Introduction:

Heart disease is the leading cause of mortality in women worldwide, and is responsible for a third (8.6 million) of the world's deaths among women each year [1]. It is well established that women who attend conventional exercise based cardiac rehabilitation (CR) programs have better outcomes [2-4]. However, although women have a greater need in terms of heart disease morbidity, they are less likely to participate in secondary as opposed to primary prevention programs [1,5], and completion rates among women who do attend CR are low[6]. Identifying the best possible gender specific secondary preventative strategies is essential to facilitate and encourage engagement in programs that mediate cardiovascular risk.

The gender bias that exists in cardiac rehabilitation service provision is multi-faceted at the patient, provider and health system levels[7,8]. Women are under-referred to CR[9] (39.6% vs 49.4% of men)[10] and fewer women participate in cardiac rehabilitation programs (38% vs 45% men) overall[7]. Under-referral of women to CR programs is problematic given that physician support and/or automatic referral[7] has been identified as vital to women's participation[11]. The mortality rate of women who participate in preventative heart disease clinical trials is also disproportionately high compared to their representation, which is significant given that these clinical trials are used to inform national guidelines for CR implementation[12].

Awareness of the impact of heart disease is low among women, with only half of Caucasian women and one third of ethnic minorities identifying heart disease as their leading cause of death[13]. Women in minority populations have identified lack of confidence, cultural misconceptions, such as limited knowledge of anatomy and physiology, association of heart disease with disability, perceived risk of greater

harm[12], restriction of physical activity and language barriers as inhibitors to participation in CR programs[14]. For these reasons, tailored and targeted preventive education programs, such as the 'Go Red for Women' and 'Making the Invisible Visible' Campaigns have been implemented to increase community awareness and empower women to identify and address their cardiovascular risk [1].

Women have different baseline clinical profiles compared to men, which presents additional barriers to participation in traditional exercise based programs and achieving optimal CR outcomes[11]. Women generally are 10 years older when experiencing their first cardiac event[15,16], more likely to be from culturally and linguistically diverse populations, unemployed, hypertensive, diabetic [11,17], have greater shortness of breath, more chronic illnesses[15,17], lower levels of physical function, and self-efficacy[8]. Decision making around CR utilisation disproportionately affects older women compared to men, as older adults are given lower priority in access to CR programs[18]. Older women also are more likely to be reliant on others, or public transportation, further hindering their participation in CR programs [15].

The American Heart Association guidelines[19] recommend integration of novel strategies to address secondary prevention outcomes for women, including depression[11,12] and other psychosocial risk factors. However implementation of comprehensive gender specific strategies[20] within conventional CR programs is slow[17,18]. Women have specific educational needs and respond to group based collaborative approaches such as mutual aid[20]. Women may also have preferences for CR program features or components that are not always included in traditional exercise based CR, such as exercise monitoring, nutritional counselling, staff contact and accessibility[11], and may benefit from different rehabilitation strategies[16]. To date, research comparing benefits of different CR approaches for women is minimal. To

address this gap in research, we undertook a systematic literature review with the following aims:

Aims/Objectives

1. To determine the effectiveness of interventions designed specifically for women with heart disease, or modifiable risk factors for heart disease, delivered in outpatient cardiac rehabilitation settings.
2. To classify key elements of effective cardiac rehabilitation interventions designed to improve outcomes for women with heart disease or modifiable risk factors for heart disease.

Methods:

Eligibility criteria

Studies were included if they recruited *women* with *modifiable cardiovascular risk factors* for heart disease, coronary heart disease, valvular disease, heart failure, or had undergone a surgical procedure (cardiac bypass surgery-coronary, aortic or valvular; pacemaker or defibrillator insertion or pericardial window) or an *interventional procedure* (coronary angiogram, percutaneous coronary intervention, ablation or other procedure), who had been referred for outpatient cardiac rehabilitation (phase 2 OCR)**.** Outpatient cardiac rehabilitation is defined by the American Association of Cardiovascular and Pulmonary Rehabilitation, American College of Cardiology, and American Heart Association as: “a program that delivers preventive and rehabilitative services to patients in the outpatient setting early after a CVD event, generally within the first 3 to 6 months after the event but continuing for as much as 1 year after the event” [21]. Interventions that offered enhanced CR approaches as alternatives or adjuncts to OCR were included. These enhanced

models included physical activity, health education, counselling, behavior modification strategies and/or support for self-management. Control groups were defined as no intervention. Comparison groups included usual care, defined as conventional phase 2 CR programs offered in outpatient healthcare settings, and other similar iterations. All outcomes were considered. Exclusion criteria were interventions involving men or paediatric populations, and phase 1 cardiac rehabilitation interventions that were entirely inpatient-based. Non-English articles and dissertations were excluded.

Information sources

This systematic review was completed according to the PRISMA 2009 Checklist. Databases searched included MEDLINE, EMBASE, CINAHL and the Cochrane Database of Systematic Reviews from 1974 to current, last searched on 5th July 2017. Reference lists were searched for additional articles. The search strategy for EMBASE is available in Supplementary Table S1.

Study selection and data collection process

All randomised controlled trials of OCR programs tailored for women were included. The title and abstract were screened for eligibility and all duplicates were removed (AR). The process was repeated independently by a second author (PN). Discrepancies regarding articles for inclusion were resolved by consensus (PN, AR). Heterogeneity between interventions precluded the use of a meta-analysis and results were synthesised in narrative form. To classify the elements of included interventions, each line of text describing the interventions were coded by one investigator[22] (AR). Each element was listed in a table until all were included.

Common elements of positive studies were then identified and tallied across interventions.

Risk of Bias

Assessment of risk of bias within and across studies was reported in accordance with the Cochrane Risk of Bias Table [23].

Results:

Study selection

The initial search generated 2166 articles. After a process of review, elimination, and hand searching, three RCTs (reported across 11 peer-reviewed journal articles) were identified and included in the review (Figure 1).

Study Characteristics

Two thirds of the included RCTs involving women referred to CR programs were conducted in the US (n = 2), with the other conducted in Canada (n = 1). Interventions were a women's only CR exercise program with gender specific education on co-morbidity self-management (1 study); combined exercise with motivational behavioural enhancement with interviews (1 study); or a multicomponent education-based intervention (1 study). The mean number of participants across the RCTs was 241 (SD ± 68); and mean age was 63.4 years (SD ± 0.3). Inclusion criteria were adult women with a history of diagnosed coronary heart disease including myocardial infarction (2 studies; n=67), coronary artery bypass surgery (2 studies; n=98), percutaneous coronary interventions (3 studies, n=343), stable angina (1 studies; n=22), angina/ACS/CAD (2 studies; n=428), and valve

surgery (1 study; n= 32). The delivery frequency of CR interventions ranged from weekly sessions for eight weeks to three times per week for 12 weeks (mean 24 sessions, SD ± 21). The women's only CR intervention duration was 1 hour, whereas the duration of two education-based programs ranged between 30 minutes to one hour [24,25]. Primary outcomes, where clearly defined, included adherence to secondary prevention guidelines [25] and CR program adherence [26]. The primary outcome was not clearly defined in one study [27]. Characteristics of included studies are described in Supplementary Table S2.

Assessment of Risk of Bias

All three studies had a high risk of bias due to inability to blind participants and personnel, which is not practicable in complex interventions. Aside this risk, the risk of bias was low in one study was low and unclear in two studies. An unclear risk of bias was assigned in these two studies for a possible selection bias due to unclear randomisation (n=1) and allocation concealment procedures (n=1); and possible detection bias due to unclear blinding of outcome assessors for patient reported outcomes (n=1). Attrition and reporting bias was low across studies. A Cochrane Risk of Bias Table detailing the risk assigned to interventions is available in Supplementary Appendix S3.

Usual care or comparison groups

Usual care or comparison groups were clearly defined in all three studies. They included encouragement to attend CR and exercise three times per week [25]; or a mixed gender exercise training program [26,28].

Outcomes

Two out of three studies had clearly defined primary outcomes, such as adherence to secondary prevention guidelines [25], and program adherence [26]. Secondary outcomes included statistically significant improvements in metabolic syndrome measures and inflammatory biomarkers [29], depression [30,31], anxiety [31] health perception [32], heart rate recovery [28], quality of life [31,33,34], exercise capacity [35], functional capacity [26], CR model adherence, satisfaction and preferences [36], heart health behaviours [31], social support [31] (refer to Characteristics of Included Studies in Supplementary Table S2).

Elements of cardiac rehabilitation interventions

Two studies encompassed comprehensive counselling and educational based strategies that addressed risk factors for heart disease (for example smoking cessation, nutrition and blood pressure control), exercise and medication management, of which one demonstrated statistically significant improvements in general health perception, social functioning, vitality, mental health [32], quality of life [33], depression [30], blood pressure [35], and a metabolic syndrome biomarker [29]. Common elements to both studies were the identification of secondary prevention goals by the participants, provision of feedback, and negotiation/agreement on achievable goals; a collaborative focus; and provision of an education booklet with information around cardiovascular risk factors and rationale and strategies for goal attainment [25,29,30,32,33,35]. The successful phase III clinical trial by Beckie et al. 2006 utilised educational material that was interactive with homework exercises to integrate strategies for change. This study also utilised motivational interviewing for risk factor modification with emphasis on a ‘stage matched approach’ whereby women identified their own reasons and advantages for behaviour change, and readiness for change. Motivational interviewing also involved affirmation of self-

directed goals and builds confidence for women to cope with obstacles, thereby supporting successful change, and adherence from giving advice without participant permission. These motivational interviewing counselling sessions were conducted by either a clinical psychologist or a clinical nurse specialist. Social support, group comment and reflection, and role play techniques were a part of the intervention; and relaxation strategies such as progressive muscle relaxation, deep breathing, and guided imagery were used at the beginning of each session.

An alternative educational approach included advice from a prevention facilitator, who was an allied health professional, regarding tailored behaviour change recommendations specific to participant needs [25]. This study also utilised a problem solving approach for practical considerations associated with non-participation, such as transportation however this study did not demonstrate statistically significant improvements in adherence to cardiovascular disease prevention guidelines. Anxiety was significantly improved in one study with women only CR and education sessions with additional focus on comorbidities specific to women [26].

Discussion

This review identifies that there are limited data to support evidence-based tailored CR models for women to improve their cardiovascular risk. The findings are overall inconclusive due to the inability of these studies to reach recruitment targets of a fully powered RCT. However, preliminary findings suggest that motivational interviewing and an educational intervention based on the Trans-theoretical Model for behaviour change can generate statistically significant improvements in a range of physiological outcomes including general health, vitality, social functioning and mental health [32], depression[30], and quality of life [33]. Reductions in depression,

increased comfort in work attire and increased satisfaction with behaviour change counselling are also tentatively supported using a gender specific CR approach compared to mixed sex exercise and education sessions[26].

The key common elements of positive CR models included: 1) inclusion of a manual for participants to guide an exercise program or to provide theoretical knowledge of cardiovascular risk factors; 2) rationale for risk factor modification and goal development strategies; and 3) use of qualified health care personnel with specialised training in motivational interviewing to guide educational or counselling-based interventions.

Strategies to enhance group cohesion and social support [37] among women are an effective educational approach to CR to improve behaviour change and adherence to therapy [38]. Favourable outcomes may predominate when the focus of the model for cardiovascular risk reduction is collaborative and participant-driven with intent to diminish resistance and communicate empathy and acceptance [24], as opposed to a goal, action and outcome driven focus. Motivational interviewing could enhance reframing processes required for women to integrate experiences of their cardiac event, and is a tailored approach that can identify individual differences in women's support needs[39]. Facilitated group discussion and health education meetings have demonstrated improvements in physiological and psychological outcomes for women with pre-existing heart failure or heart disease in the home setting, supporting further research using these approaches within gender specific CR programs [40-43].

The need to identify different CR models that increase participation, reduce readmission rates and improve quality of life and health related outcomes has been recognised [44]. Advice on how to implement recommendations received during CR exercise and education sessions is also currently lacking and an identified need

among women enrolled in CR programs [39]. A previous phase III RCT demonstrated that conventional CR is most cost effective for women when programs ran over an extended one year period compared to the standard 12 week duration [45]. This may reflect the social and emotional support needs of women attending CR programs, with longer durations reflecting increased time periods required for the development of supportive networks and relationships[46]. It is also likely to enable women to regain a feeling of 'everydayness', which has no specified time frame, as well as the resumption of roles and responsibilities[39, p.24]. Whilst none of the interventions identified in this review were longer than 12 weeks, this duration could be incorporated in future CR study designs [19]. CR models are more likely cost effective when participants are accurately referred to the program of best fit, based on levels of cardiac risk, reason for referral and demographic characteristics including gender [45]. Effective resource utilisation within CR programs could include tailored women's only exercise and education sessions, particularly as some women do not feel comfortable in mixed groups to ask questions[39], and ethnic minority populations require gender and cultural sensitivity to enable participation[14].

In order to enhance CR utilisation by underserved populations, including women, integrated solutions that address patient, provider and health system factors are required [47]. Gender specific CR programs for women that are tailored to address physiological and psychosocial factors, for example by providing women with an opportunity to ask questions and seek reassurance about their symptoms, may be one way to enhance engagement between health care providers and participants [19,48]. Such collaborative efforts in CR programs are required in order to shift perspectives towards the role of CR programs as an *integrated component of the cardiac care model* rather than an optional addition to standard cardiac care [47].

Limitations

This review is limited by the inability to conduct meta-analyses given the heterogeneity of included studies, and the small number of methodologically strong randomised controlled trials. The included studies were limited by small sample sizes, and some lacked sufficient details of interventions. These flaws inhibit study replication and decrease the generalisability of the findings. Variation in methods of delivery and study settings also reduced generalisability.

Implications for practice:

In order to increase the impact of CR programs for women, comprehensive multicomponent approaches that incorporate participant-driven collaborative models to adequately address psychosocial risk factors are required. However, elements of these approaches may not suit the needs of all women, particularly given that younger women attending CR are likely to have higher stress levels and may respond better to models that have more emphasis on stress reduction [24], whilst older women are more likely to exhibit higher rates of depression [49]. The needs of women participating in CR programs differ to men due to competing demands such as employment and household responsibilities. These may reduce participation and undermine the relative importance of CR [20,50,51]. Multicomponent strategies that are affirming for women, such as facilitated group discussion and social support may be more likely to encourage participation and integration of practices that reduce cardiovascular risk. This is consistent with the findings of one multicomponent CR strategy tailored for women that increased educational attendance by 31% and exercise attendance by four sessions [51]. Such strategies are also more likely to enhance physical, social, and symbolic safety that has been previously identified as important elements of the female CR environment[52]. Determining preferences for

home or hospital-based CR models and referring accordingly has also been identified as an appropriate approach to enhance utilisation and thereby decrease cardiovascular risk [53].

Implications for research:

There is a significant lack of randomised controlled trials based on enhanced CR approaches specifically designed for women. In order to progress gender specific CR research, fully powered RCTs tailored to women that include multicomponent approaches are required to adequately identify the combination of strategies that demonstrate improvements in cardiovascular risk. Clear reporting of intervention designs and methodologies, including randomisation, allocation concealment, and blinding procedures, are also required in future studies.

Conclusion:

There is limited evidence available to better understand and provide evidence-based tailored CR models for women to improve their cardiovascular risk. Defining the optimal models for secondary prevention of heart disease within OCR programs tailored for women is essential to optimise physiological function and improve psychosocial risk. Whilst results were inconclusive, multicomponent CR programs that incorporated participant driven collaborative models supported improvements in psychosocial risk and quality of life among women with heart disease. Further large scale RCT's are required to confirm positive findings and better understand what combination of strategies are most likely to improve adherence to CR guidelines and optimise functional independence and quality of life.

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Disclosures:

There are no conflicts to disclose.

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Figure 1: PRISMA 2009 Flow Diagram

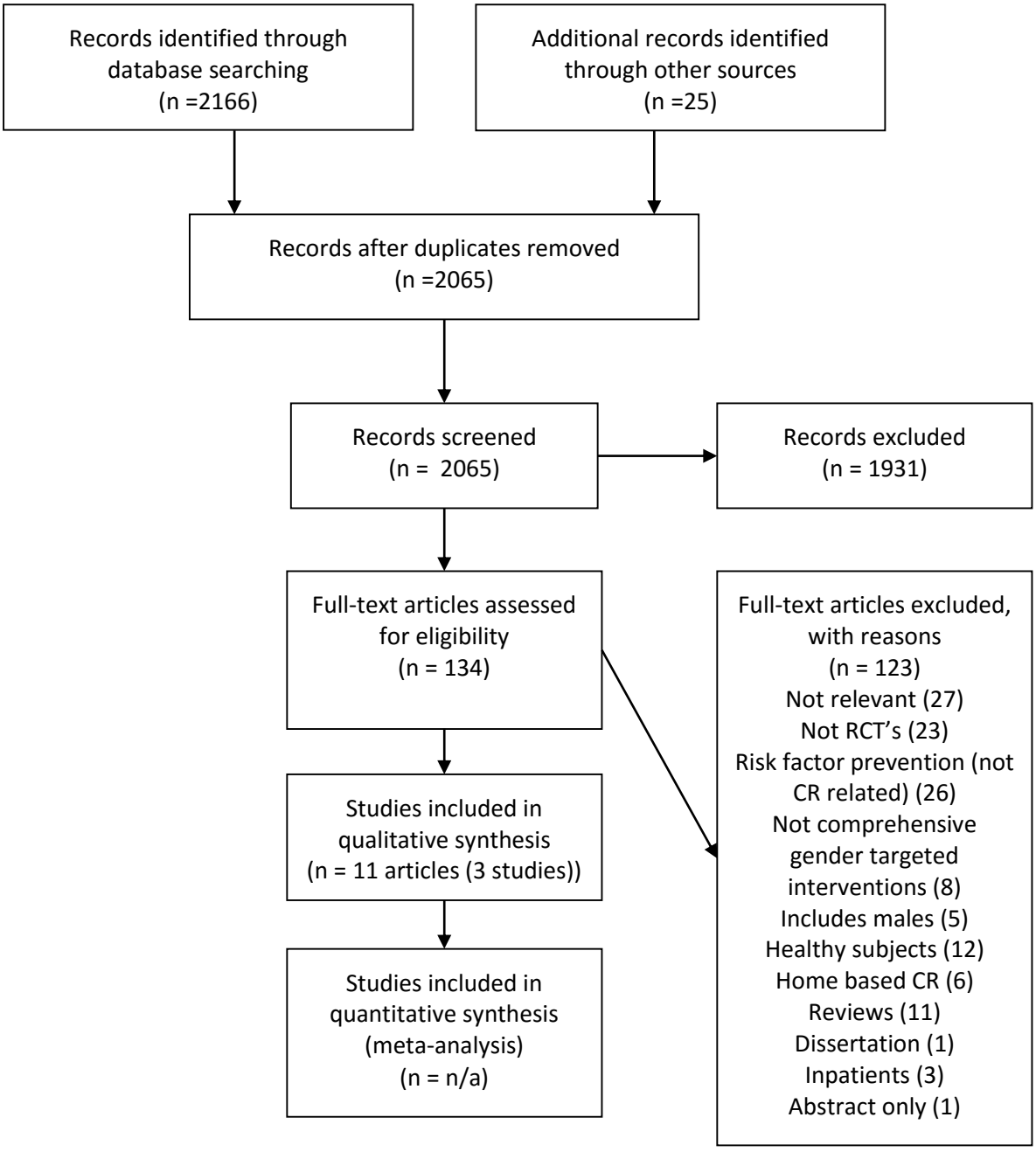

Table 1. Characteristics of Included Studies

Authors (Year) Country	Primary Outcome	Population	Study Design	Setting	Sample Size	Intervention	Comparison Group	Delivery Frequency/ Duration	Outcome Measures	Findings
Mosca, Christian, Mochari-Greenberger, Kligfield, Smith Jr[25]; Christian, Cheema, Smith, Mosca[34] USA	Adherence to secondary prevention guidelines (man summary score); HRQOL	Hospitalized CAD patients with diagnosed MI, angina (stable/ unstable), prior CAD, re-vascularization or CABG	RCT	Hospital and phase 2 CR	n = 304	Hospital and phone-based educational intervention: 1 hr structured counselling, pre-discharge, reviewing smoking, exercise, nutrition, weight, BP, cholesterol secondary prevention goals, with feedback, recommendations for personalised behavior change, follow-up scheduling; encouraged to attend CR 3-5 d/wk. Tailored exercise, BMI, nutritional counselling, smoking cessation/referral. Problem-solving re: barriers to participation	Usual care – encouraged to attend CR exercise 3x/ wk	Hospital and phone visits at 2,4, and 12 wk; phone/ clinic visit 6 wk	BP, weight, height, waist circumference, exhaled carbon monoxide levels (smoking status), lipids, lipoprotein, MOS SF-36	No significant difference in mean summary score No significant difference in 6 out of 7 MOS SF-36 subscale scores. Improved bodily pain MOS SF-36 subscale score vs CG (*P*=.02).
Beckie, Beckstead[28]; Beckie, Beckstead[29]; Beckie, Beckstead, Groer[30]; Beckie, Beckstead, Kip, Fletcher[32]; Beckie, Beckstead, Kip, Fletcher[33]; Beckie, Beckstead, Schocken, Evans, Fletcher[35] USA	Metabolic syndrome, inflammatory biomarkers; Health perception; QOL; HRR; Depression; Exercise capacity	Women with CHD (women with acute MI, stable angina, or CABG/PCI within last year)	RCT	Outpatient CR	n = 252 IG: 141 CG: 111	CR exercise training tailored for women: ECG monitoring, supervised exercise protocol: 5 min warm-up; 35-45 min aerobic exercise at 60-80% maximal HR; education class for CHD risk reduction. **Additional** CNS and clinical psychologist facilitated psychoeducational sessions (motivational interviewing counselling style).	Identical exercise training program only; MS sessions	IG: 1 hr psycho-educational sessions weekly/10 wk; interview wk 1 & 6; exercise for both groups 3x/wk for 12 wk; 30 min dietician consult	SF-36, CES-D; at baseline, 12 wk, 6 mo follow-up. HRR, SLGXT expressed in METs, BP, BMI, body fat percentage (skinfold), fasting lipid profile, serum glucose; inflammatory biomarkers at baseline, 12 wk; MDT; SASS at baseline, 1 wk post- intervention; 6 mo follow-up.	Improved general health (F=3.80; *P*=.023); social functioning (F=4.85; *P*=.008); vitality (F=5.85; *P*=.003); mental health (F=3.61; *P*=.028); QOL (MDT: F=5.94; *P*=.003; eta^2=0.026); (SASS: F=4.31; *P*=.014; eta^2= 0.019); depression (F=4.42; *P*=.013); BP (*P*<.05); intracellular adhesion molecule 1 (*P*<.05) No significant difference in HRR or exercise capacity

Grace, Midence, Oh, Brister, Chessex, Stewart, Arthur[26]; Midence, Arthur, Oh, Stewart, Grace[31]; Andraos, Arthur, Oh, Chessex, Brister, Grace[36] Canada	Program adherence; Functional capacity; Model adherence; Satisfaction; CR preferences; Health behaviors, psychosocial well-being	Female patients with CAD and/or ACS and/or CABG/PCI and/or valve surgery	RCT	Outpatient CR (hospital and home- based)	n = 169 MS: 59 WO: 55 HB: 55	WO CR based on AHA guidelines. Individualised exercise prescriptions to target heart rate; preferably exercise most days of the week –stationary cycle, treadmill, walking. Education content focused on comorbidities common to women (arthritis, osteoporosis). CR personnel included dietician, physician, exercise physiologist and nurse.	MS CR sessions	150min/wk all groups; MS & WO: 1hr 2x/wk for 4-6 mo	Number of CR sessions prescribed and completed; pedometer readings; peak VO_2 (on ET), Diet Habit Survey, MMAS, HADS, TIES	No difference in program adherence or functional capacity; health behaviours, psychosocial well-being (i.e. QOL, depression or social support) by program model. 26.6% of women did not adhere to allocated program model. No difference in satisfaction by those attending preferred model vs those who did not. Reduced anxiety in WO vs MS (*P*=.048)

Abbreviations: ACS, acute coronary syndrome; AHA, American Heart Association; BMI, body mass index; BP, blood pressure; CABG, coronary artery bypass graft; CAD, coronary artery disease; CES-D, Center for Epidemiological Studies – Depression; CR, cardiac rehabilitation; CG, control group; CS-PFP, Continuous Scale Physical Function Performance test; DEXA, dual energy X-ray absorptiometry; ECG, electrocardiogram; ET, exercise test; HADS, Hospital Anxiety and Depression Scale; HB, home-based; HRQOL, health-related quality of life; HRR, heart rate recovery; IG, intervention group; MDT, Multiple Discrepancies Theory; MET, metabolic equivalent; MI, myocardial infarction; MMAS, Morisky Medication Adherence Scale; MOS SF-36, Medical Outcomes Survey Short Form-36 questionnaire; MS, mixed sex; PCI, percutaneous coronary intervention; QOL, quality of life; RCT, randomized controlled trial; SASS, Self-Anchoring Striving Scale; SLGXT, symptom-limited graded exercise test; STAI, State Trait Anxiety Inventory; TIES, Tangible Informational and Emotional Social Support Survey; VO_2, oxygen uptake; WO, women only.

SDC Table 2. Assessment of Risk of Bias

	Selection Bias		Performance Bias	Detection Bias		Attrition Bias		Reporting Bias
Authors (Year)	**Random Sequence Generation**	**Allocation Concealment**	**Blinding of Participants and Personnel**	**Blinding of Outcome Assessors Patient-Reported**	**Blinding of Outcome: Mortality**	**Incomplete Outcome Data: Short-Term Outcomes (2-6 Wk)**	**Incomplete Outcome Data: Long-Term (>6 Wk)**	**Selective Reporting**
Mosca, Christian, Mochari-Greenberger, Kligfield, Smith Jr[25]; Christian, Cheema, Smith, Mosca[34]	Low risk Block design; central dial-in web-based system	Unclear risk No information provided	High risk Unable to blind participants; no information provided for study personnel	Unclear risk No information provided	n/a	n/a Outcomes measured at 6 mo	Low risk Intention to treat analysis used	Low risk
Beckie, Beckstead[28]; Beckie, Beckstead[29]; Beckie, Beckstead, Groer[30]; Beckie, Beckstead, Kip, Fletcher[32]; Beckie, Beckstead, Kip, Fletcher[33]; Beckie, Beckstead, Schocken, Evans, Fletcher[35]	Low risk Based coin randomization procedure	Low risk Statistician provided treatment assignment sheets that were placed in opaque envelopes, sealed and delivered to the project director	High risk Unable to blind participants or interventionist	Low risk Only project director aware of group assignment	n/a	Low risk	Low risk Intention to treat analysis used[3,4]; 9% difference in complete data (<20%)[5,8]; low attrition (1%)[6]; 16% difference in group size, low attrition (6%)[7]	Low risk
Grace, Midence, Oh, Brister, Chessex, Stewart, Arthur[26]; Midence, Arthur, Oh, Stewart, Grace[31]; Andraos, Arthur, Oh, Chessex, Brister, Grace[36]	Unclear risk Randomized; method not stated	Unclear risk Recruiters went online to ascertain randomization	High risk Patients and CR sites informed of allocation	Low risk CR program members not aware of study objectives or which patients were enrolled in the trial	n/a	n/a	Low risk Intention to treat analysis used	Low risk
Total	2 low risk 1 unclear risk	2 low risk 1 unclear risk	3 high risk	2 low risk 1 unclear risk	3 n/a	1 low risk 2 n/a	3 low risk	3 low risk

Abbreviations: CR, cardiac rehabilitation; n/a, not available.