WOMEN'S CARDIAC REHABILITATION PROGRAM ADHERENCE AND HEALTH BEHAVIOURS FOLLOWING REFERRAL TO THREE DIFFERENT PROGRAM MODELS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Cardiac rehabilitation (CR) participation is associated with significantly lower mortality and improved psychosocial well-being. However, women are less likely to participate than men. CR4HER was a single-blind, 3 parallel-arm, pragmatic, randomized controlled trial comparing CR program adherence, functional capacity, and health behaviors between women referred to mixed-sex, women-only, or home-based CR. The study occured between November 2009-July 2013. Low-risk patients with coronary artery disease were recruited from six sites in Ontario. Consenting participants completed a pre-program survey assessing health behaviors (physical activity, diet, medication adherence, and smoking), wore pedometers for 7 days, and clinical data were extracted from charts. Participants were referred to CR at one of 3 sites. After intake assessment, including a graded exercise stress test, eligible patients were randomized to supervised mixed-sex, supervised women-only, or home-based CR. Six months later, CR adherence and exit assessment data were ascertained, and participants were mailed follow-up surveys and pedometers.

Among 264 consenting patients, 169 (64.0%) were eligible and randomized. Twenty-seven (16.0%) did not attend CR and 43 (25.4%) attended a different model than that to which they were randomized, with most women switching to a model other than home-based CR. Program adherence was moderate overall (54.46±35.14%). Analysis of variance revealed no significant differences based on per protocol analysis (PP; $p=.63$), but as-treated, home-based participants attended significantly more than women-only ($p<.05$).

Overall, there was a significant increase in functional capacity pre to post-program ($p<.001$). While there were no significant differences in functional capacity by model at CR exit based on PP, there was a significant difference on an as-treated basis, which sustained

adjustment. Women attending mixed-sex CR attained significantly higher post-CR functional capacity than women attending home-based programs ($p<.05$).

Self-reported physical activity increased among women randomized to, and who attended, mixed-sex and women-only CR ($ps<.05$). Diet improved among women attending women-only CR ($p<.05$). However, analyses adjusted for confounding variables revealed no significant differences in any outcome by model.

Offering women alternative program models may not promote greater CR adherence, functional capacity, or behavioral outcomes. Nevertheless, replication is warranted. Other proven strategies such as action planning and self-monitoring should be applied.

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LIST OF ABBREVIATIONS

Acute coronary syndrome (ACS)

Analysis of covariance (ANCOVA)

Analysis of variance (ANOVA)

Canadian Cardiovascular Society (CCS)

Cardiac rehabilitation (CR)

Cardiac Rehabilitation for her Heart Event Recovery (CR4HER)

CardioPulmonary Exercise Test (CPET)

Cardiovascular disease (CVD)

Case report form (CRF)

College of Physicians and Surgeons of Ontario (CPSO)

Coronary artery bypass graft (CABG)

Coronary artery disease (CAD)

Godin Leisure-Time Exercise Questionnaire (GLTEQ)

Hamilton Health Sciences (HHS)

Informed consent form (ICF)

Least significant difference (LSD)

Left ventricular ejection fraction (LVEF)

Metabolic equivalents (METs)

Morisky Medication Adherence Scale (MMAS-4)

Myocardial infarction (MI)

Mount Sinai Hospital (MSH)

New York Heart Association (NYHA)

Peak volume oxygen consumption per minute (VO_2 peak)

Percutaneous coronary intervention (PCI)

Per protocol (PP)

Randomized controlled trial (RCT)

Sunnybrook Health Sciences Centre (SHSC)

Toronto General Hospital (TGH)

Toronto Rehabilitation Institute (TRI)

Toronto Western Hospital (TWH)

University Health Network (UHN)

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality for women world-wide, representing over 30% of global deaths [1]. Cardiac rehabilitation (CR) is an outpatient secondary prevention program composed of structured exercise and comprehensive education and counseling. CR participation results in lower morbidity and mortality, among other benefits. Unfortunately, women are significantly less likely to adhere to these programs than men [2]. While the traditional model of CR care is a hospital-based mixed-sex program, women are the minority in such programs, and state that these programs do not meet their care preferences. Two other models of CR care have been developed: hospital-based women-only (sex-specific) and monitored home-based programs. Women's adherence to these program models is not well known.

Cardiac Rehabilitation for her Heart Event Recovery (CR4HER) was a 3 parallel arm pragmatic randomized controlled trial (RCT) designed to compare women's program adherence to traditional hospital-based CR with males and females attending (mixed-sex), home-based CR, and women-only hospital-based CR.

Power calculations based on a pilot study suggested a sample size of 261 patients was needed to detect a difference in adherence by program model. Participants were female acute coronary syndrome, percutaneous coronary intervention or bypass surgery patients recruited from six inpatient and outpatient cardiac settings in Ontario, Canada. The primary outcome variable was program adherence operationalized as CR site-reported percentage of prescribed sessions completed by phone or on-site, as reported by a staff member who was blind to study objectives. The secondary outcomes included functional capacity, and health behaviours such as exercise, dietary habits, smoking and medication adherence. It was hoped that by identifying the

CR program model which resulted in the greatest adherence for women, their participation and potentially their cardiac outcomes could be optimized.

REVIEW OF THE LITERATURE

Burden of Cardiovascular Disease in Women

CVD is the leading cause of hospitalization in Canada[3], as well as one of the leading causes of death among Canadian men and women (accounting for 19.7% of all deaths in 2011[4]). It is also the leading cause of morbidity and mortality for women in Canada[5]. There is a plethora of mixed evidence with regard to sex (e.g., biology, physiology) and gender (e.g., psychosocial roles) differences in CV morbidity and early mortality in the literature[6–10]. These can often be explained by differences in defining of clinical endpoints, and particularly by the choice of prognostic factors which are statistically controlled in analyses. However, it is well established that women with CVD have a unique and hazardous constellation of risk factors (notably older age, and higher prevalence of co-morbidities such as hypertension and diabetes[11,12]), and may fare worse than men[13–15]. For instance, women who suffer an acute coronary event are more likely than men to incur morbidity and mortality during the first year of recovery[16], have lower physical function, are less physically active, and are at greater risk in the context of smoking and diabetes[17]. Since CVD affects women on average 10 years later than it does men[18], the medical problems experienced by women with CVD are compounded by those experienced simply due to ageing[19].

Women and Treatment of Cardiovascular Disease

Sex and gender have been associated with health inequity, and additionally have been shown to impact access to health care services and quality of care[20–22]. In particular, there may be sex or gender disparities in treatment after a cardiac diagnosis or event with regard to delays in diagnosis and treatment[11,13,23–26], receipt of information from health professionals[27], prescription of evidence-based medications[13], and less aggressive use of diagnostic testing, revascularization

and other interventional procedures[24,28–30]. Furthermore, fewer women with heart disease get access to secondary prevention services[6,31–33].

Physician-supervised CR programs were originally developed when the benefits of walking during prolonged hospital stays following cardiac events were observed[34]. In its present-day form, CR is an outpatient secondary prevention program composed of structured exercise training and comprehensive education and counseling addressing cardiac risk factors[35]. It is a multi-disciplinary approach, and has been defined by the Canadian Association of Cardiac Rehabilitation as "the enhancement and maintenance of cardiovascular health through individualized programs designed to optimize physical, psychosocial, social, vocational, and emotional status"[3]. Indeed, CR has been shown to reduce mortality by 25%[36], to reduce the need for re-hospitalization and the use of invasive revascularization procedures[37,38], and improved survival, functional status, and psychosocial well-being[36]. Participation in CR programs is associated with beneficial effects on cardiac risk factors such as systolic blood pressure and total cholesterol[36], while the average gains in aerobic capacity post-CR are 11-36%[39]. These benefits are all achieved in a cost-effective and economically justified manner[40,41]. CR participation also results in significant health behaviour changes such as increased exercise[42], improved diet, and lower self-reported smoking (OR=.64[36]). However, reductions in weight are generally not achieved[43]. Unfortunately, these studies do not always consider patient characteristics such as age, ethnicity, or sex and gender. However, given this abundance of empirical evidence, Class I, Level A clinical practice guideline recommendations[3,44] promote CR access for all patients.

Cardiac Rehabilitation Use

In spite of its many benefits, CR services are grossly under-used[45], with only approximately 15–30% of eligible patients in the United States and Canada participating in CR[46].

Low adherence to prescribed medical regimens is a multifaceted yet common problem, in particular among patients with chronic conditions. In relation to health care, adherence describes the extent to which patients' actual usage corresponds to prescribed interventions[47]. However, there is currently no "gold standard" for the measurement of adherence and many authors do not clearly define or even measure adherence in their studies[48]. There are several different types of adherence, and these include: seeking care (in a timely manner), participating in health programs (screening or secondary prevention), attending follow-up appointments, and following doctors' advice regarding treatment[49]. For the purposes of this study, adherence was defined as the percentage of CR sessions received (the number of CR sessions attended divided by the number of CR sessions prescribed). It should be noted that overall CR participation rates as described above do not offer a suitable representation of underserved groups within the cardiac population. The rates of CR utilization among patients of low socioeconomic status are low[50], with lower patient income predicting lower rates of CR participation [45]. Similarly, significantly lower CR participation rates have been reported among ethnic minorities as compared to whites[45,51].

Women and Cardiac Rehabilitation

Clinical practice guidelines[3,52,53], and those specifically developed for women with CVD[54] recommend that all women should participate in CR following acute coronary syndrome (ACS) or revascularization intervention (e.g., coronary artery bypass graft [CABG] or percutaneous coronary intervention [PCI]). Yet the rate of women who participate in CR is much lower than men, at approximately 11–20% [32,40,55–57]. The percentage of women in CR is lower relative to what should be expected relative to their representation in the CVD patient population[58]. As such a treatment-risk paradox is observed, such that while women are in greater need of CR programs and their associated benefits, they are significantly less likely to access

it[56,59,60]. Although this sex bias has been recognized for over a decade, there has been little improvement in women's CR participation during this time[61]. This is especially disconcerting because there exists a dose-response relationship between degree of participation and mortality[62]. While there is a dearth of literature reporting on CR program adherence, fourteen studies (reporting on data collected between 1980 and 2014, N=8176 of which 27.3% were women) were recently identified and compared (Oosenbrug E, unpublished data, November 2015). Overall CR program adherence was found to range from 36.7 to 87.0% of CR sessions, with a mean CR program adherence of 66.40±29.91% of prescribed CR sessions. CR adherence rates for men ranged from 38.61% to 89.00% (with a mean of 68.59±29.16%), whereas rates for women ranged from 34.72% to 85.00% (with a mean of 64.19±30.66%). It should be noted that while most of the 14 studies relied on patient-report alone in order to ascertain CR adherence and women accounted for less than a third of study participants, Oosenbrug's meta-analysis did find that CR program adherence was significantly greater in men compared to women.

Andersen's Behavioral Model of Healthcare Utilization

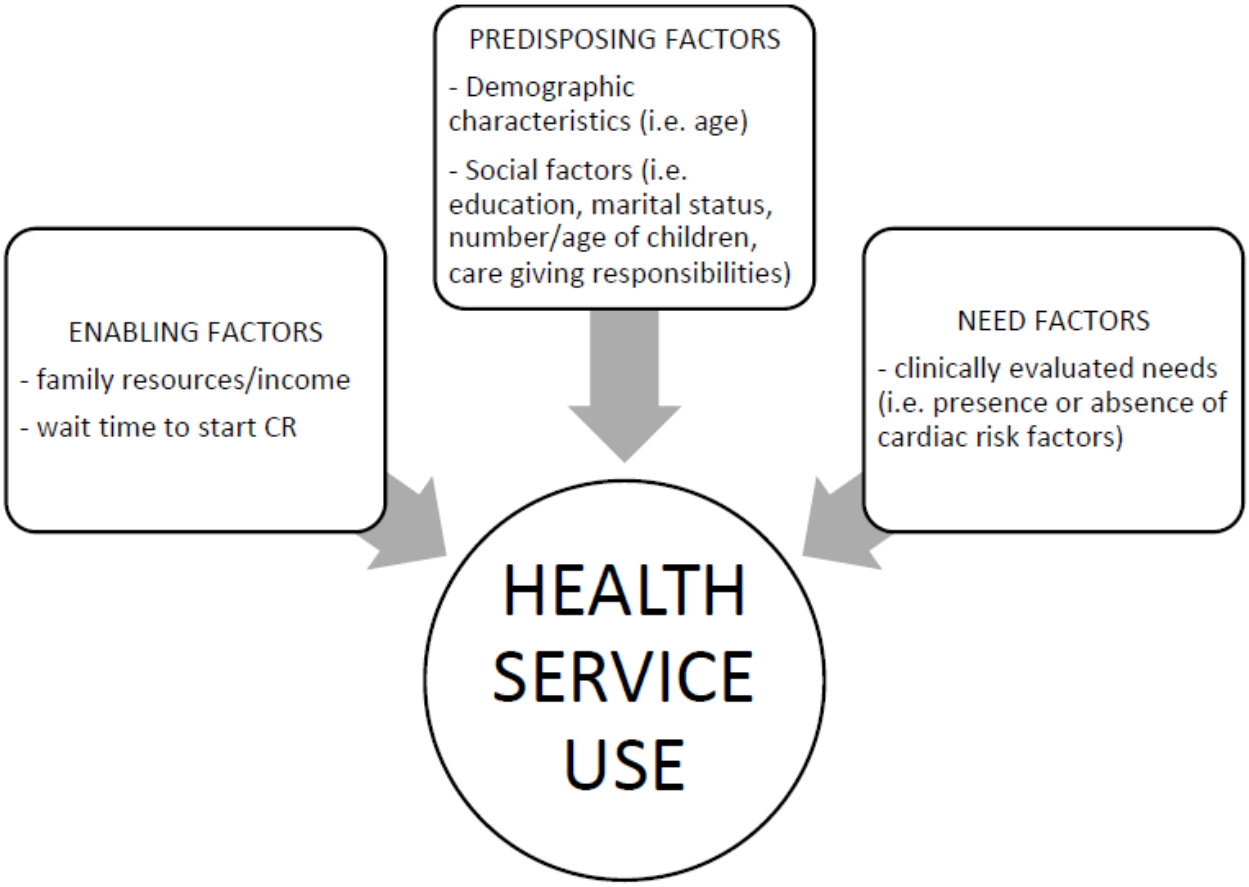
The reasons why women are missing from CR programs are multi-factorial, and include health system-level (including provider-related factors) and patient-level factors[56] that can be informed by Andersen's Behavioral Model of Healthcare Utilization[63]. Andersen's model is an explanatory framework identifying predictors of health care utilization that can be applied to a broad range of health services sectors and diseases. The goal of the model is to identify conditions that either facilitate or impede healthcare utilization, so as to develop measures of medical care access and explain patients' differing levels of use. The multilevel model (see Figure 1) states that there are three predictors of health care utilization; predisposing factors that

exist prior to illness, enabling factors that are the logistical aspects of obtaining care, and need factors that are the most direct cause of health service use[64].

With regard to health system / provider factors, while physician referral practices could be optimized for both men and women, it has been suggested that physicians may be less likely to refer female patients[46,59,65–67]. Indeed men are referred almost twice as often as women[51], and physicians may recommend participation more strongly among men than women[68].

With regard to patient factors, these are conceived as predisposing, enabling and need factors as outlined above in Andersen's model. Predisposing factors exist prior to the onset of illness and describe the inclination of individuals to use health services, enabling factors are the barriers and facilitators to the use of health services, while need factors are the objective and subjective aspects of the decision to use health services. Studies investigating moderators and barriers to CR participation have revealed the following patient-level barriers specific to females: older age (on average 10 years older than men[56]), poor spousal support and / or unmarried status, and competing work and care-giving responsibilities, which are also related to social norms (predisposing factors); travel-related barriers, costs, lower socioeconomic status, and concomitant illness[56,59,69–73] (enabling factors); and greater disease severity[55,74,75] (need factor).

Figure 1. Behavioral Model of Health Service Use



Ronald M. Andersen's Behavioral Model of Health Services Use[63] states that there are three predictors of health care utilization; predisposing factors, enabling factors, and need factors. The CR4HER baseline survey assessed predictors from each category.

Gender and Cardiac Rehabilitation

Male or female sex is related to biological features, including physical and physiological traits. Gender, on the other hand, can be defined as "the socially constructed roles, behaviours, expressions and identities"[76] of men and women. It is an important determinant of health, since its relationship to differing and often unequal income, education, and social and physical environments, influences how women and men access health services. The literature also suggests that social reality is in part derived from social beliefs[77]; how one is expected to act

influences how one does in fact act. Female gender itself, while expressed at the individual level but structured by social relations, is thus a patient-level factor predisposing lack of CR utilization, as social expectations of women can hinder their desired participation in healthy behaviours. Indeed prior research has shown that women feel health behaviors, such as exercise, are activities to be set aside until they are done caring for their family and spouses[78]. Many women may therefore be constrained by their roles as mothers and wives — preventing them from taking on their roles as recovering cardiac patients.

Where women do participate in CR, they generally obtain the same benefits as men[19]. Studies of 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[79,80 59,67], although sex differences are found for quality of life in some studies[81]. However, sex-specific data are lacking with regard to mortality and morbidity in particular[59]. Where compared, women accrue the same benefits as men, thus the consensus in the literature is that women do indeed benefit from CR[59,80]. There is no evidence to suggest that women are less likely to benefit than men; indeed women often present with lower physical fitness, and as such have greater potential to benefit from CR since the greatest improvements are normally seen in patients with the lowest fitness at the start of the program[39]. Although the studies examining women's outcomes post-CR are limited, they have been positive[42,59,82]. However, this literature suffers from low sample sizes, and lack of randomization and control groups. There are even fewer studies assessing women's behavioral outcomes following CR participation[83,84]. While studies of the effectiveness of CR have generally revealed no major differences between men and women, female-specific data are lacking on the effect of CR on mortality and morbidity[85]. In spite of national policy initiatives recommending that sex and gender-based analyses be included in the design of health research[86],

these are rarely incorporated into studies[36,41]. Instead most studies on the treatment of CVD focus and report only on outcomes involving men, and where women are included most studies fail to conduct gender-based analyses[33,87]. This also holds true for CR trials. For example, in a Cochrane review of CR, only 11% of patients enrolled in comprehensive CR studies were women[41].

Once women do enroll in CR, they are less likely to adhere to these programs than men and most studies report higher dropout rates for women than men[46,88]. In a study of 157 female CABG patients, 8% did not attend CR at all following referral, and 22% attended irregularly, citing health, time constraints and inconvenience to explain their non-adherence[89]. Given that full participation is needed for patients to achieve the benefits of CR, research is needed to improve adherence among women. Indeed, where women complete CR, they experience relative benefits even greater than those of men [2].

The low rates of enrollment and adherence in CR programs among women raise the question of whether CR programs are equally appealing to both men and women[90]. CR was originally developed in the 1970s with special regard to the needs of Caucasian middle-aged men to promote return to work post-myocardial infarction (MI)[91]. Women generally have substantial differences from men at the time of a cardiac event or procedure[92]. For instance, they are often 10 years older, more likely to be widowed and living alone, and of lower socioeconomic status than men[92]. They often have greater household and care-giving responsibilities[55,72,73], yet report fewer social support networks[71]. They are more likely to suffer from co-morbid conditions such as arthritis and osteoporosis[59,72,73] (all conditions which may impact on motivation to exercise due to pain, fatigue, and even fear[93]). They have lower functional capacity[59,79], and a greater burden of modifiable risk factors[79]. These differences suggest that women may have dissimilar

needs and preferences for CR programs than men[85]. Indeed, as outlined herein, examination of women's CR preferences reveal they are not always met by traditional CR, which could be one of the main causes of low CR adherence.

While the traditional model of CR care is a hospital-based mixed-sex program, women are the minority participants in such programs. Women report perceiving these programs as male-oriented and failing to meet their care preferences[94]. For example, women report sometimes being the only woman in a group of men, most of whom are younger than themselves. This makes them self-conscious and hinders their involvement[95]. Indeed, women have reported preferring a women-only CR program due to an increased sense of comfort in a women-only environment [96]. In a qualitative study by Moore, female hospital-based CR participants reported their likes and dislikes of the traditional program model. While their 'likes' included being monitored during exercise, receiving nutrition information, and being part of a group, their 'dislikes' included the lack of exercise alternatives to the treadmill and cycle ergometry, lack of emotional support from staff, lack of socialization opportunities, being weighed and the crowded physical space, and overall perceived the program as a "men's club"(p.126)[97]. The implication is that women may find a CR program more appealing if there is a stronger psychological emphasis, more varied exercise options, and a greater presence of female participants. The feature for which women's preferences were least well-met was the ability to choose their own exercises, with additional preferences of discussing progress, not tiring, flexible hours and setting goals. Women's preference not to experience pain or tire while exercising was significantly less well met than it was for men. Overall, women may be less likely to participate as they do not perceive the programs as meeting their needs[88]. The totality of evidence suggests

that women may benefit from alternative CR approaches[59,90], although there is a dearth of empirical evidence to test this contention.

Alternative Models of Cardiac Rehabilitation

Home-Based Cardiac Rehabilitation

In response to patient preference among other logistical considerations, home-based models of CR care were developed in the early 1980s. While there is no universally recognized definition of what constitutes a home-based program[98], for the purposes herein they will be considered monitored CR programs which make similar use of graded exercise tests to develop an individualized exercise prescription, provision of exercise protocols taught by CR personnel to be performed independently, in addition to provision of reading materials on lifestyle changes, all of which is discussed during scheduled telephone calls between allied health care providers at the CR program and patients. Home-based CR programs have been implemented to overcome distance and transportation barriers, as well as time constraints such as those due to domestic responsibilities; barriers which are commonly reported by women[69]. Women tend to put family obligations ahead of lifestyle change, as caring for family/household is a more central component to their self-concept and self-esteem[72,99,100], and thus home-based CR programs provide a feasible alternative for those patients who are either unable or unwilling to attend in-hospital CR programs[101]. Costs analyses comparing the two models suggest that home-based CR programs are cost-effective, both to the provider and to the patient [102]. Specifically where the patient is concerned, there are no travel costs associated with home-based CR programs, although the program would still be associated with a certain time investment.

A Cochrane review found that home-based CR programs are as effective as traditional in-hospital programs in improving clinical and quality of life outcomes for both men and women[103].

Specifically, research suggests that home-based CR programs result in benefits similar to hospital-based CR programs with regard to morbidity, exercise capacity, cardiac risk reduction and health behaviour changes[104,105], again among both men and women. In a meta-analysis[98], home-based CR outcomes were compared to both usual care (18 trials, N=3,925) and hospital-based CR (6 trials, N=818). With regard to the former, results showed that compared to usual care home-based participants realized a 4 mm Hg greater reduction in systolic blood pressure (95% CI 6.5, 1.5) and a reduced relative risk of being a smoker (0.71, 95% CI 0.51, 1.00). No significant differences in exercise capacity, total cholesterol, anxiety and depressive symptoms, and mortality were found, although more trials are needed to adequately compare these outcomes. Two trials reported a significant reduction in re-admission rates following home-based CR, even 6 months later. With regard to comparison to hospital-based CR, results revealed no significant differences in exercise capacity, systolic blood pressure and total cholesterol. Results of one trial found no differences in emotional outcomes, smoking or mortality. Finally, evidence suggests that home-based CR programs are more cost-effective than hospital-based CR programs[106–108], and that there are no differences in patient healthcare costs following hospital or home-based CR participation[102]. There have been no training-related complications reported in the literature due to home-based CR, and such programs are considered safe for low to moderate risk patients[98].

Given the evidence that hospital-based mixed-sex CR programs may not meet women's needs, an alternative program model such as home-based CR may be preferable. In a previous study conducted by the Grace lab, 80 home and hospital-based CR graduates were surveyed regarding their preferred program model[109]. Program model preference was not related to sex, but results showed that white patients with perceived time constraints due to work preferred

home-based CR programs over hospital-based CR. In another study[110], 106 MI patients in the United Kingdom (UK) were offered hospital-based CR or home-based CR with the Heart Manual. Overall, 47 (44%) chose the home-based program, and 41 (87%) completed it, while 35 (33%) chose the hospital-based program and 17 (49%) completed it. There were no significant sex differences in program preferences. In the CHARMS trial with preference arms[104], 45% of 279 eligible patients expressed a preference for CR program model, with 57% choosing home-based, and 43% choosing hospital-based CR, and no significant sex difference. Participation in home-based CR was 71% (with 75% completing at least 4 of 6 weeks of the Heart Manual) versus 87% for hospital-based CR. In the BRUM trial of 525 cardiac patients randomized to hospital-based or home-based CR again using the Heart Manual, patients in the home-based arm completed a significantly greater number of CR sessions than patients in the hospital-based arm ($p<.001$)[105]. Program adherence was not analyzed by sex. Overall, these results suggest male and female patients prefer home over hospital-based CR, and although evidence is mixed, that adherence might be greater in home than hospital-based programs.

Women-Only Cardiac Rehabilitation

With the evidence of women's benefit from CR participation, their under-utilization of CR, and differential CR needs and preferences, it is surprising that gender-specific CR programs or features are not more systematically discussed in practice guidelines, and have not been thoroughly evaluated. Where the Canadian guidelines are concerned, the only women-specific recommendation is that they should be provided with gender-tailored information[3].

Indeed, a recent review called into question whether contemporary CR programs are equally suited to men and women[90], while the need to adapt CR services to suit women was highlighted in another review of interventions to increase CR adherence[111]. Fear and embarrassment is a

common concern voiced by women regarding exercise, especially among patients who are older and/or belong to certain ethno-cultural groups[19]. More specifically, women are often hesitant to exercise due to a lack of prior experience, low levels of ability, and self-consciousness of their body image[112,113]. Taking into account the barriers outlined above, women-only programs may encourage more women to attend CR.

While a few gender-specific behaviour change programs to meet the needs of women following a cardiac event or procedure have been developed and evaluated (e.g., CHANGE[114]), there are only five comprehensive women-specific CR programs globally. This model of CR has not been defined and is operationalized in various ways; however, women-centered CR generally refers to the provision of exercise and/or educational sessions to women solely, and in a manner which is tailored to empirically ascertain the needs of women[85]. There is a women-only lower-intensity exercise CR program established in Glasgow, Scotland, preliminary results of which reveal a 74% uptake by women post-MI (vs. 6% prior to program inception), although adherence was not reported[115]. Uptake may have been increased due to provision of exercise at a level which does not cause pain or fatigue, and also which does not impact women's co-morbidities. In the US, Beckie and colleagues have developed a 3-month women-only CR program, consisting of 10 psycho-educational sessions, social support, and 36 on-site exercise sessions[116]. Adherence was greater in the women-specific group.

There are 3 women-only CR programs in Canada to date. Canada's first women-only comprehensive CR program was developed in 1996 to address women's needs and preferences for care as identified in the literature[97,117,118]. The 6-month program offers weekly 2-hour women-only exercise and education sessions[119]. These sessions are offered in a gender-sensitive manner, with female-focused content and delivery[120]. Individual interviews and focus groups

with 100 female patients were used to develop the program, and its evidence is supportive. A retrospective review of 315 participants between 1996 and 2004 revealed 85% program adherence[119]. Second, the CR program in Hamilton, Ontario has instituted women-only exercise and education sessions, and uncontrolled preliminary analyses reveal significant increases in self-efficacy and emotional well-being, with 75.71±22.19% program adherence[121]. Finally, the Toronto Rehabilitation Institute (TRI) and Toronto Western Hospital (TWH) also currently offer a women-only CR program.

Overall, there is a paucity of data on the ability of alternative CR program models to meet women's needs following a cardiac event. In Arthur's review of the literature[80], final research recommendations were for "more study … regarding different approaches to programming … which may be more suitable for women," and "investigation of novel approaches to increasing women's participation in CR"(p. 61D).

RESEARCH OBJECTIVES

There are no RCTs comparing women's cardiac health behaviours across alternative CR program models. While Beckie's recent work contributed to reducing this large knowledge gap, her study did not include a home-based program model, and the mixed-sex and women-only program model differed slightly in terms of content[116]. While this dissertation examines the subject area in a Canadian context, it also draws comparisons between traditional in-hospital mixed-sex CR and women-only CR, as well as home-based CR. Gender-specific CR programs or features are not discussed in Clinical Practice Guidelines, and have only recently been investigated[85].

The primary objective of the CR4HER study was to compare women's program adherence across the 3 types of CR program models, to determine which program model results

in the greatest adherence. The secondary objectives were to compare women's functional capacity and health behaviours, namely exercise, diet, medication adherence and smoking, by CR program model.

Hypothesis

CR program adherence will be significantly greater and functional capacity and health behaviours post-CR will be better in the women-only and home-based CR program models, compared to the traditional mixed-sex CR program model.

CANDIDATE'S ROLE

This trial was funded by a Heart and Stroke Foundation of Ontario grant from 2009-2013 (Grant in Aid #NA 6682). There was a funded data manager, as well as other recruitment personnel that supported the conduct of this trial.

The candidate was responsible for patient recruitment at 2 sites (TRI and SHSC) for 11 months (September 2012-July 2013), including determining patient eligibility and obtaining informed consent; communication of patient referrals and program dates to sites and participants; communication with the SHSC Research Ethics Board; maintaining study binder and documentation; participant follow-up (phone and mail); clinical data extraction; and data entry (CRFs [Case Report Forms], pedometer logs, intake report forms, post-test surveys, and discharge report forms); and contributing knowledge transfer to academic, clinical and policy audiences. The candidate also performed the statistical analyses for the objectives herein. For the last year of the trial, the candidate also took on the role of study coordinator, during which time she was in charge of ethics renewals, amendments, and eventually terminations. The candidate also closed-out the trial, including ensuring that data will be stored in accordance with University

Health Network (UHN) standard operating procedures long-term, and updating the study status on clinicaltrials.gov.

METHODOLOGY

Design

This study (registered on clinicaltrials.gov [NCT01019135]) was part of a three parallel-arm pragmatic randomized controlled trial using individual patient randomization, comparing the following CR program models: (1) mixed-sex traditional hospital-based CR (co-ed), (2) women-only hospital-based CR, and (3) monitored home-based CR. Refer to the trial overview in Figure 2.

Setting

This was a multi-center study involving CR programs at TWH and TRI of the UHN, as well as Hamilton Health Sciences (HHS). These CR programs were within close geographic proximity to all recruitment sites that did not offer on-site CR programs (Toronto General Hospital [TGH], Mount Sinai Hospital [MSH], and Sunnybrook Health Sciences Centre [SHSC]), to rule out potential patient distance barriers to program adherence. Available supervised CR programs were offered twice per week for a duration of 4 months (TWH and HHS), or on a weekly basis for a duration of 6 months (TRI). Home-based programs were offered on a weekly basis, regardless of site.

All programs included the core components of CR as recommended by the Canadian Association of CR guidelines[3]. Patients participated in an intake assessment, including a full medical history, physical and medical examination, an exercise treadmill test and personalized orientation. All intake and discharge stress testing was done with patients taking their usual

medication, employing a modified Bruce protocol where possible[122–125], however this depended on the functional capacity of the patients.

Exercise training was then individually prescribed for all patients. The type, frequency, intensity (based on stress test and ratings of perceived exertion), duration and rate of progression of aerobic exercise prescriptions were based on national guidelines[3]. Typically, female patients were encouraged to perform 30 to 60 minutes of walking, at an intensity corresponding to 60% of the peak heart rate achieved during baseline graded exercise testing and/or a perceived exertion rating of 11 (fairly light) to 13 (somewhat hard) at least 5 days/week[126]. In addition to exercise training, participants received education on CVD, risk factors and lifestyle modification (i.e., diet, medication, smoking, weight as applicable) guided by a multidisciplinary team. At TRI, education sessions were given on a weekly basis, while at TWH and HHS patients received a single “education day”.

The traditional hospital-based mixed-sex CR programs included on-site group exercise training sessions 1-2 days/week, as described above. Participants were encouraged to walk at home on alternate days of the week. Education sessions were also given in a group format. Similarly, in the women-only CR programs, participants engaged in on-site female-only group exercise sessions, as well as female-only group education sessions. In the monitored home-based programs, patients similarly attended an intake appointment where an exercise test was performed as the basis for exercise prescription. Patients were given written guidelines for aerobic conditioning based on their treadmill test. They were prescribed a walking regimen based on the parameters as outlined above, which produced an equivalent duration, mode, intensity and frequency of exercise as the hospital-based programs. While geographic and / or meteorological

factors were not accounted for, all patients received education on exercising in adverse weather conditions as well as directions to indoor walking locations throughout the area.

Patients were cautioned about symptoms, and taught how to check their heart rate during walking sessions. In the event of a change in clinical status, patients were advised to defer exercise training and to contact the program staff. Patients were provided with reading materials regarding CVD, risk factors and lifestyle modification. These were discussed with an allied health professional from the home-based CR program by telephone during weekly scheduled telephone calls. The average call duration was approximately 15 minutes. These individual sessions were similar to the group education sessions as offered in the hospital-based programs.

Procedure

The study protocol was submitted for approval by the research ethics boards at all participating institutions. The site recruiter then approached female cardiac inpatients at TGH, TWH, MSH, SHS, and SHSC to obtain informed consent, and screen for study eligibility. A person within the patient's circle of care made the initial contact with the patient by introducing the study, and then asking for permission to have the recruiter approach them to discuss the study. Study recruiters explained the study in full and allowed the patient as much time as they wished to consider participating in the study. If the patient agreed to participate, both the patient and recruiter signed and dated 2 copies of the informed consent form (ICF [Appendices A-D]). One copy of the signed ICF was provided to the patient, and another was retained for the study. In the instance of SHSC, 3 copies were signed and the additional copy was placed in the patient's chart. A note was also written in the patient's chart stating that they had consented to participate in the study.

The site recruiter also contacted low-risk female patients already referred to cardiac rehabilitation (prior to starting the program and being assigned to a class) and previously identified by CR staff, as well as female patients at the TRI surgical outpatient clinic and early education class at TWH. These patients were provided or mailed 2 copies of the applicable consent form (1 to keep and 1 to return) and the survey, to be returned in a provided postage-paid envelope.

Consenting and eligible patients were provided a baseline survey (Appendix E). In the event that the patient could not complete the baseline survey at the time of recruitment, a pre-paid, pre-addressed envelope was provided to her, in order to return the survey in the mail in the days following. The recruiter followed-up with those participants who had not returned the baseline survey via phone and /or mail at 2 week intervals, until the patient informed the staff that she was not interested in completing the survey and would like to withdraw from the study, or 6 weeks had passed since the patient was approached and the patient hadn't indicated they were working on survey completion.

Clinical data was extracted from medical charts to the case report form (CRF [Appendix F]). Clinical data extracted from medical charts included name of cardiac specialist and general practitioner, disease severity indicators (i.e., Canadian Cardiovascular Society (CCS)[127] and New York Heart Association (NYHA)[128] class), comorbid conditions, prescribed cardiac medications, blood pressure, and lipid profile. This data was needed to complete CR referral, and to describe the sample. If all clinical data was not available in the hard-copy chart during hospitalization, electronic records were reviewed 2 weeks later to extract any missing data and to verify all data points. The supervisor verified study eligibility, and signed and dated the CRF.

For participants recruited as in-patients, physician clearance for referral was secured. Physician contact information was obtained from the College of Physicians and Surgeons of Ontario (CPSO) website (http://www.cpso.on.ca/docsearch/). The recruiter solicited approval for CR referral through the specialist or general practitioner by faxing or mailing the physician clearance form (Appendix G). In the instance of non-response, a telephone call was made to the physician and/or administrative assistant, and a hard copy of the clearance form was delivered in person to the physician's office if necessary. Efforts were made to receive a response from the physicians up to 6 weeks post-patient discharge. If there was a discrepancy between GP and specialist responses regarding the clearance of the patient, attempts to clarify the reason for non-approval were undertaken via phone. Unless the physician provided signed approval, the patient was considered ineligible for the study. If clearance was not received or provided by a physician by 6 weeks post-discharge, the recruiter contacted the patient via telephone to inform them that they were not eligible for the study. The patient was invited to re-visit CR referral with their physician, should their health status change in future.

When the consent form was complete, clearance was received in the affirmative (as applicable), and when CRF data had been extracted demonstrating patients met inclusion/exclusion criteria, participants were randomized via the online randomize.net software (www.randomize.net[129]), assigned in blocks of 6, and stratified by cardiac condition (PCI/coronary artery disease (CAD) vs. CABG/valve vs. MI). When a patient was randomized the recruiter used online map software and patient home and CR site postal codes to determine which of the sites offering the assigned program model was closest to the patient's home (or work if desired by the patient). Participants were allocated to the randomized program model at the closest site, at a maximum of 45 minutes travel time one-way. CR sites were informed of

program assignment, and the recruiter completed and submitted the corresponding CR referral form (Appendices H-J) for recruited inpatients. Because the recruiter was not an MD, "study coordinator" was entered where the MD was to sign for the referral, and the MD signature on the clearance form was attached.

The recruiter called participants to inform them to which CR program they had been randomly allocated. Participants were informed that their referral information had been sent, which CR site they would be attending, and that a staff member from the CR program would be contacting them shortly with an intake appointment booking. Participants recruited as outpatients were allocated to attend the CR site to which they were referred. Participants were provided with enrollment appointment dates, location and CR contact information by the CR program. Due to the participatory nature of the study, participants and CR programs could not be blind to condition assignment. However, the CR staff conducting the assessments and recording them were unaware of the study objectives as to reduce any bias.

Baseline assessments generally occurred in the first 4 weeks post-recruitment, and follow-up assessments generally occurred 6 months after the exercise start date at CR. The baseline survey to be completed prior to CR enrollment assessed baseline exercise behaviour, medication adherence, diet and smoking status. Surveys were only identifiable by a numeric research ID for blinding. Once physician clearance for CR was received, patients were mailed a Digi-Walker SW200 pedometer. Participants were asked to wear the pedometer for the 7 days prior to their CR intake appointment, and to record their daily total number of steps on an activity log that was mailed in to the study coordinator in a postage-paid and addressed envelope (Appendix K).

A recruiter extracted stress test results from the intake appointment, as well as lipid values, waist circumference, and blood pressure using the intake report form (Appendix L). Information extracted was directly entered online (in a password-protected file, on a secure UHN network via remote access) or was handwritten and couriered to the central site. However, the persons conducting the assessments and recording them for communication to the central study site were unaware of the study objectives, to mitigate the potential of bias.

The post-test survey (Appendix M) was mailed to participants 6 months after starting their CR program, accompanied by a post-test survey cover letter (Appendix N). Considering they had consented and to retain trial integrity, any participants who became ineligible after randomization and referral to a CR program (e.g., had a subsequent cardiac event or hospitalization) were also mailed a post-test survey. This survey again assessed self-reported exercise, medication, diet and smoking behaviour. Participants were also re-mailed a Digi-Walker SW200 pedometer and activity log, along with an instruction sheet, and a postage paid return package. Response rate was optimized through repeated and personalized contacts. This included a replacement survey mailing with an appropriate cover letter (Appendix O), telephone calls and email (where possible).

Program adherence, exit stress test and other outcome data was obtained from CR sites and recorded into a discharge report form (Appendix P). It was also entered into a password-protected excel file from a shared drive within UHN Research Information Systems through remote access.

Participants

Female in-patients with documented CAD, and/or ACS, and/or undergoing revascularization (e.g., CABG or PCI) and/or valve surgery (either percutaneous or open heart

repair or replacement) were approached at SHSC, MSH, HHS, and UHN when stable. These indications for inclusion were based on eligibility for CR[3], evidence of benefit from CR, and prevalence among female patients. ACS diagnoses were confirmed based on indication in patient chart of detailed history, focused physical examination, diagnostic electrocardiogram changes (i.e., Q waves, and/or ST-T segment changes), and/or troponin levels above the 99th percentile of normal. Patients were not excluded from the study on the grounds of age.

Inclusion Criteria

The following criteria had to be met: residency in Toronto (North to Highway 7, East to the far end of Scarborough, and West to Highway 427) or Hamilton (within 45 min travel time to HHS), proficiency in the English language, written approval to participate in CR by the patient's cardiac specialist or general practitioner (in the case of inpatient recruitment), and eligibility for home-based CR (i.e., low to moderate risk as demonstrated by: [1] lack of complex ventricular dysrhythmia, [2] NYHA Class of 1 or 2, and left ventricular ejection fraction (LVEF) >40%, or [3] CCS Class 1 or 2).

Exclusion Criteria

The following criteria could not apply: musculoskeletal, neuromuscular, visual, cognitive or non-dysphoric psychiatric condition, or any serious or terminal illness not otherwise specified which would preclude CR eligibility based on CR guidelines[3] (most patients were expected to have co-morbid conditions, but given that exercise prescriptions are individually-tailored based on graded exercise testing, most patients would be eligible for CR); physician deemed patient not suitable for CR at time of intake exercise stress test (i.e., < 3 minutes completed on Bruce protocol treadmill stress test, or < 6 minutes on modified Bruce protocol treadmill stress test, or achieved a workload of < 300 kpm on a cycle ergometer test, or significant ST segment

depression, uncontrolled dysrhythmias, abnormal heart rate or blood pressure measurements in response to exercise); were planning to leave the area prior to the anticipated end of participation; were being discharged to a long-term care facility; previous participation in CR; participation in another clinical trial with behavioural interventions; and in the case of inpatient recruitment having been referred to a CR program by their healthcare provider before study randomization was completed.

Measures

The baseline survey assessed correlates from each category of health care utilization from Andersen's Behavioral Model of Health as they related to CR[130,131]. Sociodemographic characteristics such as age and social factors including education (Appendix E, Section N, Item 6), marital status (Appendix E, Section N, Item 5), number and age of children (Appendix E, Section N, Item 3), and caregiving responsibilities assessed predisposing factors. Enabling factors were evaluated by inquiring about family resources such as income (see Appendix E, Section N, Item 7), as well as wait time to start CR. Need-based factors were reflected in survey items asking about clinically evaluated needs such as the presence or absence of cardiac risk factors.

The constructs of gender and sex are important predisposing factors in Andersen's model. The sample included only women, and this constitutes the sex of the sample. A validated gender assessment tool is the Bem Sex-Role Inventory[132]. Published in 1974, this instrument assesses how people identify themselves utilizing individuals' perceptions of gender roles, or the expectations about what are appropriate traits for either sex. Respondents answer sixty questions rated from one to seven (with one indicating never or almost never true, and seven indicating always or almost always true). Responses are categorized into one of four different gender

constructs: masculine, feminine, androgynous and undifferentiated. In this research however, items assessing gender more specific to the issue of CR utilization were developed. This included most importantly women's caregiving roles and responsibilities. In the pre-test survey, see section N questions 2-4, and in the post-test survey sections B and section S question 4.

Clinical data extracted from medical charts provided further need factors, including disease severity indicators (i.e., CCS[127] and NYHA[133] class), comorbid conditions, prescribed cardiac medications (i.e., name, dose and frequency), blood pressure, lipid profile, and left ventricular ejection fraction. This data was used to describe the sample, and for completion of program referral forms.

Outcomes

The primary dependent variable of program adherence was assessed as follows: masked CR program staff members recorded the number of on-site or telephone sessions (in the case of home-based programs) prescribed and completed as per usual practice. A masked research assistant then extracted these data from the CR program charts to calculate adherence, where program adherence was defined as the number of on-site or phone sessions attended divided by the number of sessions prescribed. For patients who did not complete the program, whether the reason was clinical or not was denoted. Where the patient prematurely ended the program for clinical reasons, the date was documented and program adherence was also calculated based on participation to the clinical event. It was also ascertained whether the patient enrolled (defined as patient attendance at CR intake)[134] and completed (defined as attending at least some of the CR intervention components and having a formal re-assessment by the CR team at the end) the program.

The secondary outcomes were assessed pre- and post-CR. Functional capacity was operationalized as peak volume oxygen consumption per minute (VO_2 peak) on the exercise stress tests, measured in $mL.min^{-1}$. Exercise testing is a cardiovascular stress test using treadmill exercise with electrocardiogram and blood pressure monitoring, used to determine exercise capacity, assess the extent of coronary disease, estimate prognosis, and the effects of therapy such as CR. All patients underwent symptom-limited graded exercise testing assessed via a modified Bruce protocol[122–125]. This protocol has two 3-minute warm-up stages at 1.7mph and 0% grade, and at 1.7mph and 5% grade. Stage 2 is 2.5mph at 12% grade (equivalent to 7 metabolic equivalents [METs]). Stage 3 is 3.4mph at 14% grade (equivalent to 9 METs). Blood pressure, heart rate, and 12-lead electrocardiogram data were measured continuously throughout the test. Most assessments were done by direct measurement of oxygen uptake (CardioPulmonary Exercise Test; CPET) using a metabolic cart, with incremental data collected every 15 seconds. Where patients had CPETs done, VO_2 was measured breath by breath, and the VO_2 peak was defined as the averaged value of the three measurements taken in the last minute of exercise. As per ACC/AHA guidelines[125], exercise testing was terminated in the presence of the following indications: a drop in systolic blood pressure of greater than 10mmHg from baseline despite an increase in workload, moderate to severe angina, increasing nervous system symptoms, signs of poor perfusion, sustained ventricular tachycardia, patient desire to stop, and ST elevations ≥1mm in leads without diagnostic Q waves (other than V_1 or AVR).

Exercise behavior was assessed via pedometer and self-report (i.e., Godin Leisure-Time Exercise Questionnaire [GLTEQ][135]). With regard to the former, customary physical activity was measured by the Yamax Digi-Walker SW-200, which is a body-borne spring-levered pedometer. The SW-200 mechanical pedometer is the most widely-used research pedometer[136–139], and has

been shown to be valid and reliable in a wide range of settings[140–142]. Pedometers were worn on belts, at the right hip. Participants were asked to wear the Digi-Walker pedometer provided for 7 consecutive days before CR intake (from the time of waking up until the time of going to bed, while the fact that the pedometer could not be exposed to water was highlighted in the included instruction manual), and instructed to record the total number of steps taken per day in an activity log (Appendix K). One week following completion of the CR program, participants were asked to again wear the pedometer for 7 consecutive days, and record their total number of steps taken per day in an activity log. The average number of steps taken per day at pre-test and post-test were computed. While 10,000 steps/day is generally considered indicative of an active lifestyle, this target may be too high for patients with chronic diseases[143]. As such, pedometer data were interpreted and scored using a pedometer index for patients with CVD, whereby 6,500–8,500 steps/day are recommended to achieve the total amount of physical activity energy expenditure generally recommended for secondary prevention[144].

With regard to the latter, the GLTEQ [135] was administered in the pre- and post-test surveys. It is a brief and reliable instrument to assess usual leisure-time physical activity behaviour during a one-week period. For the first question, weekly frequencies of strenuous, moderate, and light activities were multiplied by nine, five, and three, respectively. Part two of the questionnaire calculated the frequency of weekly leisure-time activities pursued. Total weekly leisure activity was calculated by summing the products of the separate components, where higher scores indicated greater physical activity [135]. The Canadian Physical Activity Guidelines [145] recommend that adults should accumulate at least 150 minutes of moderate- to vigorous-intensity aerobic physical activity per week. Using the GLTEQ formula for computing a weekly leisure-time activity score [(9 x Strenuous) + (5 x Moderate) + (3 x Mild)][135,146], this

level of exercise is equivalent to a starting score of 25 units [147]. However, the Canadian Society for Exercise Physiology does not currently have a guideline for cardiac populations. The Core Components of Cardiac Rehabilitation [148] suggest that patients accumulate 30-60 minutes per day of moderate-intensity physical activity on at least 5 days of the week (a GLTEQ score of 25). On the other hand, a joint American Heart Association / American College of Cardiology statement for preventing heart attack and death in cardiac patients encourages a minimum of 30 to 60 minutes of moderate-intensity activity, at least 3 or 4 times weekly [149] (a GLTEQ score of 15 to 20). Thus, participants in the current study were characterized as 'active' if they reported meeting the mid-point of these guidelines (a GLTEQ score ≥20). The Godin scale provided information on the approximate intensity of physical activity in which participants engaged, which was not available from the pedometers.

The pre- and post-test surveys also included the Diet Habit Survey[150] to assess diet, an inexpensive, reliable, and valid instrument for rapid assessment of eating habits and diet composition. Its 39 questions assess the following diet categories: meat, fish, and poultry; dairy products and eggs; fats and oils; sweets and snacks; grains, beans, fruits, and vegetables; beverages; salt; restaurants and recipes; and seafood. Greater scores indicate better diets, both for the total score and for each area. The total score indicates the level of fat in the diet (with scores ≥236 corresponding to a low-fat diet [20% or less][151]). Specifically, CR education content encourages consumption of a low fat diet.

Medication adherence was measured via a self-report list from bottles (categorized by type – i.e., statins, beta-blockers), as well as the 4-item Morisky Medication Adherence Scale (MMAS-4)[152,153]. The latter is scored as yes = 0, no = 1, such that a higher score indicates higher medication adherence. Patients scoring 2 or above can be considered adherent.

Finally, smoking habits were investigated via an investigator-generated and piloted item (smoking history; never smoked vs. currently smoke vs. quit smoking). Biochemical data from the 2007-2009 Canadian Health Measures Survey confirmed that self-reported smoking status provides an accurate estimate of the prevalence of cigarette smoking[154].

Statistical Analyses

Preliminary Analyses

SPSS 22.0 was used for all analyses[155]. Once the principal investigator was satisfied that all data had been collected, entered and thoroughly cleaned and screened, the randomization variable was merged into the SPSS data file, thereby unblinding the data set. For the primary outcome of program adherence, this data cleaning consisted of a random check of 5% of data points for number of sessions prescribed and attended against CR charts. If any errors were observed they were corrected and another 5% of the data points were checked. This was reiterated until no errors were observed.

Retention rate was computed by recruitment site, by CR site, by program model to which participants were allocated, by program model which they attended, and by CR completion (yes / no). The number and percentage of participants who completed the program to which they were randomly allocated was also described.

The time between CR completion (where applicable) and post-test survey completion was computed. Pearson's correlations were performed to determine the association between the primary outcome measure and time from CR graduation to survey completion. Similarly, time elapsed (in days) between the first day wearing the post-test pedometer and the last day of CR in those who graduated was calculated. Pearson's correlation between the time in days and the pedometer count was performed, to test whether this may have been an alternative explanation

for pedometer counts. Seasonal effects in the pedometer data were explored by comparing the mean steps in patients with pre- and post-test values in December through February as compared to other months of the year. Finally, association between the pedometer data and GLTEQ [135] scores at each time point were calculated using Pearson's correlations. Mean, standard deviation, and median time (in days) between completion of pre- and post-test surveys were also calculated, and compared by site.

Overall adherence was compared by site as well as CR program model on a PP and as-treated basis. CR program adherence was also compared between study participants recruited as in-patients versus those recruited as out-patients. Further, the relationship of program-reported versus patient self-reported program adherence was evaluated by Pearson's correlations coefficients. Lastly, Pearson's correlations and t-tests as appropriate were used to assess if CR program adherence was associated to predisposing, enabling, and/or need factors as per Andersen's model[63] (Figure 1).

Respondent Characteristics

First, the equivalence of participant baseline sociodemographic and clinical characteristics by program model was tested using analysis of variance (ANOVA) with post-hoc Least Significant Difference (LSD) tests, or chi-square analyses as appropriate. This served as a check of the randomization process. Second, retention rate was computed. Third, sociodemographic and clinical characteristics of retained participants versus those lost-to-follow-up were compared to evaluate if there was a retention bias in the sample, using t-tests and chi-square as appropriate. Baseline differences in characteristics of participants who did not complete CR for clinical versus non-clinical factors were tested in similar fashion. Finally, patient adherence to randomization was described. The number and percentage of patients who

attended the CR program to which they were referred, who attended the program model to which they were allocated, and who completed any program was described.

Testing Objectives

For the primary outcome of program-verified CR adherence, ANOVAs were performed, with program model as the independent variable and percentage of sessions completed as the dependent variable. For this analysis, statistical significance was defined by $p<.05$ (2-sided). These were performed on a "per protocol" (PP; i.e., by random allocation, where outcomes were ascertained) and "as-treated" basis (i.e., the CR model actually attended). Post-hoc LSD tests were used for multiple comparisons.

With regard to functional capacity, first assessment of change from pre to post-test using paired t-tests was conducted, overall and by model. Change scores were also computed, and significant differences in these change scores were tested. To test the secondary objective, analysis of covariance (ANCOVA) was computed, with baseline VO_2 peak, along with any differences in participant characteristics which impacted retention as covariates to the model. All tests were again performed on a PP and as-treated basis, with the same approach to post-hoc analyses as above.

In terms of health behaviors, first a pre-test descriptive examination of the number and percent of participants meeting Canadian Physical Activity Guidelines[145] as assessed via pedometer and self-report was described, and those that met the cut-off to be considered "adherent" to medical therapy on the MMAS-4. Following categorization of medications reported by patients at both time points, the number and percentage of patients on each class of evidence-based pharmacotherapy was described. A descriptive examination of the Diet Habit Survey and its subscales, as well as those abstaining from tobacco use was also undertaken.

Second, assessment of change in health behaviours from pre to post-test using paired t-tests was conducted. These analyses were as above conducted in the total sample, regardless of model and by model, on a PP and as-treated basis. Smoking behaviour entailed analyzing pre-post differences in a dichotomous item, and was therefore assessed using McNemar's test.

A descriptive examination of heart-health behaviors at post-test was then undertaken, particularly in relation to established thresholds. ANCOVAs were also computed for all the post-test scores by program model, again on a PP and as-treated basis. Post-test scores served as the dependent variable, program model as the independent variable, and corresponding baseline scores along with any participant socio-demographic and clinical characteristics related to retention identified above as covariates.

Testing Objectives - Enrollees Only

In addition to running analyses in the cohorts previously outlined, ANOVAs (for CR program adherence) and paired t-tests (for functional capacity and health behaviours) were also undertaken in the sample of CR enrollees only (as they would not have 0% adherence, which may have influenced the outcomes of the tests).

RESULTS

Preliminary Results

Routine data cleaning did not reveal any discrepancy in the number of sessions prescribed and attended when the patient database was checked against CR charts. However, several missing data values were discovered. While efforts were made to mitigate this, CR program attendance data was missing in 16 of the patients charts.

Overall, retention rates were as follows; 62 (36.7%) for the CPET, 55 (32.5%) for the pedometer, and 116 (68.6%) for the survey (see Tables 1-5). On the other hand, study participants recruited at TRI were more likely than those recruited at TGH, TWH, or HHSC to have a post-CR CPET (p=.0001). There were no differences in retention by CR recruitment site for the pedometer (p=.18) or the survey (p=.18). By CR site, participants attending CR at TRI were more likely than those at TWH or HHSC to have a post-CR CPET (p=.0001). Additionally, participants attending CR at HHSC were more likely than those at TWH to have a post-CR CPET (p=.0001). There were no differences in retention by CR site for the pedometer (p=.19) or the survey (p=.44), and no differences in retention by CR program model (PP [CPET, p=.96; pedometer, p=.32; survey, p=.80]).

There were, however, differences in retention by CR program model on an as-treated basis (p=.0001), predictably with participants attending any CR model being more likely than those who did not start CR to have a post-CR CPET. As well, participants attending mixed-sex CR were more likely than those attending women-only CR or home-based CR to have a CPET, while participants attending women-only CR were more likely to do so than those attending home-based CR. There were no differences in retention by CR program model (as-treated) for the pedometer (p=.33) or the survey (p=.62). Lastly, there were differences in retention by CR completion for all three post-program components. Women completing CR were of course more likely to have a CPET (p=.0001), but were also more likely to return a pedometer (p=.008) and to return a survey (p=.0001).

Sixty-nine (51.5%) participants completed the program to which they were randomly allocated. An additional 27 (20.1%) participants completed the CR program, but switched to another CR program model.

Mean time between CR completion and post-test survey completion was 41.34±81.32 days (median=32.0). There was a positive correlation between CR adherence and time from CR graduation to survey completion (Pearson's r=.32, p=0.01). Among those who graduated CR, mean time elapsed between the first day wearing the post-test pedometer and the last day of CR was 29.07±41.13 days (median=29.1). There was no correlation between the time in days and the pedometer count (p=.068). Women who wore the pre-program pedometer during the winter (December through February) attained fewer mean daily steps (4062±2389) than those who wore the pre-program pedometer at other times (6053±2894; p=.012). Such differences were not observed, however, among women post-program (p=.28). There was no significant correlation between the pedometer data and GLTEQ [135] scores at pre-program (p=.95). At post-program, meanwhile, there was a positive correlation between the two outcomes (Pearson's r=.41, p=0.003).

There were no differences in adherence by site overall (p=0.19), nor by CR program model on a PP (women-only, p=0.19; mixed-sex, p=0.34; home-based, p=0.17) or an as-treated basis (women-only, p=0.24, mixed-sex, p=0.17, home-based, p=0.16). There was no difference in CR program adherence between study participants who had been recruited as in-patients versus those recruited as out-patients (p=.70; Figure 3). Participants self-reported a high degree of CR program adherence (84.53±27.18%, median=98.5%). There was no difference in self-reported CR adherence by CR program model on a PP (p=.85) or an as-treated (p=.14) basis. There was a positive correlation between program and patient-report of CR program adherence (Pearson's r=.61, p=0.0001).

A need factor (Indication for CR = Valve, p=.009), was significantly associated with CR program adherence. There was also a trend towards CR program adherence being associated with

predisposing factors (age, p=.062; caregiving, p=.052). There were no significant associations between CR program adherence and any other predisposing, enabling, or need factors (ps>.05).

Respondent Characteristics

A diagram of study flow is shown in Figure 4. A total of 2016 patients were approached, of which 739 (36.7%) declined to participate, mainly due to wanting to attend the CR model of their choice. Overall, 264 patients consented, of which 169/264 (64.0%) eligible patients were randomized. One hundred thirty-three of the 169 (78.7%) completed a pre-CR stress test (of which n=107/143 or 74.8% were CPETs). Furthermore, of the 169, 144 (85.2%) completed the pre-CR survey and 66 (39.1%) remitted a pre-CR pedometer log.

Table 6 displays the socio-demographic and clinical characteristics of participants by randomized model. There were no significant differences between patients randomized to each of the three models.

Through chart extraction, CR enrollment was ascertained for 164/169 (97.0%) participants. Overall, 20/169 (11.8%) did not attend CR even once for an intake assessment despite referral ("did not enroll"), and an additional 7/169 (4.1%) patients did not initiate the program following intake (Figure 4 – Allocation "did not attend"). Forty-three of the 169 (25.4%) attended a different model than the program to which they were randomly-allocated (Figure 4 – Allocation "did not receive allocated intervention"). The model to which these participants switched and reasons are reported elsewhere[96], and form the basis for the as-treated analyses. There were no differences in CR enrollment on a PP basis (p=.55).

Ninety-six of the 169 (56.8%) participants completed their CR program. Six of the 169 (3.6%) patients did not complete CR for medical reasons. They were significantly less likely to

live with someone requiring caregiving (p=.02) and less likely to have hypertension (p=.009) than the 19 patients who did not complete CR for non-clinical reasons. No other socio-demographic or clinical differences between these groups were observed (Table 7).

Of the 96 patients who completed their CR program, 62 (64.6%) had an exit CPET, while 58 (60.4%) had both a pre and post-CR CPET. Table 8 displays the socio-demographic and clinical characteristics of participants who completed an exit CPET (retained) versus those who did not. Patients who completed an exit CPET had lower incidence of MI, dyslipidemia, musculoskeletal impairment, lower resting heart rate at CR intake, smaller waist circumference at CR intake, and higher CR adherence than those who did not.

The response rate for the post-CR survey was 68.6% (116 participants), while 105 (62.1%) had both a pre and post-CR survey. Table 9 displays the socio-demographic and clinical characteristics of participants who completed a post-CR survey (retained) versus those who did not. As shown, retained participants were significantly older, less likely to provide care to someone in their household, and had higher CR adherence than those lost to follow-up.

The response rate for the post-CR pedometer log was 32.5% (55 participants), while 38 (22.5%) had both a pre and post-CR pedometer log. The socio-demographic and clinical characteristics of the 55 (32.5%) participants who remitted a post-CR pedometer log (retained; Table 10) versus those who did not were also compared. Participants who wore a pedometer post-CR were older (p=.017), had higher intake VO_2 peak (p=.024), and had higher CR adherence (p=.003) than participants who did not. No other differences in socio-demographic or clinical characteristics were observed.

Primary Outcome – Cardiac Rehabilitation Program Adherence

Overall, the mean number of sessions prescribed was 23.03±14.66 (median=24.00). The mean number of sessions prescribed did not differ by randomized model (p=.12). The mean number of sessions attended was 14.05±11.00 (median=15.00). The mean percentage of prescribed sessions attended was 54.46±35.14% overall (regardless of program model). Participants who did not enroll in CR post-referral effectively had 0% adherence; removing these participants provides a truer indication of program adherence. Among all participants who enrolled, the mean percentage of prescribed sessions attended was 63.60±29.29%.

Among the 6 patients who did not complete CR for medical reasons, the percentage of prescribed sessions attended until the date of their adverse clinical event was 58.96±25.13%. A new adherence outcome variable was computed, such that for participants who did not drop out for clinical reasons adherence was based on the number of prescribed sessions attended to those prescribed, and for patients who did drop out for clinical reasons, adherence was based on the number of sessions attended to those prescribed to the date of the clinical event. This variable was used for the analyses below.

With regard to the primary objective, there were no significant differences in the percentage of CR sessions attended by randomized model (PP; Figure 5a; p=.63, observed power=.12). However, there was a significant difference in the as-treated analysis (Figure 5b; overall model p<.001, observed power=1.00), with participants who did not initiate CR obviously adhering to significantly fewer sessions than those who initiated any other program (post-hoc LSD test p=.001), but also with home-based CR participants attending a higher percentage of sessions than women-only participants (Figure 5b; post-hoc LSD test p=.03).

Secondary Outcome – Functional Capacity

In the overall sample, participants achieved a significant increase in functional capacity from pre- to post-program (Table 11). As shown, paired t-tests revealed there was a significant increase in VO_2 peak across all 3 models over time when considered on a PP and as-treated basis, except in the home-based group for the as-treated analysis, where the increase was not significant. The degree of change did not differ by model (p=.78 PP, p=.97 as-treated).

An ANCOVA adjusted for pre-CR values and confounding retention variables; there were too many variables to adjust for given 58 pts with both pre- and post-CR CPETs, and therefore dyslipidemia, musculoskeletal impairment, resting heart rate, and waist circumference were included. There were no significant differences in functional capacity at CR exit by program model in the PP analysis (Figure 6a; p=.84, observed power=.74). However, there were significant differences in functional capacity in the adjusted as-treated analysis, with women attending a mixed-sex program achieving higher functional capacity at CR exit than women who attended a home-based program (Figure 6b; overall model p=.046, observed power=.60, with post-hoc LSD test p=.025).

Secondary Outcome – Heart-Health Behaviours

Prior to CR, 25/66 (37.9%) participants were sufficiently active (i.e., met the 6,500 step/day guideline[144]), 63/135 (46.7%) were 'active' as per self-report (i.e., Godin scores ≥20[135]), 18/140 (12.9%) consumed reduced-fat diets (i.e., total Diet Habit survey score ≥236, corresponding to a 20% or less fat diet[150]), and 114/116 (98.3%) were adherent to their medications (i.e., MMAS-4 score ≥2[152,153]). The categories of medications most often reported by patients at both time points were lipid lowering statins (pre-CR 81.3%; post-CR 78.8%), ASA

– Aspirin (79.9%; 73.7%), and beta-blockers (68.7%; 63.2%) (Table 12). Diet Habit Survey scores by category are listed in Table 13. Finally, 129/138 (93.5%) were non-smokers.

Regardless of model, there was a significant pre-post CR increase in self-reported physical activity (Table 14). In terms of the Diet Habit Survey subscale scores (Table 13), there was a significant improvement in salt intake (from 16.52±4.41 to 17.63±5.08; p=.013) and a significant worsening in "Restaurants and Recipes" (from 35.62±4.24 to 34.13±5.76; p=.013; indicating participants made fewer low-fat choices when eating in restaurants and/or cooking). No other changes were observed.

Post-CR, 22/55 (40.0%) met the 6,500 step/day guideline, 78/108 (72.2%) were active as per self-report, 14/115 participants (12.2%) consumed 20% or lower fat diets, and 113/116 (97.4%) were adherent to their medications. Finally, 109/116 (94.0%) were non-smokers.

As also shown in Table 14, by program model, paired t-tests revealed an increase in self-reported physical activity among participants randomized to mixed-sex and women-only CR pre to post-CR (PP; p=.002 and p=.001, respectively). Significant increases in self-reported physical activity among participants attending mixed-sex (as-treated; p=.014) and women-only CR (as-treated; p=.001), and significant increases in total Diet Habit Survey scores among participants attending women-only CR (as-treated; p=.039) were also observed. In terms of the diet subscale scores, there was a significant improvement in "Seafood" among women randomized to home-based CR (PP; from 6.75±2.20 to 7.63±1.75; p=.002) and in "Salt" among women randomized to mixed-sex CR (PP; from 16.56±4.67 to 18.14±5.22; p=.043). There was also a significant improvement in "Salt" among women attending mixed-sex CR (as-treated; from 17.08±4.53 to 18.59±5.43; p=.038) and in "Seafood" among women attending home-based CR (as-treated;

from 6.71±2.17 to 7.40±2.06; p=.038), and a significant decline in “Restaurants and Recipes” among women attending mixed-sex CR (as-treated; from 36.44±4.31 to 34.23±6.27; p=.028). No other differences were observed. McNemar's test revealed no significant differences in smoking by randomized CR program model (PP) or attended model (as-treated).

ANCOVAs adjusting for pre-CR values and confounding retention variables were computed to test for significant differences in post-test health behavior scores by program model, on a PP and as-treated basis. No differences by program model were observed (Figures 7a-10b).

Testing Objectives - Enrollees Only

When an ANOVA for CR program adherence was undertaken in the sample of CR enrollees only, there was still no significant difference by randomized CR program (Figure 11; p=.52). Note that an ANOVA was not conducted on an as-treated basis, as an ANOVA using enrollees only would have generated the same results as one using the whole participant population since non-enrollees would have been among the group that did not start CR. In the sample of enrollees only, paired t-tests for pre to post-CR functional capacity and health behaviours resulted in slightly different values than when using the entire participant population. However, the same trends were observed in the data; in the sample regardless of CR program model, participants achieved a significant increase in functional capacity from pre to post-program (Table 15), and as before, there was a significant increase in VO_2 peak across all 3 CR program models over time. Similarly, regardless of model, there was a significant increase in self-reported physical activity. As also shown in Table 15, by CR program model, paired t-tests revealed an increase in self-reported physical activity among participants randomized to mixed-sex and women-only CR pre to post-CR. Again, as-treated analyses were not done using only

enrollees as these would have been redundant with the as-treated analyses using the full participant sample.

DISCUSSION

This was the first study to have investigated women's CR program adherence, functional capacity, and health behaviours following the 3 most-available CR program models. Significant seasonal differences in daily steps were observed prior to CR, yet not following CR. The education that CR patients receive includes a module on exercising in adverse weather conditions. Furthermore, CR programs provide patients with directions to indoor walking locations (most often shopping centers). This finding may indicate that these education strategies are effective. Note that it remains unknown whether similar results would be maintained in the long-term. Existing research suggests that at 6 months following CR, only 30%–60% of patients report regular exercise [156–158]. However, the post-CR pedometer results from the CR4HER study are on average less than a month following CR. Similarly, prior to CR the pedometer data and the self-reported activity scores were not correlated, while at post-program the two measures were positively related. Although results herein suggest that women may have been over-estimating their physical activity even at post-test, it is possible that this may have been occurring to a lesser degree post-CR, potentially due to women being better educated where physical activity is concerned, or possibly paying more attention and actually measuring.

All the CR programs that were offered in this study were based on the Canadian Association of Cardiovascular Prevention and Rehabilitation guideline model of care[3], basing their exercise prescriptions on an exercise test, and offering multidisciplinary, comprehensive cardiovascular care. However this was a pragmatic trial, wherein there were some inherent differences between CR programs which could not be controlled for (including program site,

timing of the classes, etc). In spite of these variations, there were no differences in overall CR program adherence by CR site either on a PP or an as-treated basis.

Surprisingly, there was no difference in CR program adherence between study participants who had been recruited as in-patients versus those recruited as out-patients. It is known that physician endorsement is related to significantly greater patient participation in CR[159], thus greater CR program adherence among patients who had been recruited to the study after being cleared for and referred to CR via their physician or cardiac specialist was expected. At the same time, however, it has also been shown that female patients perceive significantly lower physician endorsement for CR [160,161]. Unfortunately, this may explain the lack of difference in CR program adherence in outpatient study recruits.

There was a significant association between CR program adherence and a need factor, as per Andersen's model. Although not significant, two predisposing factors also showed a trend towards association to CR program adherence; age and caregiving, which have previously been proposed as barriers to women's CR participation [56]. In the case of CR program adherence, Andersen's model is perhaps only moderately explanatory, and could potentially be supplemented with another framework to further explain women's CR program adherence.

Primary Outcome – Cardiac Rehabilitation Program Adherence

Women adhered moderately to all the CR models; contrary to the initial hypothesis and the trial by Beckie et al.[116], there were no significant differences by randomized model (PP). On an as-treated basis, participants who attended home-based CR had significantly higher program adherence rates than those who attended women-only CR. However, many women did not attend a home-based program despite allocation, and adherence was to phone calls only, thus higher rates of adherence to this model should be interpreted with caution. Where cross-over was

concerned, unfortunately model switching does occur in trials. Patients were randomized, and when they learned of the availability of other models and other times for sessions at the site, they sometimes asked program staff to switch. Ethically, this could not be prevented or reversed. As previously reported, a semi-structured telephone interview was conducted with the participants who attended a different CR model [96]. The items assessed reasons for switching from the model to which they were initially randomized, through a series of closed and open-ended questions. Participants most frequently switched to a supervised CR model due to the preference for on-site facilities and due to a perception that they could thereby reap greater health benefits.

High adherence to CR results in reduced morbidity and mortality for heart patients. Alter et al. recently described a 4% decrease in the predicted probability of death or hospitalization two years post-CR with each 10% increase in on-site attendance[162]. Martin et al. also reported a 1% decrease in mortality with each additional session attended[163]. Specifically among women, Colbert et al. recently found a 64% relative risk reduction in mortality in CR completers[2]. It was hoped the present study would identify a model in which women would be more likely to participate. Promoting wider availability of a program model found to be most attractive to women would represent an important and relatively simple means to improve women's meagre participation in CR. Clearly, other means to improve women's adherence to CR than program model choice are warranted. In a recent update to the Cochrane review on interventions to promote greater CR adherence, three of eight studies demonstrated improvement in adherence to CR[164]. Successful interventions included: self-monitoring of activity, action planning, and tailored counselling by CR staff. Many of these strategies were employed in the women-only CR arm of Beckie et al.'s trial[116,165] (although not herein), and indeed they showed greater program

adherence among women compared to those in mixed-sex CR, thereby suggesting that more tailored CR models are needed in order to address hard to reach populations.

Secondary Outcome – Functional Capacity

Program model allocation had no association with functional capacity, yet attended program model (as-treated) did influence functional capacity at program exit. Contrary to Beckie et al.'s findings[116], women who attended mixed-sex CR had significantly higher functional capacity at program exit than those attending home-based CR. This could be due to staff encouragement of patients to exercise at their target heart rate for the full prescribed duration in supervised settings.

Overall (in the whole patient sample, regardless of CR model), functional capacity was significantly improved at CR exit. This overall increase was roughly half of what has previously been reported among women completing CR (2.89 $mL.min^{-1}$, or 0.83 metabolic equivalents, as opposed to 1.65 metabolic equivalents) [166]. Increased functional capacity is also associated with a lower mortality rate[167]. A one MET increase in aerobic capacity equates to 13 and 15% decreases in all-cause mortality[62] and cardiovascular events, respectively[168]. This magnitude of improvement was observed on average, except among home-based CR participants. It was curious that home-based participants tended toward greater program adherence (as-treated only) but had fewer gains in functional capacity. This was likely due to the fact that women had to adhere to a call only and not make a visit on site, and they may have exercised at a lower intensity as they were not supervised. It may be concluded that home-based CR is of no particular advantage for women, and that instead mixed-sex may be advantageous. However, replication is warranted as the latter conclusion was based on as-treated analyses.

Secondary Outcome – Heart-Health Behaviours

Improvements in self-reported physical activity were observed with participation in supervised CR models (i.e., mixed-sex and women-only). While there were no significant changes in self-reported physical activity among home-based participants, their pre-CR self-reported physical activity was almost as high as the post-CR physical activity reported by the mixed-sex and women-only participants. Overall, the hypotheses regarding better behavioural outcomes following women-only CR were not supported. However, on an unadjusted basis, dietary improvements were only observed in women attending women-only CR. Taken as a whole, the findings herein suggest that behavioural outcomes were largely equivalent regardless of program model.

Women were consistently adherent to their medications, mainly non-smoking, and reported consuming roughly 25% of their calories from dietary fat. Lack of observed change or model differences in the former two health behaviours may be explained by a ceiling effect. On the other hand, an increase in self-reported physical activity was reported by patients attending supervised CR models, but well less than half were meeting the guideline post-CR when measured objectively via pedometer logs. While there were no program model-related differences in health behaviours in the adjusted analyses, women who did not attend CR did not realize any significant improvements in health behaviours. This is in line with previous research showing that women benefit when they do participate in CR[19].

Knowledge Transfer

Knowledge transfer activities for CR4HER were focused on several end-users: scientists and clinicians. With regard to the former, traditional academic dissemination occurred via various conference abstracts both in locally in Toronto (e.g., Canadian Association of

Cardiovascular Prevention and Rehabilitation Symposium, American Psychological Association Convention) and internationally (e.g. American Heart Association Scientific Sessions; Chicago, U.S.A.). Two manuscripts based on the data presented herein have also been accepted to high impact peer-reviewed journals for publication.

Where clinicians were concerned, debriefing meetings were offered to staff at the patient recruitment sites involved in the study. A debriefing letter was also e-mailed to all the recruitment sites. It was initially hoped that results could have been used to promote greater physician referral of women to CR programs which result in the greatest adherence, and refinements of the CR program models examined herein. Yet as the study was under-powered, they cannot be used to inform clinical practice or policy.

In terms of citizen engagement, debriefing letters were mailed to participants regarding study results[169]. As the study was inconclusive, it was not thought possible to do media releases in order to ensure reach to a wide audience of Canadians, as was planned at the onset of the study.

Implications

The present trial was designed to test whether participation in women-only CR results in improved program adherence, functional capacity, and health behaviours among women when compared to participation in other commonly-available models. While it was hypothesized that patients would be more engaged in women-only CR, and hence have better adherence, functional capacity, and heart-health behaviours, it may be concluded that no CR program model was of particular advantage for women. Instead, promoting greater use of CR among women[170] and wider availability of motivationally-focused CR programs as implemented by Beckie et al.[116] may represent important means to improve women's cardiac outcomes. Another key implication

of this trial was that although women perceived they increased their physical activity with CR participation, they were well below guideline recommendations for physical activity. Strategies to promote greater exercise among women should therefore be implemented.

Limitations

Caution is warranted when interpreting these findings. First, there may be selection bias, particularly given the low response rate. Women who consented to participate may have been more willing to attend CR and/or may have been more motivated to exercise and/or may have been doing better pre-CR than those who did not. However, emerging evidence suggests nonresponse bias may be less impactful than previously thought[171].

Second, while we achieved quite fulsome ascertainment of the primary objective, the secondary outcomes were assessed in a smaller proportion of the sample. In particular, functional capacity and mean daily steps were only evaluated in less than half of the sample, as perhaps the study requirements were too demanding of participants' time and effort. Indeed "high protocol burden and extensive time commitments" have previously been reported as a significant barrier to study participation by women [172]; factors not unlike those that also prevent women from participating in CR. Some retention bias was also noted, which limits the credibility and generalizability of the findings. However, the models were adjusted by these factors to mitigate this threat. Furthermore, it would only be expected to observe differences in functional capacity among patients who participate in CR, lending credence to the findings herein.

Third, the pilot study suggested a 45% recruitment rate and an 80% retention rate, meaning 725 women would need to be approached in order to end up with 261 participants at post-test. Yet, due to recruitment challenges, which have also been reported in other RCTs of women and CR[172], this target sample size to adequately test the primary outcome was not

reached. It was unfortunately not possible to extend the recruitment period, as research funds had run out prior to reaching the target number. Post-hoc analysis of power suggested the sample size was lacking for the PP analysis. Therefore, due to the possibility of Type II error, caution is warranted in concluding that women's participation in alternate program models will not result in improved adherence. Similarly, testing differences in functional capacity and health behaviours was a pre-specified secondary outcome for the trial. However, power calculations for these outcomes were not undertaken a priori. Therefore, the lack of significant effects in the adjusted models may be due to the lack of power.

Fourth, the operationalization of program adherence was different in the home-based arm (phone calls vs. on-site visits) leading to assessment bias. Fifth, while the content of the education sessions was consistent across sites and model arms as per clinical practice guidelines[173], the delivery method differed (i.e., in-person for the mixed-sex and women-only arms vs. printed material for the home-based arm). Indeed, CR includes multiple components, and as this trial was pragmatic in design, differences in the delivery of these components may have contributed to differences in CR program adherence, functional capacity, and health behaviours observed. While explanatory trials evaluate how an intervention works under ideal conditions, pragmatic trials take into account the realities of broad routine clinical practice and are designed to test interventions in the full spectrum of everyday clinical settings in order to maximize applicability and generalizability[174,175]. Yet because pragmatic trials aim towards maximal heterogeneity (in treatments, clinical settings, etc.), these studies must be large enough as to overcome the inherited heterogeneity which may lead to a dilution of the effect.

Sixth, similar to previous studies, we found significant gains in self-reported physical activity pre to post-CR in patients that attended supervised CR[176]; however, no significant gains

in mean daily steps walked using objective assessment were observed. This discrepancy was likely due to women over-estimating their physical activity. Furthermore, only a small group of patients returned both the pre and post-test pedometers. Future research is needed to robustly test the impact of CR program model on objectively-assessed physical activity among women (i.e., via accelerometers). Finally, generalizability of these findings is limited to women suitable for unsupervised exercise, and receiving care in a healthcare system where CR services are reimbursed.

Future Directions

CR4HER was a seminal trial, as it was the first to address the gap in knowledge about women's CR program adherence, functional capacity, and health behaviours following non-mixed-sex or non-hospital based CR. Although under-powered, the study did subsequently raise several questions that now warrant future research. Calculations based on a pilot study suggested a sample size of 261 patients was needed to detect a difference in adherence by CR program model at 80% power at the 5% significance level, yet this target was not achieved. Indeed, recruiting challenges in trials involving women and older adults have been previously documented [172]. It may be tempting to suggest that the study be replicated, potentially with a longer recruitment period in order to achieve fulsome sample. However, due to all the cross-over that was observed post-randomization [96], it may be more feasible to modify the trial design. Instead of a three-arm RCT, it may be more reasonable to conduct a trial with preference arms only including mixed-sex and women-only CR programs. Although random assignment has long been held as the gold standard in clinical trials, there exists the possibility that such an allocation process may not agree with the patient's preferences for the intervention or treatment. It is possible that patients may resent not receiving their treatment of choice, which may lead to non-

adherence to treatment. Patient preference arms are an alternate trial design whereby patients with no treatment preference are randomly allocated as usual, but patients expressing a treatment preference are allocated to receive their preferred treatment [177]. Indeed, a randomized study of CR that included patient preference was successfully conducted in order to compare the clinical effectiveness of home-based CR versus hospital-based CR [104]. Calculations for 80% power at the 5% significance level suggest that 126 study participants would be required for such a two-armed CR4HER follow-up study, which is an achievable sample size.

Regardless of the CR site in the CR4HER study, women-only CR programs were generally offered on a more restricted schedule than mixed-sex CR classes. Given that inconvenient program time has been shown to be a factor affecting the CR participation of women,[178] any type of study replication should be carried out with a wider availability of women-only CR classes.

Lastly, as CPETs were coordinated by the CR staff, rather than study personnel, study participants who did not enrol in CR or who did not complete CR did not have a pre-CR CPET or a post-program CPET performed, respectively. In fact, out of the 169 study participants, only 58 had both a pre and post-program CPETs done. While budgetary considerations would have to be accounted for, and though there may still be a certain degree of patients lost to follow up, it would be beneficial if any future study evaluated the functional capacity of all study participants at post-CR, even if they were non-completers. As such, resulting data may give a truer sense of the degree of improvement in functional capacity.

CONCLUSION

Results do not clearly favour any single model, but instead demonstrate women achieve clinically and statistically significant increases in functional capacity with any CR participation.

Overall however, women only attended half of prescribed exercise sessions. While diet improved with women-only CR participation, and physical activity with supervised CR participation, overall adjusted results of this trial suggest that women's outcomes are largely equivalent regardless of participation in women-only, mixed-sex or home-based CR. Although the initial hypotheses regarding the three CR program models were not proven, CR4HER still added to the knowledge gap where women and CR is concerned. Taken as a whole, study findings suggest that rather than promote different CR models with the same program content, more tailored CR models are needed in order to adequately reach women. Overall then, further research is needed on the utility of personalized program models for promoting greater CR engagement among women, including proven strategies such as self-monitoring, action planning and tailored counselling.

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TABLES

Table 1. Retention Rates by Study Recruitment Site

	CPET	Pedometer	Survey
TGH n=52 (30.8%)	9 (17.3%)	22 (42.3%)	39 (75.0%)
TWH n=15 (8.9%)	4 (26.7%)	3 (20.0%)	11 (73.3%)
SBH n=2 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TRI n=66 (39.1%)	43 (65.2%)	18 (27.3%)	41 (62.1%)
HHSC n=33 (19.5%)	6 (18.2%)	12 (36.4%)	24 (72.7%)
Advertisement n=1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
Total n=169	62 (36.7%)***	55 (32.5%)	116 (68.6%)

Differences in retention by study recruitment site were tested using chi-square; *p<.05; **p<.01; ***p<.001

CPET (CardioPulmonary Exercise Test); TGH (Toronto Genera Hospital); TWH (Toronto Western Hospital); SBH (Sunnybrook Hospital); TRI (Toronto Rehabilitation Institute); HHSC (Hamilton Health Science Centre)

Table 2. Retention Rates by CR Site

	CPET	Pedometer	Survey
TWH n=43 (25.4%)	0 (0.0%)	18 (41.9%)	32 (74.4%)
TRI n=93 (55.0%)	56 (60.2%)	25 (26.9%)	60 (64.5%)
HHSC n=33 (19.5%)	6 (18.2%)	12 (36.4%)	24 (72.7%)
Total n=169	62 (36.7%)***	55 (32.5%)	116 (68.6%)

Differences in retention by CR site were tested using chi-square; *p<.05; **p<.01; ***p<.001

CPET (CardioPulmonary Exercise Test); TWH (Toronto Western Hospital); TRI (Toronto Rehabilitation Institute);

HHSC (Hamilton Health Science Centre)

Table 3. Retention Rates by CR Program Model (PP)

	CPET	Pedometer	Survey
Women-only n=55 (32.5%)	21 (38.2%)	21 (38.2%)	38 (69.1%)
Mixed-sex n=59 (34.9%)	21 (35.6%)	15 (25.4%)	42 (71.2%)
Home-based n=55 (32.5%)	20 (36.4%)	19 (34.5%)	36 (65.5%)
Total n=169	62 (36.7%)	55 (32.5%)	116 (68.6%)

Differences in retention by CR program model were tested using chi-square; all ps>.05

PP (per protocol); CPET (CardioPulmonary Exercise Test)

Table 4. Retention Rates by CR Program Model (As-Treated)

	CPET	Pedometer	Survey
Women-only n=45 (26.6%)	16 (35.6%)	16 (35.6%)	30 (66.7%)
Mixed-sex n=70 (41.4%)	39 (55.7%)	21 (30.0%)	51 (72.9%)
Home-based n=27 (16.0%)	7 (25.9%)	12 (44.4%)	19 (70.4%)
Did not start n=27 (16.0%)	0 (0.0%)	6 (22.2%)	16 (59.3%)
Total n=169	62 (36.7%)***	55 (32.5%)	116 (68.6%)

Differences in retention by CR program model were tested using chi-square; *p<.05; **p<.01; ***p<.001

CPET (CardioPulmonary Exercise Test)

Table 5. Retention Rates by CR Completion

	CPET	Pedometer	Survey
Completed n=96 (71.6%)	62 (64.6%)	41 (42.7%)	81 (84.4%)
Did not complete n=38 (28.4%)	0 (0.0%)	7 (18.4%)	17 (44.7%)
Total n=134	62 (46.3%)***	48 (35.8%)**	98 (84.5%)***

Differences in retention by CR completion were tested using chi-square; *p<.05; **p<.01; ***p<.001

Due to missing data, valid percentages are reported.

CPET (CardioPulmonary Exercise Test)

Table 6. Pre-Test Participant Characteristics by CR Model Randomization (PP)

Characteristics	Women-Only	Mixed-sex	Home-Based	Total
	n=55 (32.5%)	n=59 (34.9%)	n=55 (32.5%)	n=169
Socio-demographic[§]				
Age, years (mean±SD)	66.22±10.21	61.56±9.73	63.13±10.94	63.64±10.42
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%)
Education, (% post-secondary)	18 (40.9%)	18 (35.3%)	18 (36.7%)	54 (37.5%)
Gross Annual Family Income (% <$50,000 CDN)	15 (39.5%)	23 (51.1%)	20 (47.6%)	58 (46.4%)
Provide care to someone in household	6 (20.0%)	5 (15.2%)	5 (16.7%)	16 (17.2%)
Have children	39 (88.6%)	39 (79.6%)	42 (87.5%)	120 (85.1%)
Clinical				
Indication for CR				
PCI	26 (47.3%)	28 (50.0%)	27 (50.0%)	81 (49.1%)
Angina/ACS/CAD	20 (36.4%)	20 (36.4%)	19 (35.8%)	59 (36.2%)
MI	19 (34.5%)	22 (38.6%)	18 (34.0%)	59 (35.8%)
CABG	16 (29.1%)	12 (21.4%)	14 (25.9%)	42 (25.5%)
Valve	10 (18.5%)	11 (19.3%)	11 (20.4%)	32 (19.4%)
Risk Factors				
Dyslipidemia	33 (84.6%)	38 (80.9%)	33 (84.6%)	104 (83.2%)
Hypertension	38 (88.4%)	32 (68.1%)	31 (70.5%)	101 (75.4%)
Obesity	16 (45.7%)	19 (46.3%)	14 (35.0%)	49 (42.2%)
Diabetes	16 (40.0%)	14 (36.8%)	8 (21.6%)	38 (33.0%)
Comorbidities				
Musculoskeletal Impairment	7 (14.3%)	6 (12.8%)	7 (19.4%)	20 (15.2%)
Depression	5 (10.4%)	6 (12.8%)	4 (11.1%)	15 (11.5%)
Cancer	2 (4.2%)	2 (4.3%)	4 (11.4%)	8 (6.2%)
Hyperthyroid	0 (0.0%)	3 (6.3%)	3 (8.6%)	6 (4.6%)
Renal Disease	1 (2.1%)	2 (4.3%)	1 (2.9%)	4 (3.1%)
PAD/PVD	0 (0.0%)	1 (2.1%)	1 (2.9%)	2 (1.5%)
Intake Assessment				
Resting Heart Rate (bpm)	75.98±12.77	76.27±17.55	74.24±14.44	75.54±15.06
Waist Circumference (cm)	96.03±16.99	92.49±12.59	93.60±12.24	94.15±14.34
Peak VO_2 (mL/(kg·min)	17.34±4.77	18.12±7.57	17.39±8.29	17.62±6.97
CR Utilization				
Adherence (% sessions)	54.40±34.72	51.33±35.70	58.12±35.39	54.46±35.14

The equivalence of participant baseline socio-demographic and clinical characteristics by program model was tested using ANOVA and chi-square as appropriate.

All $p>.05$

§n=144 participants completed the baseline socio-demographic survey. Some participants did not respond to certain items, and therefore due to missing data valid percentages are reported.

PP (per protocol); PCI (Percutaneous Coronary Intervention); ACS (Acute Coronary Syndrome); CAD (Coronary Artery Disease); MI (Myocardial Infarction); CABG (Coronary Artery Bypass Graft); PAD/PVD (Peripheral Vascular Disease/Peripheral Arterial Disease)

Table 7. Participant Characteristics by Reason for CR Non-Completion

Characteristics	Medical	Non-Medical	Total
	n=6 (24.0%)	n=19 (76.0%)	n=25
Socio-demographic[§]			
Age, years (mean ± SD)	58.50 ± 14.65	63.24 ± 9.29	62.26 ± 10.78
Marital Status, n (% married)	5 (83.3%)	6 (42.9%)	11 (55.0%)
Work Status, n (% retired)	1 (16.7%)	6 (42.9%)	7 (35.0%)
Ethnicity, n (% white)	6 (100.0%)	8 (57.1%)	14 (70.0%)
Education, n (% post-secondary)	1 (16.7%)	8 (57.1%)	9 (45.0%)
Income, n (% <$50,000 CDN)	1 (16.7%)	6 (42.9%)	7 (35.0%)
Provide care to someone in household, n	0 (0.0%)	5 (62.5%)	5 (35.7%)*
Have children, n	5 (83.3%)	14 (100.0%)	19 (95.0%)
Clinical			
Indication for CR			
MI	3 (50.0%)	10 (55.6%)	13 (54.2%)
PCI	5 (83.3%)	7 (41.2%)	12 (52.2%)
Angina/ACS/CAD	2 (33.3%)	5 (27.8%)	7 (29.2%)
CABG	0 (0.0%)	7 (41.2%)	7 (30.4%)
Valve	1 (16.7%)	0 (0.0%)	1 (4.2%)
Risk Factors			
Dyslipidemia	3 (60.0%)	11 (84.6%)	14 (77.8%)
Hypertension	1 (20.0%)	11 (84.6%)	12 (66.7%)*
Diabetes	3 (75.0%)	5 (41.7%)	8 (50.0%)
Obesity	3 (50.0%)	5 (38.5%)	8 (42.1%)
Comorbidities			
Musculoskeletal Impairment	2 (50.0%)	2 (14.3%)	4 (22.2%)
Depression	1 (25.0%)	1 (7.1%)	2 (11.1%)
Hyperthyroid	1 (25.0%)	0 (0.00%)	1 (5.6%)
Renal Disease	0 (0.00%)	1 (7.1%)	1 (5.6%)
Intake Assessment			
Resting Heart Rate (bpm)	69.83 ± 8.18	72.88 ± 18.92	72.43 ± 16.23
Waist Circumference (cm)	97.67 ± 23.95	101.72 ± 18.43	100.22 ± 18.78
Peak VO_2 (mL/(kg·min)	17.23 ± 4.67	17.56 ± 8.68	17.78 ± 8.07
CR Utilization			
Adherence (% sessions)	58.96±25.13	31.78±23.29	35.48±24.82

Socio-demographic and clinical characteristics of participants who did not complete CR due to medical reasons versus those who did not complete due to non-medical reasons were compared to evaluate if there was a bias in the sample, using t-tests and chi-square as appropriate.

*T-test or chi-square $p<.05$

§n=144 participants completed the baseline socio-demographic survey. Some participants did not respond to certain items, and therefore due to missing data valid percentages are reported.

PCI (Percutaneous Coronary Intervention); ACS (Acute Coronary Syndrome); CAD (Coronary Artery Disease); MI (Myocardial Infarction); CABG (Coronary Artery Bypass Graft); PAD/PVD (Peripheral Vascular Disease/Peripheral Arterial Disease)

Table 8. Participant Characteristics by Retention Status – Post-Program CardioPulmonary Exercise Test

Characteristics	CPET at discharge	No CPET/did not enrol	Total
	n=62 (36.7%)	n=107 (63.3%)	n=169
Socio-demographic[§]			
Age, years (mean±SD)	63.93±8.53	63.47±11.40	63.64±10.42
Marital Status, n (% married)	31 (57.4%)	41 (45.6%)	72 (50.0%)
Work Status, n (% retired)	29 (53.7%)	43 (47.8%)	72 (50.0%)
Ethnicity, n (% white)	30 (55.6%)	60 (66.7%)	90 (62.5%)
Education, n (% post-secondary)	20 (37.0%)	34 (37.8%)	54 (37.5%)
Gross Annual Family Income (% <$50,000 CDN)	24 (47.1%)	34 (45.9%)	58 (46.4%)
Provide care to someone in household, n	3 (8.8%)	13 (22.0%)	16 (17.2%)
Have children, n	44 (83.0%)	76 (86.4%)	120 (85.1%)
Clinical			
Indication for CR			
PCI	32 (53.3%)	49 (46.7%)	81 (49.1%)
Angina/ACS/CAD	19 (32.8%)	40 (38.1%)	59 (36.2%)
MI	15 (25.0%)	44 (41.9%)	59 (35.8%)*
CABG	15 (25.0%)	27 (25.7%)	42 (25.5%)
Valve	13 (21.7%)	19 (18.1%)	32 (19.4%)
Risk Factors			
Dyslipidemia	35 (94.6%)	69 (78.4%)	104 (83.2%)*
Hypertension	35 (81.4%)	66 (72.5%)	101 (75.4%)
Obesity	14 (40.0%)	35 (43.2%)	49 (42.2%)
Diabetes	10 (32.3%)	28 (33.3%)	38 (33.0%)
Comorbidities			
Musculoskeletal Impairment	3 (6.1%)	17 (20.5%)	20 (15.2%)*
Depression	6 (12.2%)	9 (11.0%)	15 (11.5%)
Cancer	1 (2.0%)	7 (8.8%)	8 (6.2%)
Hyperthyroid	3 (6.0%)	3 (3.7%)	6 (4.6%)
Renal Disease	1 (2.0%)	3 (3.7%)	4 (3.1%)
PAD/PVD	1 (2.0%)	1 (1.2%)	2 (1.5%)
Intake Assessment			
Resting Heart Rate (bpm)	72.35±14.11	77.36±15.35	75.54±15.06*
Waist Circumference (cm)	91.35±12.46	96.90±15.60	94.15±14.34*
Peak VO_2 (mL/(kg•min))	16.33±4.74	18.63±8.19	17.62±6.97
CR Utilization			
Adherence (% sessions)	75.39±19.12	41.58±36.54	54.46±35.14***

Socio-demographic and clinical characteristics of participants retained for stress testing versus those lost to follow-up were compared to evaluate if there was a retention bias in the sample, using t-tests and chi-square as appropriate.

*T-test or chi-square p<.05; **p<.01; ***p<.001

§n=144 participants completed the baseline sociodemographic survey. Some participants did not respond to certain items, and therefore due to missing data valid percentages are reported.

CPET (CardioPulmonary Exercise Test); PCI (Percutaneous Coronary Intervention); ACS (Acute Coronary Syndrome); CAD (Coronary Artery Disease); MI (Myocardial Infarction); CABG (Coronary Artery Bypass Graft); PAD/PVD (Peripheral Vascular Disease/Peripheral Arterial Disease)

Table 9. Participant Characteristics by Retention Status – Post–Program Survey

Characteristics	Retained	Lost to Follow-Up	Total
	N=116 (68.6%)	N=53 (31.4%)	N=169
Socio-demographic[§]			
Age, years (mean±SD)	64.79±9.57	61.10±11.80	63.64±10.42*
Marital Status, n (% married)	50 (47.6%)	22 (56.4%)	72 (50.0%)
Work Status, n (% retired)	56 (53.3%)	16 (41.0%)	72 (50.0%)
Ethnicity, n (% white)	65 (61.9%)	25 (64.1%)	90 (62.5%)
Education, n (% post-secondary)	40 (38.1%)	14 (35.9%)	54 (37.5%)
Gross Annual Family Income (% <$50,000 CDN)	47 (50.0%)	11 (35.5%)	58 (46.4%)
Provide care to someone in household, n (% yes)	6 (9.1%)	10 (37.0%)	16 (17.2%)**
Have children, n (% yes)	88 (85.4%)	32 (84.2%)	120 (85.1%)
Clinical (% yes)			
Indication for CR			
PCI	56 (49.1%)	25 (49.0%)	81 (49.1%)
Angina/ACS/CAD	37 (33.0%)	22 (43.1%)	59 (36.2%)
MI	40 (35.4%)	19 (36.5%)	59 (35.8%)
CABG	29 (25.4%)	13 (25.5%)	42 (25.5%)
Valve	26 (23.0%)	6 (11.5%)	32 (19.4%)
Risk Factors			
Dyslipidemia	70 (84.3%)	34 (81.0%)	104 (83.2%)
Hypertension	68 (73.1%)	33 (80.5%)	101 (75.4%)
Obesity	35 (44.9%)	14 (36.8%)	49 (42.2%)
Diabetes	23 (28.7%)	15 (42.9%)	38 (33.0%)
Comorbidities			
Musculoskeletal Impairment	14 (15.9%)	6 (13.6%)	20 (15.2%)
Depression	10 (11.4%)	5 (11.6%)	15 (11.5%)
Cancer	6 (6.7%)	2 (4.9%)	8 (6.2%)
Hyperthyroid	4 (4.5%)	2 (4.8%)	6 (4.6%)
Renal Disease	2 (2.3%)	2 (4.8%)	4 (3.1%)
PAD/PVD	1 (1.1%)	1 (2.4%)	2 (1.5%)
Intake Assessment			
Resting Heart Rate (bpm)	75.15±14.80	76.38±15.73	75.54±15.06
Waist Circumference (cm)	92.53±12.95	97.28±16.42	94.15±14.34
Peak VO_2 (mL/(kg•min))	18.10±7.29	16.59±6.17	17.62±6.97
CR Utilization			
Adherence (% sessions)	62.54±33.22	35.66±32.49	54.46±35.14***

Socio-demographic and clinical characteristics of participants returning a post-program survey versus those lost to follow-up were compared to evaluate if there was a retention bias in the sample, using t-tests and chi-square as appropriate.

*T-test or chi-square p<.05; **p<.01; ***p<.001

§n=144 participants completed the baseline sociodemographic survey. Some participants did not respond to certain items, and therefore due to missing data valid percentages are reported.

PCI (Percutaneous Coronary Intervention); ACS (Acute Coronary Syndrome); CAD (Coronary Artery Disease); MI (Myocardial Infarction); CABG (Coronary Artery Bypass Graft); PAD/PVD (Peripheral Vascular Disease/Peripheral Arterial Disease)

Table 10. Participant Characteristics by Retention Status – Post–Program Pedometer

Characteristics	Pedometer	No pedometer	Total
	n=55 (32.5%)	n=114 (67.5%)	n=169
Socio-demographic[§]			
Age, years (mean±SD)	66.39±9.55	62.29±10.61	63.64±10.42*
Marital Status, n (% married)	30 (56.6%)	42 (46.2%)	72 (50.0%)
Work Status, n (% retired)	30 (56.6%)	42 (46.2%)	72 (50.0%)
Ethnicity, n (% white)	35 (66.0%)	55 (60.4%)	90 (62.5%)
Education, n (% post-secondary)	22 (41.5.0%)	32 (35.2%)	54 (37.5%)
Gross Annual Family Income (% <$50,000 CDN)	18 (34.0%)	40 (44.0%)	86 (59.7%)
Provide care to someone in household, n	3 (8.6%)	13 (22.4%)	16 (17.2%)
Have children, n	48 (90.6%)	72 (81.8%)	120 (85.1%)
Clinical			
Indication for CR			
PCI	23 (42.6%)	58 (52.3%)	81 (49.1%)
Angina/ACS/CAD	14 (26.9%)	45 (40.5%)	59 (36.2%)
MI	21 (39.6%)	38 (33.9%)	59 (35.8%)
CABG	12 (22.2%)	30 (27.0%)	42 (25.5%)
Valve	15 (28.3%)	17 (15.2%)	32 (19.4%)
Risk Factors			
Dyslipidemia	31 (79.5%)	73 (84.9%)	104 (83.2%)
Hypertension	30 (73.2%)	71 (76.3%)	101 (75.4%)
Obesity	16 (42.1%)	33 (42.3%)	49 (42.2%)
Diabetes	10 (25.0%)	28 (37.3%)	38 (33.0%)
Comorbidities			
Musculoskeletal Impairment	8 (20.0%)	12 (13.0%)	20 (15.2%)
Depression	4 (10.0%)	11 (12.1%)	15 (11.5%)
Cancer	2 (4.9%)	6 (6.7%)	8 (6.2%)
Hyperthyroid	0 (0.0%)	6 (6.6%)	6 (4.6%)
Renal Disease	0 (0.0%)	4 (4.4%)	4 (3.1%)
PAD/PVD	0 (0.0%)	2 (2.2%)	2 (1.5%)
Liver Disease	1 (2.5%)	0 (0.0%)	1 (0.8%)
Intake Assessment			
Resting Heart Rate (BPM)	78.53±16.60	74.19±14.18	75.54±15.06
Waist Circumference (cm)	91.20±12.06	95.35±15.07	94.15±14.34
Peak VO_2 (mL/(kg•min)	19.65±7.58	16.72±6.52	17.62±6.97*
CR Utilization			
Adherence (% sessions)	62.97±33.29	48.53±34.74	54.46±35.14**

Sociodemographic and clinical characteristics of participants returning a post-program pedometer log versus those lost to follow-up were compared to evaluate if there was a retention bias in the sample, using t-tests and chi-square as appropriate.

*T-test or chi-square p<.05; **p<.01; ***p<.001

§n=144 participants completed the baseline sociodemographic survey. Some participants did not respond to certain items, and therefore due to missing data valid percentages are reported.

PCI (Percutaneous Coronary Intervention); ACS (Acute Coronary Syndrome); CAD (Coronary Artery Disease); MI (Myocardial Infarction); CABG (Coronary Artery Bypass Graft); PAD/PVD (Peripheral Vascular Disease/Peripheral Arterial Disease)

Table 11. Functional Capacity Indicators in Participants Completing CardioPulmonary Exercise Test Both Pre and Post-Program, N=58

VO_2 peak	Per Protocol			As-treated		
	Pre-CR	Post-CR	Change	Pre-CR	Post-CR	Change
Overall	16.34±4.66	19.23±5.14	2.89***			
Mixed-sex	15.50±3.39	19.40±4.97	3.91**	15.76±4.04	19.11±5.18	3.35***
Women-only	17.29±3.91	19.54±4.70	2.26**	18.01±5.94	20.07±5.53	2.06*
Home-based	16.05±6.52	18.63±6.11	2.58**	14.92±3.01	17.32±3.67	2.40

Assessment of change in functional capacity from pre to post-test was conducted using paired t-tests; *p<.05; **p<.01; ***p<.001

Table 12. Categories of Medications Reported by Participants Pre and Post-CR

	Per Protocol		As-treated	
	Pre-CR	Post-CR	Pre-CR	Post-CR
Lipid Lowering-Statins	109 (81.3%)	89 (78.8%)	-	-
Mixed-sex	35 (74.5%)	30 (73.2%)	47 (82.5%)	36 (72.0%)
Women-only	33 (80.5%)	28 (75.7%)	28 (82.4%)	23 (76.7%)
Home-based	41 (89.1%)	31 (88.6%)	18 (81.8%)	16 (94.1%)
Did not start	-	-	16 (76.2%)	14 (87.5%)
ASA – Aspirin	107 (79.9%)	84 (73.7%)	-	-
Mixed-sex	37 (78.7%)	28 (68.3%)	45 (78.9%)	36 (70.6%)
Women-only	33 (80.5%)	31 (81.6%)	29 (85.3%)	26 (86.7%)
Home-based	37 (80.4%)	25 (71.4%)	18 (81.8%)	12 (70.6%)
Did not start	-	-	15 (71.4%)	10 (62.5%)
Beta-Blockers	92 (68.7%)	72 (63.2%)	-	-
Mixed-sex	34 (72.3%)	27 (65.9%)	37 (64.9%)	28 (54.9%)
Women-only	26 (63.4%)	24 (63.2%)	24 70.6%)	22 (73.3%)
Home-based	32 (69.6%)	21 (60.0%)	17 (77.3%)	13 (76.5%)
Did not start	-	-	14 (66.7%)	9 (56.3%)
Antiplatelets	70 (52.2%)	40 (35.4%)	-	-
Mixed-sex	25 (53.2%)	17 (42.5%)	33 (57.9%)	22 (44.0%)
Women-only	23 (56.1%)	12 (31.6%)	15 (44.1%)	7 (23.3%)
Home-based	22 (47.8%)	11 (31.4%)	12 (54.5%)	5 (29.4%)
Did not start	-	-	10 (47.6%)	6 (37.5%)
ACE Inhibitors	53 (40.2%)	51 (44.7%)	-	-
Mixed-sex	16 (34.0%)	17 (41.5%)	24 (42.9%)	25 (49.0%)
Women-only	16 (40.0%)	15 (39.5%)	11 (32.4%)	10 (33.3%)
Home-based	21 (46.7%)	19 (54.3%)	11 (50.0%)	10 (58.8%)
Did not start	-	-	7 (35.0%)	6 (37.5%)
Diuretics	27 (20.3%)	22 (19.5%)	-	-
Mixed-sex	8 (17.0%)	6 (15.0%)	11 (19.3%)	8 (16.0%)
Women-only	10 (25.0%)	7 (18.4%)	10 (30.3%)	8 (26.7%)
Home-based	9 (19.6%)	9 (25.7%)	4 (18.2%)	4 (23.5%)
Did not start	-	-	2 (9.5%)	2 (12.5%)
Psychoactives	22 (16.4%)	29 (25.4%)	-	-
Mixed-sex	7 (14.9%)	13 (31.7%)	11 (19.3%)	18 (35.3%)
Women-only	5 (12.2%)	8 (21.1%)	5 (14.7%)	4 (13.3%)
Home-based	10 (21.7%)	8 (22.9%)	4 (18.2%)	4 (23.5%)
Did not start	-	-	2 (9.5%)	3 (18.8%)
Anticoagulants	22 (16.8%)	21 (18.6%)	-	-
Mixed-sex	6 (12.8%)	8 (20.0%)	7 (12.3%)	8 (16.0%)
Women-only	7 (17.9%)	4 (10.5%)	6 (18.2%)	4 (13.3%)
Home-based	9 (20.0%)	9 (25.7%)	6 (28.6%)	5 (29.4%)
Did not start	-	-	3 (15.0%)	4 (25.0%)
Angiotensin II Receptor Blockers	22 (16.4%)	19 (16.7%)	-	-
Mixed-sex	7 (14.9%)	8 (19.5%)	10 (17.5%)	10 (19.6%)
Women-only	5 (12.2%)	4 (10.5%)	4 (11.8%)	4 (13.3%)
Home-based	10 (21.7%)	7 (20.0%)	4 (18.2%)	2 (11.8%)
Did not start	-	-	4 (19.0%)	3 (18.8%)
Calcium Antagonists	20 (15.0%)	15 (13.2%)	-	-
Mixed-sex	4 (8.5%)	6 (14.6%)	8 (14.0%)	8 (15.7%)
Women-only	9 (22.5%)	4 (10.5%)	7 (21.2%)	3 (10.0%)
Home-based	7 (15.2%)	5 (14.3%)	2 (9.1%)	0 (0.0%)
Did not start	-	-	3 (14.3%)	4 (25.0%)
Nitrates	11 (8.2%)	11 (9.6%)	-	-

Mixed-sex	5 (10.6%)	6 (14.6%)	10 (17.5%)	7 (13.7%)
Women-only	2 (4.9%)	3 (7.9%)	0 (0.0%)	3 (10.0%)
Home-based	4 (8.7%)	2 (5.7%)	1 (4.5%)	1 (5.9%)
Did not start	-	-	0 (0.0%)	0 (0.0%)
Insulin	8 (6.0%)	5 (4.4%)	-	-
Mixed-sex	5 (10.6%)	5 (12.2%)	6 (10.5%)	4 (7.8%)
Women-only	1 (2.4%)	0 (0.0%)	1 (2.9%)	0 (0.0%)
Home-based	2 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Did not start	-	-	1 (4.8%)	1 (6.3%)
Oral Hypoglycemics	4 (3.0%)	12 (10.5%)	-	-
Mixed-sex	1 (2.2%)	5 (12.2%)	2 (3.4%)	5 (9.8%)
Women-only	2 (4.8%)	4 (10.5%)	1 (2.9%)	2 (6.7%)
Home-based	1 (2.2%)	3 (8.6%)	0 (0.0%)	2 (11.8%)
Did not start	-	-	1 (5.0%)	3 (18.8%)
Digoxin	4 (3.0%)	2 (1.8%)	-	-
Mixed-sex	3 (6.4%)	2 (4.9%)	3 (5.3%)	2 (3.9%)
Women-only	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Home-based	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Did not start	-	-	1 (4.8%)	0 (0.0%)
Antiarrhythmics	4 (3.0%)	0 (0.0%)	-	-
Mixed-sex	2 (4.3%)	0 (0.0%)	2 (3.5%)	0 (0.0%)
Women-only	0 (0.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)
Home-based	2 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Did not start	-	-	1 (4.8%)	0 (0.0%)
Prescribed Antismoking Medications	2 (1.5%)	2 (1.8%)	-	-
Mixed-sex	2 (4.3%)	1 (2.4%)	2 (3.5%)	1 (2.0%)
Women-only	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)
Home-based	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Did not start	-	-	0 (0.0%)	1 (6.3%)

Some participants did not respond to certain items, and therefore due to missing data valid percentages are reported.

Table 13. Mean (± standard deviation) Diet Habit Survey Sub-Category Scores in Participants Pre and Post-CR

	Per Protocol			As-treated		
	Pre-CR	Post-CR	Change	Pre-CR	Post-CR	Change
Meat, Fish, and Poultry	17.98±5.18	18.78±4.33	0.81	-	-	-
Mixed-sex	17.39±5.38	18.16±4.29	0.77	17.14±5.11	18.47±4.24	1.33
Women-only	18.58±5.53	19.14±4.70	0.56	19.47±4.67	19.68±5.11	0.21
Home-based	17.94±4.60	19.09±4.01	1.14	18.04±4.65	18.47±3.97	0.43
Did not start	-	-	-	17.47±6.96	18.28±3.27	0.81
Dairy Products and Eggs	22.39±6.60	23.31±6.23	0.92	-	-	-
Mixed-sex	21.34±7.14	22.08±6.42	0.73	21.90±7.11	23.29±7.00	1.40
Women-only	22.71±5.92	22.71±6.03	-.0059	23.19±5.34	23.39±5.44	0.21
Home-based	23.26±6.72	25.42±5.87	2.17	21.85±6.50	23.30±5.77	1.45
Did not start	-	-	-	23.22±8.06	23.23±6.31	0.0091
Fats and Oils	19.08±4.57	19.93±4.13	0.85	-	-	-
Mixed-sex	18.13±5.11	19.03±4.25	0.91	18.23±5.03	19.12±4.19	0.89
Women-only	19.40±3.96	20.17±4.34	0.77	20.25±4.12	21.28±4.44	1.03
Home-based	19.85±4.45	20.73±3.67	0.87	18.76±4.29	20.01±3.32	1.24
Did not start	-	-	-	20.18±3.64	19.82±3.88	-0.36
Sweets and Snacks	10.23±3.38	10.61±3.46	0.39	-	-	-
Mixed-sex	10.08±3.56	10.29±3.66	0.21	9.49±3.71	10.22±3.68	0.73
Women-only	10.24±3.24	10.88±3.22	0.64	11.04±2.79	10.98±3.35	-.059
Home-based	10.38±3.41	10.70±3.57	0.32	10.19±2.59	10905±3.30	0.71
Did not start	-	-	-	11.22±3.70	10.85±3.36	-0.38
Grains, Beans, Fruits, and Vegetables	58.23±25.60	60.02±22.87	1.79	-	-	-
Mixed-sex	57.21±25.20	60.02±19.48	2.81	62.40±30.64	62.53±20.77	0.13
Women-only	55.11±25.51	57.61±21.37	2.50	52.70±16.87	58.89±22.11	6.19
Home-based	62.84±26.33	62.66±26.00	-0.17	63.33±22.55	58.55±29.11	-4.78
Did not start	-	-	-	47.37±22.47	54.91±24.31	7.54
Beverages	13.48±2.33	13.26±2.69	0.22	-	-	-
Mixed-sex	13.40±1.99	12.80±3.06	-0.60	13.71±2.22	12.89±3.18	-0.82
Women-only	13.32±2.57	13.50±2.47	0.18	12.79±2.44	13.29±1.86	0.50
Home-based	13.73±2.48	13.50±2.49	-0.23	13.68±2.52	13.85±2.03	0.18
Did not start	-	-	-	14.00±2.11	13.80±3.26	-0.20
Salt	16.52±4.41	17.63±5.08	1.11*	-	-	-
Mixed-sex	16.56±4.67	18.14±5.22	1.58*	17.08±4.53	18.59±5.43	1.51*
Women-only	15.51±3.83	16.63±4.34	1.12	16.50±4.16	17.20±4.94	0.70
Home-based	17.58±4.57	18.15±5.65	0.56	17.00±4.39	16.94±4.52	-.059
Did not start	-	-	-	13.55±3.88	15.91±4.61	2.36
Restaurants and Recipes	35.62±4.24	34.13±5.76	-1.49*	-	-	-
Mixed-sex	36.17±4.26	34.40±6.45	-1.76	36.44±4.31	34.23±6.27	-2.21*
Women-only	35.12±3.78	33.06±4.80	-2.06	34.96±4.13	34.05±4.66	-0.91
Home-based	35.55±4.75	35.00±5.88	-0.55	34.41±4.08	33.91±6.38	-0.50
Did not start	-	-	-	35.82±4.33	34.27±5.90	-1.55
Seafood	6.77±2.09	7.12±2.05	0.35	-	-	-
Mixed-sex	6.49±2.38	6.68±2.44	0.19	6.59±2.28	6.96±2.34	0.37
Women-only	7.07±1.63	7.11±1.78	0.044	7.33±1.28	7.67±1.35	0.35
Home-based	6.75±2.20	7.63±1.75	0.88**	6.71±2.17	7.40±2.06	0.69*
Did not start	-	-	-	6.14±2.74	5.86±1.87	-0.27

Assessment of change from pre to post-CR was conducted using paired t-tests; *p<.05; **p<.01

Table 14. Mean (± standard deviation) Health Behavior Scores in Participants Pre and Post-CR

	Per Protocol			As-treated		
	Pre-CR	Post-CR	Change	Pre-CR	Post-CR	Change
Step counts	5443±2875	6108±3762	666	-	-	-
Mixed-sex	6339±2870	6022±2960	-317	5772±2799	5873±2797	101
Women-only	4429±2327	5240±3106	811	5391±2675	6290±3055	900
Home-based	5888±3317	7273±4984	1384	6074±3480	7803±5793	1728
Did not start	-	-	-	3184±2263	2998±2670	-186
GLTEQ score	21.98±17.85	30.42±19.28	8.44***	-	-	-
Mixed-sex	19.81±15.19	31.15±21.71	11.34**	20.12±16.84	30.16±20.86	10.04*
Women-only	19.38±16.61	29.85±20.03	10.47**	22.38±17.56	33.58±19.26	11.19**
Home-based	28.65±21.65	30.19±14.76	1.54	30.38±21.22	28.53±15.33	-1.84
Did not start	-	-	-	15.67±14.32	26.92±20.25	11.25
Diet Habit Survey total score	198.46±37.37	204.46±28.97	6.00	-	-	-
Mixed-sex	196.71±34.11	201.05±28.10	4.34	202.78±38.35	206.00±30.32	3.22
Women-only	192.07±42.15	200.74±24.20	8.67	198.31±24.72	205.66±27.50	7.35*
Home-based	207.72±34.52	212.63±33.78	4.91	203.98±22.00	203.33±30.00	-0.64
Did not start	-	-	-	174.84±63.30	197.50±28.19	22.66
MMAS-4 score	3.69±0.74	3.60±0.72	-0.082	-	-	-
Mixed-sex	3.53±0.95	3.50±0.88	-0.031	3.73±0.61	3.62±0.72	-0.11
Women-only	3.74±0.59	3.74±0.53	0.00	3.73±0.63	3.73±0.55	0.00
Home-based	3.81±0.56	3.59±0.69	-0.22	3.78±0.65	3.56±0.70	-0.22
Did not start	-	-	-	3.22±1.39	3.33±1.12	0.11
Smoking (n, % current)	7 (6.7%)	6 (5.8%)	1 (1.0%)	-	-	-
Mixed-sex	3 (7.9%)	3 (7.9%)	0	3 (6.8%)	2 (4.5%)	1 (2.3%)
Women-only	2 (5.9%)	1 (2.9%)	1 (2.9%)	0	1 (3.6%)	1 (3.6%)
Home-based	2 (6.3%)	2 (6.3%)	0	2 (11.1%)	2 (11.1%)	0
Did not start	-	-	-	2 (14.3%)	1 (7.1%)	1 (7.1%)

Assessment of change in daily steps, GLTEQ scores, Diet Habit Survey scores, and MMAS-4 scores from pre to post-CR was conducted using paired t-tests, and smoking using McNemar's test; *p<.05; **p<.01; ***p<.001

GLTEQ (Godin Leisure Time Exercise Questionnaire); MMAS-4 (Morisky Medication Adherence Scale)

Table 15. Mean (± standard deviation) Health Behaviour Scores in Participants Pre and Post-CR – Enrolees Only

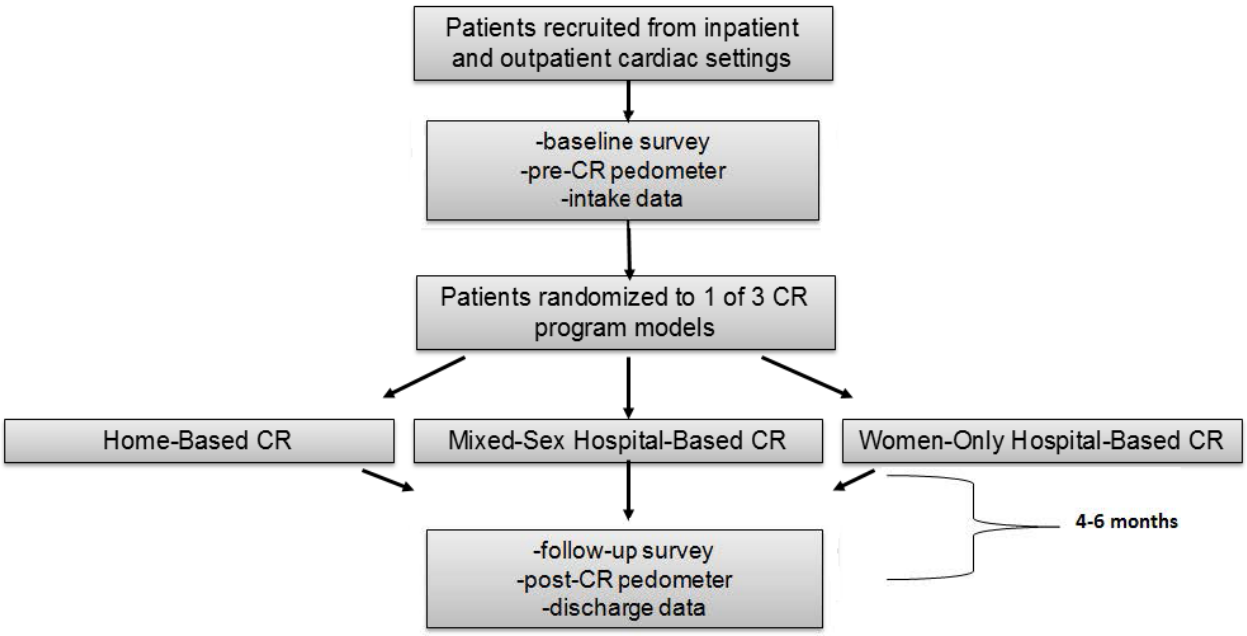
	Per Protocol		
	Pre-CR	Post-CR	Change
VO_2 peak	16.33±4.74	19.12±5.17	2.80***
Mixed-sex	15.38±3.33	19.31±4.85	3.93**
Women-only	17.29±3.91	19.54±4.70	2.26**
Home-based	16.21±6.59	18.44±6.18	2.23**
Step counts	5488.96±2938.77	6296.75±3776.60	807.79
Mixed-sex	6339.42±2870.35	6022.13±2959.79	-317.29
Women-only	4490.32±2402.23	5230.28±3131.44	939.96
Home-based	5909.49±3478.52	7674.14±5019.02	1764.65
GLTEQ score	22.34±18.03	30.62±18.91	8.28***
Mixed-sex	19.45±15.20	30.43±22.18	9.89**
Women-only	19.95±16.77	29.84±19.18	10.98**
Home-based	29.66±21.71	31.98±13.71	2.32
Diet Habit Survey total score	200.79 ±31.30	204.45±29.10	3.66
Mixed-sex	194.47±34.49	198.37±27.53	3.90
Women-only	196.63±26.78	200.87±24.41	4.23
Home-based	212.49±30.17	215.22±33.78	2.72
MMAS-4 score	3.70±0.74	3.62±0.69	-0.076
Mixed-sex	3.54±0.96	3.54±0.79	0.00
Women-only	3.76±0.60	3.76±0.52	0.00
Home-based	3.81±0.57	3.59±0.70	-0.23

Assessment of change in functional capacity, daily steps, , GLTEQ scores, Diet Habit Survey scores, and MMAS-4 scores from pre to post-CR was conducted using paired t-tests; *p<.05; **p<.01; ***p<.001

GLTEQ (Godin Leisure Time Exercise Questionnaire); MMAS-4 (Morisky Medication Adherence Scale)

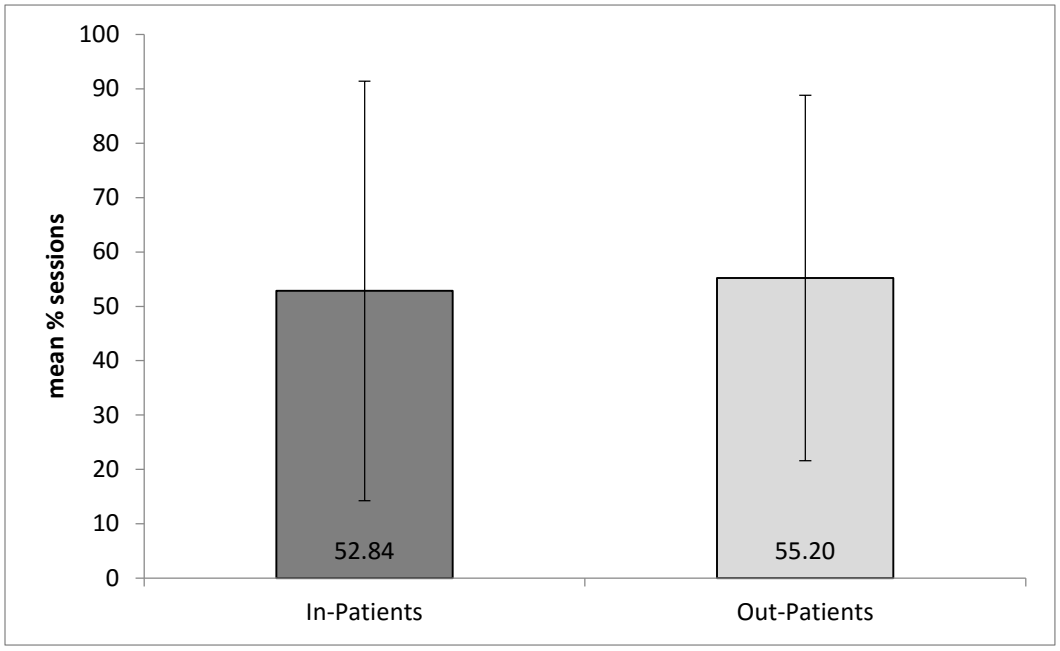
FIGURES

Figure 2. CR4HER Trial Overview



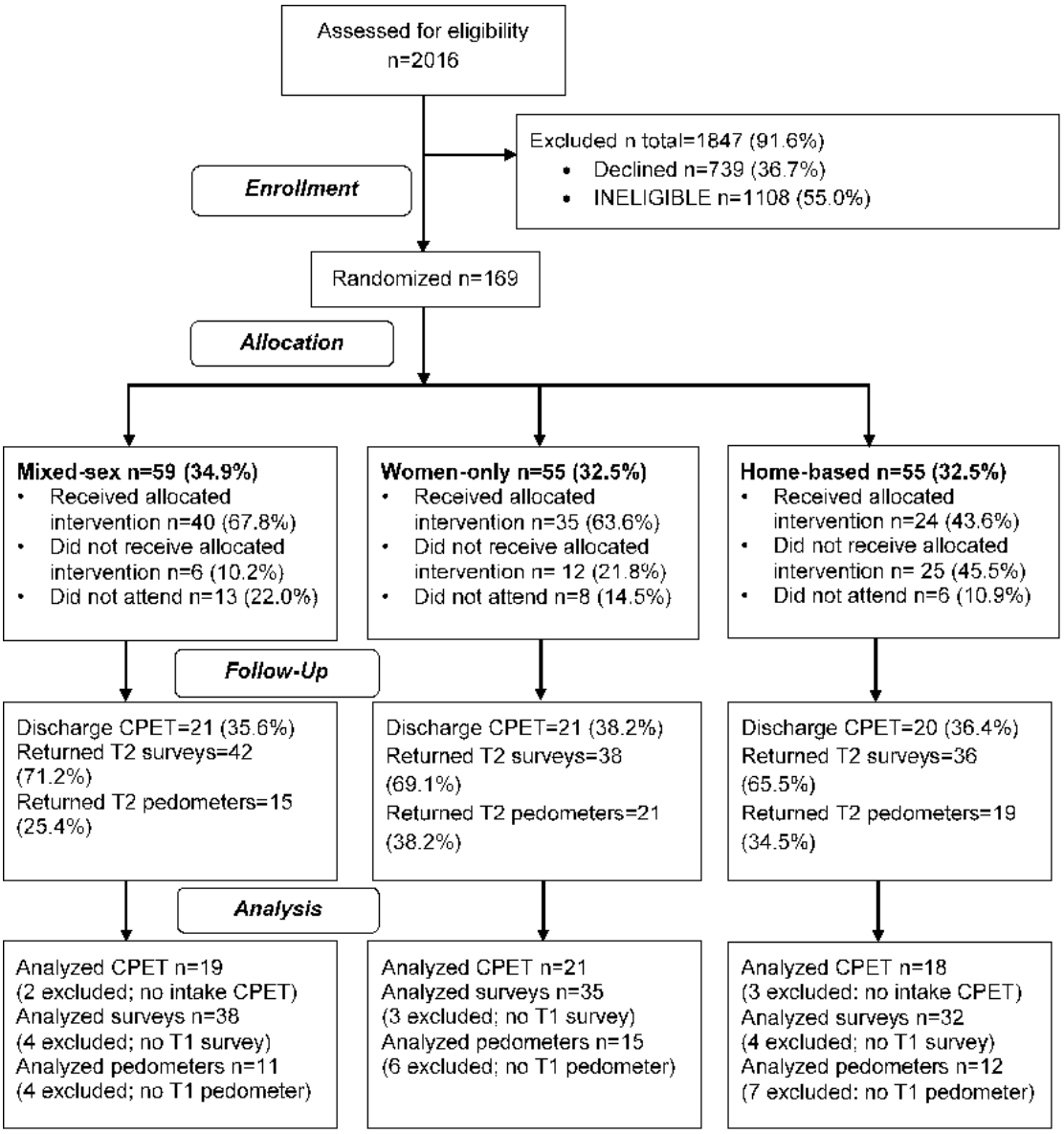
CR4HER was a 3 parallel arm pragmatic RCT designed to compare CR program adherence to traditional hospital-based CR with males and females, home-based CR, and women-only hospital-based CR. The trial was registered on ClinicalTrials.gov (identifier number: NCT01019135).

Figure 3. CR Adherence by Study Participant Recruitment Type



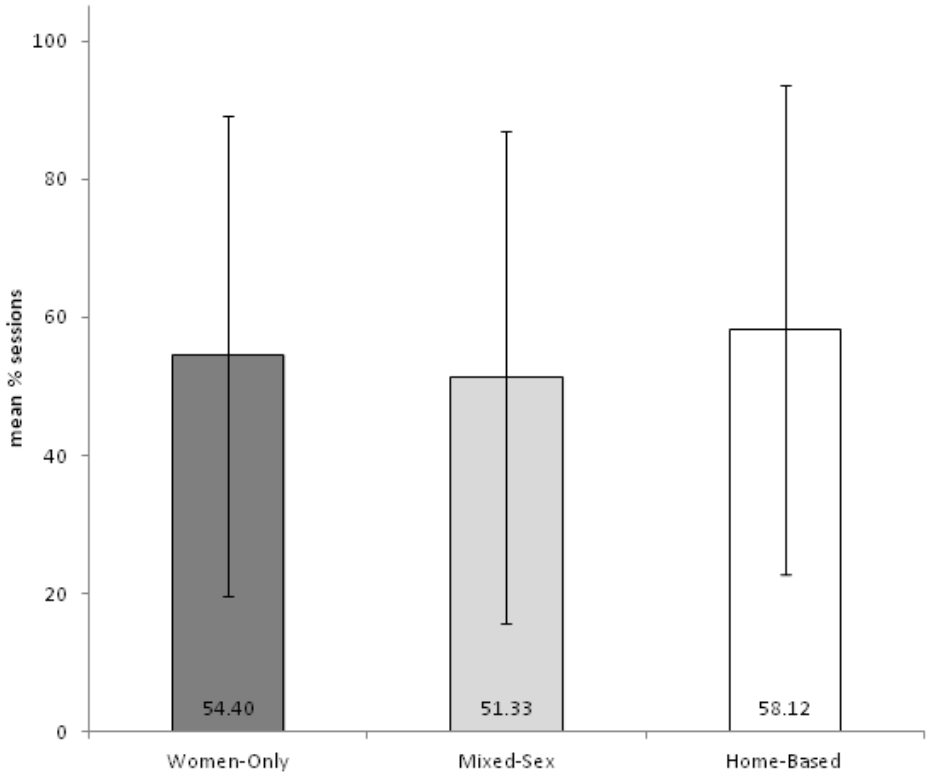
No significant difference between participants recruited as in-patients versus out-patients using t-test; p=.70

Figure 4. CR4HER Study Flow Diagram



"Did not attend" includes both patients who did not enrol post-referral, as well as those who enrolled (i.e., attended an intake assessment) but then did not partake in at least some of the CR intervention components.

Figure 5a. CR Adherence by Program Model (PP), N=153

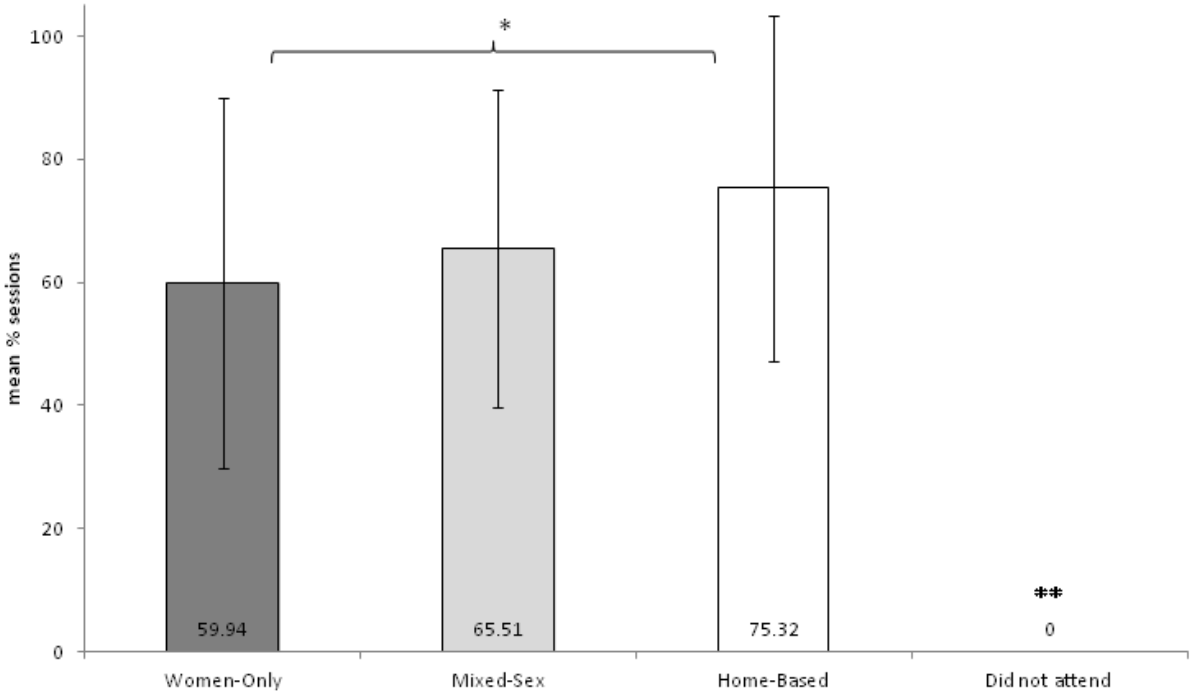


No significant difference between participants randomized to different CR program models using ANOVA.

Overall model p=.63, observed power=.12

Error bars represent standard deviation.

Figure 5b. CR Adherence by Program Model (As-Treated), N=153

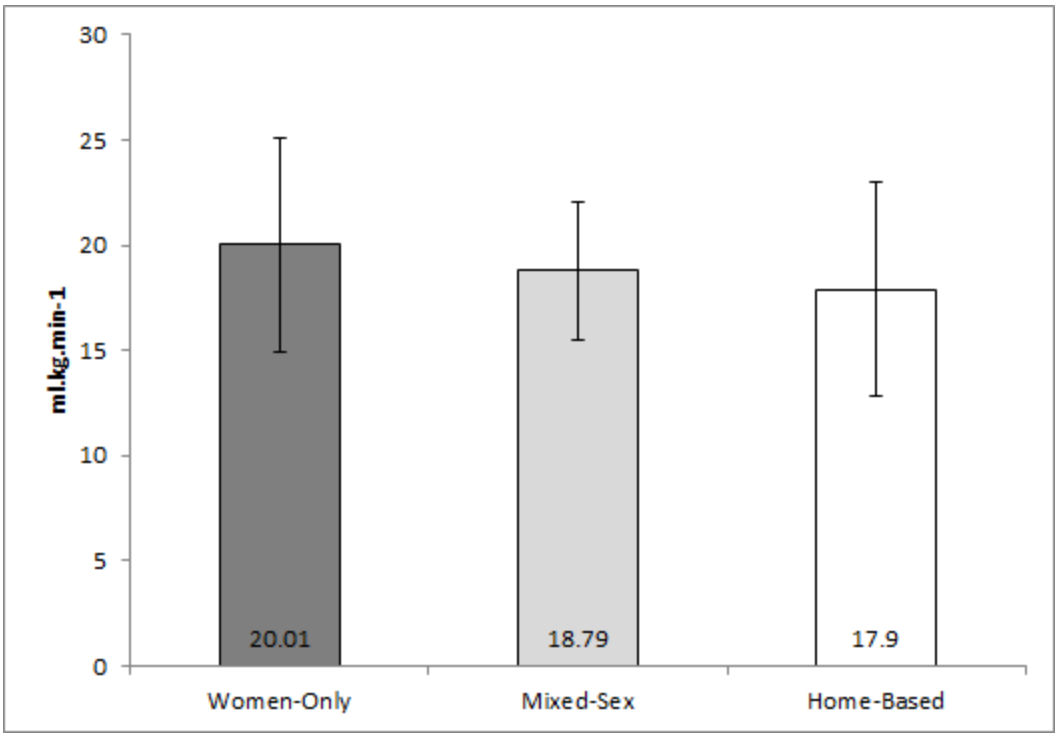


Difference in mean program adherence between home-based vs. women-only is 15.38%. Denotes significant difference between participants attending different CR program models using ANOVA (LSD post-hoc test); *p<.05; **p<.001

Overall model p<.001, observed power=1.00

Error bars represent standard deviation.

Figure 6a. Post-CR Peak VO_2 by Program Model (PP), N=58

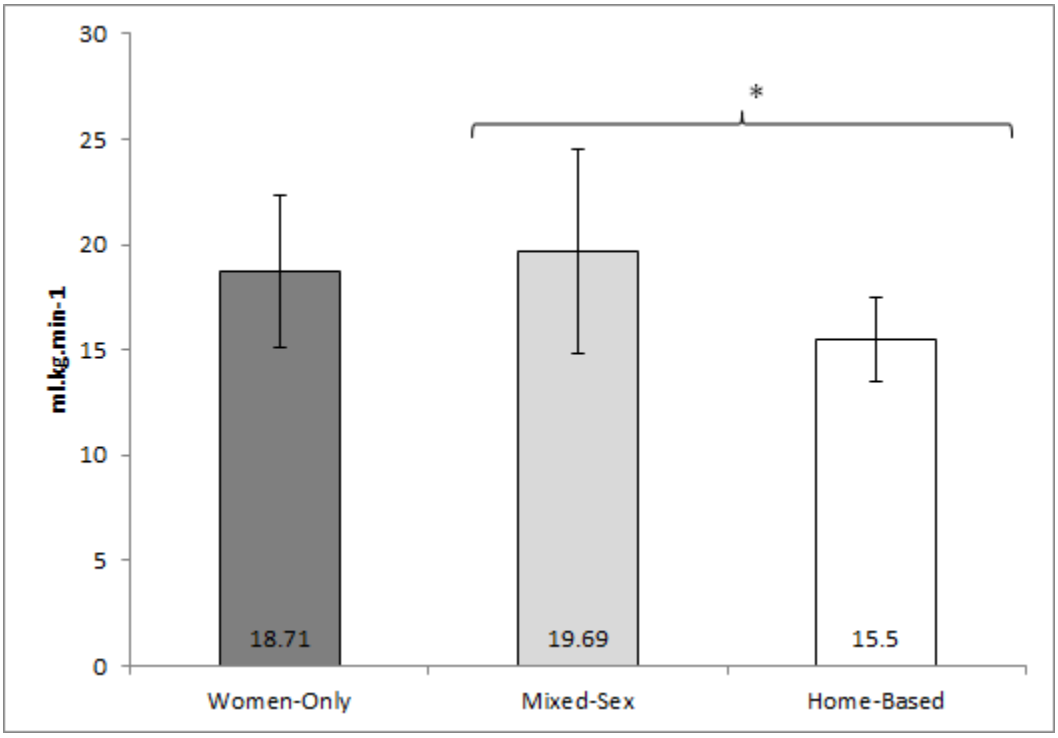


No significant difference in estimated marginal means between participants randomized to different CR program models using ANCOVA adjusting for dyslipidemia, musculoskeletal impairment, resting heart rate, waist circumference, and baseline peak VO_2.

Overall model p=.84, observed power=.074

Error bars represent standard deviation.

Figure 6b. Post-CR Peak VO_2 by Program Model (As-Treated), N=58

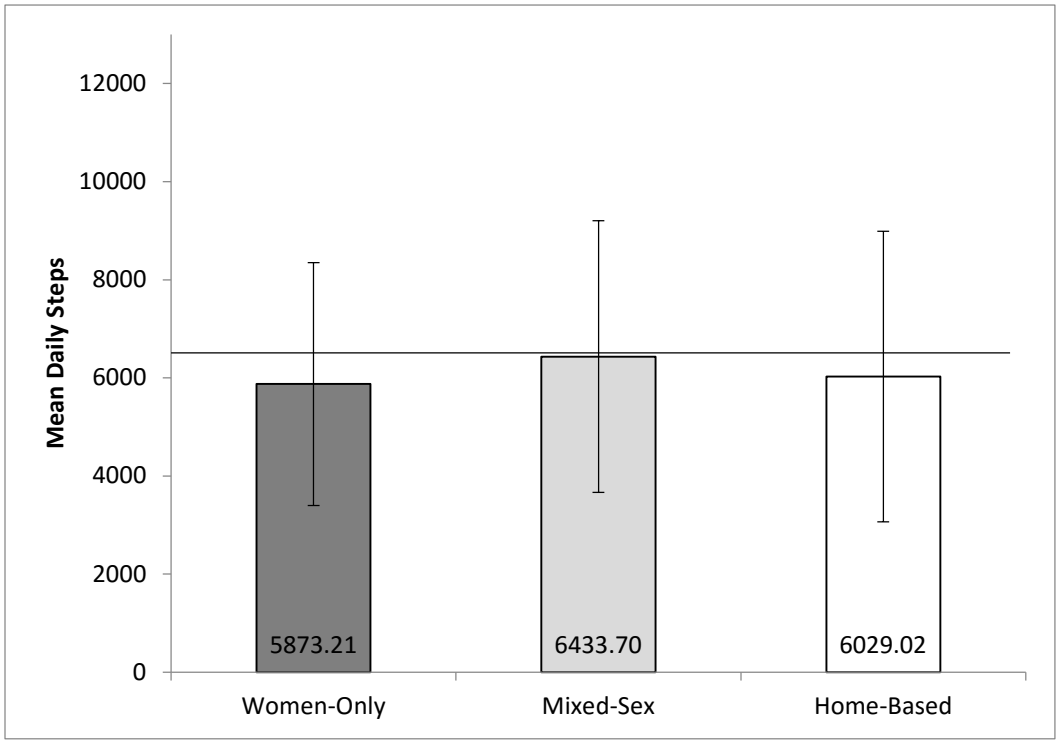


Difference in estimated marginal means post-CR peak VO_2 between home-based vs. mixed-sex is 4.19. Denotes significant difference between participants attending different CR program models using ANCOVA adjusting for dyslipidemia, musculoskeletal impairment, resting heart rate, waist circumference, and baseline peak VO_2. (LSD post-hoc test); *p<.05

Overall model p<.05, observed power=.60

Error bars represent standard deviation.

Figure 7a. Post-CR Pedometer Step Counts by Program Model (PP)

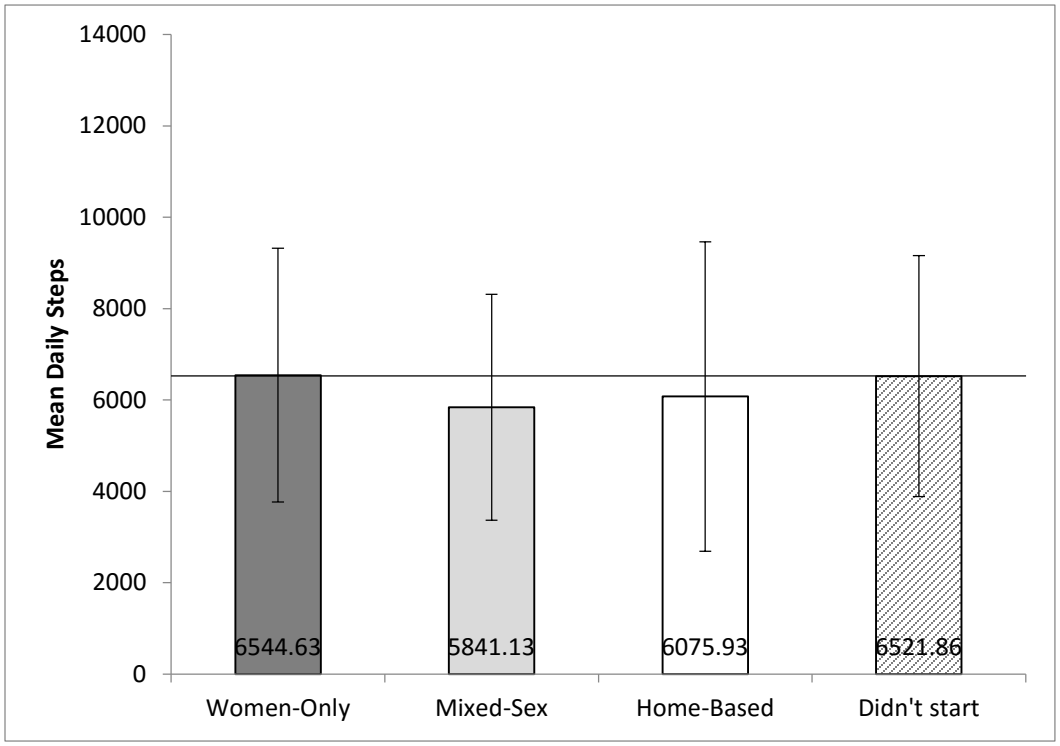


No significant difference in estimated marginal means between participants randomized to different CR program models using ANCOVA adjusting for age, intake peak VO_2, CR program adherence, and baseline CR pedometer step counts.

Overall model p=.98, observed power=.05

Error bars represent standard deviation, and the horizontal line represents ≥6,500 steps/day which are recommended for patients with chronic diseases to achieve the total amount of physical activity energy expenditure generally recommended for secondary prevention.

Figure 7b. Post-CR Pedometer Step Counts by Program Model (As-Treated)

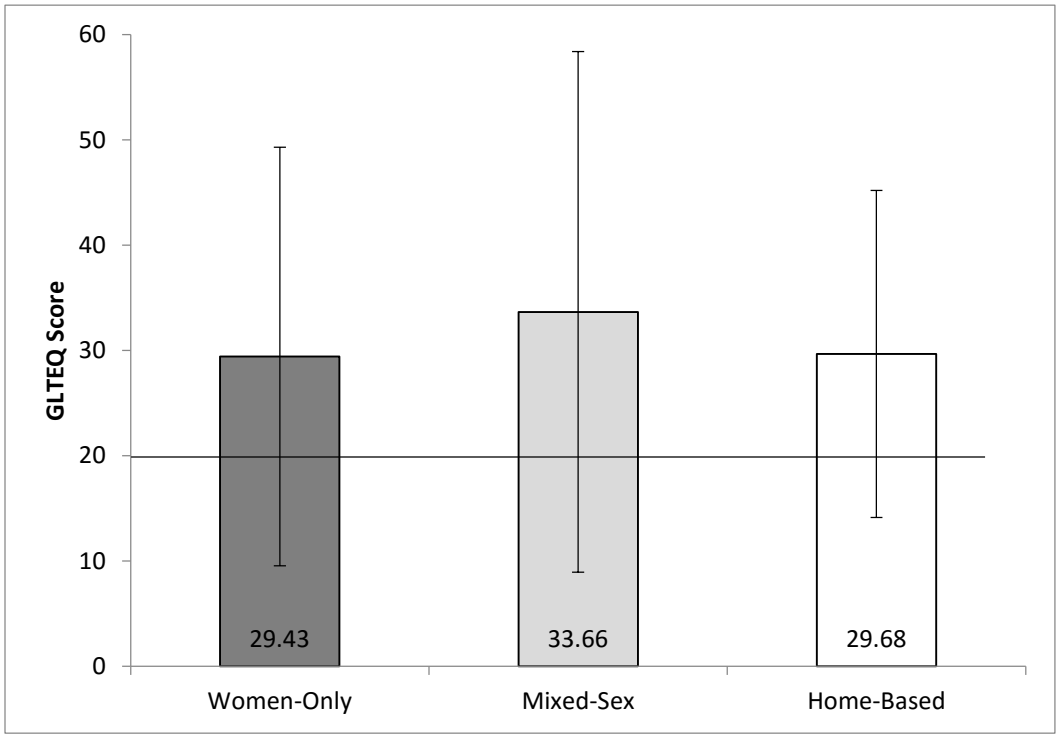


No significant difference in estimated marginal means between participants attending different CR program models using ANCOVA adjusting for age, intake peak VO_2, CR program adherence, and baseline CR pedometer step counts.

Overall model p=.75, observed power=.12

Error bars represent standard deviation, and the horizontal line represents ≥6,500 steps/day which are recommended for patients with chronic diseases to achieve the total amount of physical activity energy expenditure generally recommended for secondary prevention.

Figure 8a. Post-CR Self-Reported Physical Activity by Program Model (PP)

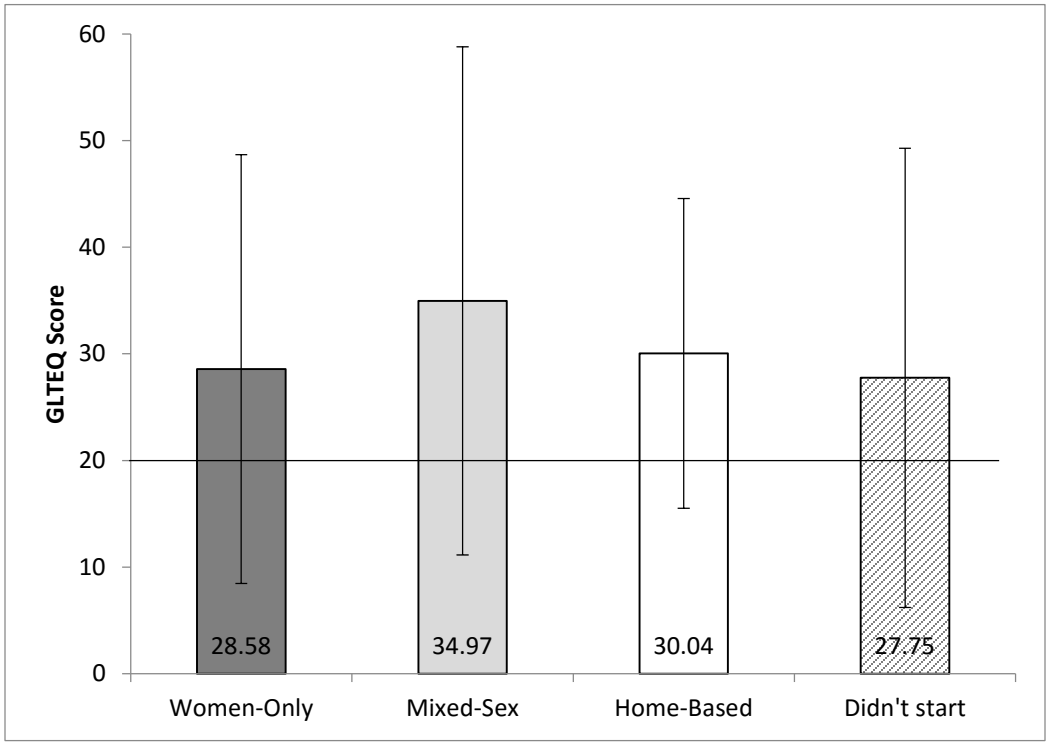


No significant difference in estimated marginal means between participants randomized to different CR program models using ANCOVA adjusting for age, caregiving duties, CR program adherence, and baseline self-reported physical activity.

Overall model p=.42, observed power=.20

Error bars represent standard deviation, and the horizontal line represents scores ≥20 which are indicative of someone who is 'active".

Figure 8b. Post-CR Self-Reported Physical Activity by Program Model (As-Treated)

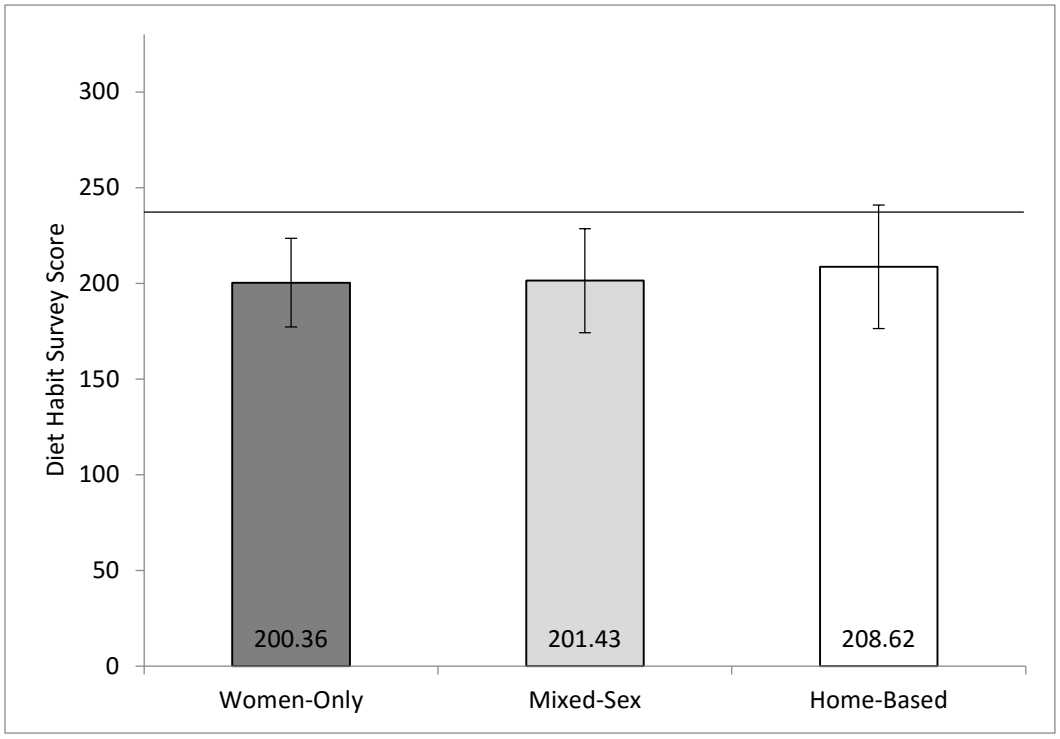


No significant difference in estimated marginal means between participants attending different CR program models using ANCOVA adjusting for age, caregiving duties, CR program adherence, and baseline self-reported physical activity.

Overall model p=.47, observed power=.22

Error bars represent standard deviation, and the horizontal line represents scores ≥20 which are indicative of someone who is 'active".

Figure 9a. Post-CR Diet Habit Survey Score by Program Model (PP)

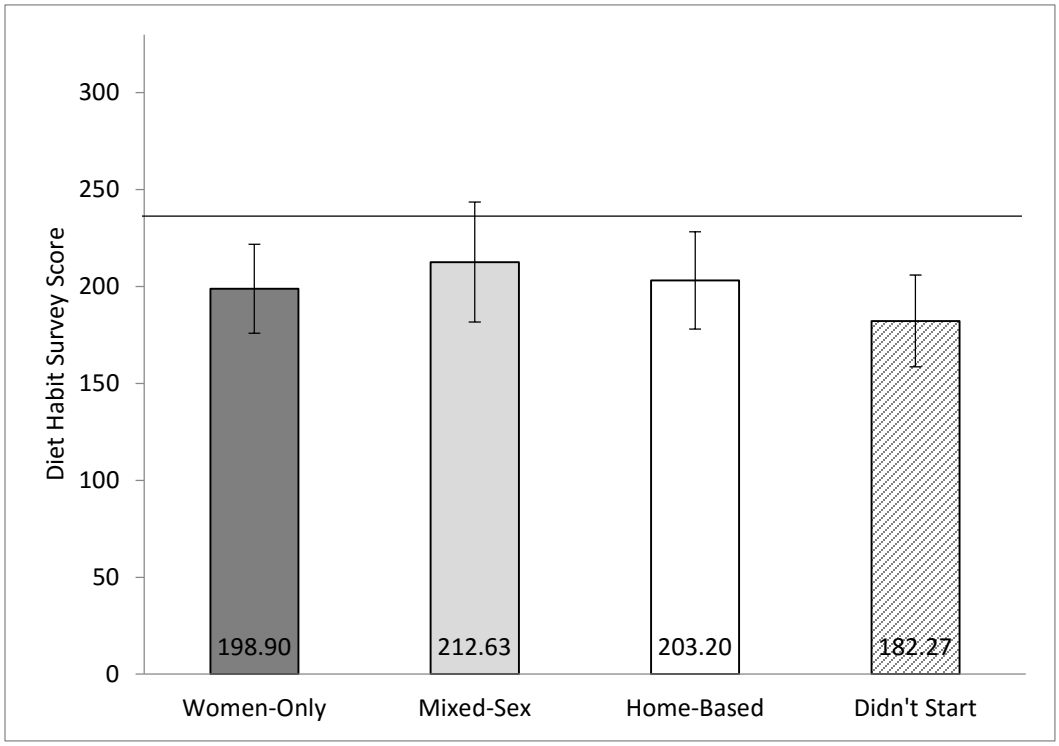


No significant difference in estimated marginal means between participants randomized to different CR program models using ANCOVA adjusting for age, caregiving duties, CR program adherence, and baseline Diet Habit Survey score.

Overall model p=.51, observed power=.16

Error bars represent standard deviation, and the horizontal line represents scores ≥236 which corresponds to a low-fat diet (20% or less).

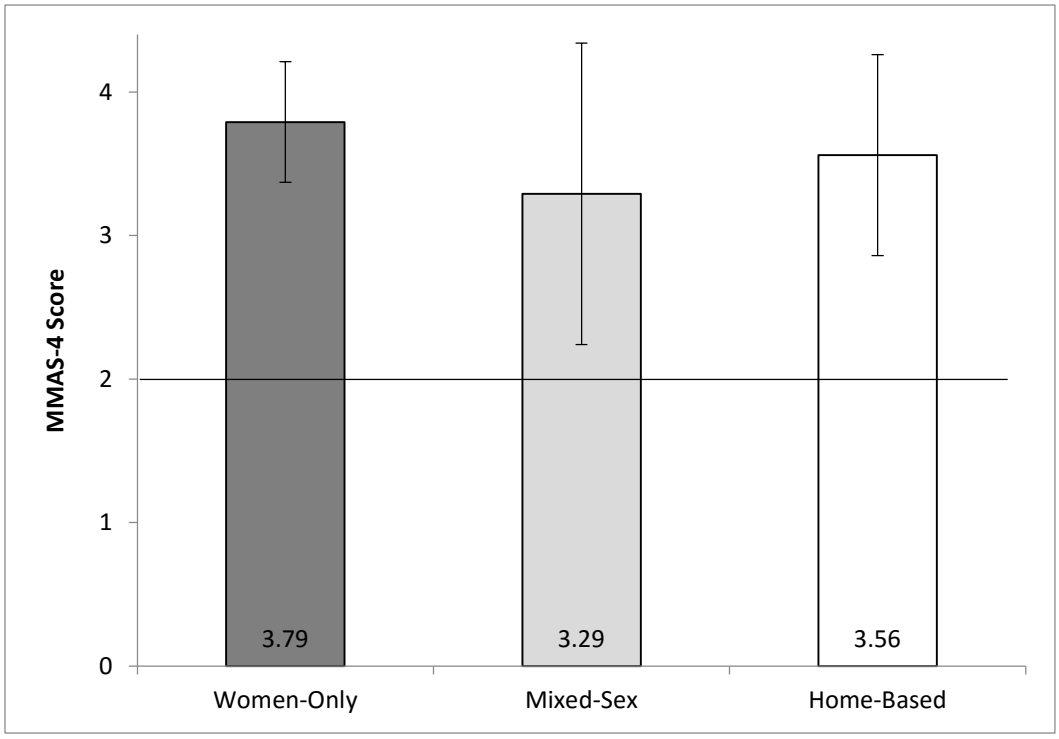
Figure 9b. Post-CR Diet Habit Survey Score by Program Model (As-Treated)



No significant difference in estimated marginal means between participants attending different CR program models using ANCOVA adjusting for age, caregiving duties, CR program adherence, and baseline Diet Habit Survey score. Overall model p=.24, observed power=.36

Error bars represent standard deviation, and the horizontal line represents scores ≥236 which corresponds to a low-fat diet (20% or less).

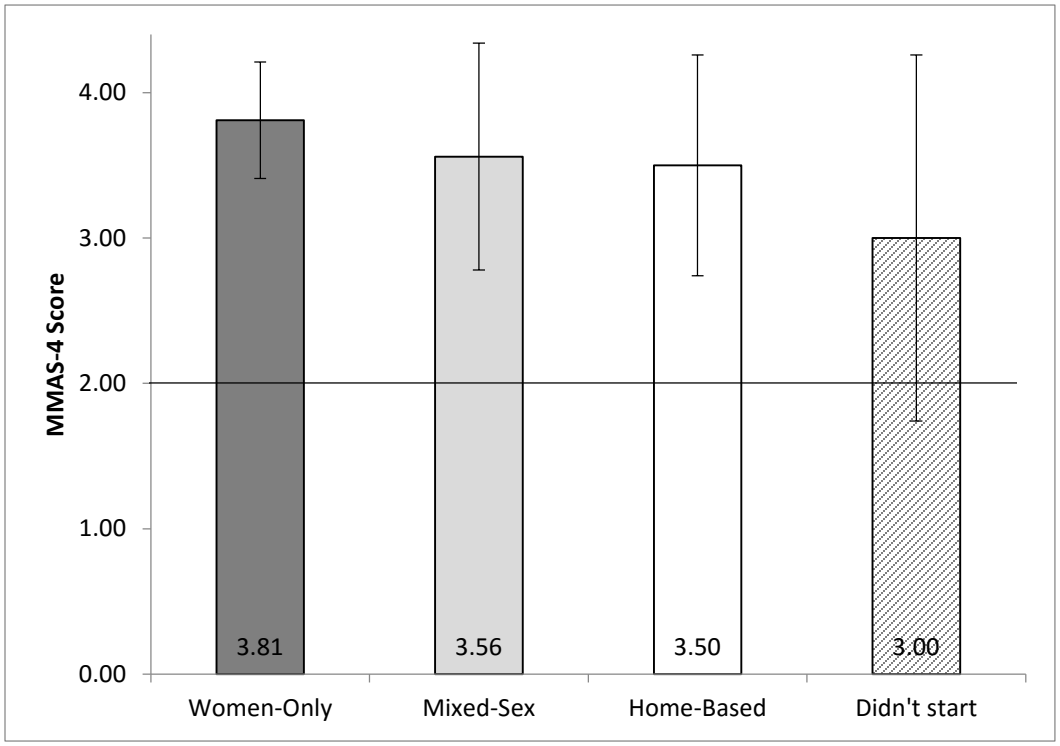
Figure 10a. Post-CR Medication Adherence Score by Program Model (PP)



No significant difference in estimated marginal means between participants randomized to different CR program models using ANCOVA adjusting for age, caregiving duties, CR program adherence, and baseline MMAS-4 score. Overall model p=.62, observed power=.13

Error bars represent standard deviation, and the horizontal line represents the cut-off for adherence (≥2).

Figure 10b. Post-CR Medication Adherence Score by Program Model (As-Treated)

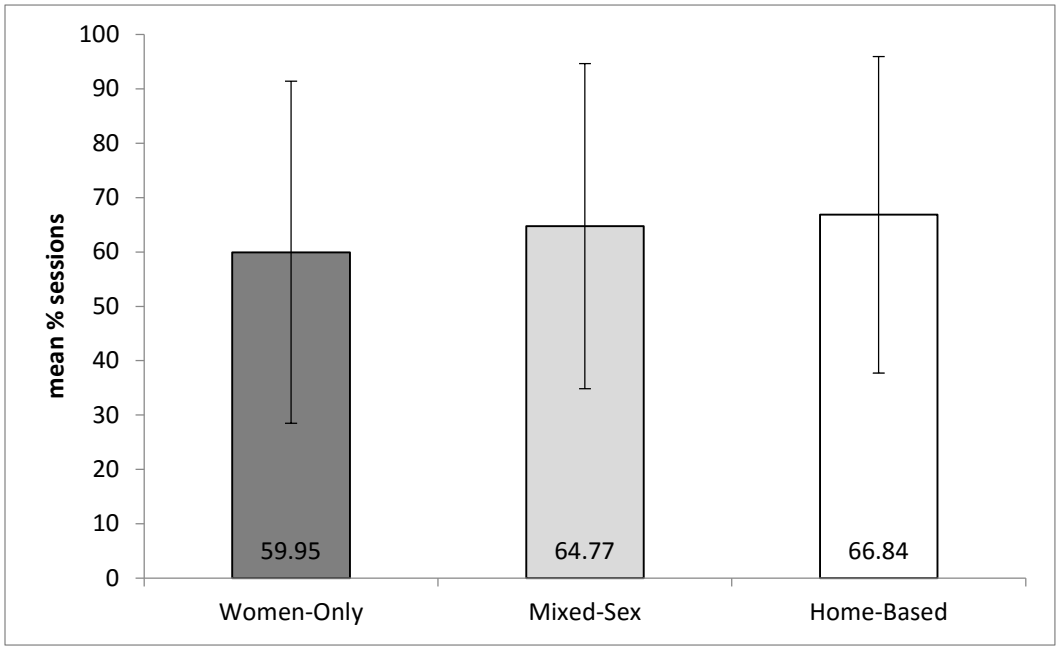


No significant difference in estimated marginal means between participants attending different CR program models using ANCOVA adjusting for age, caregiving duties, CR program adherence, and baseline MMAS-4 score.

Overall model p=.77, observed power=.12

Error bars represent standard deviation, and the horizontal line represents the cut-off for adherence (≥2).

Figure 11. CR Adherence by Program Model – Enrollees Only (PP), N=131



No significant difference between participants randomized to different CR program models using ANOVA.

Overall model p=.52, observed power=.16

Error bars represent standard deviation.

APPENDICES

Appendix A – Informed Consent Form (UHN)

University Health Network

Toronto Rehab
Everything Humanly Possible

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 (xxx) xxx-xxx
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 xxx-xxx-xxxx or the study coordinator at xxx-xxx-xxxx.

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 xxx-xxx-xxxx or Please call the Toronto Rehab Research Ethics Board Office at (xxx) xxx-xxxx.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 B – Informed Consent Form (MSH)

MOUNT SINAI HOSPITAL
Joseph and Wolf Lebovic Health Complex
Samuel Lunenfeld Research Institute

Toronto Rehab
Everything Humanly Possible

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 Grace, PhD., Scientist and Associate Professor (xxx) xxx-xxxx
Co-Investigators	Donna E. Stewart, MD, Professor and Scientist 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 Caroline Chessex, MD, Cardiologist
Sponsor	Heart and Stroke Foundation of Ontario

Introduction

You are being invited 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 Mount Sinai Hospital.

- 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 5 hospitals will be in the study. If you agree to participate, you will be one of 109 patients in this study recruited from Mount Sinai 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 109 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 (all types), and Toronto Rehabilitation Institute (all types). If you live in the Hamilton area, Hamilton Health Sciences is also involved in the study (all types). 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 feeling depressed, we will send a letter to your family

doctor. You can complete the survey in hospital and seal it in the envelope provided. The study coordinator will pick it up from you.
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 six 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, we will securely get some of your results they measure as part of standard care including personal health information (i.e., stress test, waist circumference, blood pressure, cholesterol). We will also contact the CR program to find out your participation level and dates. This information will be kept with the central study coordinator at Toronto General Hospital

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. Information learned from this study may help other people with heart disease in the future. You also will be paid $20 to participate in this study after all your final assessments are completed.

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,
- age,
- 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.
- 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 xxx-xxx-xxxx or the Study Coordinator at xxx-xxx-xxxx or xxx@xxx.com.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph.D., of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at xxx-xxx-xxxx, or Dr. Paul Oh, Chair of the Toronto Rehabilitation Institute Research Ethics Board, xxx-xxx-xxxx. 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 C – Informed Consent Form (HHS)

INFORMATION / CONSENT FORM (PARTICIPANT)

Title of Study	A Randomized Controlled Trial of Women's Adherence to Women-only, Home-based, and Traditional Cardiac Rehabilitation
Local Investigator	Heather M. Arthur, PhD. McMaster University & Hamilton Health Sciences (xxx) xxx-**xxxx**
Principal Investigator	Sherry L. Grace, PhD. York University & University Health Network (xxx) xxx-xxxx
Sponsor	Heart and Stroke Foundation of Ontario

Invitation to Participate in Research

You are being invited to be in a research study. You are being approached to consider participating in this study because you are a female patient receiving cardiac care at Hamilton Health Sciences.

Participation in this study is voluntary. Choosing not to participate will not have any negative consequences for you.

Why is This Study Being Done?

This research study examines women's participation in cardiac rehabilitation (CR) programs.

CR is a 4-6 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.

How Many Participants Will be Involved in this Study?

About 326 female heart patients from 5 hospitals in the Greater Toronto Area will be in the study. If you agree to participate, you will be one of about 109 patients in this study recruited from Hamilton Health Sciences Centre.

What Will Happen to Participants in This Study?

- 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 109 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.

- All of these CR types are offered in the Cardiac Health and Rehabilitation Center at the Hamilton Health Sciences.

- You will be in the study for 6 months.

<u>Study Procedures</u>

1. first survey - After the study coordinator approaches you 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, for your safety we will send a letter to your family doctor. You can complete the survey in hospital and seal it in the envelope provided. The study coordinator will pick it up from you.
We would also like your permission to access some basic medical information from your health records. 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.

If you were approached to participate when you were still in the hospital, 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 Hamilton Health Science Centre for 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.

The study coordinator will contact you to let you know which CR program type you will be participating in. The CR program 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, we will extract some of your results they measure as part of standard care at both intake and discharge. This will include stress tests, waist circumference, blood pressure, quality of life, and cholesterol. We will also record your participation level and dates. This information will be securely couriered to the central study coordinator at Toronto General Hospital.

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.

Are There Any Risks?

There are no foreseeable 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.

Are There Any Benefits?

You may receive direct benefit from being in this study due to participating in CR. Information learned from this study may help other women with heart disease in the future. Results will be mailed to participants at the end of the study.

Will I be Paid to Participate in the Study?

You also will be paid $20 to participate in this study after all your final assessments are completed.

Will There be Any Costs to Me in this 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.

What Will Happen to my Personal Information?

If you agree to join this study, the investigators and study staff will look at your personal health information and collect only the information they need for the study. We will collect the following information: your name, address, telephone number, and age. We will also collect specific elements of new or existing medical records, such as the types, dates and results of medical tests or procedures, your heart risk factors, medications you are taking, and other health conditions you may have.

The information that is collected for the study will be kept in a locked and secure area by the principal investigator for 10 years. Only the study staff will be allowed to look at your records.

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 numbered code. This code will be linked to your name in a separate and secure file. You will not be named in any reports, publications, or presentations that may come from this study.

Representatives of the Research Ethics Board, a group of people who oversee the ethical conduct of research studies 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.

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.

Can Participation End Early?

The investigators may decide to remove you from this study without your consent for the following reason:

- Your intake CR stress test results demonstrate you are not eligible for participation in CR.

If you are removed from this study, the investigators will discuss the reasons with you and plans will be made for your continued care outside of the study.

You can also choose to end your participation at any time. If you withdraw voluntarily from the study, you are encouraged to contact the study coordinator at (xxx) xxx-xxxx.

We will give you new information that is learned during the study that might affect your decision to stay in the study. If you leave the study, the information about you that was collected before you left the study will still be used. No new information about you will be collected without your permission.

Are There Any Alternatives I Should Know About?

If you decide not to participate in this study, you may still discuss getting a CR referral to the program and site of your choice with any one of your healthcare providers.

What Happens If I Have a Research-Related Injury?

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.

If I Have Questions About the Study, Who Should I Call?

If you have any questions, concerns or would like to speak to the study team for any reason, please call the study coordinator of the University Health Network at xxx-xxx-xxxx. Alternatively, you may also contact Dr. Heather Arthur, the local Principal Investigator McMaster University, at xxx-xxx-xxxx.

Consent

Participant:
I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name	Signature	Date

Person obtaining consent:
I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study	Signature	Date

This study has been reviewed by the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (HHS/FHS REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HHS/FHS REB at xxx-xxx-xxxx.

Appendix D – Informed Consent Form (SHSC)

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full 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]).

Principal Investigator: Paul Oh, MD
Medical Director and Assistant Professor (xxx) xxx-xxxx

Co-Investigators: Sherry L. Grace, PhD. Scientist and Associate Professor
Kenneth Melvin, MD. Cardiologist
Heather Arthur, PhD. Professor and Research Chair
Louise Pilote, MD. Associate Professor and Research Chair
Stephanie Brister, MD. Medical Director and Associate Professor
Donna E. Stewart, MD. Professor and Research Chair

Sponsor: This study is being funded by the Heart and Stroke Foundation of Ontario.

INFORMED CONSENT

You are being invited to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study, the tests and procedures involved, possible risks and benefits, and the rights of participants.

Please read this form carefully and ask any questions you may have. You may take as much time as you wish to decide whether or not to participate. Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

INTRODUCTION

You are being asked to consider participating in this study because you are a female patient receiving cardiac care at Sunnybrook Health Sciences Centre. This research study examines women's participation in cardiac rehabilitation (CR) programs. CR is an outpatient program where you learn about heart disease and behaviour changes that can improve your heart health. CR is proven to improve the health of participants, but not many women attend.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to 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.

WHAT WILL HAPPEN DURING THIS STUDY?

Participants in this study will be randomly (by chance) placed in one of three study conditions:

1) Co-ed CR (both women and men are participating),

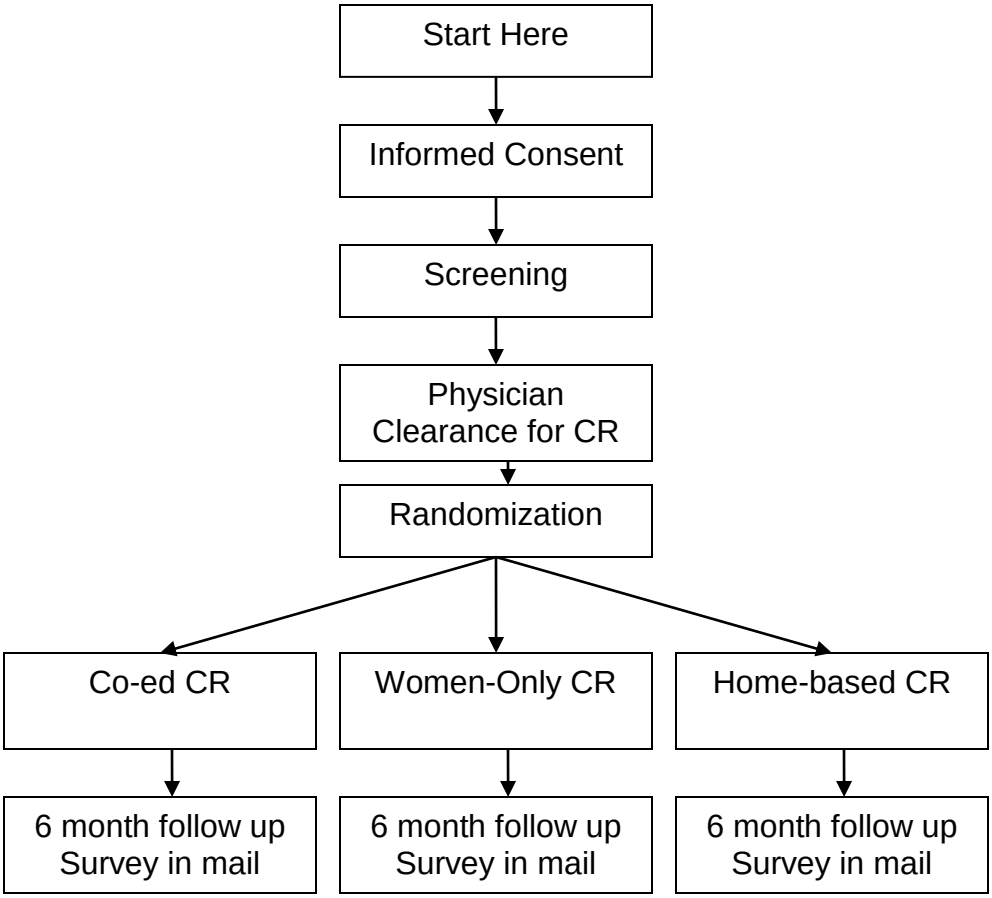
2) Women-only CR (only women participating), OR

3) Home-based CR (you will be supported in making heart healthy changes at home by telephone).

Neither you, the study staff nor the investigator(s) can influence which CR type you are in. You will have a 33% chance of being referred to any of the CR types. You and the study staff will know which CR type you are in.

These CR types are offered at 2 local hospitals: Toronto Western Hospital, and Toronto Rehabilitation Institute. We will refer you to the program that is closest to your home or work.

Another way to find out what will happen during this study is to read the study plan below. Start reading at the top and read down the list, following the arrows.



HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

It is anticipated that about 326 people will participate in this study, recruited from about three centres within Toronto. About 108 people will participate in this study at Sunnybrook. The length of this study for participants is 6 months. The entire study is expected to take about 36 months to complete and the results should be known in 4 years.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you decide to participate in this study you will be asked to do the following:

Screening: If you provide informed consent to participate in this study, the study coordinator will discuss with you in the hospital whether you are eligible for the study. This will involve asking you a few questions, mainly about your cardiac condition or procedure, and general location of your residence and/or work. There is a chance that you will not be eligible to participate in the study after screening is completed.

We would like your permission to access some basic medical information from your health records. This personal health information will help us ensure you are eligible for

the study and to complete your CR referral form. 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.

First survey: If you are eligible for the study, the study coordinator will provide you with a paper-and-pencil survey to complete. The survey will require about 30 minutes of your time to complete. The study coordinator will provide you a clipboard and pen to complete the survey. The survey asks questions about your feelings, supports, your exercise and eating habits, smoking status, alcohol use, medications and other health conditions. You have the choice not to answer any questions. You will only be identified by a study identification number. You can complete the survey in hospital and seal it in the envelope provided. The study coordinator will pick it up from you.

While CR is very safe and will be tailored to your needs, 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.

CR is part of the regular care for heart patients. If you enroll in the program after referral, this could involve weekly visits to the CR program or regular phone calls with CR staff.

Measuring steps: If you are interested, a pedometer package will be mailed to you to objectively measure exercise behaviour. This is completed 7 days before you begin CR and 9 months later or when you are asked to complete your second and final survey. 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 write down on a daily basis the number of steps showing for each day in 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. You can choose not to participate in this part of the study.

If you enroll in CR after being referred, you will undergo both CR intake and discharge assessments. The CR program will securely send some of your results 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.

Final survey: Nine 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. Once again, this survey will take about 30 minutes to complete and will ask similar questions as the first survey. We will include a pre-paid, pre-addressed return envelope so you can mail your completed survey back at no charge to you. If we do not receive your completed survey in the following 3 weeks, we may try to reach you by telephone or email.

The total time commitment to participate in this study is approximately 2 hours if you do not participate in the step measurement portion of the study, and approximately 6 hours if you do.

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.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS 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.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not directly benefit from being in this study. However, possible benefits include lower rates of death and disability, and better lifestyle and quality of life if you fully participate in CR. Information learned from this study may or may not help other people with heart disease in the future.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The investigators may decide to remove you from this study without your consent for any of the following reason:

- Your intake CR stress test results demonstrate you are not eligible for participation in CR.

If you are removed from this study, the investigators will discuss the reasons with you and plans will be made for your continued care outside of the study.

You can also choose to end your participation at any time. If you withdraw voluntarily from the study, you are encouraged to contact Mary Attia, at (xxx) xxx-xxxx.

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

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

Participation in this study will not involve any additional costs to you or your private health care insurer.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

You will be paid $20 to participate in this study after all your final assessments are completed. You will not be reimbursed for transportation costs to, or parking for your CR sessions, nor for your time to complete the surveys. If you participate in the pedometer portion of the study, upon return of the pedometer and log, you will receive a complimentary pedometer in the mail.

WHAT OTHER CHOICES ARE THERE?

If you decide not to participate in this study, you may still discuss getting a CR referral to the program and site of your choice with any one of your healthcare providers.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

There are no conflicts of interest to declare related to this study.

COMMUNICATION WITH YOUR FAMILY DOCTOR

For the purposes of this research study, we will be soliciting approval for you to participate from your family doctor.

Should you enroll, your family doctor may receive progress summaries from the CR program.

Should your questionnaire responses indicate that you are having suicidal thoughts, for your safety we will send a letter to your family doctor.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

All participants in a research study have the following rights:

1. You have the right to have this form and all information concerning this study explained to you and if you wish translated into your preferred language.

2. Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care. Should you choose to withdraw from the study you are encouraged to contact **the Study Coordinator, at (416) 340-4800 ext.6593#**.

3. You have the right to receive all significant information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study. If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) **Paul Oh, Cardiology, xxx-xxx-xxxx**. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call **Dr. Philip C. Hébert, Chair of the Sunnybrook Research Ethics Board at (xxx) xxx-xxxx,** or **the Toronto Rehabilitation Institute Research Ethics Board**, xxx-xxx-xxxx.

4. You have the right to have any information about you and your health that is collected, used or disclosed for this research study to be handled in a confidential manner.

   If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your;
   - name,
   - address,
   - telephone number,
   - date of birth,
   - new and existing medical records, or
   - the types, dates and results of various tests and procedures.

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

   - Representatives of the Sunnybrook Research Ethics Board, a group of people who oversee the ethical conduct of research studies at Sunnybrook; and

   Access to your personal health information will take place under the supervision of the Principal Investigator.

   In addition, any study data about you that is collected will be securely transported to the central study site at Toronto General Hospital using a numbered code, and will remain separate from forms that contain your name or address, or any information that directly identifies you. “Study data" is information about you that is collected for the research study, but that does not directly identify you.

   Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.

The investigators, study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

When the results of this study are published, your identity will not be disclosed.

The Principal Investigator will keep any personal information about you in a secure and confidential location for 10 years and then destroyed as required by Sunnybrook policy.

5. By signing this consent form, you do not give up any of your legal rights.

6. You have the right to receive a copy of this signed and dated informed consent form before participating in this study.

7. You have the right to be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.

8. You have the right to access, review and request changes to your personal health information.

9. You have the right to be informed of the results of this study once the entire study is complete.

DOCUMENTATION OF INFORMED CONSENT

Full 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]).

Name of Participant: _____

Participant/Substitute decision-maker

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal health information (medical record) and research study data as explained in this form
- I have agreed for the study coordinator to obtain consent from my family doctor or cardiac specialist for my eligibility to participate in cardiac rehabilitation
- I have agreed to participate in this study or agree to allow the person I am responsible for to participate in this study

_____	_____	_____
Name of participant/Substitute decision-maker (print)	Signature	Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____	_____	_____
Name of Person obtaining consent (print)	Signature	Date

Statement of Investigator

I acknowledge my responsibility for the care and well being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

_____	_____	_____
Name of Investigator (print)	Signature	Date

ASSISTANCE DECLARATION □ (check here if not applicable)

The participant/substitute decision-maker was assisted during the consent process as follows:

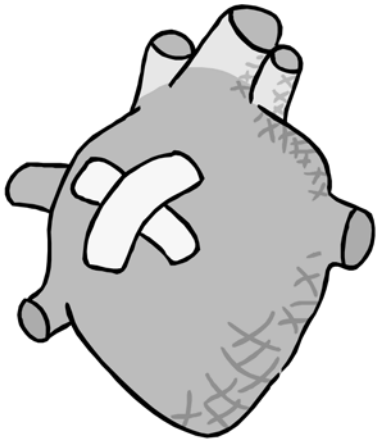
- ❑ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant/substitute decision-maker.
- ❑ The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker, and believe that that participant/substitute decision-maker has understood the information translated.

_____	_____	_____
Name of Person Assisting (Print)	Signature	Date

Appendix E – Baseline Survey

Cardiac Rehab for Her Study

(CR4HER)



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.

SECTION A: 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 B: OTHER HEALTH PROBLEMS

Instructions: Please check ✓ whether or not you experience the following health problems in the circle provided:

Health Problem	Have it?	If yes, please specify
a. **Joint repair or replacement** (such as hips, knees)	YES ☐ NO ☐	
b. **Arthritis**	YES ☐ NO ☐	
c. **Osteoperosis**	YES ☐ NO ☐	
d. **Asthma**	YES ☐ NO ☐	
e. **Chronic Obstructive Pulmonary Disease (COPD)**	YES ☐ NO ☐	
f. **Diabetes**	YES ☐ NO ☐	Type 1 _____ Type 2 _____
g. **Chronic Renal Failure (liver)**	YES ☐ NO ☐	
h. **Urinary Incontinence**	YES ☐ NO ☐	
i. **Cancer** (such as breast, lung, cervix, stomach, colon, kidney, bone, metastasis or spread, lymphoma, leukemia, others)	YES ☐ NO ☐	
j. **Other** health problems	YES ☐ NO ☐	

SECTION C: 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. Cardiac rehabilitation is an outpatient program of structured activity and education to maximize your recovery. For example, you might go to a hospital outpatient program to exercise 1-3 times per week for 6 months or so.

Have you previously attended a cardiac rehabilitation program?

- ❑ Yes
- ❑ No

SECTION D: 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, office use only muffins, scones, cookies, cakes)? ***Do not count fat free versions***

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 us 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 E: 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 F: MOOD

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

1. Sadness

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

2. Pessimism

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

3. Past Failure

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

4. Loss of Pleasure

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

7. Self-Dislike

- ❑ I feel the same about myself as ever.
- ❑ I have lost confidence in myself.
- ❑ I am disappointed in myself.
- ❑ I dislike myself.

8. Self-Criticalness

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

9. Suicidal Thoughts or Wishes

- ❑ I don't have any thoughts of killing myself.
- ❑ I have thoughts of killing myself, but I would not carry them out.
- ❑ I would like to kill myself.
- ❑ I would kill myself if I had the chance.

10. Crying

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

5. Guilty Feelings

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

6. Punishment Feelings

- ❑ I don't feel I am being punished.
- ❑ I feel I may be punished.
- ❑ I expect to be punished.
- ❑ I feel I am being punished.

11. Agitation

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

12. Loss of Interest

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

13. Indecisiveness

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

18. Changes in Appetite

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

14. Worthlessness

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

15. Loss of Energy

- ❑ I have as much energy as ever.
- ❑ I have less energy than I used to have.
- ❑ I don't have enough energy to do very much.
- ❑ I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

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

19. Concentration Difficulty

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

20. Tiredness or Fatigue

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

21. Loss of Interest in Sex

- ❑ I have not noticed any recent changes in my interest in sex.
- ❑ I am less interested in sex than I used to be.
- ❑ I am much less interested in sex now.
- ❑ I have lost interest in sex completely.

17. Irritability

❑ I am no more irritable than usual.

❑ I am more irritable than usual.

❑ I am much more irritable than usual.

❑ I am irritable all the time.

SECTION G: MOOD CONTINUED

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3

SECTION H: 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 I: 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 J: 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 bit	Often	Most 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 K: SLEEPING DIFFICULTIES

These questions ask about your sleep habits. Please mark **1** 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	□ Average quality	□ Restless	□ Very Restless

	or restful			

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

(I) History of Depressed Mood

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

1b. **If yes,** how many years has it been since you first had problems with depressed mood? _____(yrs)

1c. **If yes**, how many times in your life have you had problems with depressed mood? _____ (times)

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

2b. **If yes**, how many years ago were you first given the diagnosis? _____ (yrs)

2c. **If yes**, who diagnosed you with depression?
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other:

_____

(II) History of Anxiety

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

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

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

4b. **If yes**, how many years ago were you first given the diagnosis? _____ (yrs)

4c. **If yes**, who diagnosed you with anxiety?
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other:

_____

(III) Current Depression or Anxiety

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

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

5c. **If yes**, who is treating you for these problems? (check all that apply)
☐ Family doctor
☐ Heart doctor (cardiologist)
☐ Psychiatrist or psychologist
☐ Nurse
☐ Other:

_____

☐ Not being treated by health care provider

5d. **If yes**, what treatments are you using: ☐ Medication (antidepressant or anti-anxiety pills)

(check all that apply) ☐ Counseling/Talk therapy

☐ Exercise

☐ Other: _____

☐ My depression/anxiety is not being treated

(IV) Treatment for Depression or Anxiety

6. Have you ever taken anti-depressant or anti-anxiety medications?

☐ Never taken ☐ I took them in the past ☐ I take them now: (name: _____)

7. Have you ever had counseling or 'talk therapy' for depression or anxiety?

☐ Never had ☐ I had it in the past ☐ I'm in counseling/therapy now

(V) Mood and Anxiety Since Start of Heart Problems

8. How often do you feel down or blue because of your heart condition?

☐ Never ☐ Sometimes ☐ A lot of the time

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

_____

_____

_____

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

9b. If yes, who asked about your mood or anxiety? ☐ Family doctor

(check all that apply) ☐ Heart doctor (cardiologist)

☐ Psychiatrist or psychologist

☐ Nurse

☐ Other: _____

10. Since being diagnosed with a heart problem, have you ever been asked to fill in a survey or had an interview with questions about your mood or anxiety?

☐ Survey ☐ Interview ☐ Both ☐ Neither

If yes to either survey or interview:

10b. Please describe the survey or interview:

_____

_____

_____

_____

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

10d. What happened next (check all that apply)?

☐ I was prescribed medicine for my mood or anxiety
☐ I was referred to a psychiatrist, psychologist or counselor
☐ I was referred for other mental health treatment – please specify:

_____

☐ My healthcare provider is going to follow-up with me about this
☐ Nothing (and I do have problems with mood or anxiety)
☐ Nothing (and I do not have problems with mood or anxiety)
☐ Other, please specify: _____
☐ I don't know

SECTION N: DEMOGRAPHICS and CARDIAC RISK FACTORS

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

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

- ❑ Multiple cultural backgrounds (**specify**: _____)

2a) Who do you live with?

- ❑ Family (spouse, children, etc.)
- ❑ Alone (skip to question #3)
- ❑ Other (specify:_____)

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

c) Do you live with someone who requires caregiving (e.g., ill spouse, grandchildren)?

- ❑ Yes
- ❑ No

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

1._____
_____

2._____
_____

3._____
_____

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

☐ ☐ ☐ ☐ ☐

Excellent **Very good** **Good** **Fair** **Poor**

3a) Do you have children?

- ❑ Yes
- ❑ No

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

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

_____ hours per week

5. What is your marital status:

- ❑ Married/common-law
- ❑ Separated/divorced
- ❑ Single
- ❑ Widow/Widower

6. What is the highest level of education you have completed?

- ❑ less than grade 9
- ❑ less than high school
- ❑ completed high school
- ❑ some college or university courses
- ❑ completed college or university degree
- ❑ Graduate School/Professional Program

7. What is your gross annual family income?

- ❑ $19, 999 or less
- ❑ $20, 000 – $29, 999
- ❑ $30, 000 – $39, 999
- ❑ $40, 000 – $49, 999
- ❑ $50, 000 - $59, 999
- ❑ $60, 000 - $69, 999
- ❑ $70,000 or greater

8. Which option best matches your work status?

- ❑ full-time work
- ❑ part-time work
- ❑ full-time caregiver or homemaker (inside your home)
- ❑ unemployed
- ❑ receiving disability
- ❑ retired
- ❑ other: _____

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

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

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

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

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

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

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

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

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

16. Have you <u>previously</u> experienced any of the following health problems? Please ✓ all that apply:
    - ❑ Heart Attack
    - ❑ Angina
    - ❑ Angioplasty (stent)
    - ❑ Bypass Surgery
    - ❑ Valve Surgery
    - ❑ Heart Failure
    - ❑ Arrhythmia (irregular heart rhythm)
    - ❑ Heart transplant

- ❑ Cardiac device: pacemaker or implantable cardioverter defibrillator
- ❑ Stroke / TIA (i.e., blocked arteries in neck or brain)
- ❑ Peripheral Vascular Disease (e.g., blockages in legs)
- ❑ None of the above

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

18. Please check your medication bottles. Please list below the names of <u>all of the medications</u> you are currently taking and <u>the dose per day</u>.

Others:

_____

_____

_____

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 envelope provided to the study coordinator personally, OR mail it in the stamped envelope to:

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

Appendix F - Case Report Form

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: _____ Date: _____	CRF Entered By: _____ 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 ☐ Non-Primary ☐ Unknown	☐ LM ☐ RCA ☐ 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 ☐ Replace	☐ Aortic ☐ Tricuspid ☐ Bicuspid ☐ Pulmonary

☐ MI Date:_____

11. Current Medications (*check all)*:

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

_____

☐ Normal ☐Mild ☐Moderate ☐Severe
☐ Date assessed:
_____

17. Complications during stay:

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:_____

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:_____

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

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

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: _____

29. Referral Date: _____ yyyy

30. Call to patient re: program site & model:
☐ Yes ☐ No
Date: _____

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 - Request for Physician Clearance

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 (**xxx) xxx-xxxx**.

Appendix H - Referral for Cardiac Rehabilitation (TRI)

Toronto Rehabilitation Institute
A Teaching Hospital of
the University of Toronto

Rumsey Centre
347 Rumsey Road, Toronto, Ontario M4G 1R7
Tel: (xxx) xxx-xxxx Fax: (xxx) xxx-xxxx
www.torontorehab.on.ca

Name: _____DOB: _____/_____/____ Sex: M __ F

Street Address: _____ Apt. # :_____

City: _____ Postal Code: _____ Health Card # _____

Tel: (_____)_____ (_____)_____
(_____)_____
Home Business Cell
Relative or Contact Person: _____ Tel
(Mandatory if patient does not speak English)

Referral Diagnosis	**Date**		**Date**
MI	**_____**	**Heart Failure**	**_____**
PTCA	**_____**	**Stable angina**	**_____**
AC Bypass	**_____**	**Valve surgery**	**_____**
Pacemaker/ICD	**_____**	**Arrhythmia**	**_____**
Other	**_____**	**CVA/TIA**	**_____**

LV (if known) Grade I ___II ___III ___IV __

Does patient have and orthopedic/neuromuscular/vascular limitations? If yes, briefly describe:
_____
_____
_____
_____

Include with:
All referrals: discharge summary & post event ECG.
Add:
Surgical patients: pre-op assessment, discharge medications
PCI patients: pre-cath assessment, cath diagram
Heart Failure patients: echo result

Interventionalist: _____Cardiologist: _____ Surgeon
_____

Physicians – please 'cc' Toronto Rehab, Cardiac Rehab Program, 347 Rumsey Road on discharge summaries and procedure notes

_ _

Patient Waiver for Disclosure of Personal Health Information

____ _____/_____/____
(Print) Last Name First Name Date of Birth (D/M/Y)

I hereby authorize Sunnybrook Health Sciences Centre to release to Toronto Rehab Institute any pertinent Medical Records or information concerning my recent admission. I understand that this information is to be used for the provision of heath care services.

Signature of patient/
Legal Representative: _________________________ Witness: ________________________ Date: ______________

Relationship (if not patient): ___________________ Print Name of Witness: _________________________________

Appendix I – Referral for Cardiac Rehabilitation (TWH)

University Health Network
Toronto General Hospital | Toronto Western Hospital | Princess Margaret Hospital

Cardiovascular Rehabilitation & Prevention

(Chronic Disease Mgmt & Risk Reduction)

Peter Munk Cardiac Centre

REFERRAL FORM

FAX completed form to: **(xxx) xxx-xxxx**

REFERRALS ***INTERNAL*** TO UHN – clinical information will be extracted from EPR.
Please complete #1-8:

1. Date of Referral: _____ (dd) _____ (mmm) _____ (yyyy)
2. **I agree my patient can undergo a medically-supervised exercise stress test for the purpose of exercise prescription and triage (please check ☑ one box): ☐ Yes ☐ No**
   (see below for timing considerations, *if any*):
   ☐ anytime after referral ☐ 2 weeks after referral ☐ 4 weeks after referral ☐ other: _____
3. **Physician signature:** _____
4. Referring Physician: _____
5. Family Physician: _____ ☐ Send intake & d/c summaries to GP only
6. Referral Source: ☐ Cardiologist ☐ CV Surgery ☐ GP ☐ Internist ☐ PCI Unit ☐ Other clinic/office
7. Name of relative/contact person if limited English proficiency: _____, ☎ (____) _____
8. Interpreter required: ☐ Yes, specify language of proficiency: _____

REFERRALS ***EXTERNAL*** TO UHN – in addition to completing #1-8 above, please provide information below:

1. Please fax discharge summary, consult notes and all available cardiac / respirology investigations with referral form (i.e., EKG, echo, perfusion scan, angiogram, lipid profile), discharge medications.
2. Indication for Referral (check ☑ all that apply, and specify date where applicable):

☐ MI / ACS _____ ☐ CABG and / or valve surgery _____

☐ PCI _____ ☐ Congenital HD _____

☐ Pre/post heart or heart & lung transplant _____ ☐ Stable CHF _____

☐ PVD / PAD _____ ☐ Pacemaker, ICD, Other: _____

☐ Stroke / TIA (pt can ambulate) _____ ☐ Diabetes,

with multiple cardiac risk factors

3. Known cardiac risk factors (check ☑ all that apply):

☐ Hyperlipidemia	☐ Diabetes	☐ Sedentary	☐ Psychosocial
☐ Hypertension	☐ Obesity	☐ Smoking	

4. Any notes, specific issues of concern with this patient

(e.g., comorbidities, restrictions, contraindications):

_____

Appendix J – Referral to Cardiac Rehabilitation (HHS)

HAMILTON HEALTH SCIENCES
Cardiac Health & Rehabilitation Centre
TELEPHONE: xxx-xxx-xxxx FAX: xxx-xxx-xxxx

Name:
Last Name First Name Mr./Mrs./Miss/Ms.

Address:

Telephone Number:

Hospital ID Number: _____ HIN _____

RISK FACTORS (if present) :

REASON FOR REFERRAL (Check all that apply)

ST Elevation Non ST Elevation **Location:** Anterior Posterior Right Ventricle

Inferior Lateral

Post MI: Date _____ Streptokinase TN rTP
Thrombolytics: Date

Cardiac Surgery: Date: _____ CABG Valve Other:

Coronary Angioplasty: Date: _____ Vessel(s) _____

Stent

Coronary Angiogram No Yes Date:

Vessels Diseased: RCA LAD Circumflex Other: _____

Angina

Peripheral Vascular Disease CHF Defibrillator (ICD) Pacemaker

LV Function: Greater than 50% 35-49% 20-34% Less than 20%

MEDICATIONS
(Name and Dose and Frequency)

LIPID PROFILE

Date: _____ Total cholesterol _____ LDL _____ HDL _____ Triglycerides

Date _____ Fasting Blood Sugar _____ A_{IC} _____

Height _____ cm

Weight _____ g

Post Event Complications/Health Care Team Concerns:

Appointment Date and Time: _____Information Package Given

Completed By: _____ Date: _____

Signature of most responsible physician: _____ Date: _____

Appendix K – Pedometer Log

Participant #: _____ Assign Date: ___/____/_____
Pedometer #: _____

CR4HER Pedometer Activity Log Sheet

Instructions: Record the start date of your log. At the end of each day, write down the number of steps that's shown on the pedometer in the slot of that corresponding day. Keep recording for 7 days. Record the end date of your log.

Contact the study coordinator with any questions – xxx-xxx-xxxx

Start Date: ___/____/_____

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Record number of steps here	Record number of steps here	Record number of steps here	Record number of steps here	Record number of steps here	Record number of steps here	Record number of steps here

End Date: ___/____/_____

Send completed log sheet, along with the pedometer, back to: University Health Network, TWH 8e-403, using the postage-stamped envelope.

Appendix L – Intake Report Form

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

Appendix M – Post-Test 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.

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?

3. Did you participate in cardiac rehabilitation?

□ YES

□NO

(If Yes)

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

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

Why?

□ acceptable

□ unacceptable

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

% of sessions completed

(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:

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. ofwork 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 D: 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?

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?

(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)?

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***

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 us 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.

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?

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?

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)?

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 …… .

B) A Heart Specialist …… .

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? .

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 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 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 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

Worrying thoughts go through my mind

□ A great deal of the time
□ A lot of the time
□ Not too often
□ Very little

I feel cheerful

□ Never
□ Not often
□ Sometimes
□ Most of the time

I feel as if I am slowed down

□ Nearly all the time
□ Very often □ Sometimes
□ Not at all

I get a sort of frightened feeling like 'butterflies' in the stomach

□ Not at all
□ Occasionally
□ Quite often □ Very often

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 feel restless as if I have to be on the move

□ Very much indeed
□ Quite a lot
□ Not very much
□ Not at all

I can sit at ease and feel relaxed

- Definitely
- Usually
- Not often
- Not at all

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 get sudden feelings of panic

- Very often indeed
- Quite often
- Not very 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 EVERYDAY
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.

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 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 =1, always =4)

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

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 **1** 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: □ Medication (antidepressant or anti-anxiety pills)
(check all that apply) □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? □ Family doctor
(check all that apply) □ 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:

_____

_____

_____

_____

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 check 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 current 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.

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
Toronto General Hospital

200 Elizabeth Street
Toronto, ON
M5G 2C4

Appendix N – Survey Cover Letter

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

Dear Ms. _____

I am writing to request that you complete the second and final survey in our research study on women's participation in cardiac rehabilitation programs, the study that you consented to participate in 6 months ago while in hospital. We very much appreciate the time and effort you have put into helping us with this study and hope that you will be willing to complete this final questionnaire.

This survey, like the previous one, requests information on your perception of your health care, your feelings and mood, as well as specific information regarding any participation in a cardiac rehabilitation program. Enclosed is a pre-addressed and stamped envelope in which you can return the completed survey.

If you have any questions regarding the survey or the study please feel free to contact the study coordinator at (xxx) xxx-xxxx.

We want to stress that your participation in this study is completely voluntary, and will not impact the care or services you or your family receive. Please know that your help would be greatly appreciated and any information you could give us would further aid us in improving the quality of cardiac rehabilitation for female heart patients such as yourself.

Thank you for your consideration.

Sincerely,

Dr. Sherry L. Grace
Toronto General Hospital and
York University

University Health Network
Toronto General Hospital Toronto Western Hospital Princess Margaret Hospital

Appendix O – Replacement Survey Cover Letter

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

Dear Ms. _____:

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 xxx-xxx-xxxxx.

Sincerely,

D. Grace

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

University Health Network
Toronto General Hospital | Toronto Western Hospital | Princess Margaret Hospital

Appendix P - Discharge Report Form

1. Participant ID#: _____

2. Date of data extraction:

dd	mmm	yyyy

3. Did the patient complete the program (circle one)? Yes No

*2b. If **yes***: Date of discharge:

dd	mmm	yyyy

*2c. If **no***, Date last attended rehab:

dd	mmm	yyyy

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

2e. Describe:

_____

_____

4. Number of Sessions prescribed (on site or via telephone): _____

5. Number of sessions completed (on site or via telephone): _____

6. Number of Sessions prescribed to drop out for medical reason (if applicable):_____

7. Number of Sessions completed to drop out for medical reason (if applicable):_____

8. Blood lipid profile:

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

9. Waist Circumference (cm): _____

10. Discharge Exercise Stress Test:

    a. Resting SBP blood pressure:_____

    b. Resting DBP blood pressure:_____

    c. Peak METs: _____

    d. Peak VO_2: _____

    e. CPA Completed: Yes No

11. Other comments:

    _____

    _____