p=0.001$], and perceived a significantly less 'competitive environment' compared to patients in the home-based program [$F(2,91)=4.03$, $p=0.02$].

CR preferences

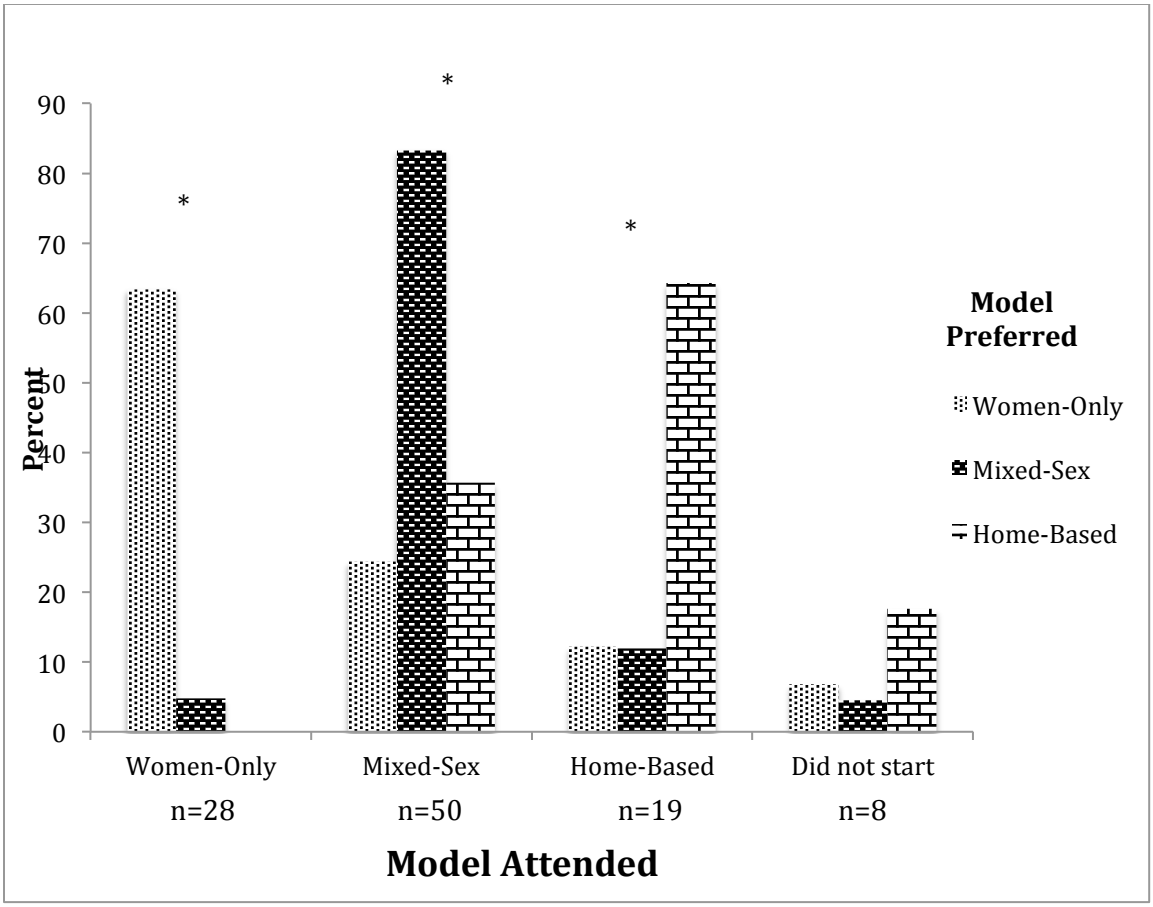
Eleven (/116; 9.5%) participants did not report a preferred model. Participants equally preferred the women-only (n=44, 41.9%) and mixed-sex (n=44, 41.9%) models over the home-based model (n=17, 16.2%). Responses were consistent among those who enrolled. Of the 105 retained participants who reported a preference, 70 (66.7%) enrolled in their preferred model; Figure 2 displays patient model preference by model attended. There was a significant difference in model preference by model attended [$\chi^2(1)=62.72$],

TABLE 3: Gender-Tailored Satisfaction at post-test among enrollees overall, and by model attended

	Model Attended			Total
Item (mean ± SD)	**Women-Only n=30 (28.3%)**	**Mixed-Sex n=56 (52.8%)**	**Home-Based n=20 (18.9%)**	**N=106§**
Felt comfortable in my workout clothes	4.77±0.43††	4.27±0.72††	4.56±0.51	4.47±0.65**
Satisfied with education in the program	3.86±1.04	3.86±1.03	4.19±0.83	3.91±1.00
Satisfied with life role direction given	3.86±1.11	3.84±1.07	3.67±1.05	3.63±1.08
Satisfied with psychosocial issues discussion	3.54±1.17	3.59±1.06	3.27±1.10	3.52±1.09
Behaviour change counselling suited me	3.56±1.16	3.27±1.05	3.36±1.01	3.37±1.07
Satisfied with women's health issues discussion	3.30±1.14	3.02±1.14	2.80±1.32	3.06±1.17
Competitive environment	1.43±0.68†	1.77±1.17	2.31±0.95†	1.76±1.03*

*p<0.05, **p=0.01 for analysis of variance (ANOVA). †p<0.01, ††p=0.001 for post-hoc Least Significant Difference (LSD) test.
SD, Standard Deviation.
Note: Scores ranged from 1 "Very Unsatisfied" to 5 "Very Satisfied".
§ n=10 participants did not enroll in CR.

Figure 2: Preference for cardiac rehabilitation model by model attended, N=105§



*p<0.001 for chi-square test.

§n=11 participants did not report their preferred model: 2 of whom did not enroll in CR, 1 attended home-based, 6 attended mixed-sex, and 2 attended women-only.

with patients significantly more likely to prefer the model in which they enrolled. There was no significant difference in CR satisfaction among patients who attended their preferred CR model versus those who did not (4.31±1.12 versus 4.21±0.99; F(2,86)=0.08, p=0.69).

A total of 89 (/116=76.7%) retained patients answered the open-ended question regarding why they preferred their chosen model. Of these, 40 (44.9%) participants preferred the women-only model. Patients most-often reported preference for this model due to a sense of comfort in a women-only environment (n=11, 27.5%), a focus on women's concerns (n=8, 20.0%), the supervision/structure of hospital-based CR (n=8, 20.0%), the social setting (n=6, 15.0%), and the ability to talk freely (n=5, 12.5%), among other responses (n=2, 5.0%).

There were 35 (/89=51.4%) patients who answered the open-ended question who reported a preference for the mixed-sex CR model. Participants most-often reported preference for this model due to the social interactions (n=18, 51.4%), education provided for both genders (n=5, 14.3%), supervision/structure of hospital-based CR (n=5, 14.3%), and motivation (n=3, 8.6%), among other reasons (n=4, 11.4%). Finally, 14 (15.7%) of the 87 patients who answered the open-ended question regarding preference preferred the home-based CR model. Participants most-often reported preference for this model due to the flexibility/convenience (n=9, 64.3%), and independence (n=2, 14.3%) that this model afforded, among other reasons (n=3, 21.4%).

Table 4 displays patients mean preference scores on the CRPF-R[111] scale overall. There were no significant differences in total scores among participants who attended

their randomly-allocated versus another program model, nor by model attended.

However, there were significant differences by model preferred [F(2,101)=4.43, p=0.01].

TABLE 4: Cardiac rehabilitation preferences at post-test overall and by program model preferred.

	Preferred Model			Total
Items (mean ± SD)	**Women-Only n=44 (41.9%)**	**Mixed-Sex n=44 (41.9%)**	**Home-Based n=17 (16.2%)**	**N=105‡**
Discuss Progress	2.50±0.55††	2.81±0.39†† §	2.35±0.61§	2.61±0.53**
Receive encouragement from professionals	2.58±0.59	2.67±0.47	2.33±0.49	2.58±0.53
Discuss problems	2.54±0.59	2.60±0.54	2.29±0.59	2.53±0.57
Not have pain while exercising	2.39±0.65	2.56±0.55	2.18±0.53	2.42±0.60
Receive individualized attention	2.94±0.63††	2.49±0.55†§	2.00±0.71†† §	2.41±0.63**
Ease of learning exercises	2.43±0.50	2.40±0.62	2.18±0.39	2.38±0.54
Set own goals	2.45±0.59	2.28±0.63	2.35±0.49	2.36±0.59
Not get overly tired	2.36±0.61	2.44±0.50	2.12±0.60	2.36±0.57
Acceptable distance from home	2.27±0.66	2.40±0.66	2.24±0.66	2.32±0.66
Flexible hours	2.16±0.72	2.32±0.57	2.18±0.64	2.23±0.64
Convenience of parking	2.30±0.63	2.07±0.81	2.00±0.79	2.16±0.74
Exercise not boring	2.07±0.66	2.23±0.68	2.18±0.64	2.15±0.66
Available transport	2.21±0.67	2.16±0.78	1.82±0.73	2.13±0.74
Exercise with someone	2.20±0.637††	2.12±0.79†	1.65±0.70† ††	2.08±0.73*
Does not interfere with other activities	2.04±0.68	2.05±0.73	1.82±0.64	2.01±0.69
Total	2.33±0.345†	2.38±0.306††	2.11±0.312† ††	2.31±0.33*

SD, Standard Deviation.
*p<0.05, **p<0.01 for analysis of variance (ANOVA). Post-hoc test Least Significant Difference (LSD), †p<0.05, †† and § p<0.01
Note: response options on the Cardiac Rehabilitation Preference Form- Revised (CRPF-R)[111] ranged from 1"Little Importance" to 3 "Very Important".
‡n=11 participants did not report their preferred model.

As shown in Table 4, women preferring the mixed-sex model scored significantly higher on the item 'discuss progress' compared to both women-only and home-based participants. In addition, patients who preferred the home-based model scored significantly lower on items 'receive individualized attention' and 'exercise with someone' compared to both mixed-sex and women-only participants.

Discussion

This is the first study to have investigated women's satisfaction with and preference for the 3 most-available CR program models. Similar to studies assessing satisfaction with home versus mixed-sex CR[114], women were highly satisfied with CR, and there were no significant differences in satisfaction among patients attending any of the 3 models. Participants attending women-only CR were significantly more comfortable in workout clothes than participants attending mixed-sex CR. Women reported equal preference for women-only and mixed-sex CR, and least preferred home-based. Indeed, many women randomly-assigned to home-based CR did not adhere to treatment allocation.

Over one-quarter of participants did not adhere to their random model allocation. This demonstrates patients' strong preferences for program model. The results herein reiterate that patient preference should play a key role in CR model allocation. For patients who are at low-risk of an adverse event, perhaps if they prefer a site-based program, this could be accommodated by the program to ensure patient-centeredness. Given there are no evidence-based algorithms for program model allocation, the results herein suggest that this is an important avenue for future research.

Consistent with previous research[115,116], choice of the home-based program seemed to be based on constraints such as time conflicts and transportation barriers, rather than a first preference. Similar to Madden et al.'s findings, women's choices were also highly impacted by restricted choice of times to attend the supervised programs. When patients learned that women-only CR was offered only once per week, many reported they were not available at that time interval. Women then opted for mixed-sex CR, during a session when the timing was more convenient. Particularly in smaller programs, it may not be feasible to offer more women-only sessions to enhance availability for women, and this approach could lead to unintended consequences of: (1) fewer women in mixed-sex classes (rendering any women in those classes to perceive CR as even more of a "men's club"[67]), and in addition, given that there are fewer women than men in CR, (2) under-subscribed classes. Thus, the implications are that programs should offer women-only CR, as it may have the desired impact of attracting more women to the program, even though quite a few women will likely end up choosing their mixed-sex model.

The low preference for home-based CR was not consistent with other studies. In a study by Dalal et al[117]., myocardial infarction patients in the United Kingdom were offered mixed-sex or home-based CR with the Heart Manual. Overall, 47 (44%) chose the home-based program, while only 35 (33%) chose the mixed-sex program, with no significant sex differences in model preferences. In the CHARMS trial with preference arms[80], 57% chose home-based and 43% chose mixed-sex CR, with again no significant sex differences. The reasons given for their preference for supervised versus home-based CR in the current study were consistent with the literature[115,118]. The difference in model

preference compared with our findings could be explained by the nature of the samples. In the current study, many participants were recruited from the CR program. These patients may be more likely to desire supervised CR than the average cardiac patient who has not enrolled. Indeed, in post-hoc analyses it was observed that while preference for a supervised versus home-based model did not differ between participants recruited as inpatients versus outpatients, participants recruited as inpatients (n=69; 46.0%) were significantly more likely to attend home-based CR than were participants recruited as outpatients at CR (30.4% versus 8.6%, respectively; $\chi^2(1)=11.66$, p=0.001). Therefore, it should not be concluded that home-based CR does not meet women's needs.

Caution is warranted in interpreting the results herein. First, there may be bias in participants' reports of their preferred model. Participants would be less informed about the models they did not attend, which may have led to the high concordance between attended and preferred models. Second, while the current study presents results of a planned tertiary objective of the trial, the trial was powered to assess the primary outcome of program adherence. Third, the satisfaction and "gender-tailored" preference items administered herein were investigator-generated, and hence their validity is unknown. Fourth, the findings are limited due to patient deviations from random allocation. The approach to the statistical analyses should have mitigated this limitation, and indeed similar results were found when the data were treated on an "intention-to-treat" and "as-treated" basis. Fifth, multiple comparisons were performed with regard to gender-tailored satisfaction and CR preferences. Type I error may be inflated and hence the associations observed may be spurious. These findings should not be over-interpreted, and warrant replication. Finally, the findings may be limited in their generalizability.

Women categorized as low-risk, and hence eligible for the home-based program, were included in the trial. Therefore the findings on preference and satisfaction may not be applicable to women who are higher-risk. More importantly, the response rate was very low and therefore selection bias may have affected the results.

In conclusion, women are highly satisfied with CR. They have strong preferences for CR program model. They reported an increased sense of comfort in workout attire and perceived the environment as 'less competitive' when attending a women-only program, and preferred the individualized attention and exercising with peers in this setting compared to other models. However, the infrequent availability of women-only classes was a deterrent to participation. Further research is warranted prior to drawing conclusions regarding greater provision of women-only CR, however offering model choice to women is highly supported by this trial.

Extended Results and Discussion

Retention Bias

As part of preliminary analyses, it was tested whether retention differed based on sites and models, among other considerations. First, there was no significant difference observed by recruitment site (χ^2=10.85, p=0.09). Retention rates varied from 37.5-80.8%. The women's class as Hamilton Health Sciences had the lowest retention rate of 37.5% followed by Toronto Rehabilitation Institute with 56.8% retention. There were also no significant differences observed by CR site attended (χ^2=2.11, p=0.35). Retention varied from 62.0%-67.2%.

With regard to design, randomized patients were significantly more likely to be retained compared to observational patients (69.0% versus 31.0%, χ^2=5.53, p=0.02). There were no significant differences by CR model to which patients were randomized (home-based 65.5%, mixed-sex 71.2%, women-only 69.1%; χ^2=0.44, p=0.80) or CR model attended (home-based 66.7%, mixed-sex 66.7%, women-only 62.4%; χ^2=0.47, p=0.79).

Satisfaction and Preferences

Preliminary analyses also included consideration of differences in the main outcomes by CR site. No significant difference in satisfaction was found across the three sites (F=2.50, p=0.09). However, there was a significant difference in the mean score of the Gender-Tailored Satisfaction Scale between the three site (F=6.28, p<0.01). Participants attending CR at Toronto Rehabilitation Institute (3.60±0.55) scored significantly higher than participants attending CR at Toronto Western Hospital (3.36±0.60, p=0.04) and Hamilton Health Sciences (3.15±0.75, p=0.001). Four items on

the Gender-tailored satisfaction scale different significantly between CR sites. Patients attending CR at Toronto Rehabilitation Institute were significantly more satisfied with discussions on 'psychosocial issues' (3.94±0.98) and 'women's health issues' (3.48±1.14) compared to participants attending CR at Toronto Western Hospital (3.28±0.93, $p<0.01$ and 2.86±1.03, $p<0.001$, respectively) and Hamilton Health Sciences (2.96±1.23, $p<0.01$ and 2.50±1.01, $p<0.001$, respectively). In addition, patients attending CR at Toronto Rehabilitation Institute were significantly more satisfied with 'life role direction' (3.88±0.95) and 'behaviour change counseling' (3.62±1.01) compared to patients attending CR at Hamilton Health Sciences (3.25±1.26, $p<0.01$ and 3.00±1.31, $p=0.02$, respectively).

Analysis of satisfaction by CR site by model attended revealed no significant difference among home-based participants. However, there were significant differences among mixed-sex and women-only participants when comparing satisfaction by site. Specifically, patients attending the women-only model at Toronto Rehabilitation Institute were significantly more satisfied with CR compared to patients attending the women-only model at Hamilton Health Sciences (4.57±0.87 versus 3.64±1.75, $p=0.02$). Also, patients attending the mixed-sex model at Toronto Rehabilitation Institute were significantly more satisfied with discussions on 'psychosocial' (3.92±1.00) and 'women's health' (3.35±1.07) issues compared to mixed-sex patients at both Toronto Western Hospital (3.19±0.81, $p<0.01$ and 2.65±1.04, $p=0.02$, respectively) and Hamilton Health Sciences (2.40±0.89, $p=0.001$ and 2.17±0.98, $p=0.01$, respectively). Finally, patients attending the mixed-sex model at Toronto Rehabilitation Institute were significantly more

satisfied with 'education' compared to mixed-sex participants at Hamilton Health Sciences (4.16±0.80 versus 3.00±1.26, p<0.01).

There was no significant difference in CR model preference between the three sites (χ^2=6.27, p=0.18). There was also no significant differences in the CRPF-R [111] scores between participants attending different CR sites (F=1.73, p=0.18).

Barriers

The total CR barrier score did not vary significantly by randomized CR model (F=1.08, p=0.34). In addition, subscale barrier scores did not differ between randomized groups.

CRBS scores different significantly by model attended (F=3.46, p=0.03), and are displayed in Table 6. Overall, participants attending home-based CR reported significantly greater barriers than those attending women-only CR (p=0.02). Barrier items were then analyzed based on the four subscales[119]. Participants in the home-based model (2.03±0.75) reported significantly higher barrier scores for the 'Health Care' subscale compared to participants attending mixed-sex (1.64±0.73, p=0.02) and women-only models (1.46±0.59, p=0.01). No other subscale differences were observed among participants. The overall barrier score did not significantly differ between patients who attended their randomized model versus those who did not (1.90±0.80 versus 1.80±0.81, p=0.61).

Overall CR barrier scores did not significantly differ between participants who attended supervised versus unsupervised CR models (1.86±0.83 versus 2.26±1.06, p=0.18). However, participants in the unsupervised model scored significantly higher in

barrier subscale ‘Health Care’ compared to participants attending the supervised CR models (2.03±0.75 versus 1.56±0.67, p=0.03). In addition, participants in the unsupervised CR models reported significantly higher barrier score for items ‘don’t know about CR’, ’already exercise at home,’ and ‘prefer to take care of my health alone’ compared to participants attending the supervised models (2.13±1.19 versus 1.51±0.96, p=0.02; 2.71±1.38 versus 1.94±1.21, p=0.03; and 2.21±1.12 versus 1.49±0.77, p=0.03, respectively).

Discussion

There were no differences in retention between participants recruited at different hospital sites nor by CR site attended. In addition, randomized patients had significantly increased retention rates compared to observational patients. This may be due to the age difference; observational patients were significantly older than randomized patients as discussed above. Home-based participants reported greater barriers; this is consistent the concept discussed that often the “choice” for home-based is based on constraints rather than preference

In terms of the original hypothesis, patients did not report higher satisfaction for the home-based and women-only model as initially expected. As hypothesized, women did indeed prefer the women-only model and but preference for the home-based program was limited to a small subset of the population. In addition, patients in the women-only model reported significantly higher satisfaction for a number of items on the gender-tailored satisfaction scale compared to participants attending the mixed-sex and home-based model. Finally, a number of barrier items were also significantly lower in women-only participants compared to co-ed as expected; however the hypothesis regarding

home-based barriers was not supported as home-based participants reported higher barrier scores than other participants.

Directions for Future Research

There are several directions for future research which flow from this this. First, future research is necessary to test whether providing the option of women-only CR increases female enrollment in CR. In interpreting the results from the main hypotheses, we suggest that offering women-only CR will attract more women, as this is their preferred model. This could be tested by comparing women's rates of CR enrollment since women-only CR has been initiated at a given CR program to a historical control.

Second, the preference of women for each of the models cannot truly be determined as they were exposed to only one of the three models. A crossover design trial could overcome this limitation: a randomized, controlled 3-program 6-sequence (fully counter-balanced) crossover study. The advantages of the crossover design are the opportunity for each patient to participate in each CR model enabling 'within subject' program comparisons and more informed assessments of relative preference.

Conclusion

This study has contributed to the understanding of alternative CR models in meeting women's needs following a cardiac event or procedure. Most women have strong preferences for CR model, but overall prefer women-only CR when conveniently scheduled. These findings will inform the larger trial results testing women's adherence to each of the program models. Taken together, evidence-based policy recommendations on whether to promote delivery of women-only CR can be developed.

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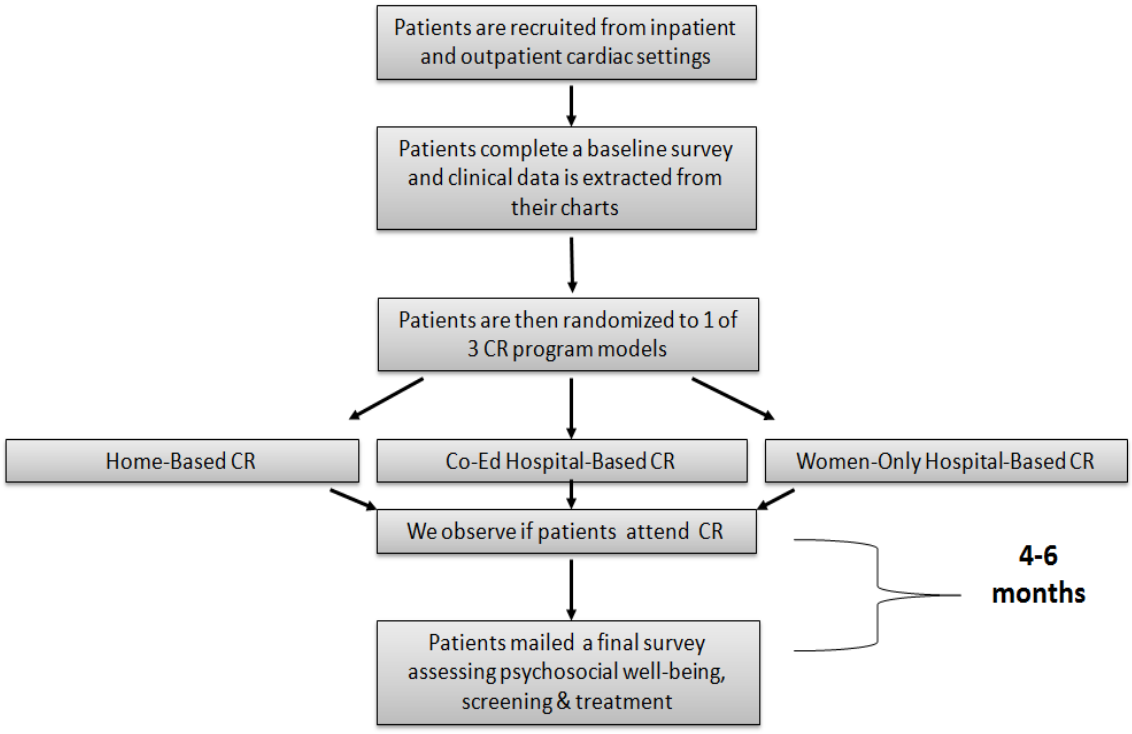
Appendices

Appendix A: Trial Overview



Appendix B: Poster

APPROVED FOR POSTING
UNTIL September 14th, 2012
UHN RESEARCH ETHICS BOARD

CR4HER Hosp Poster: V1; June 2, 2011

HEART & STROKE FOUNDATION
Finding answers. For life.

CR4HER

Cardiac Rehabilitation for her Heart Event Recovery

Attention Female Heart Patients from the GTA!

Cardiac Rehabilitation is a medically-supervised outpatient disease management program that includes exercise, education on heart healthy living, and counseling to help you in your recovery. It is recommended that all heart patients go, as it greatly improves your health over the long-term.

We are doing a study to understand how we can better meet the needs of female heart patients. This study involves having an equal chance to attend either a co-ed, women-only or home-based cardiac rehab program. The program is provided at no charge to you. We ask you to fill out a survey before and after the program.

Please contact Lori the study coordinator to find out more.

Sincerely,

D. Grace

Dr. Sherry Grace
Director of Research
Cardiovascular Rehab & Prevention
Peter Munk Cardiac Centre
University Health Network

Peter Munk Cardiac Centre
University Health Network

MOUNT SINAI HOSPITAL
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CR4HER – Lori
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Appendix C: Informed Consent Form

University Health Network

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title	A Randomized Controlled Trial of Women's Adherence to Women-only, Home-based, and Traditional Cardiac Rehabilitation (Cardiac Rehabilitation for her heart event recovery [CR4HER]).
Investigator	Sherry L. Grace, PhD. Scientist and Associate Professor (416) 340-4800 x. 6455#
Co-Investigators	Kenneth Melvin, MD. Cardiologist Heather Arthur, PhD. Professor and Research Chair Louise Pilote, MD. Associate Professor and Research Chair Paul Oh, MD. Medical Director and Assistant Professor. Stephanie Brister, MD. Medical Director and Associate Professor Donna E. Stewart, MD. Professor and Research Chair Caroline Chessex, MD. Cardiologist
Sponsor	Heart and Stroke Foundation of Ontario

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

- You are being approached to consider participating in this study because you are a female patient receiving cardiac care at University Health Network.
- This research study examines women's participation in cardiac rehabilitation (CR) programs.

- CR is a six-month outpatient program where you learn about heart disease and behaviour changes that can improve your heart health. It is the standard of care for heart patients. CR is proven to improve the health of participants, but not many women attend.

- This study will explore different types of CR for female heart patients, to see which ones women prefer to participate in. We are particularly interested in the number of sessions women attend, and how this might be different depending on the type of program you participate in.

- We will also explore women's exercise, eating habits, pill-taking and smoking, and see if they are different depending on what type of cardiac rehab program you participate in. Finally, we will also explore whether your mood or supports might affect how many CR sessions women attend.

- About 326 female heart patients from 3 hospitals will be in the study. If you agree to participate, you will be one of 218 patients in this study recruited from University Health Network, which includes Toronto General Hospital and Toronto Western Hospital.

Study Design

- If you agree, we would like to randomly (by chance) assign you to 1 of 3 study conditions. One of these conditions is co-ed CR so there are women and men participating, one of the conditions has only women participating, and one of the conditions is home-based CR so you will be supported in making heart healthy changes at home by telephone.

- This means that we will randomly refer 107 patients in each of the 3 CR types, and that you will have an equal chance (33%) of being referred to any of the CR types. This is like flipping a coin or rolling the dice. You will be referred to 1 CR type only.

- These CR types are offered at 2 local hospitals: Toronto Western Hospital , and Toronto Rehabilitation Institute. We will refer you to the hospital offering the program type you were randomly chosen to attend which is closest to your home or work.

- You will be in the study for 6 months.

Study Procedures

A study recruiter will approach you in the hospital to determine your interest and eligibility for the study.

1. first survey - After the study coordinator approaches you in the hospital for consent, she will ask you to complete a paper-and-pencil survey, which will require approximately 30 minutes of your time. The survey asks questions about your feelings, supports, your exercise and eating habits, smoking status, alcohol use, medications and other health conditions. You will only be identified by a study identification number. Should your responses indicate that you are having suicidal thoughts or depression, for your safety we will send a letter to your family doctor. You can complete the survey in hospital or you can take it home, and return it to us in the pre-paid, pre-addressed envelope provided.

We would also like your permission to access some basic medical information from your health records. This personal health information will help us refer you to CR. This will include the nature of your cardiac problem and heart history, your age, medications, other health problems, heart risk factors, diagnostic test results, and the name of your doctors. We would also like your consent to ask your family doctor or cardiac specialist if it would be safe for you to participate in a CR program.

Once we have completed these steps, we will arrange your CR referral to the site closest to your home offering the CR program type you were randomized to. Copies of your heart-related health records (i.e. blood work, ECG, discharge notes) will be sent to the CR program, in order to help them process the referral so that they are fully informed of your health status. They will contact you to book an intake appointment where a tailored program will be set up to meet your needs. We are not involved in your direct relationship with the CR program, except that they will share some of your assessments with us.

2. final survey - Six months after you complete the first survey or when you graduate from CR, a second paper-and-pencil survey will be mailed to your home. This will also take approximately 30 minutes to complete. The survey asks questions about your feelings, supports, your exercise and eating habits, and other health conditions. In the mailed package we will include a pre-paid, pre-addressed return envelope so you can mail your completed survey back at no charge to you.

If your survey responses suggest you attended a different type of CR program than we thought, we may call you to ask why, if you are willing.

At both time points, interested participants will be mailed a pedometer package, to objectively measure exercise behaviour.

3. measuring steps –For this portion, we would provide you a pedometer (a device that measures the number of steps you take while walking around) that would record your physical activity during the time that you wear it. You would also receive an activity log. We would ask you to wear the pedometer for 7 days, and then note the number of steps showing, on a daily basis, on the log provided. Once the log is complete, we would ask you to return to us by mail (in a postage-paid envelope provided) the pedometer and the completed activity log-sheet. If you are interested, we would ask you to record your steps for 7 days before CR, and again 6 months later when you are asked to complete your second and final survey.

If you enroll in CR after being referred, at both intake and discharge, CR programs will securely send some of your results they measure as part of standard care including personal health information to the central study coordinator at Toronto General Hospital (i.e., stress test, waist circumference, blood pressure, quality of life, cholesterol). We will also contact the CR program to ask about your participation level and dates.

While you are in this study you may continue with everything your family doctor or cardiac specialist has recommended. In all groups, you will still receive your usual care from your family doctor and cardiac specialist. You do not have to stop or change anything.

Risks Related to Being in the Study

There are no medical risks if you take part in this study, but being in this study may make you feel uncomfortable. You may refuse to answer questions at any time if there is any discomfort.

Benefits to Being in the Study

You may receive direct benefit from being in this study. You may be offered a compensation of $20 for the final survey you complete and return. Also, the information learned from this study may help other people with heart disease in the future.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Confidentiality

Personal Health Information
If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- address,
- date of birth,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee.
- University Health Network Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a

code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for any of the CR sessions involved with this study. You will not be reimbursed for transportation to CR sessions or for your time to complete the surveys. Those that participate in the pedometer portion of the study, upon return of the pedometer and log, you will receive a complimentary pedometer in the mail.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Sherry Grace, PhD at 416-340-4800 x. 6455# or the study coordinator at 416-340-4800 x. 6593#.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph.D., Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-946-4438 or Please call the Toronto Rehab Research Ethics Board Office at (416) 597-3422 x 3081.The REB is a group of people who oversee the ethical conduct of research studies.These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions..

Print Name of Person Obtaining Consent	Signature	Date

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant

Appendix D: Informed Consent Form (Sub-Study)

University Health Network

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title	A Randomized Controlled Trial of Women's Adherence to Women-only, Home-based, and Traditional Cardiac Rehabilitation by Program Model (Cardiac Rehabilitation for her Heart Event Recovery [CR4HER]) Adherence to Women-only Cardiac Rehabilitation - (Sub-Study)
Investigator	Sherry L. Grace, PhD. Scientist and Associate Professor (416) 340-4800 x. 6455#
Co-Investigators	Kenneth Melvin, MD. Cardiologist Heather Arthur, PhD. Professor and Research Chair Louise Pilote, MD. Associate Professor and Research Chair Paul Oh, MD. Medical Director and Assistant Professor. Stephanie Brister, MD. Medical Director and Associate Professor Donna E. Stewart, MD. Professor and Research Chair Caroline Chessex, MD. Cardiologist
Sponsor	Heart and Stroke Foundation of Ontario

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

- You are being approached to consider participating in this study because you are a female patient participating in the women-only cardiac rehabilitation program at University Health Network.
- This research study will explore the number of sessions women attend in women-only cardiac rehabilitation (CR) programs, and the factors that may influence this, such as

mood or supports. We will also explore women's exercise, eating, pill-taking and smoking habits.

- About 60 female heart patients from 3 hospitals will be in this sub-study. If you agree to participate, you will be one of 30 patients in this study recruited from University Health Network.

Study Design

- This is a 6 month observational study that is being done as part of the bigger CR4HER study which compares women's adherence to 3 different types of CR program

Study Procedures:

If you agree to participate in the study:

1. You will be asked to complete survey questionnaires before you start the Cardiac Rehab program and then again 6 months after you start the program. The Questionnaires will ask you about your lifestyle (diet, exercise, habits, etc) as well as questions about your health and emotional well-being. Completion of the Questionnaires will require approximately 30 minutes of your time.

You may complete the Survey while in the hospital or you may take it home, and return it to us in the pre-paid, pre-addressed envelope provided.

2.. Measuring steps - During both times you are asked to complete the Questionnaires, you will also be provided with a pedometer (a device that measures the number of steps you take while walking around) that would record your physical activity during the time that you wear it, along with an activity log. You will be given instructions to wear the pedometer for 7 days, and then note the number of steps showing, on a daily basis, on the activity log provided. Once the log is complete, we would ask you to return the pedometer and the completed activity log, in the pre-paid envelope provided. This will be done to assess the level of your physical activity, but is an optional part of this sub-study. This means you have a choice on whether or not to do this activity.

3.Finally, as part of the study, we will also review your medical records to obtain information about your diagnosis and your medical history, including the nature of your cardiac problem, heart history and medications. We will also collect the information obtained as part of your rehab program, which includes test results, blood pressure and waist measurements, cholesterol levels , as well as your participation level and dates of attendance

Patient Reminders:

While you are in this study you may continue with everything your family doctor or cardiac specialist has recommended. You will still receive your usual care from your family doctor and cardiac specialist. You do not have to stop or change anything.

Risks Related to Being in the Study

There are no medical risks if you take part in this study, however, some of the survey questions might make you feel uncomfortable . Your responses to some of the Questionnaires may also reveal feelings of depression and thoughts about harming yourself. Should this be identified, your family doctor will be informed to insure that you get the proper help.

Benefits to Being in the Study

You may not receive any direct benefit from your participation in this research. Information learned from this study may help other women with heart disease in the future.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Confidentiality

Personal Health Information
If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- address,
- date of birth,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee.
- University Health Network Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for any of the CR sessions involved with this study. You will not be reimbursed for transportation to CR sessions or for your time to complete the surveys. Those that participate in the pedometer portion of the study, upon return of the pedometer and log, you will receive a complimentary pedometer in the mail.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Sherry Grace, PhD at 416-340-4800 x. 6455# or Lori VanLangen at 416-340-4800 x. 6593#.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) at 416-581-7849 or please call the Toronto Rehab Research Ethics Board Office at (416) 597-3422 x 3081.The REB is a group of people who oversee the ethical conduct of research studies.These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions..

Print Name of Person Obtaining Consent	Signature	Date

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant

Appendix E: Physician Clearance Form

CR4HER Trial
Request for Physician Clearance

Date: _____

Dear Dr. _____:

Your patient _____ has provided written consent to participate in the Cardiac Rehabilitation for her Heart Event Recovery (CR4HER) trial funded by HSF, being conducted at the University Health Network, Sunnybrook Health Sciences Centre, Toronto Rehabilitation Institute, Mount Sinai, and Hamilton Health Sciences Centre. As you know, CR is an evidence-based outpatient program of structured exercise and education. Patients who attend CR have 25% lower mortality rates, fewer rehospitalizations and recurrent events, improved quality of life, and risk factor reduction. Clinical practice guidelines promote CR as the standard of care, yet few patients actually enroll and participate. The physical activity component of each CR program is based on a graded exercise test supervised by a physician, which enables individualized recommendations for moderate-intensity activity such as walking at a target heart rate. Cardiac rehab is very safe and is facilitated by multi-disciplinary health professionals.

We are randomizing patients to one of three study conditions: (1) hospital-based co-ed CR, (2) hospital-based women-only CR, or (3) home-based CR. **We will complete the referral for eligible patients**. Six months later, we will mail participants a survey to assess program adherence, lifestyle, and risk factors. As you can see, your patient's participation in this study may result in health benefits, while there is no extra work for you. You may receive a CR discharge summary.

We are writing to **request 'clearance'** for your patient to participate in a cardiac rehab program. Please ☑check one.

_____ has clearance to participate in a cardiac rehab program as part of the CR4HER trial.
(Patient's Name)

☐ Yes ☐ No

_____ _____
Physician signature Date

When complete, please fax this form to Study Coordinator at (416) 340-4185.

Please be in touch with the Principal Investigator, Sherry Grace, PhD of York University and University Health Network with any questions or comments. She can be reached at sgrace@yorku.ca or (416) 340-4800 x.6455#. Thank you in advance for your cooperation.

CR4HER. V5. January 18, 2012
Page 1 of 1

Appendix F: 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 Surgery
- ☐ Angina / ACS / CAD
- ☐ MI
- ☐ Valve surgery

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 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

☐ 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/CAD Confirmation Date: _____
☐ ECG ☐ Angiogram ☐ Enzymes ☐ Symptoms

☐ Other cardiac cond(s) Date: _____

☐ Aneurysm	☐ Arrhythmia
☐ Infection	☐ Congenital HD
☐ Heart Failure	☐ Cardiomyopathy
	☐ Other: _____

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: _____

17. 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#: _____

18. 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: _____

19. CRP: _____
Date assessed: _____

20. Heart rate: _____
Date assessed: _____

21. Previous cardiac diagnosis?

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

22. Comorbid Conditions

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

ONLY FILL IF PATIENT IS AN INPATIENT

23. Family Physician:
_____
Phone #: _____

24. Cardiac Specialist:
_____
Phone #: _____

24. Clearance Received:
☐ Yes ☐ No

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

26. Cleared for CR referral:
☐ Yes ☐ No

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

28. Site referred to:

☐ TRI ☐ TWH ☐ HHSC

29. Referral Date: ☐☐ ☐☐☐ ☐☐☐☐
dd mmm yyyy

30. Call to patient re: program site & model:
☐ Yes ☐ No
Date: ☐☐ ☐☐☐ ☐☐☐☐
dd mmm yyyy

Notes:
_____
_____

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

CR4HER Case Report Form (CRF)

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*):

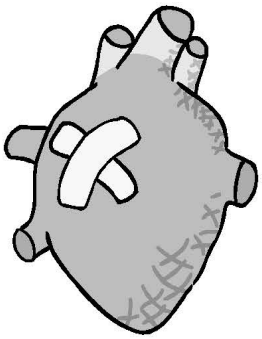
Name	
Relationship	
Telephone	

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

Appendix G: Baseline Survey

Cardiac Rehab for Her Study
(CR4HER)

In-hospital Survey



Instructions for completing the survey questions appear at the beginning of each section.

Please seal your completed questionnaire in the stamped envelope provided, and return it to the study coordinator.

Participant # _____ Version 5, August 13, 2012

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) prior to your cardiac event?
    - ❑ Yes
    - ❑ No

15. Did a doctor tell you that you were diagnosed with heart disease before this hospitalization?
    - ❑ Yes
    - ❑ No

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

16. Have you previously 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

17. Are you (☑ check one):
- ❑ Pre-menopausal
- ❑ Going through menopause
- ❑ Post-menopausal

18. 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_____

Others: _____

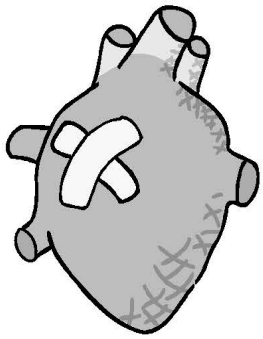
_____

_____

Appendix H: Final Survey

Cardiac Rehab for Her Study (CR4HER)

Final Survey



Instructions for completing the survey questions appear at the beginning of each section.

Please seal your completed questionnaire in the stamped envelope provided, and return it by mail to the study coordinator.

Participant # _____ Version 3, December 10, 2010

SECTION A: CARDIAC REHABILITATION PARTICIPATION

Instructions: Cardiac rehabilitation (CR) is an outpatient program of structured exercise and education to maximize your recovery. Please check the appropriate box in response to each question. If your checked answer has an arrow leading to another box, answer the questions in the attached box. Please print any written answers clearly.

1. Did you attend a cardiac rehabilitation assessment (intake appointment)?

☐ **Yes** →
(If Yes) 1.Where? _____
2. How many minutes did you take you to travel there one-way? _____ mins

☐ **No** →
(If No) Why not?

2. Did you participate in cardiac rehabilitation?

☐ **Yes** →
(If Yes)

1. Approximately how many weeks passed between being discharged from hospital, and starting the cardiac rehab program? _____ wks

2. Did you consider this to be an acceptable or unacceptable length of time to wait for cardiac rehab?

☐ acceptable
☐ unacceptable

Why?

3. Approximately what percentage of cardiac rehabilitation sessions did you complete on the phone or at the hospital?

_____ % of sessions completed

☐ **No** →
(If No) Why not? Please be as specific as you can.

SECTION B: CARDIAC REHAB BARRIERS

The following questions ask about some of the factors influencing your participation in cardiac rehabilitation sessions. Please answer **all of the questions** on this page regardless of whether you participated or **did not** participate, and whether you participated in a home-based **or** hospital-based cardiac rehabilitation program. If you participated in a **home-based program**, answer these questions in reference to your visits to the cardiac rehabilitation site and your telephone visits.

I did not attend a cardiac rehabilitation program, or if I did attend, I missed some sessions because:	**Strongly Disagree**	**Disagree**	**Neither Agree or Disagree**	**Agree**	**Strongly Agree**
1. …of distance (e.g., not located in your area, too far to travel)	☐	☐	☐	☐	☐
2. …of cost (e.g., parking, gas)	☐	☐	☐	☐	☐
3. …of transportation problems (e.g., access to car, public transportation)	☐	☐	☐	☐	☐
4. …of family responsibilities (e.g., caregiving)	☐	☐	☐	☐	☐
5. …I didn't know about cardiac rehab (e.g., doctor didn't tell me about it)	☐	☐	☐	☐	☐
6. …I don't need cardiac rehab (e.g., feel well, heart problem treated, not serious)	☐	☐	☐	☐	☐
7. …I already exercise at home, or in my community	☐	☐	☐	☐	☐
8. …severe weather	☐	☐	☐	☐	☐
9. …I find exercise tiring or painful	☐	☐	☐	☐	☐
10. …travel (e.g., holidays, business, cottage)	☐	☐	☐	☐	☐
11. …of time constraints (e.g., too busy, inconvenient class time)	☐	☐	☐	☐	☐
12. …of work responsibilities	☐	☐	☐	☐	☐
13. …I don't have the energy	☐	☐	☐	☐	☐
14. …other health problems prevent me from going (specify:_____)	☐	☐	☐	☐	☐
15. …I am too old	☐	☐	☐	☐	☐
16. …my doctor did not feel it was necessary	☐	☐	☐	☐	☐
17. … many people with heart problems don't go, and they are fine	☐	☐	☐	☐	☐
18. … I can manage my heart problem on my own	☐	☐	☐	☐	☐
19. … I think I was referred, but the rehab program didn't contact me	☐	☐	☐	☐	☐
20. …it took too long to get referred and into the program	☐	☐	☐	☐	☐
21. …I prefer to take care of my health alone, not in a group	☐	☐	☐	☐	☐

22. Other reason (s) for not attending a cardiac rehabilitation program:

_____

SECTION C: CARDIAC REHABILITATION PROGRAM PREFERENCES

Please rate the importance of each of the following cardiac rehabilitation program features.
Please answer **all of the questions** on this page regardless of whether you attended or **did not** attend a cardiac rehabilitation program. Please also answer if you attended a home-based or hospital-based program.

	Little Important	Important	Very Important
1. Discuss progress	☐	☐	☐
2. Ease of learning exercises	☐	☐	☐
3. Not get overly tired	☐	☐	☐
4. Set own goals	☐	☐	☐
5. Discuss problems	☐	☐	☐
6. Not have pain while exercising	☐	☐	☐
7. Exercises are not boring	☐	☐	☐
8. Receive individualized attention	☐	☐	☐
9. Receive encouragement from professionals	☐	☐	☐
10. Exercise with someone	☐	☐	☐
11. Acceptable distance from home	☐	☐	☐
12. Convenience of parking	☐	☐	☐
13. Flexible hours	☐	☐	☐
14. Does not interfere with other activities	☐	☐	☐
15. Available transport	☐	☐	☐

SECTION D: USUAL ACTIVITIES

Instructions: The following questions have to do with your current activity status. Circle (Yes) or (No) in response to each question.

1. Can you take care of yourself, that is, eating, dressing, bathing or using the toilet? **Yes** **No**

2. Can you walk indoors, such as around your house? **Yes** **No**

3. Can you walk a block or two on level ground? **Yes** **No**

4. Can you climb a flight of stairs or walk up a hill? **Yes** **No**

5. Can you run a short distance? **Yes** **No**

6. Can you do light work around the house like dusting or washing dishes? **Yes** **No**

7. Can you do moderate work around the house like vacuuming, sweeping floors, or carrying in the groceries? **Yes** **No**

8. Can you do heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?

   Yes **No**

9. Can you do yard work like raking leaves, weeding or pushing a power mower? **Yes** **No**

10. Can you have sexual relations? **Yes** **No**

11. Can you participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football?

    Yes **No**

12. Can you participate in strenuous sports like swimming, singles tennis, football, basketball or skiing?

    Yes **No**

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. ☐

3. In the past 9 months, what kinds of physical activities did you engage in (check all that apply)?

- ❑ walking
- ❑ swimming
- ❑ gardening
- ❑ others (please specify:_____)

4. On average, for how many minutes did you engage in the activity each session? _____ minutes

5. Where did you exercise in the last 9 months?

- ❑ At home or in my community
- ❑ At cardiac rehabilitation only
- ❑ At home or in my community AND at cardiac rehabilitation
- ❑ I didn't exercise anywhere

6. Describe your experiences exercising at home or in your community.

_____
_____
_____

SECTION F: NUTRITION

MEAT, FISH AND POULTRY

Consider your eating habits during the last month. **For each question, circle all numbers that apply.**

1. Which type of ground meat do you usually eat? **office use only**

1 Regular hamburger (30% fat)
2 Lean ground beef (25% fat)
3 Extra lean/ground chuck (20% fat)
4 Ground round (15% fat)
5 Super lean (4% - 10% fat), ground sirloin (10% fat), ground turkey breast, ground chicken breast
6 **Eat no ground meat** Score_____

2. Which best describes your typical lunch? "Lunch meat" means ham, bologna, salami, pastrami, etc.

1 Cheeseburger, pizza, typical cheeses, egg dishes (egg salad, quiche, frittata, etc)
2 Sandwich (lunch meat, hamburger, grilled cheese,), meat/chicken entree (plain/fried), regular hot dog
3 **Skip lunch** or sandwich (tuna, fish, peanut butter, chicken or turkey lunch meat/light mayo, etc), turkey hot dog, vegetarian dishes
4 Tuna sandwich (w/mayo: 1 gm fat or less/Tbsp, Veggie burger (*Garden, Boca*), entree (fish [not fried], small bits of chicken or meat), low-fat yogurt,
5 Salad (low-cal dressing), low-fat vegetarian dishes, hot dog (0-2 gm fat), deli meats/fat free sandwich (w/mayo: 1 gm fat or less/Tbsp), bagel (light cream cheese)
6 Fat free vegetarian dishes, salad (fat free dressing), Veggie dog, Garden Vegan (fat free burger), nonfat yogurt, dry cereal (skim milk), bagel (fat free cream cheese) Score_____

3. Circle all of the choices that reflect the entree at your main meal.

1 Cheese (Cheddar, Jack, etc), eggs, organ meats (liver, etc), pizza, vegetarian dishes once a week or more
2 Beef, lamb, pork or ham once a week or more
3 Very lean red meat (top round or flank steak), rabbit, veal, venison or elk once a week or more
4 Chicken, turkey, crab, lobster or shrimp twice a week or more
5 Fish, scallops, oysters, clams, low-fat vegetarian dishes twice a week or more
6 Fat free vegetarian dishes, fat free seafood dishes every day Score_____

4. Estimate the number of ounces of meat, cheese, fish *and* poultry you eat in a typical day. Include all meals and snacks. (To guide you in your estimate (a piece the size of a deck of cards = 3 oz)

1 hot dog = 1 ½ oz 1 chicken thigh = 2-3 oz 1 slice cheese = 1 oz
4 strips bacon = 1 oz ½ chicken breast = 3 oz 1-inch cube cheese = 1 oz
1 small burger patty = 3-4 oz average T-bone steak = 8 oz meat in sandwiches = 2-3 oz

1 Eleven or more ounces a day
2 Nine to 10 ounces a day
3 Six to 8 ounces a day
4 Four to 5 ounces a day
5 Up to 1 ounce cheese *or* 3 oz lean meat, poultry, shrimp, crab, lobster *or* 6 oz fish, clams, oysters, scallops a day
6 **None** or up to 3 ounces shrimp, crab, lobster *or* 6 ounces fish, clams, oysters, scallops a day Score_____

5. Which of these have you eaten in the past month?

1 Bacon, sausage
2 Canadian bacon, turkey or chicken sausage
4 Vegetarian sausage (*Morningstar* links or patties, other soy sausage)
6 **None** Score_____

TOTAL SCORE (MEAT, FISH AND POULTRY)_____

DAIRY PRODUCTS AND EGGS

Consider your eating habits during the last month. **For each question, circle all numbers that apply.**

6. Which do you usually use for drinking (don't forget lattes/mochas) or cooking? **office use only**
(Most lattes/mochas contain whole milk unless you request otherwise).

1 Whole milk
2 Two percent milk
4 One percent milk, buttermilk
5 **None** or skim (nonfat) milk, nondairy beverages (*Edensoy*, *Rice Dream*, etc) Score_____

7. Which toppings do you use?

1 Sour cream (real or imitation including *IMO*), whipped cream
2 Light/low-fat sour cream, *Cool Whip*, *Reddi-Whip* aerosol dairy
3 *Cool Whip Lite*, regular cottage cheese, whole milk yogurt
4 Low-fat yogurt, low-fat cottage cheese, *Reddi-Whip* aerosol nondairy
5 1% fat cottage cheese, *Cool Whip Free,* soy yogurt
6 **None** or nonfat yogurt, nonfat sour cream, nonfat cottage cheese Score_____

8. Which frozen desserts are you most likely to eat at least once a month?

1 Regular ice cream (5 g to 18 g fat per ½ cup)
2 Light ice cream (4 g fat per 1/ 2 cup)
3 Ice milk, most soft ice cream, frozen yogurt (cream added), *Tofutti*
4 Sherbet, low-fat frozen yogurt, *Soy Delicious*
5 **None** or nonfat frozen yogurt, sorbets, Popsicles Score_____

9. Which kind of cheese do you use?

2 Cheddar, Swiss, Jack, Brie, Feta, Montrachet, Blue, Jarlsberg, whole milk mozzarella, Neufchatel or regular cream cheese, processed cheese (*Velveeta*, American, *Cheese Whiz*), *Kraft Delux Slices*, *Easy Cheese*, Parmesan
5 Part-skim mozzarella, light cream cheese, light Cheddar, light Jack, (*Kraft Light Naturals, Alpine Lace-Lo, Velveeta Light* or other part-skim cheeses), Cabot Vermont Cheddar (50% Light), string cheese
8 Jarlsberg Lite, *Athenos Reduced Fat Feta Cheese*
10 Light part-skim mozzarella, low-fat and light ricotta, Lite-Line, nonfat Parmesan, Cabot Vermont cheddar (75% Light), *Parm Plus*, soy/rice cheese (cheddar, mozzarella)
12 **None** or fat free cheeses (Cheddar, Jack, ricotta, cream, *Healthy Choice*, *Alpine Lace*, etc), soy (Tofu Rella), Almond (cheddar, mozzarella, etc) Score_____

10. Check the type and number of "visible" eggs you eat (scrambled, fried, etc).

1 Six or more whole eggs a week
2 Three to five whole eggs a week
3 One to two whole eggs a week
4 One whole egg a month
5 **None** or egg whites, egg substitute (*Nulaid, Egg Beaters, Scramblers, Second Nature*, etc) Score_____

11. Check the type of eggs usually used in food prepared at home or bought in grocery stores.

1 Whole eggs or mixes containing whole eggs (complete pancake mix, slice-and-bake cookies, etc)
3 Combination of egg whites, egg substitute and whole eggs
5 **None** or egg whites, egg substitute Score_____

TOTAL SCORE (DAIRY PRODUCTS AND EGGS)_____

FATS AND OILS

Consider your eating habits during the last month. **For each question, circle all numbers that apply.**

12. Which kinds of fats are used most often to cook your food (vegetables, meats, etc)? **office use only**

1 Butter, shortening (with animal fat), lard, bacon grease, chicken fat
2 Shortening (with vegetable fat), vegetable oil (cottonseed)
3 Tub or stick margarine (all except canola), vegetable oil (soybean, olive)
4 Vegetable oil (safflower, corn), tub or stick margarine (canola)
5 Vegetable oil (canola)
6 **None** or use nonstick cooking spray

Score_____

13. How much of these "added" fats do you eat in the typical day: peanut butter, margarine, mayonnaise, or salad dressing (including those made with olive oil)? *Do not count fat free products.*

		Examples of amounts people often use:
1	Ten teaspoons or more	***on toast:*** *2 tsp margarine*
2	Eight to 9 teaspoons	***on salads:*** *12 tsp salad dressing*
3	Six to 7 teaspoons	***on vegetables:*** *3 tsp margarine*
4	Four to 5 teaspoons	***on sandwiches:*** *6 tsp mayonnaise, 2 tsp margarine*
5	Three teaspoons	***on potatoes:*** *3 tsp margarine*
6	**None**	***on pasta, rice:*** *3 tsp margarine, oil or 6 tsp pesto*

Score_____

14. How often do you eat potato chips, corn or tortilla chips, fried chicken, fish sticks, French fries, doughnuts, other fried foods, croissants or Danish pastries? *Do not count fat free products*

1 Two or more times a day
2 Once a day
3 Two to 4 times a week
4 Once a week
5 Less than twice a month
6 **Never**

Score_____

15. Which best describes the amount of margarine, butter, peanut butter, mayonnaise or cream cheese that you put on breads, muffins, bagels, etc? *Do not count fat free products*

1 Average
2 Lightly spread (can see the bread through it)
4 "Scrape" (can barely see the spread)
5 **None**

Score_____

16. Which kind of salad dressings do you use?

1 Real mayonnaise
2 *Miracle Whip*, light mayo, Caesar, Thousand Island dressing
3 *Best Food's Low-Fat Mayo* (1gm fat/Tbs), Ranch, French, Blue Cheese or Roquefort, vinegar and oil, Italian, Russian, low-fat mayonnaise dressing, *Miracle Whip Light* dressing and Italian dressings
4 Ranch Dressing (mix and light mayo)
5 Low-cal salad dressing, Ranch Dressing (mix and low-fat yogurt)
6 **Use no salad dressing** or fat free mayonnaise, *Miracle Whip* fat free, fat free salad dressings, Ranch dressing (mix and nonfat dairy or yogurt/sour cream), vinegar, lemon juice

Score_____

TOTAL SCORE (FATS AND OILS)_____

SWEETS AND SNACKS

Consider your eating habits during the last month. **For each question, circle all numbers that apply.**

17. How often do you eat desserts or baked goods (sweet rolls, doughnuts, muffins, scones, cookies, cakes)? *Do not count fat free versions* **office use only**

1 Once a day
2 Five to 6 times a week
3 Three to 4 times a week
4 Two times a week
5 One time a week or less
6 **Never** Score_____

18. Which of the following desserts or snacks have you eaten in the last month?

1 Croissants, cheesecake, typical cakes with frosting
2 Pies, cookies, cupcakes, muffins, scones, frosted doughnuts
3 Granola bars (*Nature Valley, Quaker Chewy*)
4 Low-fat muffins, desserts made using low-fat recipes, low-fat cookies (fig bars, ginger snaps, *Snackwell's*), low-fat granola bars (*Power Bar, Quaker Chewy low-fat*)
5 Fat free desserts including angel food cake, fat free cookies
6 **Never eat baked goods listed above** or eat fruit for dessert Score_____

19. Which of the following snacks have you eaten in the last month?

1 Chocolate, commercial popcorn, *Poppy Cock* popcorn, caramel corn
2 Nuts, potato chips, corn chips, *Doritos* chips, microwave popcorn, homemade popcorn w/butter, *Cracker Jack*, French fries, peanut butter, party/snack crackers (*Ritz*)
4 Tortilla chips, baked potato chips, pretzels, light microwave popcorn, lightly buttered popcorn (1 tsp margarine for 3 cups popcorn), low-fat crackers (soda, graham), *Toby's Tofu Pate Original*
5 Baked tortilla chips, homemade popcorn w/no fat, fat free soda crackers and other fat free crackers, *Toby's Tofu Pate Lite*
6 **Do not eat snacks** or eat fruits and vegetables as snacks Score_____

TOTAL SCORE (SWEETS AND SNACKS)_____

SEAFOOD

Consider your eating habits during the last month. **For each question, circle all items that apply.**

20. How often do you eat fish? (tuna, snapper, perch, sole, halibut, cod, salmon, shrimp/prawns, crab, lobster, scallops, clams, oysters, sardines, etc). **office use only**

1 **Do not eat fish** *or* eat fish less than once a month
2 One to 3 times a month
3 Once a week
4 Two times a week
5 Three or more times a week *or* **eat vegetarian with no added fat** Score_____

21. Which fish (fresh, frozen or canned) have you eaten in the last month?

1 **Ate no fish in the last month**
2 Scallops, clams, mussels, snowcrab (surimi)
3 White fish (perch, cod, sole, halibut, snapper), oyster, lobster, tuna, crab
4 Trout, steelhead, herring, catfish, salmon (Atlantic, pink)
5 Salmon (Coho, red, Chinook), mackerel, sardines, shrimp/prawns, squid *or* **eat vegetarian with no added fat**

Score_____

TOTAL SCORE (FISH)_____

GRAINS, BEANS, FRUITS AND VEGETABLES

Consider your eating habits during the last month. For this part of the quiz, list the number of servings of the following foods you eat each day or week, as specified for the question.

office use only

22. How many pieces of fruit or cups of fruit juice do you consume a day? (not "fruit-flavored" drinks)

_____ cups or pieces Score (cups x 5)_____

23. How many cups of vegetables do you eat a day (tossed salad, cooked vegetables, soups, casseroles, etc)? (A typical serving size for tossed salad is 1 to 1 1/2 cups)

_____ cups Score (cups x 5)_____

24. How many cups of legumes do you eat a week (refried beans, split peas, white beans, black beans, blackeye peas, lentils, chili, etc)?

_____ cups Score (cups x 5)_____

25. List the number of servings of the following you ate last week. (A typical cereal bowl holds 1 1/2 to 2 cups; people typically eat 9 to 12 cups of popcorn).

	Amount eaten LAST WEEK
cooked cereal	_____ bowls/week
ready-to-eat cereal	_____ bowls/week
English muffin	_____ #/week
hamburger bun	_____ #/week
bagel (plain or flavored)	_____ #/week
Pita or pocket bread	_____ #/week
eight-inch tortilla	_____ #/week
plain popcorn (4 cups/serving)	_____ servings/week (1 microwave bag holds 10 ½ cups)
fat free or low-fat muffin	_____ muffins/week
cornbread	_____ pieces/week

Total_____ Score (svgs x 1.2)_____

	Amount eaten LAST WEEK
bread or toast	_____ slices/week
dinner or hard roll	_____ rolls/week
French/Sourdough bread	_____ slices/week
four-inch pancake	_____ pancakes/week
low-fat crackers such as soda, graham, etc (8/serving)	_____ servings/week
regular sized rice cakes (3/serving)	_____ servings/week
mini sized rice cakes (8/serving)	_____ servings/week
pretzels (1 cup or 1 large soft)	_____ cups or #/week

Total_____ Score (svgs x 0.7)_____

26. How many servings of grains and potatoes did you eat last week? Be sure to count these foods when they are in a mixed dish (casserole, burrito, etc). This includes breakfast, lunch and dinner.

	Number of servings eaten LAST WEEK
macaroni, spaghetti and other pastas	_____ cups/week
mashed potato	_____ cups/week
baked potato	_____ large potato/week
rice, corn, bulgur, barley, couscous, other grains	____ cups/week

Score_____

Score: (cups macaroni, etc x 1.5) + (cups mashed potato x 1.5) + (number baked potatoes x 2) + (cups rice, corn, etc x 2)

TOTAL SCORE (GRAINS, BEANS, FRUITS AND VEGETABLES)_____

BEVERAGES

Consider your eating habits during the last month. **For each question, circle all numbers that apply.**

27. Which of the following reflects your habits regarding alcoholic beverages? **office use only**

1 drink = *12 ounces beer*
1 1/2 ounces whiskey, gin, rum, etc
4 ounces wine
1 ounce liqueur

1 One or more drinks a day
2 Four to 6 drinks a week
3 Three drinks a week
4 One to 2 drinks a week
5 One to 3 drinks a month
6 **Do not drink alcoholic beverages**

Score_____

28. Which of the following reflects your habits regarding soda pop, sweetened seltzers, sports drinks, fruit punch, etc? ***Do not count sugar free (diet) drinks***

1 can = 12 ounces
Big Gulp = 32 ounces
1 Liter = 33 ounces
2 Liter = 67 ounces

1 More than 48 ounces a week
2 33-48 ounces a week
3 25-32 ounces a week
4 12-24 ounces a week
5 **None** or less than 12 ounces a week

Score_____

29. How much coffee do you drink? This includes espressos, lattes, mochas, etc.

Guidelines for Espresso Drinks

"Short" = 8-10 ounces
Small ("Tall") = 12 ounces
Medium ("Grande") = 16 ounces
Large ("Venti") = 20 ounces

1 More than 40 ounces (more than 5 cups) a day
3 25-40 ounces (4 to 5 cups) a day
4 6-24 ounces (1 to 3 cups) a day
5 **None** or less than (1 cup) a day

Score_____

TOTAL SCORE (BEVERAGES)_____

SALT

Consider your eating habits during the last month. **For each question, circle all numbers that apply.**

30. Which type of "salt" do you normally use? **office use only**

1 Regular salt, sea salt, flavoring salts (seasoned salt, garlic salt, onion salt, celery salt, lemon pepper, etc), regular soy sauce
3 Combination of regular and *Lite Salt*
4 *Lite Salt*, lower-sodium soy sauce, reduced-sodium flavoring salts
5 **None** or salt substitute (100% potassium chloride), Salt-free products (*Mrs. Dash*, etc)

Score_____

31. How often do you add salt to your food at the table?

1 Always
2 Frequently
4 Occasionally
5 **Never**

Score_____

32. Which type of salt and how much do you use in cooking potatoes, rice, pasta, vegetables, meat, casseroles and soups?

1 Regular salt (typical amount) or eat in restaurants 4 or more times a week
2 Regular salt (1/2 typical amount) or *Lite Salt* (typical amount)
4 *Lite Salt* (1/2 typical amount)
5 **None** or salt-free products (*Mrs. Dash*, etc), salt substitute

Score_____

33. Which type of cereals do you use?

1 Typical dry cereals (sweetened or unsweetened) or cereals cooked with regular salt (typical amount)
3 Combination of typical dry cereals and salt-free dry cereals (Shredded Wheat, Puffed Wheat, Puffed Rice) *or* cereals cooked with regular salt (1/2 typical amount) or *Lite Salt* (typical amount)
5 **Do not eat cereal** or eat salt-free dry cereals (Shredded Wheat, Puffed Wheat, Puffed Rice, etc) *or* cereals cooked without salt

Score_____

34. How often do you use typical canned, bottled, or packaged foods:

salsa	*salad dressings*	*boxed noodle entrees*
Picante sauce	soups (chicken broth)	frozen entrees
BBQ sauce	chili	canned beans
ketchup	cured meats (lunch meat)	canned vegetables

1 More than 15 times a week or eat in restaurant 4 or more times a week
2 Ten to 14 times a week
3 Six to 9 times a week
5 Five times a week or less

Score_____

TOTAL SCORE (SALT)_____

RESTAURANTS AND RECIPES

Consider your eating habits during the last month.
For each question, circle all numbers or check the choices that apply.

35. How often do you eat breakfast at a restaurant or cafeteria (this includes coffee shops)? **office use only**

1 More than twice a week
2 Once or twice a week
3 Once a week if you eat low-fat (unbuttered toast or English muffin, oatmeal)
5 Less than once a month
6 **Never**

Score_____

36. How often do you eat lunch at a restaurant or cafeteria or eat "take out"?

1 Daily
2 Five days a week
3 Two to 4 days a week
4 One day a week
5 Less than once a month
6 **Never**

Score_____

37. How often do you eat dinner at a restaurant or cafeteria or eat "take out"?

1 More than 3 times a week
2 Two to 3 times a week
3 Once a week
4 Once or twice a month
5 Less than once a month
6 **Never**

Score_____

38. Check the choices you make when eating in restaurants or cafeterias.

___Select restaurants that offer low-fat choices and order those choices
___Order toast, muffins, cereal, pancakes, waffles for breakfast
___Order soup (not cream), salad or other meatless, cheeseless entrees for lunch
___Order vegetarian pizzas with half the cheese
___Avoid cheese, eggs, bacon on salads and avoid potato and macaroni salads
___Put garbanzo or kidney beans on salad at the salad bar
___Use a very small amount of salad dressing
___Order a fish, shellfish, chicken or lean red meat entree (but not fried)
___Use no more than 1 pat of margarine at any meal
___Order fruit, sorbet, sherbet, frozen yogurt or skip dessert

SCORE: (0-1 checks = 1; 2-3 checks = 2; 4-5 checks = 3; 6-7 checks = 4; 8-10 checks; or eat out less than once a month = 5) Score__
__

39. How often do you eat foods made using low-fat recipes or cook low-fat without recipes?

1 Once a month or less
2 One to 2 times a week
3 Three to 4 times a week
4 Five to 6 times a week
5 Everyday

Score_____

TOTAL SCORE (RESTAURANTS AND RECIPES)_____

SECTION G: USING MEDICAL CARE

Instructions: Please answer the questions below by entering in the number of times in the past 9 months that you have seen:

A) Your family doctor …… ☐ Times.

B) A Heart Specialist …… ☐ Times.

C) Gone to the Emergency Department for your symptoms related to your heart ……. ☐

D) Been admitted to the hospital for symptoms related to your heart? ☐ Times.

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).

   _____ %

SECTION I: FOLLOW-UP WITH YOUR FAMILY DOCTOR

1. Have you had an appointment with your family doctor or nurse practitioner since graduating from cardiac rehab?
   - ☐ Yes
   - ☐ No
   - ☐ I have an upcoming appointment booked
   - ☐ I do not have a family doctor or nurse practitioner
   - ☐ I did not attend cardiac rehab

2. At your last appointment with your family doctor or nurse practitioner, did your healthcare provider have any mail or letters from the cardiac rehab program?
   - ☐ Yes
   - ☐ No
   - ☐ I don't know
   - ☐ Not applicable, because I didn't go to cardiac rehab

3. Did your healthcare provider discuss with you your experiences and health changes from the cardiac rehab program?
   - ☐ Yes
   - ☐ No
   - ☐ Not applicable, because I didn't go to cardiac rehab

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

SECTION K: MOOD

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

SECTION L: PERSONALITY

Instructions: Below are a number of statements that people often use to describe themselves. Please read each statement and then circle the appropriate number next to that statement to indicate your answer. There are no right or wrong answers. Your own impression is the only thing that matters.

	False	**Rather False**	**Neutral**	**Rather True**	**True**
1. I make contact easily when I meet new people	0	1	2	3	4
2. I often make a fuss about unimportant things	0	1	2	3	4
3. I often talk to strangers	0	1	2	3	4
4. I often feel unhappy	0	1	2	3	4
5. I am often irritated	0	1	2	3	4
6. I often feel inhibited in social interactions	0	1	2	3	4
7. I take a gloomy view of things	0	1	2	3	4
8. I find it hard to start a conversation	0	1	2	3	4
9. I am often in a bad mood	0	1	2	3	4
10. I am a closed kind of person	0	1	2	3	4
11. I would rather keep other people at a distance	0	1	2	3	4
12. I often find myself worrying about something	0	1	2	3	4
13. I am often down in the dumps	0	1	2	3	4
14. When socializing, I don't find the right things to talk about	0	1	2	3	4

SECTION M: SOCIAL SUPPORT

Instructions: Please read the following questions and circle the number that most closely describes your current situation.

HOW OFTEN WOULD THERE BE….	All or Most of the Time	Some of the Time	None of the Time
1. Someone to encourage you to follow a healthy diet?	2	1	0
2. Someone available to help you to prepare healthy meals?	2	1	0
3. Someone to encourage you to take your medications?	2	1	0
4. Someone available to help you get access to your medications (getting your prescriptions filled)?	2	1	0
5. Someone available to actually take you to go with you to the hospital/doctor when you are sick?	2	1	0
6. Someone to encourage you to exercise?	2	1	0
7. Someone who could participate in exercise with you?	2	1	0
8. Someone to encourage you to quit smoking?	2	1	0
9. Someone who could discuss your condition or health concerns with your doctor?	2	1	0
10. Someone who you can talk to about important things in your life?	2	1	0
11. Someone who could visit you or check up on you while you are in the hospital or at home?	2	1	0
12. Someone who makes you laugh?	2	1	0
13. Someone you can go out with just for fun (go to the movies)?	2	1	0
14. Someone who could make sure you get enough rest and relaxation?	2	1	0
15. Someone to encourage you, tell you "things will be okay," or reassure you?	2	1	0
16. Someone (other than your doctor) you could turn to for general advice regarding your health (eating, dieting, exercise, medications)?	2	1	0

SECTION N: YOUR THOUGHTS

Instructions:

People think and do many different things when they feel sad, blue, or depressed. Read each of the following items. Using a four-point scale, please indicate whether you never, sometimes, often, or always think or do each one when you feel sad, down, or depressed. Please indicate what you generally do, not what you think you should do.

	Never	Sometimes	Often	Always
1. I think about how alone I feel	1	2	3	4
2. I think about my feelings of fatigue and achiness	1	2	3	4
3. I think about how hard it is to concentrate	1	2	3	4
4. I think about how passive and unmotivated I feel	1	2	3	4
5. I think "Why can't I get going?"	1	2	3	4
6. I think about a recent situation, wishing it had gone better	1	2	3	4
7. I think about how sad I feel	1	2	3	4
8. I think about all my shortcomings, failings, faults, and mistakes	1	2	3	4
9. I think about how I don't feel up to doing anything	1	2	3	4
10. I think "Why can't I handle things better?"	1	2	3	4

SECTION O: YOUR IRRITABILITY

Instructions: Please mark "**x**" in the box beside each item that best describes how you have been feeling in the past week:

	Not at All	A little or some of the time	Often	Most or all of the time
1. I have been feeling mad	☐	☐	☐	☐
2. I have been feeling ready to explode	☐	☐	☐	☐
3. I have yelled at others	☐	☐	☐	☐
4. I have been irritable when someone touched me	☐	☐	☐	☐
5. I have been easily flying off the handle	☐	☐	☐	☐
6. It feels like there has been a cloud of anger over me	☐	☐	☐	☐
7. I have been rather sensitive	☐	☐	☐	☐
8. I have been quick to criticize others	☐	☐	☐	☐
9. Noises have seemed louder	☐	☐	☐	☐
10. I have been getting annoyed with myself	☐	☐	☐	☐
11. I have been so angry that I lost control	☐	☐	☐	☐
12. There has been a flood of tension through my body	☐	☐	☐	☐
13. I said nasty things to others that I did not mean	☐	☐	☐	☐
14. It took very little for things to bother me	☐	☐	☐	☐

SECTION P: SLEEPING DIFFICULTIES

These questions ask about your sleep habits. Please mark **one** of the answers for each of the following questions. Pick the answer that best describes how often you experienced the situation in the **past 4 weeks**.

1. Did you have trouble falling asleep?				
□ No, not in the past 4 weeks	□ Yes, less than once a week	□ Yes, 1 or 2 times a week	□ Yes, 3 or 4 times a week	□ Yes, 5 or more times a week

2. Did you wake up several times at night?				
□ No, not in the past 4 weeks	□ Yes, less than once a week	□ Yes, 1 or 2 times a week	□ Yes, 3 or 4 times a week	□ Yes, 5 or more times a week

3. Did you wake up earlier than you planned to?				
□ No, not in the past 4 weeks	□ Yes, less than once a week	□ Yes, 1 or 2 times a week	□ Yes, 3 or 4 times a week	□ Yes, 5 or more times a week

4. Did you have trouble getting back to sleep after you woke up too early?				
□ No, not in the past 4 weeks	□ Yes, less than once a week	□ Yes, 1 or 2 times a week	□ Yes, 3 or 4 times a week	□ Yes, 5 or more times a week

5. Overall, was your typical night's sleep during the past 4 weeks?				
□ Very sound or restful	□ Sound or restful	□ Average quality	□ Restless	□ Very Restless

SECTION Q: QUALITY OF LIFE

Please check the box (☑) on one sentence for each of the following groups that reflect the state of your **general health IN THE PAST 4 WEEKS**.

A. Mobility
☐ No problems walking about
☐ Some problems walking about
☐ Confined to bed

B. Self-Care
☐ No problems with washing or dressing
☐ Some problems with washing or dressing
☐ Unable to wash or dress myself

C. Usual Activities (e.g. work, study, housework, leisure)
☐ No problem with performing usual activities
☐ Some problems with performing usual activities
☐ Unable to perform usual activities

D. Pain and Discomfort
☐ No pain or discomfort
☐ Moderate pain or discomfort
☐ Extreme pain or discomfort

E. Anxiety and Depression
☐ Not anxious or depressed
☐ Moderately anxious or depressed
☐ Extremely anxious or depressed

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

SECTION S: CARDIAC REHAB PROGRAM TYPE

1. Please indicate your degree of satisfaction with the CR program you were referred to (check one):

- ❑ Very unsatisfied
- ❑ Unsatisfied
- ❑ Neither satisfied nor unsatisfied
- ❑ Satisfied
- ❑ Very satisfied
- ❑ I did not enroll in the program

2b. Please tell us why you were satisfied or why you were unsatisfied with your CR program:

_____

_____

_____

3. If you were given a choice, which CR program type would you **prefer** to attend?

- ❑ Women-only hospital-based
- ❑ Men and women hospital-based
- ❑ Home-based

3b) Please tell us why you would prefer this particular type of CR program:

_____

_____

4.

Please rate how much you agree or disagree with each statement, regardless of what cardiac rehab program you attended.	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
a. I felt comfortable in my workout clothes when exercising.	☐	☐	☐	☐	☐
b. I was satisfied with the amount of discussion in cardiac rehab about psychosocial issues.	☐	☐	☐	☐	☐
c. I was satisfied with the amount of discussion of women's health issues such as menopause and bone health / osteoporosis.	☐	☐	☐	☐	☐
d. The environment I exercised in felt too competitive.	☐	☐	☐	☐	☐
e. I was satisfied with the nature of the education I received in the program.	☐	☐	☐	☐	☐
f. I was satisfied with the direction I received about resuming my household, caregiving and other life roles.	☐	☐	☐	☐	☐
g. I felt that the behaviour change counseling I received suited my situation as a woman.	☐	☐	☐	☐	☐

SECTION T: DEMOGRAPHICS and HEART RISK STATUS

1. What is today's date?

Day	Month	Year

2. Have you experienced any of the following heart problems or procedures **in the last 9 months** since you were recruited for this study from the hospital? Please ✓ all that apply:
   - ❑ Heart Attack
   - ❑ Angina
   - ❑ Angioplasty (stent)
   - ❑ Bypass Surgery
   - ❑ Valve Surgery
   - ❑ Heart Failure
   - ❑ Heart transplant
   - ❑ Cardiac device: pacemaker or implantable cardioverter defibrillator
   - ❑ Stroke
   - ❑ Peripheral Vascular Disease
   - ❑ None of the above

3a) What is your height? _____ feet and _____ inches **or** (_____ cm)

3b) What is your weight? _____ pounds **or** (_____ kgs)

4. Please describe your current smoking status:
   - ❑ I have never smoked
   - ❑ I currently smoke
     - How many cigarettes do you smoke per day, on average? _____ cigarettes per day
     - For how many years have you smoked? _____ years
   - ❑ I quit smoking
     - When did you quit smoking? month _____ year _____
     - How many cigarettes did you smoke per day, on average? _____ cigarettes per day
     - For how many years did you smoke? _____ years

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

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

7. Do you know your blood pressure numbers from the last time it was assessed?
   - ☐ Yes
   - ☐ No

8. Is your blood pressure under control at present? (i.e., it is below cut-off values, possibly from medications to lower your blood pressure)
   - ☐ Yes
   - ☐ No

9. Do you know your cholesterol numbers from the last time it was assessed?
   - ☐ Yes
   - ☐ No

10. Is your cholesterol under control at present? (i.e., it is below cut-off values, possibly from medications to lower it)
   - ☐ Yes
   - ☐ No

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 _____

Thank you for taking the time to complete this survey. Your assistance in providing this information is very much appreciated. If there is anything else you would like to tell us about this survey, or about your experiences with cardiac disease and/or recovery, please do so in the space provided below.

Please return your completed questionnaire in the stamped and addressed envelope provided to the study coordinator by mail:

CR4HER Study Coordinator
EN7-235
Toronto General Hospital
200 Elizabeth Street
Toronto, ON
M5G 2C4

Appendix I: Survey Replacement Cover Letter

«Date_of_9Month_Survey_Replacement»

«Salutation» «First_Name» «Last_Name»
«Street_Address»
«City» «Province» «Postal_Code»

RE: *Cardiac Rehab for Her* Study (CR4HER)

Dear «Salutation» «Last_Name»:

About four weeks ago I sent a questionnaire to you that asked about any participation in cardiac rehabilitation after hospitalization for your heart problem. To the best of our knowledge, it's not yet been returned.

The comments of people who have already responded include a wide variety of answers regarding their experiences in cardiac rehab along with potential barriers that may have hindered their adherence to this program. We think the results are going to be very useful to improve secondary prevention programs for female cardiac patients.

We are writing again because of the importance that your questionnaire has for helping to get accurate results. It's only by hearing from nearly everyone in the sample that we can be sure that the results are truly representative.

A comment on our survey procedures: a questionnaire identification number is printed on the pages of the questionnaire so that we can check your name off of the mailing list when it is returned. The list of names is then destroyed so that individual names can never be connected to the results in any way. Protecting the confidentiality of people's answers is very important to us.

We hope that you will fill out and return the questionnaire soon, but if for any reason you prefer not to answer it, please let us know by returning a note or blank questionnaire in the enclosed stamped envelope.

If you have any questions about this funded study, please feel free to contact the study coordinator at 416-340-4800 ext. 6593#.

Sincerely,

D. Grace

Dr. Sherry L. Grace
University Health Network, Toronto General Hospital and York University

University Health Network

CR4HER V3. Feb 29, 2012
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Appendix J: Telephone Interview

CR4HER Telephone Contact Script
for Participants Who Switched Program Models Post-Allocation

Participant ID#: _____

Date (dd/mmm/yyyy): _____

Personnel who Performed Call (please print): _____

Research Assistant (RA): "Hello my name is _____. I work at the [University Health Network / Hamilton Health Sciences]. During the last 6 months you have been taking part in our 'cardiac rehab for her' research study. Thank you for returning your final survey. I was wondering if you had approximately 5 minutes to answer some quick questions about your program choices?

If no, find another convenient time to call back: _____.
If they are not willing, thank them for their time and hang up.

If yes: We see from your survey responses that you participated in a cardiac rehab program model that was different than the one you were originally allocated to about six months ago. Specifically, we thought we had referred you to the [co-ed supervised / home-based / women only] program, yet I believe you participated in the [co-ed supervised / home-based / women only] program.

We are happy that you went to cardiac rehab, but we are calling to check if we got this right, and if you would be willing to tell us why you switched. Anything you say will be kept confidential."

Obtain verbal consent. Go through questions. Record responses by circling

RA:

1. Can you describe to me the main reasons that you switched program models?

_____
_____

For patients who switched to home-based:

1. Did you have any transportation or distance issues getting to the _____ program you were randomized to?

   Yes No

2. Did you have time constraints such as work or caregiving that hindered your participation in set CR classes?

   Yes No

For participants who switched to women-only or co-ed on-site models:

3. Did you feel motivated to exercise in the _____program you were randomized to?

   Yes No

4. IF APPLICABLE: Did you want to be supervised during your exercise sessions for safety reasons?

   Yes No

5. IF APPLICABLE: Did you want an on-site program for peer support?

   Yes No

6. IF APPLICABLE: Did you want an on-site program for the social interaction?

   Yes No

7. IF APPLICABLE: Did you want an on-site program for the facilities available?

   Yes No

8. IF APPLICABLE: Did you want an on-site program because you thought you would derive more health benefit than you would from a home-based program?

   Yes No

9. IF APPLICABLE: Were the class times of the _____ program you were originally randomized to convenient?

   Yes No

RA: Thank you!

Hang up.

Appendix K: Voicemail Script

CR4HER
Voice message script
for Participants Who Switched Program Models Post-Allocation

Hello Ms. _____. My name is _____, and I work at the University Health Network. You participated in our 'cardiac rehab for her' research study, and we wanted to thank you for returning your final survey. I was calling to ask you some quick questions about your program choices.
Please call me back at _____ - it should take no longer than 5 minutes.
Thank you.

Appendix L: Table 6 – Cardiac Rehabilitation Barriers Overall and by Program Model Attended

	Model Attended				
Item (Mean ± SD)	**Women-Only** n=100 (38.9%)	**Mixed-Sex** n=101 (39.3%)	**Home-Based** n=30 (11.7%)	**Did not Enroll** n=26 (10.1%)	**Total** N=257
Other health problems	2.20±1.54	2.32±1.39	2.21±1.25	2.56±1.24	2.29±1.42
Travel	2.48±1.54	2.19±1.33	2.13±1.06	2.00±0.94	2.28±1.36
Tiring/Painful exercise	2.00±1.31	2.19±1.25	1.93±0.83	2.18±1.17	2.09±1.23
Severe weather	1.87±1.18	2.21±1.34	2.21±1.19	1.90±1.10	2.06±1.25
Exercise at home	1.71±1.05††	2.15±1.31	2.71±1.38††	2.00±1.05	2.02±1.23*
Don't have energy	1.73±0.99	2.22±1.31	2.07±1.00	2.40±1.07	2.02±1.16
Family responsibilities	1.96±1.26	1.94±1.24	2.00±1.13	1.90±0.88	1.95±1.20
Transportation Problems	1.65±1.02	2.13±1.38	1.78±0.80	2.60±1.35	1.94±1.22
Time constraints	1.84±1.19	1.97±1.21	2.21±1.05	2.30±1.25	1.96±1.18
Work responsibilities	1.68±1.10	2.02±1.30	1.93±0.73	2.40±1.50	1.90±1.20
Cost	1.49±0.84†† ≠≠	2.06±1.35††	1.93±1.14	2.60±1.50≠≠	1.87±1.20*
Distance	1.51±0.81†††	1.91±1.23††	2.07±1.38†	3.00±1.41† †† †††	1.86±1.18***
Took too long to get referred	1.64±1.06	1.75±1.04	1.93±1.07	2.00±1.12	1.74±1.05
Prefer to take care of my health alone	1.38±0.63††† ≠	1.55±0.86†	2.21±1.12† †††	2.00±1.12≠	1.58±0.86**
Don't know about CR	1.49±1.02	1.53±0.92	2.13±1.19	1.60±0.84	1.58±0.99
Doctor didn't encourage me to attend	1.44±0.79	1.53±0.80	1.71±0.73	1.67±0.87	1.52±0.79
Many people with heart problems don't go	1.42±0.68	1.56±0.78	1.64±0.63	1.67±0.87	1.52±0.73
Referred but never contacted	1.34±0.55	1.63±0.94	1.57±0.51	1.67±0.71	1.51±0.76
Confident in managing my own health	1.38±0.62	1.55±0.80	1.64±0.63	1.78±0.97	1.51±0.73
Don't need CR	1.38±0.65	1.51±0.94	1.57±0.76	1.90±0.88	1.49±0.82
I am too old	1.35±0.65	1.53±0.78	1.64±0.63	1.56±0.73	1.47±0.72
Total	1.70±0.64†	2.00±0.94	2.26±1.06†	2.21±0.88	1.93±0.87*

*p<0.05, **p<0.01, ***p=0.001 for ANOVA. † p<0.05, †† and ≠≠ p<0.01, ††† p<0.001

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