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Full Title: Profile of women choosing mixed-sex women-only, and home-based cardiac rehabilitation models and impact on utilization

Authors: Fiorella A. Heald, MD^{a,b}; Susan Marzolini, PhD^{a,b}; Tracey J.F. Colella, RN, PhD^b;

Paul Oh, MD^{a,b}; Rajni Nijhawan, MD^b; Sherry L. Grace, PhD, FAACVPR, FCCS^{a,b}

^aFaculty of Health, York University, Toronto, Ontario, Canada

^bKITE-Toronto Rehabilitation Institute, University Health Network, University of Toronto,

Ontario, Canada

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Corresponding Author: Prof. Sherry L. Grace, PhD, CRFC; Bethune 368, York University, 4700 Keele Street, Toronto, Ontario, M3J 1P3, Canada; Phone: (416) 736-2100 ext. 22364; Email: <u>sgrace@yorku.ca</u>; Twitter: @sherrylgrace; ORCID: http://orcid.org/0000-0001-7063-3610

ABSTRACT

This study compared characteristics and program utilization in women electing to participate in mixed-sex, women-only, or home-based cardiac rehabilitation (CR). In this retrospective cohort study, electronic records of CR participants in Toronto who were offered the choice of program model between January 2017-February 2020 were analyzed. There were 727 women (74.7% mixed, 22.0% women-only, 3.3% home-based) who initiated CR. There were significantly more women who were not working in women-only than mixed-sex (80.4% vs 64.1%; P=.009). Session adherence was significantly greater with mixed-sex (58.8±28.9% sessions attended/25) than women-only (54.3±26.3% sessions attended/25; P=.046); program completion was significantly lower with home-based (33.3%) than either supervised model (59.7%; P=.035). Participation in women-only CR may be less accessible. Further research is needed to investigate offering remote women-focused sessions or peer support.

Key words: cardiac rehabilitation; coronary heart disease; utilization; women; access

INTRODUCTION

Cardiovascular Disease (CVD) is the leading cause of morbidity (13.5% of total disabilityadjusted life years) and mortality (33% of total deaths) for women globally.(Institute for Health Metrics and Evaluation 2021) Furthermore, women with CVD experience worse outcomes than men,(Norris et al. 2020) with higher mortality rates following myocardial infarction, percutaneous coronary intervention (PCI), and coronary artery bypass graft (CABG) surgery.(Wenger 2004; Mehta et al. 2016) With regard to morbidity, women with acute coronary syndrome and those after coronary revascularization have longer hospitalizations and higher inhospital mortality, and have 30% more readmissions within 30 days after the index hospitalization compared to men.(Mehta et al. 2016)

Cardiac rehabilitation (CR) is an outpatient, comprehensive model of care for secondary prevention, which can mitigate the above burden. These programs are generally offered in clinical centres under supervision. CR has been shown to improve outcomes, including quality of life,(Francis et al. 2019) hospital readmission rates, revascularization rates, and mortality.(Kabboul et al. 2018; Anderson et al. 2016) While there is little randomized data on women's CR outcomes specifically,(Ghisi et al. 2019) observational data suggests women may have even lower mortality than men when they fully participate.(Colbert et al. 2015) Clearly, women are in great need of these services given their poorer cardiovascular outcomes, outlined above. Given the observational data on the benefits in women as well,(Daniels et al. 2012; Engberding and Wenger 2013; Budnick et al. 2009) the clinical practice guidelines for women with CVD recommend referral to CR.(Mosca et al. 2011)

However, CR utilization is sub-optimal,(Santiago de Araújo Pio et al. 2020) and even lower in women.(Oosenbrug et al. 2016; Samayoa et al. 2014; Colella et al. 2015) Women's CR barriers have been extensively studied, (Supervía et al. 2017; Grace et al. 2009) and womenfocused models have been developed to address them. (Price et al. 2005; Turk-Adawi et al. 2021; Mamataz et al. 2021) Moreover, home-based models (i.e., patients are supported remotely in their risk reduction) (Thomas et al. 2019) may overcome women's common barriers such as transportation and time constraints due to family role obligations, and indeed some women prefer this approach. (Andraos et al. 2015; Grace et al. 2010) Equivalent outcomes are observed with home-based and supervised programs. (Anderson et al. 2017)

Our recent review revealed there are a limited number of studies regarding women-only CR that include comparison groups, and even fewer comparing women in all 3 models. (Mamataz et al. 2022[;] Mamataz et al. 2021) Therefore, the objectives of this study were to: (1) compare the sociodemographic and clinical characteristics of women who elect to participate in supervised mixed-sex, supervised women-only, or home-based CR models; (2) compare program utilization in terms of (i) session adherence and (ii) program completion between women in the three CR models. It was hypothesized that utilization by women would be lower in mixed-sex versus the other models.

MATERIALS AND METHODS

DESIGN AND PROCEDURE

This was a retrospective cohort study, with 3 groups. Data used in this study were extracted from an electronic patient management record utilized across the University Health Network (UHN) Cardiovascular Prevention and Rehabilitation sites located in Toronto from January 1, 2017 to February 28, 2020; data were extracted from pre and post-program. Institutional research ethics board approval was obtained from UHN (ID#20-6035).

SETTING

UHN is an academic health sciences center comprised of several hospitals, with an advanced cardiac program. There are 2 CR programs (at Toronto Western Hospital [acute care centre] and Toronto Rehabilitation Institute [large outpatient centre]). The programs are staffed by a multi-disciplinary team, with exercise specialists' case-managing patients. The cost of the CR program (including the home-based model) is covered by provincial health insurance; however, patients pay for parking each visit.

Patients are systematically referred from the inpatient cardiology unit of the institution, as well as another proximate hospital; outpatient referrals are also accepted from primary care and outpatient cardiology clinics. Before starting the program, every patient completes an intake assessment. A follow-up appointment for an exercise stress test is scheduled.

Models

At the time of the exercise stress test, patients are given the option to choose between the supervised program at the centres or the home-based program, and women have the additional option of the supervised women-only program. Model selection is primarily based on patient preference rather than clinical criteria, although patients are encouraged to enroll in a class that best suits their medical condition. There are fewer class time options for women-only (1x/week for women-only at both sites vs 13x/week at Toronto Rehab and 6x/week at Toronto Western for mixed-sex), and there are no evening options as with the mixed-sex model. Details regarding the models are summarized below, but full details including what is delivered for each component is available in a companion publication reporting on patient outcomes in the cohort.(Heald et al.

2021)

Both the supervised mixed-sex and women-only models offer a comprehensive program that consists of structured exercise, patient education

(https://www.healtheuniversity.ca/en/cardiaccollege/Pages/default.aspx)(Ghisi et al. 2015), risk factor management, dietary as well as psychosocial counselling, in addition to other components as needed. After the intake assessment, there are weekly classes on-site over 6 months (25 sessions total); each class lasts approximately 90 minutes. Aside from women being the only sex participating in the women-only program and that examples during patient education are tailored to the audience, all aspects of the program are consistent with supervised mixed-sex program (i.e., not gender-tailored content). Mixed-sex had 40 to 50 patients with two supervisors/case managers and women-only had the same.

The home-based model is a personalized program supported by online patient education.(Scane et al. 2012) In addition to the on-site assessments as outlined above, homebased patients also come to the centre for a one-on-one orientation, as well as an aerobic exercise trial and resistance training instruction at the start of the program. Patients have weekly telephone consultations for the first 3 months, with less frequent telephone consultation thereafter through month 6 (same overall program duration as supervised models), each lasting for 15 minutes on average, for a total average of 15 calls. Each consultation consists of reviewing goals from the previous week, reviewing the exercise diary submitted by patients electronically, the exercise prescription and potential progression, any clinical items (e.g., risk factor control), an education module (same as per the supervised models above)(Ghisi et al. 2015), addressing patient questions, and finally setting goals for next consultation. Patients come on-site for stress management and/or 1-1 dietary counselling as per their needs, and for their exit assessment as in the supervised programs.

PARTICIPANTS

To be included in the program, patients had to be 18 years or older with at least one of the following indications: coronary artery disease (CAD) / acute coronary syndrome, spontaneous coronary artery dissection, atrial fibrillation, adult congenital heart disease, cardiomyopathy, following cardiac interventions (i.e., PCI, CABG, valve intervention/surgery, implantable rhythm device, aneurysm repair, and ablation), and those at risk for developing CVD (minimum of 3 risk factors). Those who had exercise-limiting medical issues such as pulmonary disease, were at significant risk of a fall, and with significant cognitive and/or uncontrolled serious mental health (i.e., not anxiety or depression) issues which would impede safe participation were excluded from the program (any model).

Study-specific inclusion criteria were female patients who attended at least 1 on-site exercise session for supervised models and 1 telephone consultation for the home-based model.

MEASURES

Sociodemographic characteristics were obtained from questionnaires that patients completed prior to program initiation, including marital and work status, as well as CR travel time. Clinical data were also extracted from the referral form (e.g., cardiac event/procedure). The above data were used to compare the characteristics of women choosing each model. Wait times were also extracted from CR charts.

Model Utilization

Program model attended was recorded in the electronic record (supervised mixed-sex, women-only or home-based). Session adherence was operationalized as the number of on-site

sessions attended in supervised mixed-sex and women-only models (of 25 prescribed) and completed telephone consultations in the home-based model (of 15 prescribed); given the lower number for home-based and that we were capturing calls rather than on-site visits, adherence to home-based was considered separately. Patients were considered to have completed the program if they did not fail to attend 2-3 consecutive CR sessions (telephone consultations for homebased model) without notice and respond to communication attempts made by the program, as well as if they completed the post-program assessments.(Grace et al. 2014) The reasons for missing sessions were recorded; these were categorized by the exercise specialists as due to medical (e.g., comorbidities, need for revascularization) or other reasons (e.g., work responsibilities).

STATISTICAL ANALYSIS

Statistical analyses were performed using IBM SPSS Statistics for Macintosh, version 26.0, with statistical significance defined as P<.05.

First, descriptive statistics were used to describe the characteristics of participants at CR intake, by model. Variables were scrutinized to determine whether they were normally distributed; non-parametric tests were applied where they were not, as outlined below.

For the first objective, sociodemographic and clinical characteristics were compared between women choosing supervised mixed-sex, supervised women-only, and home-based models using the Kruskal-Wallis test for continuous variables with non-normally distributed data (with post-hoc analyses using Bonferroni where significant). For objective 2 regarding program utilization, the Kruskal-Wallis test was used to compare session adherence (i.e., proportion of attended to prescribed supervised sessions or home-based telephone calls) between the three models; the Mann-Whitney U test was used to compare the number of sessions attended out of 25 between women in the mixed-sex and women-only model. Chi-square tests were used to compare program completion and reasons for dropout between models.

RESULTS

COHORT CHARACTERISTICS

The female cohort during the period of study comprised 543 participants in the supervised mixed-sex, 160 in supervised women-only, and 24 in the home-based model; thus, there were 727 participants in total. Their sociodemographic and clinical characteristics are shown in Table 1; other referral indications were primarily aneurysm, congenital heart disease, and heart transplant.

The median wait time from referral to intake assessment (first visit) was 70.0 (Q1, Q3: 50.0, 104.0) days in mixed-sex, 73.0 (Q1, Q3: 52.0, 115.8) days in women-only, and 55.5 (Q1, Q3: 33.8, 102.5) days in home-based; wait times did not differ significantly among women between models (P=.281).

CHARACTERISTICS OF WOMEN CHOOSING EACH CR MODEL

As shown in Table 1, 22.0% chose women-only and 3.3% of women chose home-based. By program model, for sociodemographic characteristics, there was a significantly higher proportion of participants who were retired or had no formal employment in the women-only compared to the mixed-sex model (P=.009). In terms of clinical characteristics, there were significantly more women with family history of CVD in mixed-sex than in women-only (P=.024). No other differences were observed in other characteristics.

PROGRAM UTILIZATION

Table 2 displays program utilization by model. Women in the mixed-sex model adhered to a higher proportion (P=.046) of sessions compared to those in the women-only model. Overall, where reason was available, 62 (45.3%) women missed sessions for clinical reasons (in descending order these were: musculoskeletal issues, cardiac event, psychological issue, or other medical conditions); there were no significant differences by model in the proportion missing sessions for clinical vs non-clinical reasons. Of those missing sessions for non-clinical reasons, in descending order these were: personal choice, work responsibilities, family/caregiver responsibilities, relocation, transportation issues, travel distance, and other reasons.

Program completion is also shown in Table 2. Women completers in the mixed-sex program attended a mean of 18.2 ± 5.3 sessions/25 prescribed, in the women-only program 16.6 ± 4.6 sessions/25 (*P*<.001 when compared to mixed-sex), and in the home-based 12.4 ± 6.5 sessions/15. With regard to model differences in program completion (Table 2), women in the home-based model had a lower completion rate compared to mixed-sex (*P*=.031) and women-only models (*P*=.042).

DISCUSSION

This novel study has examined women's characteristics and utilization in all available CR models. While caution is warranted due to generalizability limits and because the women-only program was not gender-tailored in terms of components, education content, exercise modality or

professionals delivering, (Mamataz et al. 2021) contrary to hypotheses, the benefit of womenonly CR was not evident. The main factor explaining difference in model choice appeared to be work status, such that women with more time flexibility could elect to attend supervised womenonly CR, which is necessarily offered less frequently at any program due to participant exclusivity. Contrary to conjecture in the literature, (Grace et al. 2016) women attending mixedsex attended more sessions than those in women-only. Moreover, women in home-based were less likely to come on-site for post-program assessment, to be considered program completers.

In this study, there were very few women patients who selected home-based; this has been shown in some other research, (Andraos et al. 2015) but whether this is due to limits on the number of spaces in home-based at the centre under study cannot be known; some patients seem to prefer home-based, but others preferring in-person monitoring and encouragement gravitate toward supervised models.(Grace et al. 2005) Indeed, in this study we did not have information on why participants elected the model they did, but the lack of differences in clinical characteristics suggests it was not often the clinicians encouraging patients for medical reasons. In line with previous literature, more working women elected this model, suggesting working likely impedes on-site participation.(Grace et al. 2009)

Indeed, the only difference between women who elected supervised women-only over mixed-sex was that they were less often in paid employment. As shown in previous research,(Andraos et al. 2015) because women-only cannot be offered as often as mixed-sex classes, many women cannot accommodate attending women-only classes due to time constraints, despite potentially wanting to. In addition, at the program under study, the mixed-sex class was available outside of business hours, but women-only was not (in home-based patients could exercise at a time that suited them but calls with staff were held during business hours as well). This greatly limits the potential impact of women-only CR and raises accessibility biases for this already-underserved group. Given that there are fewer women in CR it is not possible to offer women-focused models as often in any program, but it should be made more available than once per week, including outside of business hours. Then a true test of whether this model is more appealing to women could be undertaken.

UTILIZATION

The greater adherence in mixed-sex than women-only was inconsistent with previous research; (Mamataz et al. 2021) 2 randomized trials comparing adherence in women-only vs mixed-sex showed either the opposite effect of greater adherence with women-only (note: it included motivational interviewing), (Beckie and Beckstead 2010) or equivalent adherence between these supervised models. (Grace et al. 2016) The magnitude of difference was not great, and may relate to the fact that the content in the women-only program at the centres (the same 2 of 3 centres included in the latter trial summarized above) is very similar to the mixed-sex; there are currently efforts under way to tailor programming to women. (Grace et al. 2016) The benefit of women-only would likely be greater if this tailoring did better engage women in the programming and risk reduction behaviours. The program has recently undertaken some evaluation and will work to improve the program to better meet women's needs.

While there was a small sample size, it did appear adherence to home-based was somewhat greater than in supervised models, but completion was lower. More research is needed on patient engagement in supervised versus unsupervised given the sudden move to remote delivery in the midst of the COVID-19 pandemic,(Thomas, Gallagher, and Grace 2020) and that exploiting technology-enhanced home-based may enable significant increases in capacity so a larger proportion of indicated patients can receive CR services. It is likely that adherence appears higher than in supervised because it is much easier to answer a call than travel to a site. The lower completion could be explained in that home-based patients have to travel on-site for that assessment, and they likely chose the home-based model because they have constraints to going on-site, be they time and/or travel-related.

We need to better engage women in CR, to ensure they achieve optimal outcomes. CR programs in about 45 countries globally offer some form of women-focused programming,(Turk-Adawi et al. 2021) although the nature of this programming is not well-characterized.(Mamataz et al. 2021) The CR community must consider how to deliver high-quality, women-engaging CR consistently in practice, in a feasible way such that it could be available at most programs, and not be limited in availability such that women have barriers to attending sessions. This could include online women-only sessions or peer support for example. Whether full gender-tailored programs are advantageous requires more controlled, large-scale investigation.

Caution is warranted when interpreting these findings due to several study limitations. Chiefly, generalizability is limited due to the fact that the study was conducted at one academic health science centre, so the women-only offerings may be different than at other centres. Moreover, as CR programs in this study are available at no cost to patients; utilization data would likely be different in CR with different payment models. Moreover, the CR programs in this study offer a fairly high dose of CR compared to other jurisdictions,(Turk-Adawi et al. 2021) which may impact utilization rates.

Second, the sample size in home-based was small, and this is compounded by the low retention mentioned above, rendering analyses likely under-powered. Finally, the study design was not randomized, therefore causal conclusions cannot be drawn.

CONCLUSIONS

Only one-fifth of patients elected the women-only model, who were mostly not working and had low fitness, and less than 5% chose home-based. Those in mixed-sex (59% of sessions) adhered to the program more than women-only (54%). Home-based participants were significantly less likely to come on site to complete their post-program assessment than women in the supervised models, with only a third completing the program.

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Conflict of Interest: All authors declare no conflicts of interest

Data Availability: Due to the nature of this research, participants of this study did not agree for their individual-level data to be shared publicly, so supporting data cannot not be made publicly available. Data are available upon request to the corresponding author by qualified investigators with appropriate approvals.

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Table 1. Participant's Sociodemographic and Clinical Characteristics Pre-Program by

Model

	Mixed-sex Women-only H		Home-based	Total†	
	N=543 (74.7%)	N=160 (22.0%)	N=24 (3.3%)	N=727	
Sociodemographic					
Age	66.7 ± 12.1	68.1 ± 12.1	61.3 ± 16.9	66.9 ± 12.3	
Marital status (%					
married / common-	257 (67.8%)	67 (63.2%)	9 (60.0%)	333 (66.6%)	
law)					
Highest educational					
attainment (% ≥high	299 (92.3%)	79 (94.0%)	12 (100.0%)	390 (92.9%)	
school)					
Language spoken (%	411 (96.3%)	111 (98.2%)	20 (100.0%)	542 (96.8%)	
English)					
Occupational status					
Retired/no formal	220 (64.1%)††	74 (80,4%)††	6 (54,5%)	300 (67.3%)†	
employment		/ . (/тт	c (c		
Full-time/part-time/					
modified/restricted	103 (30.0%)‡	16 (17.4%)‡	4 (36.4%)	123 (27.6%)†	
duties					
Other (e.g.,	20 (5.8%)	2 (2 2%)	1 (9 1%)	23 (5.2%)	
disability)	20 (3.670)	2 (2.270)	1 (9.170)	25 (5.270)	

Travel time to CR centre (% 0-30 mins)	143 (61.1%)	34 (58.6%)	2 (40.0%)	179 (60.3%)
Living situation				
With spouse/partner	201 (50.9%)	44 (43.6%)	11 (68.8%)	256 (50.0%)
Alone	123 (31.1%)	37 (36.6%)	4 (25.0%)	164 (32.0%)
With				
family/friends/other	71 (18.0%)	20 (19.8%)	1 (6.3%)	92 (18.0%)
S				
Clinical characteristic	S		L	
Referral				
event/procedure§				
PCI	185 (34.4%)	54 (34.0%)	7 (31.8%)	246 (34.2%)
Valvular heart disease	62 (11.5%)	20 (12.6%)	1 (4.5%)	83 (11.5%)
CABG	50 (9.3%)	21 (13.2%)	1 (4.5%)	72 (10.0%)
Stroke/TIA	52 (9.7%)	13 (8.2%)	2 (9.1%)	67 (9.3%)
Primary prevention	41 (7.6%)	10 (6.3%)	1 (4.5%)	52 (7.2%)
Arrhythmia/Rhythm device	35 (6.5%)	14 (8.8%)	0 (0.0%)	49 (6.8%)
Heart failure	22 (4.1%)	3 (1.9%)	1 (4.5%)	26 (3.6%)
Angina pectoris (stable/unstable)	21 (3.9%)	3 (1.9%)	1 (4.5%)	25 (3.5%)

Cardiomyopathy	17 (3.2%)	4 (2.5%)	3 (13.6%)	24 (3.3%)
MI	17 (3.2%)	4 (2.5%)	1 (4.5%)	22 (3.1%)
PVD	13 (2.4%)	5 (3.1%)	1 (4.5%)	19 (2.6%)
SCAD	3 (0.6%)	2 (1.3%)	0 (0.0%)	5 (0.7%)
Other	20 (3.7%)	6 (3.8%)	3 (13.6%)	29 (4.0%)
Cardiovascular risk				
factors				
Hypertension	314 (58.0%)	96 (60.4%)	13 (54.2%)	423 (58.4%)
Family history	300 (55.7%)‡	70 (43.8%)‡	14 (58.3%)	384 (53.1%)†
Dyslipidemia	273 (50.7%)	77 (48.1%)	12 (50.0%)	362 (50.1%)
Diabetes	128 (23.7%)	46 (28.9%)	6 (25.0%)	180 (24.9%)
Comorbidities				
Sleep apnea	76 (14.0%)	19 (11.9%)	4 (16.7%)	99 (13.6%)
Osteoarthritis	72 (13.3%)	26 (16.3%)	6 (25.0%)	104 (14.3%)
Cancer	56 (10.3%)	15 (9.4%)	3 (12.5%)	74 (10.2%)

Note: N (valid % based on available data) or mean \pm standard deviation shown

†Kruskal-Wallis or chi-square test for difference between model among women: †p<.05;

††p<.01; †††p<.001

‡post-hoc test results, where above significant: \$p<.05; \$\$p<.01; \$\$\$p<.001</pre>

§main referral event or procedure for each participant; in women, comparisons were only

between supervised models due to low sample size in home-based

CABG=coronary artery bypass graft; CAD=coronary artery disease; CR=cardiac rehabilitation;

MI=myocardial infarction; N=sample size; PCI=percutaneous coronary intervention;

PVD=peripheral vascular disease; SCAD=spontaneous coronary artery dissection; TIA=transient ischemic attack

	Mixed-sex	Women-only	Home-based	
	N=543	N=160	N=24	
Session adherence	I	<u> </u>	I	1
Number of sessions attended§	$14.7\pm7.2\dagger$	13.6 ± 6.6 †	9.9 ± 5.6 (of 15)	
Proportion of prescribed sessions attended (%)∧	58.8 ± 28.9‡	54.3 ± 26.3‡	65.8 ± 37.1	
Dropout reason^_		L	I	<u> </u>
Clinical reasons	48 (46.2%)	12 (42.9%)	3 (42.9%)	Τ
Other reasons	56 (53.8%)	16 (57.1%)	4 (57.1%)	+
Program completion	324 (59.7%)□	96 (60.0%)‡	8 (33.3%)‡□	

Table 2. Program Utilization by Model

Note: N (%) or mean \pm standard deviation shown

[†]Mann-Whitney U, Kruskal-Wallis or chi-square test for difference between model among

women: †p<.05

post-hoc test results, where above significant: p<.05

§of 25 for supervised and 15 for home-based

||compared between mixed-sex and women-only only, as home-based has lower number of

prescribed sessions and they are calls, not visits

 \land compared between all models

°mean for women's 2 supervised models only, as home-based denominator smaller

_not available for all participants who did not complete the post-program assessment (i.e.,

completion)

N=sample size