Women's Health Behaviors and Psychosocial Well-Being by Cardiac Rehabilitation Program Model: A Randomized Controlled Trial

Short Title: Women's Outcomes by CR Model: an RCT

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Abstract

Background: Cardiac rehabilitation (CR) is associated with significantly lower mortality and improved psychosocial well-being. However, women are less likely to participate than men. This trial tested whether participation in women-only CR results in better health behaviors and psychosocial outcomes versus other models.

Methods: CR4HER was a single-blind, 3 parallel-arm, randomized trial. Low-risk cardiac patients were recruited from 6 sites in Ontario. Consenting participants completed surveys assessing health behaviors (physical activity, diet, medication adherence, smoking) and psychosocial well-being (social support, quality of life, depressive symptoms) and wore pedometers for 7 days. Following intake assessment, eligible participants were randomized to mixed-sex, women-only or home-based CR. Participants were mailed follow-up surveys and pedometers 6 months later.

Results: 169 patients were randomized, and 116 (68.6%) were retained. Self-reported physical activity increased among women in mixed-sex and women-only CR (per-protocol and as-treated, ps<.05). Diet improved among women in women-only CR (as-treated, p<.05). Quality of life improved among women in mixed-sex (per-protocol and as-treated, ps<.05) and women-only CR (per-protocol, p<.05; as-treated, p<.01). Post-test, women in mixed-sex CR had higher anxious symptoms versus those in women-only (per-protocol, p=.017), and those who in mixed-sex CR had higher depressive symptoms versus those in women-only (as-treated, p=.001). Analyses adjusted for confounding variables revealed no significant differences in any outcome by model. Post-hoc equivalency tests were computed on a perprotocol basis, and all outcomes were equivalent by model.

Conclusion: Behavioral and psychosocial outcomes were largely equivalent regardless of model, however women-only programs may confer an advantage for anxiety and depressive symptoms.

Brief Summary

Cardiac rehabilitation (CR) participation is associated with significantly lower mortality and improved psychosocial well-being. However, women are less likely to participate than men. This trial tested whether participation in women-only CR results in better health behaviors and psychosocial outcomes versus other models, among low-risk cardiac patients recruited from Ontario. Results suggest health behaviors and psychosocial outcomes were largely equivalent regardless of model, however women-only programs may confer an advantage for anxiety and depressive symptoms.

Introduction

Cardiovascular disease (CVD) is the leading cause of mortality for women globally[1]. Furthermore, women who suffer an acute coronary event may be more likely to incur morbidity and mortality during the first year of recovery[2], have lower physical function, are less physically active, and are at greater hazard in the context of smoking and diabetes than men[3]. Women are also two times more likely to suffer from comorbid depression than men[4], a comorbidity related to 2 times greater mortality[5].

Cardiac rehabilitation (CR) is an outpatient secondary prevention program composed of structured exercise training and comprehensive education and counseling, addressing this cardiac risk[6]. Participation has been shown to reduce cardiovascular mortality by 26%[7], and lower re-hospitalization and revascularization[8,9]**.** CR participation is also associated with heart health behavior changes such as increased exercise[10], improved diet, and smoking cessation[11], and improvements in psychosocial well-being[12]. Arguably these heart-health behaviours are key clinical outcomes in CR as they are modifiable, and they also impact risk reduction and hence hard outcomes. Moreover, quality of life (QoL) is a key outcome from a patient's perspective.

Despite the benefits, and women-specific clinical practice guideline recommendations for CR referral as a Class 1, Level A indication[3], a recent meta-analysis showed significantly lower CR enrollment among women (39%) than men (45%)[13]. The question of whether traditional, mixed-sex CR meets the needs of women has been raised in the literature[14], with the suggestion that women should be referred to alternative CR models[14,15], although there is a dearth of empirical evidence to test this contention. For instance, home-based models were developed 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[16]. Women-only programs have also been developed[17,18].

Where women do participate in mixed-sex CR, they often achieve 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 improvements in risk factors and QoL[20,21 15,22], although sex differences are found for QoL in some studies[23]. CR participation has also been shown to reduce depressive symptoms and anxiety in women[15], and increase physical activity[10].

However, to date, there has been only one randomized controlled trial (RCT) evaluating the effects of women's participation in a women-only CR program compared to any other model. Results showed that participation in the women-only program was associated with improved psychosocial outcomes than participation in mixed-sex CR[24–26]. Specifically, women in the women-only group had reduced depressive symptoms and increased QoL while women in mixed-sex CR did not. While the trial was seminal, it did not include a home-based CR arm, and the mixed-sex and women-only programs differed not just in sex composition but in approach. Further, health behaviors other than smoking were not examined. The objectives of the current study were thus to compare health behaviors (i.e., exercise, diet, medication adherence, and smoking), and psychosocial well-being (i.e., depressive symptoms, anxiety, social support, and QoL) among women by program model, namely mixed-sex, women-only or home-based CR. It was hypothesized that patients would have better heart-health behaviors and psychosocial outcomes with participation in women-only CR.

Methods

Design and Procedure

This Cardiac Rehabilitation for her Heart Event Recovery (CR4HER; ClinicalTrials.gov registration number NCT01019135) trial was a single-blind, 3 parallel-arm (1:1:1 allocation) pragmatic[27] RCT. Female patients were randomized to one of the following CR models: (1) supervised mixed-sex CR; (2) supervised women-only CR; or (3) home-based CR (Figure 1). CR4HER was designed to assess differences in CR adherence (primary outcome) by program model. Herein results from pre-specified secondary outcomes are reported. The trial was powered based on the primary outcome.

Recruitment occurred from October 2009 to July 2013, with patient follow-up 6 months post-CR enrollment. Patients were recruited from six inpatient and outpatient cardiac settings in the Greater Toronto Area of Ontario, Canada. Female patients were identified through ward/program censuses, and invited to participate. Where patients consented, clinical charts were reviewed for inclusion / exclusion criteria. If the participant was recruited from an inpatient unit, physician clearance for CR participation was required prior to enrolment in the trial.

Baseline assessments occurred prior to the start of CR, around the time of consent. Patients were asked to complete a baseline self-report survey assessing sociodemographic characteristics, as well as heart-health behaviors and psychosocial well-being. They were also scheduled for their CR intake assessment (at the program where they were recruited for outpatients, or the closest program to their home or work for inpatients; included graded exercise stress test and anthropometric assessments). Consenting patients who met inclusion criteria were then randomized to one of the three CR models.

The randomization sequence was computer-generated, in blocks of 6, and stratified by condition (myocardial infarction / percutaneous coronary intervention or coronary artery disease

/ coronary artery bypass graft +/- valve surgery) through randomize.net. Hence, allocation was concealed. Recruiters went online to ascertain random allocation, and informed patients and CR sites.

As a manipulation check, a masked research assistant checked CR charts to confirm the program model attended at the expected CR discharge date, and the proportion of prescribed sessions attended. Post-test CR data extraction was also undertaken by the masked research assistant. Participants were mailed the post-test survey, again assessing heart-health behaviors and psychosocial well-being, and a pedometer with a log to record daily steps. For detailed methodology, including Participants, Measures, and Statistical Analysis, see Supplementary Materials.=

Results

Respondent characteristics

A diagram of study flow is shown in Figure 1. A total of 2016 patients were approached, of which 739 (36.7%) declined to participate. One hundred and sixty-nine (8.4%) consenting patients who met inclusion criteria and did not decline randomization were randomized. Of these 169, 144 (85.2%) completed the pre-CR survey and 66 (39.1%) remitted a pre-CR pedometer log.

Overall, 144/164 (87.8%) participants ultimately enrolled in CR (defined as patient attendance at the CR intake assessment), of which 99 (68.8%) attended (defined as partaking in at least some of the CR intervention components) their randomized model (Figure 1; see Andraos et al.[54]). There were no significant differences in the sociodemographic and clinical characteristics of patients randomized to each of the 3 CR models (see Andraos et al.[54]).

Table S1 (Supplementary Materials) displays the sociodemographic and clinical characteristics of participants by model (as-treated). Participants who did not attend any CR program were less likely to be married than participants who attended women-only CR programs (p=.043). Participants who attended women-only or mixed-sex CR programs were more likely to be retired than participants who attended home-based CR programs (p=.022). Lastly, participants attending mixed-sex and women-only CR programs, as well as those participants who did not start CR, were all more likely to have hypertension than participants who attended home-based CR (p=.008). No other differences were observed.

Table S2 (Supplementary Materials) displays the sociodemographic 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 sociodemographic and clinical characteristics of the 55 (32.5%) participants who remitted a post-CR pedometer log (retained; Figure 1) versus those who did not were also compared (data not shown). Participants who wore a pedometer post-CR were older (p=.017), had higher intake peak VO_2 (p=.024), and had higher CR adherence (p=.003) than participants who did not. No other differences in sociodemographic or clinical characteristics were observed. There were no significant differences in program adherence by CR model (data reported elsewhere[55]).

Heart-Health Behaviors

Prior to CR, 25/66 (37.9%) participants were sufficiently active (i.e., met the 6500 step/day guideline[41]), 63/135 (46.7%) were 'active' as per self-report (i.e., Godin scores ≥20[32]),

18/140 (12.9%) consumed healthy diets (i.e., total Diet Habit survey score ≥236, corresponding to a 20% or less fat diet[42]), and 114/116 (98.3%) were adherent to their medications (i.e., MMAS-4 score ≥2[44,45]). Diet Habit Survey scores by category are listed in Table S3 (Supplementary Materials). Finally, 129/138 (93.5%) were non-smokers.

Pre to post-CR in the total sample, regardless of model, there was a significant increase in self-reported physical activity (Table S4 in Supplementary Materials). In terms of the Diet Habit Survey subscale scores (Table S3), 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 6500 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 S4, by program model, paired t-tests revealed an increase in self-reported physical activity among participants in 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 in 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 in 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 in home-based CR (PP; from 6.75±2.20 to 7.63±1.75; p=.002) and in "Salt" among women in 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 in

mixed-sex CR (as-treated; from 17.08±4.53 to 18.59±5.43; p=.038) and in "Seafood" among women in 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 in 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 CR program model on a PP or as-treated basis.

ANOVAs 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, and therefore no ANCOVAs were performed. Given the lack of significant differences observed, post-hoc equivalency tests were run[56], to establish whether these health behaviours could be considered equivalent by program model at post-test on a PP basis. Step counts, self-reported physical activity, diet, and medication adherence scores were all considered "equivalent".

Psychosocial Outcomes

Pre-CR PHQ-2 scores were 1.15±1.62. Pre to post-CR in the total sample, regardless of model, there was a significant increase in QoL (Table S5 in Supplementary Materials). No other changes were observed. Post-CR, 102/113 (90.3%) participants were not reporting elevated depressive symptoms, and 81/113 (71.7%) were not anxious (i.e., below the HADS cut-off of 8).

By program model, pre to post-CR, paired t-tests revealed an increase in QoL among participants in mixed-sex and women-only CR (PP; Table S5; p=.047 and p=.019, respectively). Significant increases in QoL among participants in mixed-sex (as-treated; p=.046) and women-only CR (as-treated; p=.007) were also observed. There were no significant changes in social support.

Differences in anxiety and depressive symptoms by model at post-test were tested by ANOVA. Figure 2a displays post-test anxiety symptom scores by model (PP). As shown, participants in mixed-sex CR had significantly higher scores as compared to those in women-only CR (PP; overall p=.048, post-hoc LSD test p=.017). There were no significant differences by model (as-treated). With regard to depressive symptoms, there were no significant differences by model (PP). Figure 2b shows post-test depressive symptom scores by model on an as-treated basis. As shown, similarly, participants in mixed-sex CR had significantly higher scores as compared to those in women-only CR (overall p=.005, post-hoc LSD test p=.001). ANOVAs revealed no significant differences in social support or QoL by model at post-test, whether PP or as-treated.

ANCOVAs were computed to test for significant differences in post-test anxiety and depressive symptom scores by program model, on a PP and 'as-treated' basis. The models were adjusted for age, caregiving, CR program adherence, and PHQ-2 score pre-CR. No significant differences were observed. Given this, post-hoc equivalency tests were run[56], to establish whether these psychosocial indicators could be considered equivalent by program model at post-test on a PP basis. Social support, QoL, as well as depressive and anxious symptoms were all considered "equivalent".

Discussion

This was the first trial to have investigated women's health behaviors and psychosocial outcomes attending one of 3 CR program models. Improvements in physical activity and quality of life were observed with participation in supervised CR models (i.e., mixed-sex and women-only). While there were no significant changes in physical activity among home-based participants, their pre-CR physical activity was almost as high as the post-CR activity reported

by the mixed-sex and women-only participants. Overall, the hypotheses regarding better behavioural and psychosocial outcomes with participation in women-only CR were not supported. However, on an unadjusted basis, dietary improvements were only observed in women attending women-only CR (i.e., as-treated). Moreover, women randomized to women-only CR (i.e., PP) had significantly lower anxiety symptoms than women in mixed-sex CR, and women attending women-only CR had significantly lower depressive symptoms than women in mixed-sex CR (i.e., as-treated). Taken as a whole, the findings herein suggest that behavioral and psychosocial outcomes were largely equivalent regardless of program model, however women-only programs may confer an advantage for anxiety and depressive symptoms.

Women were consistently adherent to their medications, mainly non-smoking, and reported consuming the equivalent of roughly a 25% fat diet. Lack of observed change or model differences in the former two health behaviors 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. While there were no program model-related differences in health behaviors in adjusted analyses, women who did not attend CR did not realize any significant improvements in health behaviors. This is in line with previous research showing that women benefit when they participate in CR[19].

With regard to quality of life, there was a significant improvement overall pre to post-program, but particularly among those in a supervised model. Contrarily, in Beckie et al.'s trial of mixed-sex versus women-only CR, they found participation in women-only but not mixed-sex CR was associated with significantly improved quality of life[25]. However, arguably non-traditional QoL measures were administered, and the CR programs differed in more ways than

just sex composition. Similar to the Cochrane review[57], our adjusted results and equivalency test support the equivalence of home-based and mixed-sex programs in improving quality of life, and extend them to suggest that similar effects are achieved with women-only CR participation. However, given that this study presents secondary outcomes of the CR4HER trial, it is possible that this study was not sufficiently powered to demonstrate model differences. Future research is needed to assess whether supervised CR is superior to home-based CR for women with regard to improving quality of life.

Surprisingly there were no model differences in social support, even considering the women who did not initiate CR or attended a home-based program where they would not have interaction with peers. Also unanticipated was the fairly low degree of depressive symptoms among women[4]. In contrast, there was a high degree of anxiety post-CR indicating that perhaps this mental health concern was not adequately addressed by CR programming.

Implications

The present trial was designed to test whether participation in women-only CR results in improved health behaviors and psychosocial well-being 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 heart-health behaviors and psychosocial outcomes, in conjunction with the primary outcomes of this trial showing no model differences in program adherence (data found elsewhere[55]), it may be concluded that no CR program model is of particular advantage for women. Instead, promoting greater use of CR among women[13] and wider availability of motivationally-focused CR programs as implemented by Beckie et al.[24] may represent important means to improve women's cardiac outcomes.

Another key implication of this trial is 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 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 motivated to exercise than those who did not. However, emerging evidence suggests nonresponse bias may be less impactful than previously thought[58]. Second, some retention bias was also noted, which limits the generalizability of the findings. The main models were adjusted by these factors to mitigate this threat. Third, many participants did not adhere to randomization, and this high degree of crossover could have biased findings. Fourth, testing differences in health behaviors and psychosocial outcomes 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 lack of power. Fifth, similar to previous studies, we found significant gains in self-reported physical activity pre to post-CR in patients that attended supervised CR[59]; however, no significant gains in daily steps walked using objective assessment were observed. This discrepancy is likely due to women over-estimating their physical activity. Furthermore, only a small group of patients returned both the pre and post-test pedometers, and thus this analysis was likely under-powered. Future research is needed to robustly test the impact of program model on objectively-assessed physical activity among women. 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.

In conclusion, while diet improved and depressive and anxious symptoms were lower with women-only CR participation, and physical activity and quality of life improved with supervised CR participation, overall adjusted results of this trial suggest that women's outcomes are equivalent regardless of participation in women-only, mixed-sex or home-based CR. Participation in women-only CR was associated with significantly lower anxiety symptoms post-program when compared to participation in mixed-sex CR in PP analyses. While this association did not sustain adjustment, given the high degree of anxiety observed this finding warrants replication. Overall, strategies to ensure more women utilize CR, regardless of model, should be implemented.

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Figure Legends and Captions:

Figure 1. CR4HER Study Flow Diagram

Figure 2a. Mean Anxious Symptoms at Post-Test by Program Model (Per Protocol), N=113

Denotes significant difference between participants randomized to different CR program models using ANOVA (post-hoc LSD test) - *p<.05

Overall model p<.05

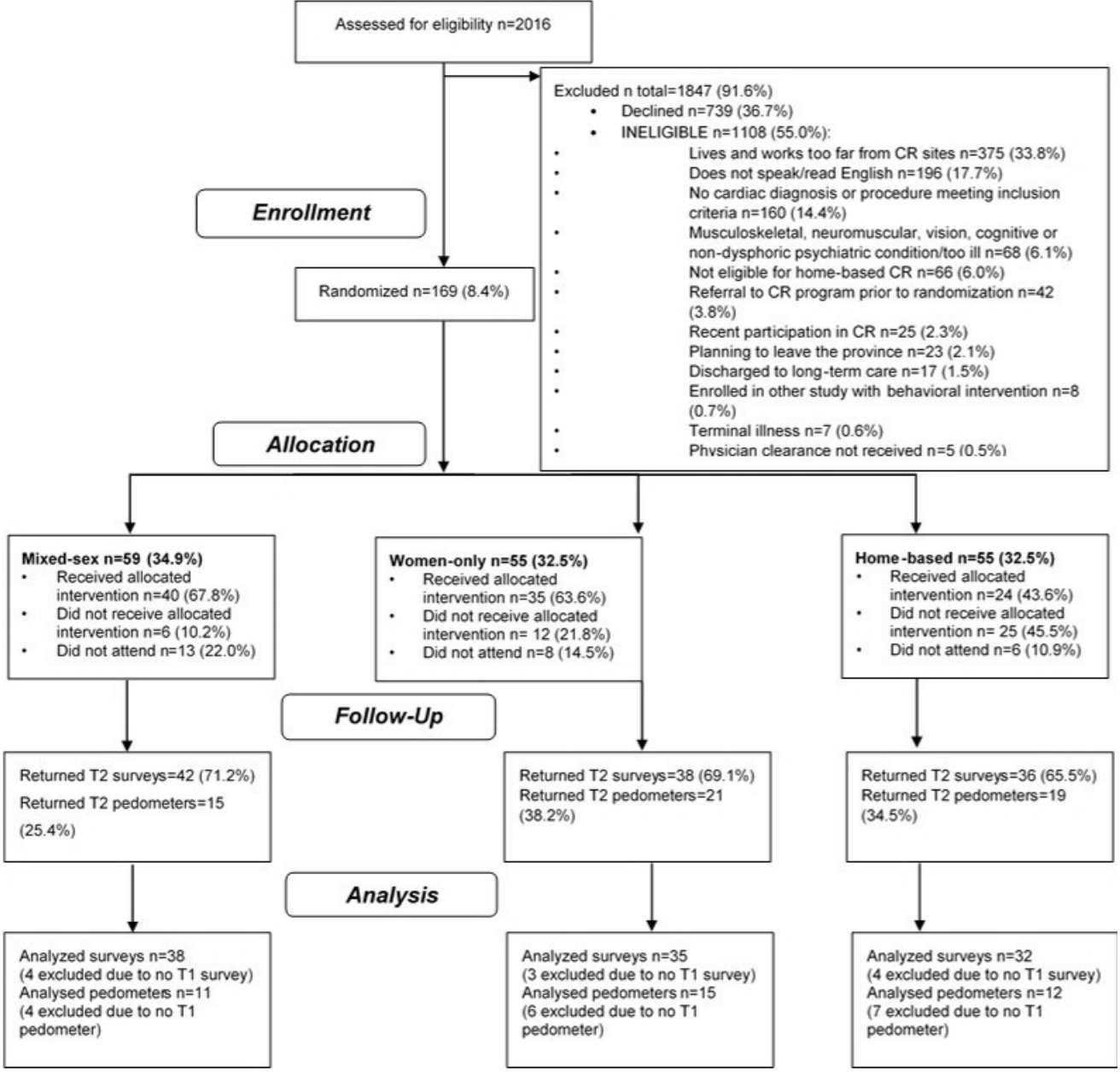
Whiskers represent minimum and maximum values.

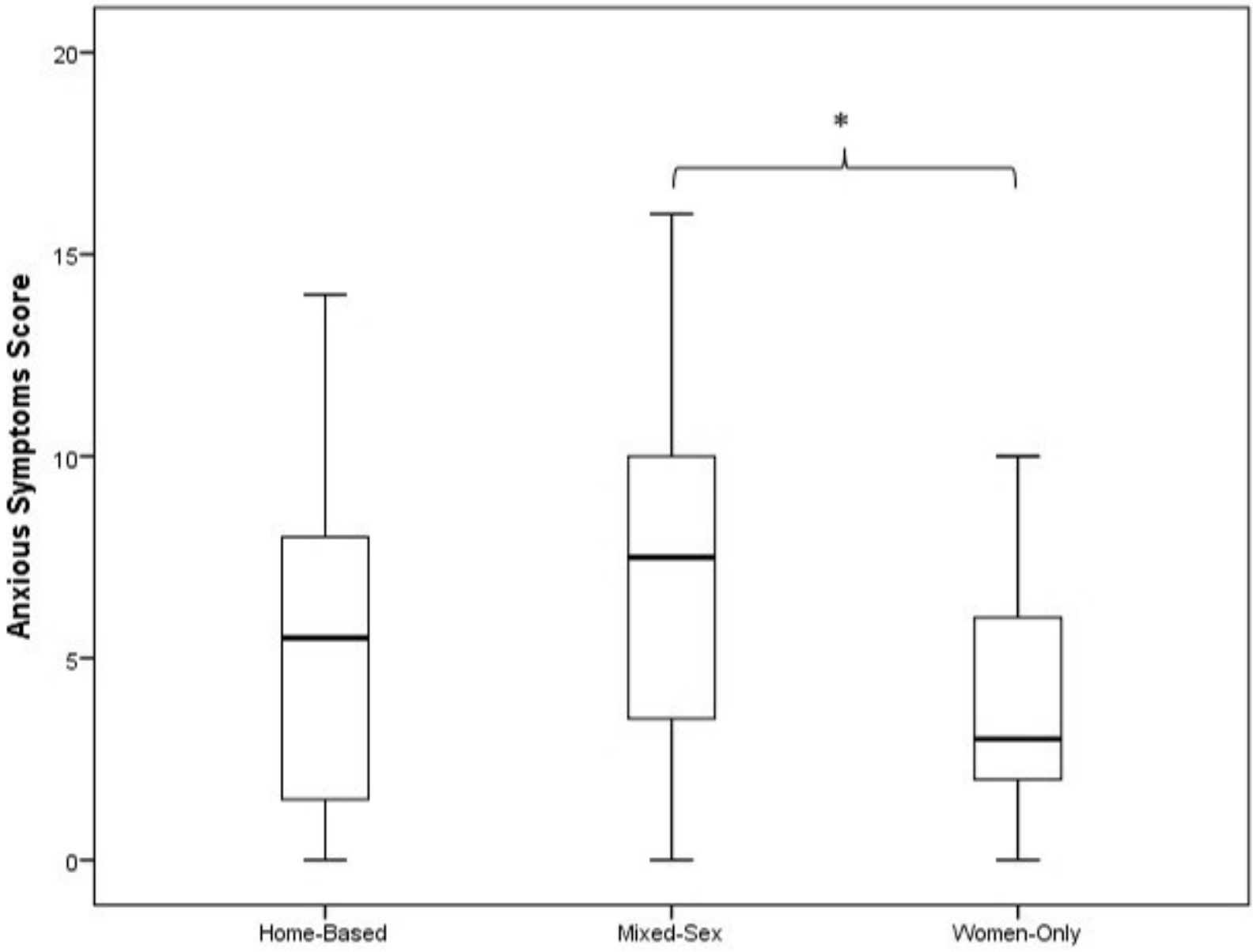
Figure 2b. Mean Depressive Symptoms at Post-Test by Program Model (As-Treated), N=113

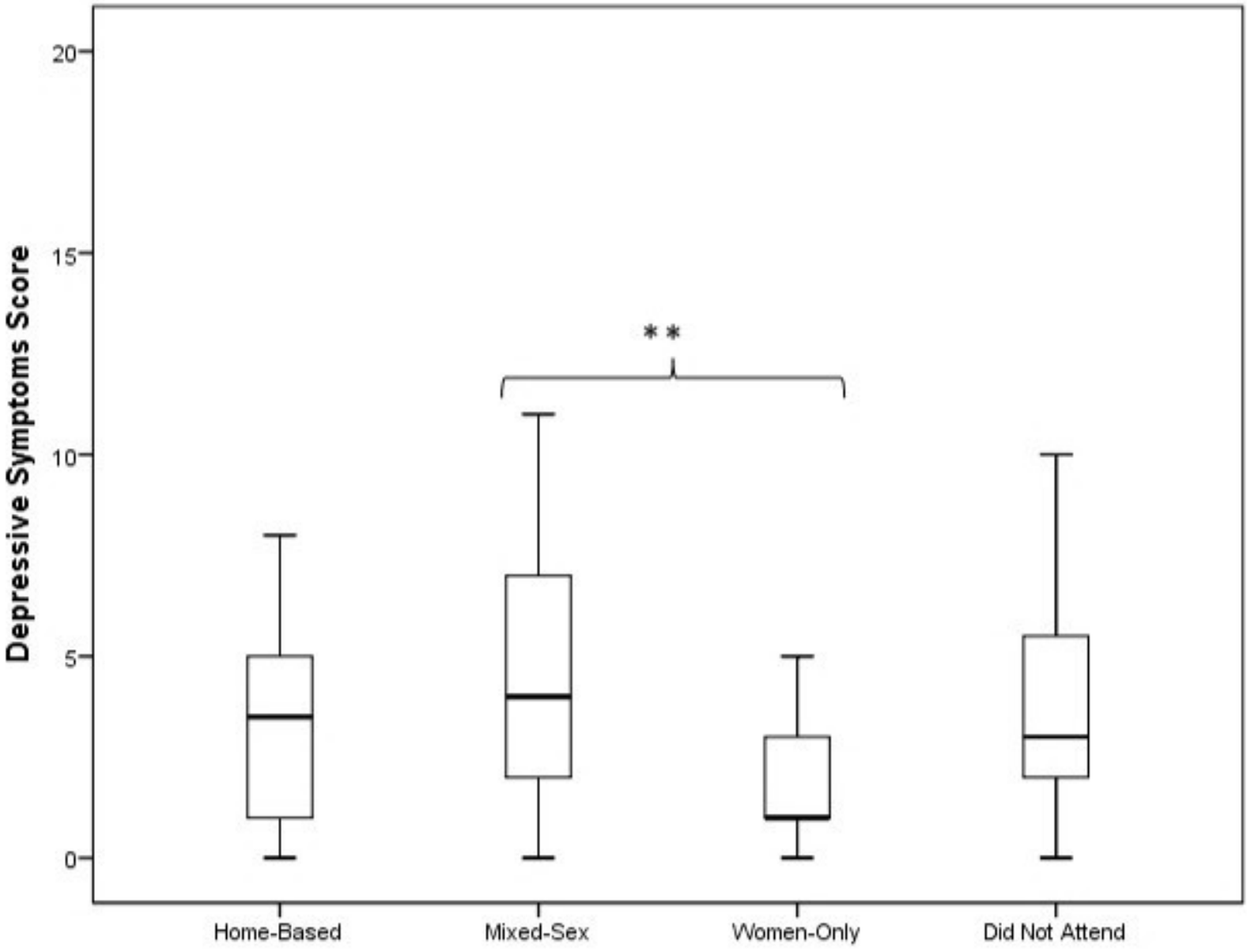
Denotes significant difference between participants attending different CR program models using ANOVA (post-hoc LSD test) - **p<.01

Overall model p<.01

Whiskers represent minimum and maximum values.


Assessed for eligibility n=2016
Excluded n total=1847 (91.6%)
Declined n=739 (36.7%)
INELIGIBLE n=1108 (55.0%):
Lives and works too far from CR sites n=375 (33.8%)
Does not speak/read English n=196 (17.7%)
No cardiac diagnosis or procedure meeting inclusion criteria n=160 (14.4%)
Musculoskeletal, neuromuscular, vision, cognitive or non-dysphoric psychiatric condition/too ill n=68 (6.1%)
Not eligible for home-based CR n=66 (6.0%)
Referral to CR program prior to randomization n=42 (3.8%)
Recent participation in CR n=25 (2.3%)
Planning to leave the province n=23 (2.1%)
Discharged to long-term care n=17 (1.5%)
Enrolled in other study with behavioral intervention n=8 (0.7%)
Terminal illness n=7 (0.6%)
Physician clearance not received n=5 (0.5%)
Enrollment
Randomized n=169 (8.4%)
Allocation
Mixed-sex n=59 (34.9%)
Received allocated intervention n=40 (67.8%)
Did not receive allocated intervention n=6 (10.2%)
Did not attend n=13 (22.0%)
Women-only n=55 (32.5%)
Received allocated intervention n=35 (63.6%)
Did not receive allocated intervention n= 12 (21.8%)
Did not attend n=8 (14.5%)
Home-based n=55 (32.5%)
Received allocated intervention n=24 (43.6%)
Did not receive allocated intervention n= 25 (45.5%)
Did not attend n=6 (10.9%)
Follow-Up
Returned T2 surveys=42 (71.2%)
Returned T2 pedometers=15 (25.4%)
Returned T2 surveys=38 (69.1%)
Returned T2 pedometers=21 (38.2%)
Returned T2 surveys=36 (65.5%)
Returned T2 pedometers=19 (34.5%)
Analysis
Analyzed surveys n=38
(4 excluded due to no T1 survey)
Analysed pedometers n=11
(4 excluded due to no T1 pedometer)
Analyzed surveys n=35
(3 excluded due to no T1 survey)
Analysed pedometers n=15
(6 excluded due to no T1 pedometer)
Analyzed surveys n=32
(4 excluded due to no T1 survey)
Analysed pedometers n=12
(7 excluded due to no T1 pedometer)


Anxious Symptoms Score
20
15
10
5
0
*
Home-Based
Mixed-Sex
Women-Only


Depressive Symptoms Score
20
15
10
5
0
**
Home-Based
Mixed-Sex
Women-Only
Did Not Attend

There were 3 CR sites involved in the trial, each offering CR delivered as per guidelines[28]. The programs lasted four to six months. Participants attending on-site CR programs exercised in the facility 1-2 times per week, for up to one hour. The only differences between the site based programs were the sex composition and some education session content (e.g. focus on different comorbidities such as osteoporosis and arthritis which is more prevalent among women). Home-based participants exercised at home and were phoned at varying intervals, depending on CR site protocols. All participants were encouraged to accumulate at least 150 minutes of exercise per week at their target heart rate, preferably exercising most days of the week[29]. CR personnel at all sites included a physician, dietitian, exercise physiologists, and a nurse. CR program staff members were not aware of study objectives, or which participants were involved in the trial.

Participants

Female patients with documented coronary artery disease, and/or acute coronary syndrome, and/or undergoing revascularization (e.g., coronary artery bypass graft surgery or percutaneous coronary intervention), and/or valve surgery, who were eligible for CR were approached. The inclusion criteria were: residency in the city where the CR programs were offered, proficiency in the English language, written approval to participate in CR by the patient's cardiac specialist or general practitioner, and eligibility for home-based CR (i.e., low to moderate risk of an adverse event during exercise as demonstrated by: [1] lack of complex ventricular dysrhythmia, [2] New York Heart Association[30] Class of 1 or 2, and left ventricular ejection fraction >40%, or [3] Canadian Cardiovascular Society[31] Class 1 or 2). Exclusion criteria were: musculoskeletal, neuromuscular, visual, cognitive or serious mental illness, or any serious or terminal illness not otherwise specified which would preclude CR eligibility based on

CR guidelines[28]; physician deemed patient not suitable for CR at time of intake exercise stress test; patient planned to leave the area prior to the anticipated end of participation; patient discharged to a long-term care facility; and participation in another clinical trial with behavioral interventions.

Measures

Sociodemographic characteristics such as income, education, age, marital status, number and age of children, and caregiving responsibilities were assessed through forced-choice items in the initial survey. Clinical data extracted from medical charts included disease severity indicators (e.g., Canadian Cardiovascular Society[31] and New York Heart Association[30] classes), comorbid conditions, prescribed cardiac medications, and risk factors (e.g., blood pressure, lipid profile). The below outcome measures were assessed at pre and post-test.

Heart-Health Behaviors

Exercise behavior was assessed via pedometer and self-report (i.e., Godin Leisure-Time Exercise Questionnaire[32]). 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[33–36], and has been shown to be valid and reliable in a wide range of settings[37–39]. 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, and instructed to record the total number of steps taken per day in an activity log. 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 10000 steps/day is generally considered indicative of an active lifestyle, this target may be too high for patients with chronic diseases[40]. As such, pedometer data were interpreted and scored using a pedometer index for patients with CVD, whereby 6500–8500 steps/day are recommended to achieve the total amount of physical activity energy expenditure generally recommended for secondary prevention[41].

With regard to the latter, the Godin survey[32] is a brief and reliable instrument to assess usual leisure-time physical activity during a one-week period. For the first question, weekly frequencies of strenuous, moderate, and light activities are assessed. 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 (where scores ≥20 are indicative of someone who is 'active'[32]). The Godin scale provided information on the intensity of physical activity in which participants engage, which was not available from the pedometers.

The pre and post-test surveys also included the Diet Habit Survey[42] to assess nutrition behavior, which is a reliable and valid instrument for rapid assessment of eating habits and diet composition. The 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[43]).

Medication adherence was assessed via the 4-item Morisky Medication Adherence Scale (MMAS)[44,45]. Questions are scored as yes=0, no=1, such that a higher score indicates higher medication adherence. Patients scoring >2 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 confirm that self-reported smoking status provides an accurate estimate of the prevalence of cigarette smoking[46].

Psychosocial Well-Being

Depressive and anxiety symptoms were assessed with the Hospital Anxiety and Depression Scale (HADS)[47]. The HADS is a 14-item scale, wherein 7 items each relate to anxiety and depressive symptoms. Each item is scored from 0-3 such that total scores can range from between 0 and 21 for either subscales. Scores above the cut-off point of 8 are indicative of elevated anxiety or depressive symptoms[48]. This was administered at post-test only. Depressive symptoms were evaluated via the 2-item Patient Health Questionnaire (PHQ-2[49]) at pre-test.

Social support was assessed using the Tangible, Informational, and Emotional Social Support Survey (TIES)[50]. The survey consists of 16 items scored from 0-2 that assess these types of social support. Higher scores are indicative of greater social support.

QoL was assessed via the EuroQOL five dimensions questionnaire (EQ-5D)[51], a standardized measure of health status applicable to a wide range of health conditions and treatments. The survey assesses mobility, self-care, usual activities, pain/discomfort and anxiety/depression, where each dimension has 3 levels: no problems, some problems, severe

problems. A single index value ranging from 0-1 can be generated for health status, where higher values indicating higher QoL.

Statistical Analyses

SPSS 22.0 was used for all analyses[52]. 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. Next, sociodemographic and clinical characteristics of retained participants retained versus those lost to follow-up were compared to evaluate if there was a retention bias in the sample, using t-tests and chi-squares as appropriate.

First, a pre-test descriptive examination of the number and percent of participants meeting Canadian Physical Activity exercise guidelines[53] as assessed via pedometer and self-report was described, as well as those abstaining from tobacco use, and those that met the cut-off to be considered "adherent" to medical therapy on the MMAS-4. A descriptive examination of the Diet Habit Survey and its subscales was also undertaken. Similar descriptive analyses of the PHQ-2, TIES, and EQ5d were undertaken to ascertain the degree of depressive symptoms, social support, and QoL, respectively.

Second, assessment of change in health behaviours and psychosocial indicators from pre to post-test using paired t-tests was conducted. These analyses were conducted in the total sample, regardless of model and by model, on a: (1) 'per protocol' (PP), and (2) "as-treated" basis. Results are presented consistently in this order. Smoking behavior was assessed using McNemar's test.

A descriptive examination of heart-health behaviors and psychosocial well-being at post-test was then undertaken, particularly in relation to established thresholds. ANOVAs were also computed for all the post-test scores by program model, again on a PP, and "as-treated" basis. Lastly, ANCOVAs were computed where ANOVAs were significant. Post-test scores served as the dependent variable, program model as the independent variable, and corresponding baseline scores (for the ANCOVA for depressive symptoms, the PHQ-2 was entered) along with any participant sociodemographic and clinical characteristics related to retention identified above as covariates.

Table S1. Pre-Test Participant Characteristics by CR Model (As-Treated)

Characteristics	Women-Only	Mixed-sex	Home-Based	Did Not Attend	Total
	N= 45 (26.6%)	N=70 (41.4%)	N=27 (16.0%)	N=27 (16.0%)	N=169
Sociodemographic[§]					
Age, years (mean±SD)	66.49±9.38	63.55±9.28	60.22±11.94	62.52±12.23	63.64±10.42
Marital Status (% married)	24 (64.9%)	29 (47.5%)	13 (54.2%)	6 (27.3%)	72 (50.0%)*
Work Status (% retired)	24 (64.9%)	32 (52.5%)	6 (25.0%)	10 (45.5%)	72 (50.0%)*
Ethnicity (% white)	21 (56.8%)	37 (60.7%)	17 (70.8%)	15 (68.2%)	90 (62.5%)
Education, (% post-secondary)	13 (35.1%)	26 (42.6%)	8 (33.3%)	7 (31.8%)	54 (37.5%)
Gross Annual Family Income (% <$50,000 CDN)	13 (39.4%)	26 (49.1%)	9 (40.9%)	10 (58.8%)	58 (46.4%)
Provide care to someone in household (% yes)	4 (16.0%)	6 (16.2%)	2 (11.1%)	4 (30.8%)	16 (17.2%)
Children (% yes)	30 (81.1%)	51 (86.4%)	21 (87.5%)	18 (85.7%)	120 (85.1%)
Clinical (% yes)					
Indication for CR					
PCI	16 (35.6%)	37 (56.1%)	12 (44.4%)	16 (59.3%)	81 (49.1%)
Angina/ACS/CAD	16 (35.6%)	26 (40.0%)	7 (26.9%)	10 (37.0%)	59 (36.2%)
MI	13 (28.9%)	24 (35.8%)	11 (42.3%)	11 (40.7%)	59 (35.8%)
CABG	16 (35.6%)	15 (22.7%)	4 (14.8%)	7 (25.9%)	42 (25.5%)
Valve	12 (27.3%)	9 (13.4%)	8 (29.6%)	3 (11.1%)	32 (19.4%)
Risk Factors					
Dyslipidemia	28 (84.8%)	43 (84.3%)	12 (66.7%)	21 (91.3%)	104 (83.2%)
Hypertension	31 (88.6%)	39 (73.6%)	11 (50.0%)	20 (83.3%)	101 (75.4%)**
Obesity	16 (51.6%)	18 (41.9%)	8 (38.1%)	7 (33.3%)	49 (42.2%)
Diabetes	12 (41.4%)	15 (34.9%)	4 (19.0%)	7 (31.8%)	38 (33.0%)
Comorbidities					
Musculoskeletal Impairment	6 (15.4%)	4 (7.3%)	3 (18.8%)	7 (31.8%)	20 (15.2%)
Depression	4 (10.3%)	8 (14.5%)	2 (12.5%)	1 (4.8%)	15 (11.5%)
Cancer	2 (5.1%)	3 (5.5%)	1 (7.1%)	2 (9.1%)	8 (6.2%)
Hyperthyroid	0 (0.0%)	2 (3.6%)	2 (12.5%)	2 (9.5%)	6 (4.6%)
Renal Disease	1 (2.6%)	2 (3.7%)	0 (0.0%)	1 (4.8%)	4 (3.1%)
PAD/PVD	0 (0.0%)	1 (1.9%)	1 (6.3%)	0 (0.0%)	2 (1.5%)
Intake Assessment					

Resting Heart Rate (bpm)	75.81±13.78	74.06±15.76	74.21±15.11	79.96±15.24	75.54±15.06
Waist Circumference (cm)	93.96±17.29	94.09±12.58	92.40±12.91	98.83±15.30	94.15±14.34
Peak VO_2 (mL/(kg·min)	18.39±7.49	16.40±5.36	19.73±9.20	17.89±8.22	17.62±6.97

*p<.05; **p<.01

SD, Standard Deviation; PCI, Percutaneous Coronary Intervention; ACS, Acute Coronary Syndrome; CAD, Coronary Artery Disease; MI, Myocardial Infarction; CABG, Coronary Artery Bypass Graft; PAD/PVD, Peripheral Arterial Disease/ Peripheral Vascular Disease; Peak VO_2, Peak Oxygen Uptake.

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

Table S2. Participant Characteristics by Retention Status

Characteristics	Retained†	Lost to Follow-Up	Total
	N=116 (68.6%)	N=53 (31.4%)	N=169
Sociodemographic§			
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***

*T-test p<.05; ** p<.01; *** p<.001
SD, Standard Deviation; PCI, Percutaneous Coronary Intervention; ACS, Acute Coronary Syndrome; CAD, Coronary Artery Disease; MI, Myocardial Infarction; CABG, Coronary Artery Bypass Graft; PAD/PVD, Peripheral Arterial Disease/ Peripheral Vascular Disease; Peak VO_2, Peak Oxygen Uptake.

†completed a post-test survey.

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

Table S3. Mean (± standard deviation) Diet Habit Survey Sub-Category Scores in Participants Pre and Post-CR, N=99

	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	10380±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 S4. 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†	5442.73±2875.36	6108.32±3761.54	665.58	-	-	-
Mixed-sex	6339.42±2870.35	6022.13±2959.79	-317.29	5771.71±2799.30	5872.72±2797.40	101.01
Women-only	4428.90±2327.04	5240.13±3106.09	811.24	5390.76±2675.18	6290.44±3055.43	899.68
Home-based	5888.06±3317.47	7272.55±4983.56	1384.49	6074.48±3480.38	7802.61±5792.55	1728.13
Did not start	-	-	-	3183.71±2263.37	2997.93±2669.80	-185.79
Self-reported physical activity	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
Medication Adherence 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, Godin Leisure Time-Exercise Questionnaire 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

Table S5. Mean (± standard deviation) Social Support and Quality of Life Scores in Participants Pre and Post-CR

	Per Protocol			As-treated		
	Pre-CR	Post-CR	Change	Pre-CR	Post-CR	Change
Social support	18.63±7.72	18.75±8.13	0.12	-	-	-
Mixed-sex	17.44±8.67	17.62±9.07	0.18	17.23±7.52	17.05±7.94	-0.19
Women-only	18.23±8.04	18.09±7.80	-0.14	18.96±8.47	19.71±8.10	0.75
Home-based	20.39±5.99	20.74±7.28	0.35	20.76±6.13	20.82±6.99	0.059
Did not start	-	-	-	19.83±8.59	19.67±10.08	-0.17
Quality of life	0.78±0.17	0.83±0.18	0.054**	-	-	-
Mixed-sex	0.74±0.18	0.79±0.20	0.053*	0.74±0.21	0.81±0.21	0.064*
Women-only	0.78±0.15	0.86±0.16	0.076*	0.78±0.16	0.88±0.14	0.093**
Home-based	0.81±0.18	0.84±0.19	0.033	0.84±0.096	0.87±0.15	0.036
Did not start	-	-	-	0.80±0.088	0.74±0.20	-0.051

Assessment of change in TIES scores and EQ5d scores from pre to post-CR was conducted using paired t-tests; *p<.05; **p<.01