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Cardiac Rehabilitation Program Adherence and Functional Capacity Among Women: A Randomized Controlled Trial

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Abstract

Objective: To compare program adherence and functional capacity between women referred to supervised mixed-sex, supervised women-only, or home-based cardiac rehabilitation (CR).

Patients and Methods: Cardiac Rehabilitation for Heart Event Recovery (CR4HER) was a single-blind, 3 parallel-arm, pragmatic randomized controlled trial. The study took place between November 1, 2009, and July 31, 2013. Low-risk patients with coronary artery disease were recruited from 6 hospitals in Ontario, Canada. Consenting participants completed a preprogram survey, and clinical data were extracted from charts. Participants were referred to CR at 1 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.

Results: Of the 264 consenting patients, 169 (64.0%) were eligible and randomized. Twenty-seven (16.0%) did not attend, and 43 (25.4%) attended a different model. Program adherence was moderate overall (54.46%±35.14%). Analysis of variance revealed no significant differences based on per-protocol analysis ($P=.63$), but as-treated, home-based participants attended significantly more than did women-only participants ($P<.05$). Overall, there was a significant increase in functional capacity preprogram to postprogram ($P<.001$). Although there were no significant differences in functional capacity by model at CR exit based on per-protocol analysis, 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 did women attending home-based programs ($P<.05$).

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

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For editorial comment, see page 125; for related articles, see pages 129 and 149

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Cardiovascular disease is the leading cause of mortality for women in the United States.[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 are men.[3]

Cardiac rehabilitation (CR) is a cost-effective[4] outpatient secondary prevention program composed of structured exercise training and comprehensive education and counseling, addressing cardiac risk.[5-7] Participation has been shown to reduce cardiovascular mortality by 26%,[8] with a dose-response association between degree of program adherence and mortality reductions.[9,10] Participation also reduces the need for rehospitalization and revascularization procedures[11,12] and leads to improved functional status[13] when compared with usual care.[4]

Studies examining women's outcomes after CR specifically are limited, yet similarly positive.[14] 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[15] reported

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considerably lower CR utilization among women (39%) than among men (45%).

Once women enroll in CR, they are less likely to adhere to these programs than do men[16,17]; as such, they would be less likely to achieve the associated health benefits. The question of whether CR programs are equally appealing to both sexes has been raised in the literature,[18] with the suggestion that women may benefit from alternative CR models.[18,19] However, 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 that are commonly reported by women.[20] Moreover, fear and embarrassment are common concerns voiced by women when considering group exercise, which is overcome with home-based exercise, especially in patients who are older or belong to certain ethnocultural groups.[21] In addition, women are often hesitant to exercise in mixed-sex settings because of a lack of experience, low levels of functional ability, and self-consciousness regarding body image.[22,23] Accordingly, women-only programs have also been developed.[24,25]

To date, there has been only 1 randomized controlled trial (RCT) evaluating a women-only program compared with a mixed-sex CR program.[26,27] The study results found that participation in the women-only program was associated with greater program adherence than was participation in the mixed-sex CR program but that functional capacity improved regardless of the program. Although the trial was seminal, it did not include a home-based arm, which is the second most commonly offered program model.[28] Moreover, mixed-sex and women-only programs differed not only in sex composition but also in approach (ie, motivational orientation). The objectives of the present trial were to compare program adherence among patients randomized to (1) supervised mixed-sex, (2) supervised women-only, or (3) home-based CR and secondarily to compare functional capacity across these 3 CR program models. It was hypothesized that both program adherence and functional capacity would be significantly greater with women-only CR.

PATIENTS AND METHODS

Design and Procedure

This was a single-blind, 3 parallel-arm pragmatic RCT,[29] with 1:1:1 allocation concealed. Female patients were randomized to 1 of 3 models: (1) supervised mixed-sex, (2) supervised women-only, or (3) home-based CR (Figure 1). 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 and/or valve surgery) through randomize.net.

Recruitment occurred from November 2009 to July 2013, with patient follow-up 6 months after CR enrollment. Patients were recruited from 6 inpatient and outpatient cardiac settings in the Greater Toronto Area of Ontario, Canada. There are only 3 CR sites that offer all 3 program models investigated herein in this region. These CR programs were selected to serve as sites for the trial, with recruitment carried out in the inpatient cardiac units that referred patients to said sites, so as to increase the generalizability of the sample.

Female patients were identified through ward/program censuses and invited to participate. The study was approved by institutional review boards at all sites involved, and participants signed written informed consents. 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 before enrollment in the trial.

Baseline assessments occurred before the start of CR, around the time of consent. Patients were asked to complete a baseline self-report survey including sociodemographic characteristics. 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), which included a graded exercise stress test. Consenting patients who met inclusion criteria and did not decline randomization were then randomized to 1 of the 3 CR models. Recruiters went online to ascertain random allocation and informed patients and CR sites.

There were 3 CR sites involved in the trial, each offering all 3 models of CR, delivered as per American guidelines.[5] The programs lasted

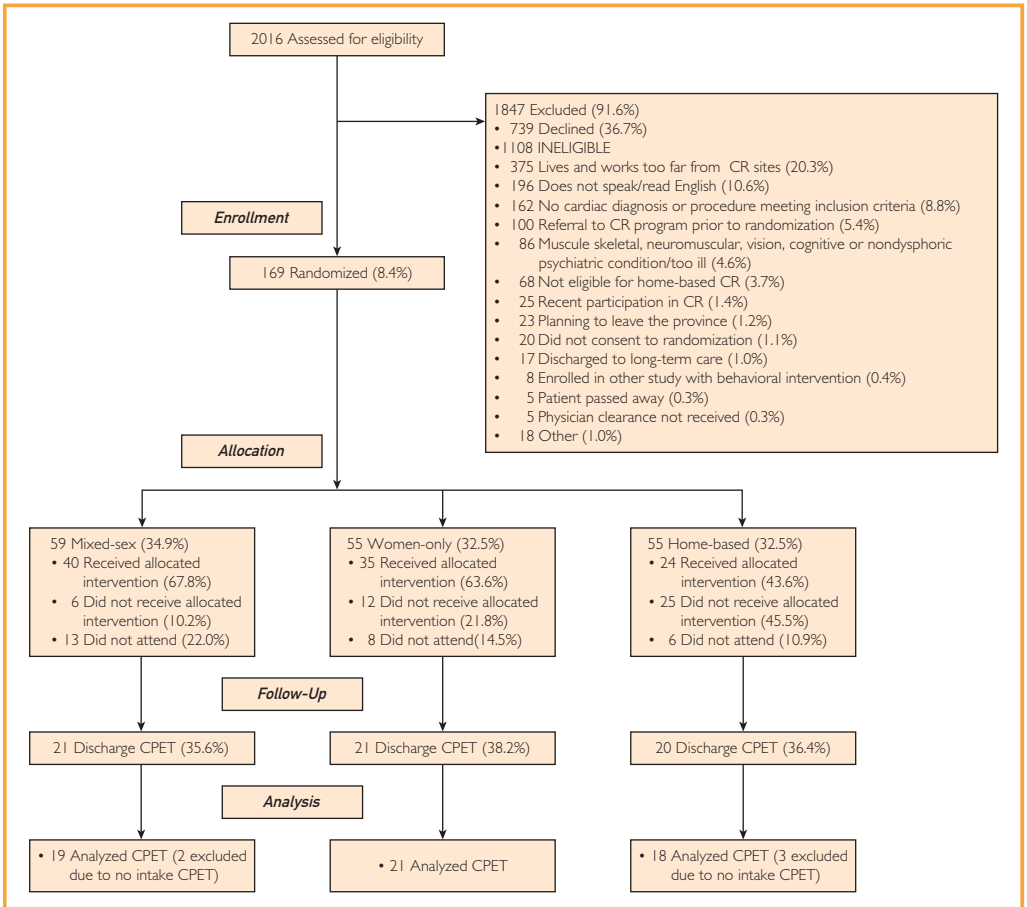

FIGURE 1. Cardiac Rehabilitation for Heart Event Recovery (CR4HER) study flow diagram. "Did not attend" includes both patients who did not enroll postreferral and those who enrolled (ie, attended an intake assessment) but then did not attend any supervised exercise classes.

4 to 6 months, with provincial insurance covering the cost of the programs. At each site, a graded exercise stress test was performed preprogram and postprogram. Results were used to develop individualized exercise prescriptions on the basis of established guidelines,[30] and 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[31] via stationary bicycle/treadmill/walking. Participants attending onsite CR programs exercised in the facility 1 to 2 times/wk for up to 1 hour. The only differences between the site-based program models were the sex composition and some education session content (eg, focus on different comorbidities such as osteoporosis and arthritis, which are more preponderant among women). Home-based CR participants had at least 3 onsite visits and then exercised at home. They were phoned weekly or biweekly, depending on program protocols and based on patient need. They were provided the same education materials as patients attending the supervised models at their initial visit, which was reviewed on the phone with program staff. The CR personnel at all sites included a physician, a dietitian, exercise physiologists, and a nurse. The CR program staff members were not aware of study objectives or which participants were involved in the trial.

As a manipulation check, a masked research assistant checked CR charts to confirm the program model attended at the expected CR

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discharge date. Posttest CR data extraction, including stress test results, and program adherence were also undertaken by the masked research assistant.

Female patients with documented coronary artery disease, and/or acute coronary syndrome, and/or undergoing revascularization (eg, coronary artery bypass graft surgery or percutaneous coronary intervention), and/or valve surgery, who were eligible for CR were approached.

Inclusion criteria were residency in the city where the CR programs were offered, proficiency in the English language, written approval to participate in the CR program by the patient's cardiac specialist or general practitioner, and eligibility for home-based CR (ie, low to moderate risk of an adverse event during exercise as demonstrated by lack of complex ventricular dysrhythmia, New York Heart Association[32] class 1-2 classification, and left ventricular ejection fraction of >40%, or Canadian Cardiovascular Society[33] class 1-2 classification). Exclusion criteria were musculoskeletal, neuromuscular, visual, cognitive, or serious mental illness, or any serious or terminal illness not otherwise specified that would preclude CR eligibility on the basis of CR guidelines[5]; physician deemed patient not suitable for CR at the time of intake of exercise stress test; patient planned to leave the area before the anticipated end of participation; patient discharged to a long-term care facility; and participation in another RCT with behavioral interventions.

Measures

Sociodemographic characteristics were assessed through forced-choice items in the initial survey. Clinical data extracted from medical charts included disease severity indicators, comorbid conditions, prescribed cardiac medications, and risk factors (eg, blood pressure and lipid profile).

The primary dependent variable of program adherence was assessed as follows: CR program staff members recorded the number of onsite 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 onsite 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 on the basis of participation in the clinical event. It was also ascertained whether the patient enrolled (defined as patient attendance at CR intake)[34] and completed (defined as attending at least some of the CR intervention components and having a formal reassessment by the CR team at the end)[34] the program. Exercise adherence as measured by pedometer and by self-report was part of the secondary outcomes of the trial, and will be reported elsewhere (L. Midence, unpublished data, 2015).

The secondary outcome was assessed before and after CR. Functional capacity was operationalized as peak volume oxygen consumption per minute (peak V_{O_2}) on the exercise stress tests, measured in milliliters per minute. All patients underwent symptom-limited graded exercise testing assessed via a modified Bruce protocol.[35] 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, V_{O_2} was measured breath by breath, and the peak V_{O_2} defined as the averaged value of the 3 measurements taken in the last minute of exercise. Exercise testing was terminated prematurely where indicated as per American College of Cardiology/American Heart Association guidelines.[36]

Statistical Analyses

SPSS 21.0 (IBM) was used for all analyses.[37] For all analyses, statistical significance was defined by $P<.05$ (2-sided).

Power calculations based on a pilot study (with 75.37% program adherence for mixed-sex vs 80.36% for women-only and 87.00% for home-based[38-40]) suggested that a sample size of 261 patients was needed to detect a difference in adherence by program model at 80% power at the 5% significance level.

For the primary outcome of program-verified CR adherence, analysis of variance was 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; ie, by random allocation, where outcomes were ascertained) and "as-treated" (ie, the CR model actually attended) basis. Post hoc least significant difference (LSD) tests were used for multiple comparisons if equal variance in program adherence across program models was found, and Games-Howell test was used if equal variances were not found.

With regard to functional capacity, first assessment of change from pretest to posttest using paired *t* tests was conducted, overall and by model. To test the secondary objective, analysis of variance was used with posttest peak V_{O_2} as the dependent variable and program model as the independent variable. Then, analysis of covariance was computed, adding baseline peak V_{O_2}, along with any differences in participant characteristics that 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.

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. Overall, 264 patients consented, of which 169 (64.0%) eligible patients were randomized. One hundred thirty-three of the 169 (78.7%) completed a pre-CR stress test (of which 107 of 143 or 74.8% were CPETs).

Supplemental Table 1 (available online at http://www.mayoclinicproceedings.org) presents the sociodemographic and clinical characteristics of participants by randomized model. There were no significant differences between patients randomized to each of the 3 models (all $P>.05$).

Through chart extraction, CR enrollment was ascertained for 164 of 169 (97.0%) participants. Overall, 20 of 169 (11.8%) participants did not attend the CR program even once for an intake assessment despite referral, and an additional 7 of 169 (4.1%) patients did not initiate the program following intake (Figure 1, Allocation "did not attend"). Forty-three of the 169 (25.4%) participants attended a different model than the program to which they were randomly allocated (Figure 1, Allocation "did not receive allocated intervention"). The model to which these participants switched and reasons are reported elsewhere[41] 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 the CR program 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 patients who dropped out for nonclinical reasons. No other sociodemographic or clinical differences between groups were observed.

Of the 96 patients who completed their CR program, 62 (64.6%) had an exit CPET, whereas 58 (60.4%) had both a pre-CPET and a post-CR CPET. Supplemental Table 2 (available online at http://www.mayoclinicproceedings.org) presents the sociodemographic and clinical characteristics of participants who completed an exit CPET (retained) vs those who did not. Patients who completed an exit CPET had a lower incidence of myocardial infarction, 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.

Primary Outcome—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. Participants who did not enroll in CR postreferral effectively had 0% adherence; removing these participants provides a truer indication of program adherence. Among participants who enrolled, the mean percentage of prescribed sessions attended was 63.60%±29.29%.

Among the 6 patients who did not complete the CR program 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

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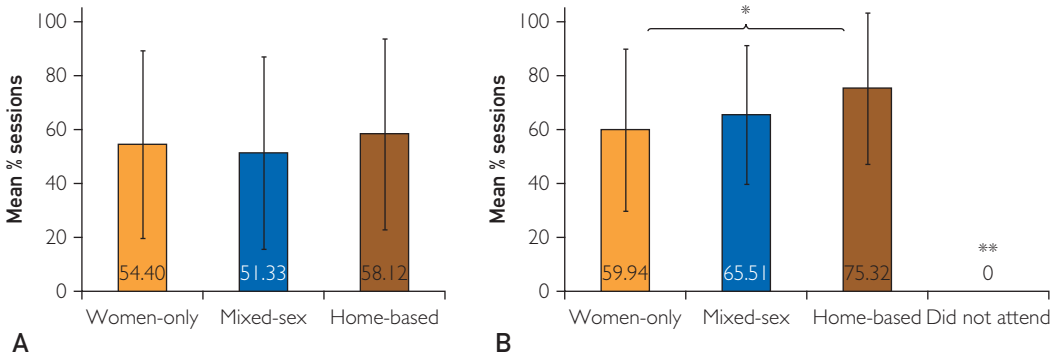

FIGURE 2. A, CR adherence by program model (PP) (N=153). No significant difference between participants randomized to different CR program models using ANOVA. Overall model, *P*=.63. Error bars represent SD. B, CR adherence by program model (as-treated) (N=153). Difference in mean program adherence between home-based and women-only programs is 15.38% (95% CI,1.57%-29.19%). Denotes significant difference between participants attending different CR program models using ANOVA (LSD post hoc test). **P*<.05; ***P*<.001. Overall model, *P*<.001. Error bars represent SD. ANOVA = analysis of variance; CR = cardiac rehabilitation; LSD = least significant difference; PP = per-protocol.

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 2, A; *P*=.63). However, there was a significant difference in the "as-treated" analysis (Figure 2, B; overall model, *P*<.001), with participants who did not initiate the CR program obviously adhering to significantly fewer sessions than did those who initiated any other program (post hoc LSD test, *P*=.001) and home-based CR participants attending a higher percentage of sessions than did women-only participants (Figure 2, B; overall model, *P*<.001; post hoc LSD test, *P*=.03; 95% CI, 1.57-29.19).

Secondary Outcome—Functional Capacity

In the overall sample, participants achieved a significant increase in functional capacity from preprogram to postprogram (Supplemental Table 3, available online at http://www.mayoclinicproceedings.org). As shown, paired *t* tests revealed that there was a significant increase in peak V_{O_2} 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. The degree of change did not differ by model (PP, *P*=.78; as-treated, *P*=.97).

An analysis of covariance adjusted for pre-CR values and confounding retention variables; there were too many variables to adjust for the given 58 patients with 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 3, A; *P*=.84). 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 home-based programs (Figure 3, B; overall model, *P*=.046; post hoc LSD test, *P*=.025; 95% CI, 0.50-6.80).

DISCUSSION

This was the first study to have investigated women's CR program adherence and functional capacity following the 3 most available CR program models. Women adhered moderately to all the CR models; contrary to the initial hypothesis and the trial by Beckie et al,[27] 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 did those attending 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

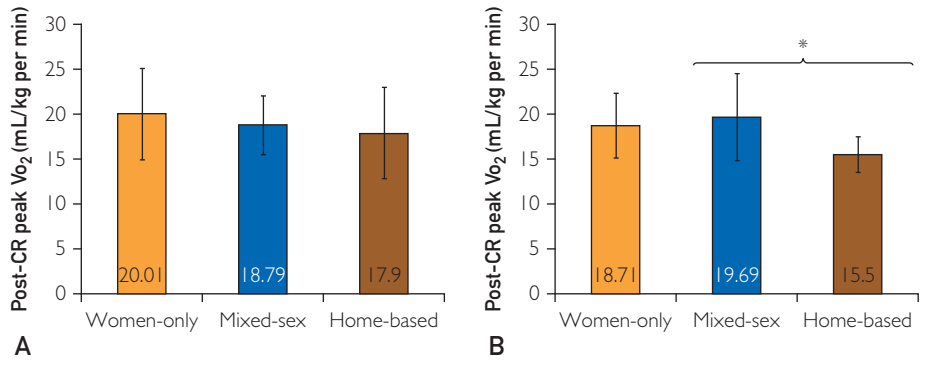

FIGURE 3. A, Post-CR peak Vo_2 by program model (PP) (N=58). No significant difference between participants attending different CR program models using ANCOVA adjusting for dyslipidemia, musculoskeletal impairment, resting heart rate, waist circumference, and baseline peak Vo_2. Overall model, *P*=.84. Error bars represent SD. B, Post-CR peak Vo_2 by program model (as-treated) (N=58). Difference in mean post-CR peak Vo_2 between home-based and mixed-sex CR program is 4.19 (95% CI, 0.50-6.80). Denotes significant difference between participants attending different CR program models using ANCOVA (LSD post hoc test). **P*<.05. Overall model, *P*<.05. Error bars represent SD. ANCOVA = analysis of covariance; CR = cardiac rehabilitation; LSD = least significant difference; PP = per-protocol; Vo_2 = oxygen uptake.

this model should be interpreted with caution. Program model allocation had no association with functional capacity, yet attended program model (as-treated) did influence functional capacity at program exit. Contrary to findings of Beckie et al,[27] women who attended mixed-sex CR had significantly higher functional capacity at program exit than did those attending women-only or 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 the supervised setting.

High adherence to CR results in reduced morbidity and mortality for heart patients. Alter et al[9] recently described a 4% decrease in the predicted probability of death or hospitalization 2 years post-CR with each 10% increase in onsite attendance. Martin et al[10] also reported a 1% decrease in mortality with each additional session attended. Specifically among women, Colbert et al[42] recently found a 64% relative risk reduction in mortality in CR completers. It was hoped that 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 meager participation in the CR program. Clearly, other means to improve women's adherence to the CR program than program model choice are warranted. In a recent update to the Cochrane review[43] on interventions to promote greater CR adherence, 3 of 8 studies demonstrated improvement in adherence to CR. Successful interventions included self-monitoring of activity, action planning, and tailored counseling by CR staff. Many of these strategies were used in the women-only CR arm of the trial by Beckie et al,[26,27] and indeed they found greater program adherence among women than among those in mixed-sex CR.

Functional capacity was significantly improved at CR exit. Increased functional capacity is also associated with a lower mortality rate.[44] A 1 metabolic equivalent of task increase in aerobic capacity equates to 13% and 15% decrease in all-cause mortality[45] and cardiovascular events, respectively.[46] 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; and the CI was very wide) but had fewer gains in functional capacity. This is likely because women had to adhere to a call only and not make a visit onsite, and they may have exercised at a lower intensity because they were not supervised. It may be concluded that home-based CR is of no

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particular advantage for women and that mixed-sex CR may be advantageous. However, replication is warranted because the latter conclusion was based on as-treated analyses.

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 than those who did not. Second, although we achieved quite fulsome ascertainment of the primary outcome, the secondary outcome was assessed only in half the sample. Some retention bias was also noted, which limits the credibility of the findings. However, it would only be expected to observe differences in functional capacity among patients who participate in the CR program, lending credence to the findings herein. Third, because of recruitment challenges, which have also been reported in other RCTs of women and CR,[47] the target sample size to adequately test the primary outcome was not reached. A post hoc analysis of power suggested that the sample size was lacking. Therefore, caution is warranted in concluding that women's participation in alternate program models will not result in improved adherence. Fourth, the operationalization of program adherence was different in the home-based arm (phone calls vs onsite visits), leading to assessment bias. Fifth, although the content of the education sessions was consistent across sites and model arms as per clinical practice guidelines,[5] the delivery method differed (ie, in-person for the mixed-sex and women-only arms vs printed material for the home-based arm). Indeed, CR includes multiple components, and because this trial was pragmatic in design, differences in the delivery of these components may have contributed to differences in adherence and functional capacity observed. Finally, generalizability of these findings is limited to women suitable for unsupervised exercise and receiving care in a health care system where CR services are reimbursed.

CONCLUSION

This was the first RCT to have investigated women's CR program adherence and functional capacity following referral to the 3 most available CR program models. The results do not clearly favor any single model, but instead demonstrate that women achieve clinically and statistically significant increases in functional capacity with any CR participation. Overall, however, women attended only half the prescribed exercise sessions. Although more research is needed on the utility of alternative program models for promoting greater CR engagement among women, proven strategies such as self-monitoring, action planning, and tailored counseling should be applied more widely.

SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at http://www.mayoclinicproceedings.org. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: **CPET** = CardioPulmonary Exercise Test; **CR** = cardiac rehabilitation; **LSD** = least significant difference; **PP** = per-protocol; **RCT** = randomized controlled trial

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