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ORIGINAL ARTICLE

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.

Trial Registration: clinicaltrials.gov Identifier: NCT01019135.

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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