

A randomized controlled trial of an exercise maintenance intervention in men and women post-cardiac
rehabilitation (ECO-PCR)

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Short Title: Exercise Maintenance Post-Cardiac Rehab

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Brief Summary

Cardiac Rehabilitation (CR) is considered standard of care. Most patients can achieve the recommended levels of physical activity per week however long-term maintenance is often a challenge. Our randomized controlled trial involved an exercise facilitator led post-CR intervention to assist with exercise maintenance. Physical activity levels were measured after 26 and 52 weeks. Secondary

measures included; exercise capacity, risk factors and quality of life. The intervention showed promise in women but was not effective in men.

Abstract

Background

Exercise maintenance interventions are needed for cardiac rehabilitation (CR) graduates to maintain moderate and vigorous-intensity physical activity (MVPA). We tested an exercise facilitator intervention (EFI) to promote exercise maintenance compared to usual care (UC) separately in men and women.

Methods

This was a 3-site, randomized (1:1), parallel-group, superiority trial (ECO-PCR). CR graduates were stratified by site and sex, and randomly allocated (concealed). EFI participants received a face-to-face introductory session, 5 small-group counseling teleconferences, and 3 personal calls from a trained facilitator over 50 weeks. In-person assessments were undertaken at baseline, 26 and 52 weeks after randomization. The primary outcome was weekly minutes of MVPA, measured by accelerometer. Secondary outcomes were exercise capacity, risk factors, quality of life and enrolment in community-based exercise programs. Effects were tested using linear mixed models.

Results

449 graduates (135 women, 314 men) were randomized (n=226 EFI, n=223 UC). In the intent-to-treat analysis for men and for women, there were no significant effects for treatment or time on MVPA. In a planned secondary analysis that considered only those adherent to EFI (completed $\geq 66\%$ of sessions; per-protocol), bouts MVPA was higher in women in the EFI group (mean=132.6 \pm 135.2 minutes/week at 52 weeks) compared to UC (111.8 \pm 113.1; $P=0.013$). With regard to secondary outcomes, in women, a treatment group main-effect was observed for blood pressure ($P=0.011$) and exercise capacity ($P=0.019$; both per-protocol) favoring EFI; no other differences were observed.

Conclusions

In this trial of CR completers, an EFI showed promise for women, but was ineffective in men.

Clinical Trial Registration

URL:<http://www.clinicaltrials.gov> Unique identifier: NCT01658683

Key Words

Coronary disease, exercise, physical activity, cardiac rehabilitation, maintenance, behavioral

BACKGROUND

Cardiac rehabilitation (CR) is standard of care. Exercise is a core component of CR, and guidelines recommend that patients accumulate ≥ 150 minutes of moderate and vigorous-intensity physical activity (MVPA) to and improve outcomes.^{1,2} While less common in women,³ most CR participants achieve this by the end of their program. However, long-term maintenance continues to be a problem⁴; This could put patients back at increased risk of further cardiovascular events.⁵

Interventions to improve long-term MVPA maintenance after program completion are not routinely included as a component of CR programs.⁶ In a recent systematic review of exercise maintenance interventions, we found that interventions post-CR helped participants maintain PA for the long-term,⁷ but results were dominated by a European study comprising a 3-year intervention delivered face-to-face in clinical settings, which is not very feasible.⁸

The present trial was designed to evaluate the benefit of a home and community-based, remotely-delivered, exercise facilitator intervention (EFI) on long-term MVPA levels among women and men who complete CR. It was hypothesized that patients completing CR who receive support over a 50-week period from a trained exercise facilitator will be engaging in more MVPA 52 weeks following the completion of CR compared to usual care.

METHODS

Trial Design and Procedure

Ecologically-Optimizing Exercise Maintenance in Men and Women Post-Cardiac Rehabilitation (ECO-PCR) was an efficacy trial examining the effects of an EFI on MVPA (primary outcome), exercise capacity, coronary heart disease (CHD) risk factors, quality of life and participation in community exercise programs (secondary outcomes; tertiary outcomes [theoretical constructs] reported

elsewhere).^{9, 10} Women and men who had completed CR underwent baseline measurements on-site with the research coordinators (e.g., EW, MM) and were randomly assigned to either usual care (UC) or EFI. Study group assignments were generated by an external statistical consultant, concealed (opaque envelopes), and stratified by sex and site, using permuted blocks of random size. Participants were assessed on-site again mid-way (26 weeks), and after (52 weeks), the treatment period (50 weeks). Outcome assessors (other staff, trainees) were blinded to participants' group assignment.

Participants

Consecutive women and men with documented CHD completing centre-based CR programs of ≥ 8 -week duration in Ottawa (1 site) and Toronto (2 sites), Ontario were screened for eligibility. Exclusion criteria included: New York Heart Association class III or IV heart failure¹¹; inability to walk unaided at 3.2 kilometers per hour; inability to read and understand English or French; and inability to participate in unsupervised exercise (in the opinion of the qualified investigator).

The protocol was approved by the Ottawa Regional and University Health Network research ethics boards, and written informed consent was obtained from all participants. The first participant was randomized in August 2012, and the last follow-up assessment was completed in January 2018. In men, the trial was ended when our recruitment goal was met. In women, the trial was ended when all awarded research funds were expended.

A priori power estimates suggested that we would have 80% power to detect a 45 minute/week difference in weekly MVPA in bouts of ≥ 10 minutes between groups with 192 women and 412 men assigned to EFI and UC groups.⁹

Measures

At initial assessment, participants self-reported sociodemographic characteristics on a questionnaire, and clinical characteristics were extracted from CR charts. The below outcomes (except functional capacity) were measured at baseline, and 26 and 52 weeks.

MVPA

The primary outcome of physical activity during daily life was quantified by measuring levels of activity, steps, and activity intensity on 9 successive days with the Actigraph GT3X+ accelerometer (Actigraph, Pensacola, Florida). Participants wore the accelerometer over the right hip, excluding periods when they were sleeping, swimming, or bathing. The Actigraph GT3X+ has been shown to be valid and reliable using treadmill walking at known speed and a laboratory shaker.¹² Data were recorded in 5-second epochs over the recording period. The vector magnitude, a composite measure of all 3 axes from the accelerometer was used. An adaptation of the Godin Leisure Time Exercise Questionnaire¹³ was also administered to capture modes of exercise not assessed well by accelerometer.¹⁴

Exercise Capacity

A random subset of participants completed a symptom-limited, graded exercise test with electrocardiographic monitoring using a ramp protocol on a treadmill¹⁵ or bike protocol (post-CR and 52 weeks only; oxygen directly measured at 1 site). A sample of 208 participants for graded exercise testing was randomly selected to provide 93% power to detect a minimal clinically-important difference of 1 metabolic equivalent of task (MET) from post-CR to 52 weeks later (equivalent to approximately 3.5 ml O₂/kg/min).^{16,17} The exercise mode (treadmill or bicycle, the latter being infrequent) was held constant across the assessments.

CHD Risk Factors

Height and weight were measured for the determination of body mass index (BMI). Waist circumference (WC) was measured using a non-stretchable standard tape measure according to World Health Organization protocol.¹⁸ Blood pressure (BP) was measured in a seated position after a five-minute rest period using an automated, non-invasive BP monitor (BPTru)¹⁹ that averaged six measurements.

Quality of Life

Quality of life was measured using the EuroQoL 5D (EQ-5D)²⁰ questionnaire visual analogue scale. Respondent's self-rated their health on a 0-100 vertical scale, where the endpoints are labeled '100- best imaginable health state' and '0 - worst imaginable health state'.

Participation in Community Exercise Programs

Enrollment in community-based programs was queried at each follow-up time point (yes/no) in the paper-and-pencil questionnaire.

Interventions

Usual Care

Usual care included strategies currently in place at the Ottawa and Toronto sites to transition CR participants to self-care upon program completion; they were very comparable. Participants were provided with an updated exercise prescription based on their exit stress tests, which were also shared with their primary care providers. Information about suitable exercise locations in the community (<http://heartwise.ottawaheart.ca/locations>)²¹ and exercise maintenance strategies were reviewed with exercise staff. Note the Toronto sites had a maintenance program; use of these programs were notated, and sensitivity analyses undertaken.

Exercise Facilitator Intervention

The EFI was delivered in 9 sessions over a 50-week intervention period, by an exercise physiologist, physiotherapist or trainee exercise physiologist. Participants in the intervention group were provided with a pedometer, daily physical activity log and workbook.

The timing and content of each session is summarized elsewhere.⁸ A combination of face-to-face, group teleconference and individual telephone counseling sessions was offered. Attendance records were kept for all contacts.

The EFI was designed using an ecological perspective encompassing ‘individual’ (e.g. knowledge, attitudes, skills), ‘social-environmental’ (e.g. friends, family, and social networks) and ‘physical-environmental’ (e.g. home, neighbourhood and community characteristics; climate) factors known to influence exercise behavior.^{22,23} The recommended standard for exercise maintenance in patients with CHD (≥ 150 minutes MVPA/week in bouts of ≥ 10 minutes) was the behavioral objective of the intervention. The facilitator helped participants develop plans for adhering to this exercise standard. At each intervention session, participants prepared and/or updated action plans for when, where and how they intended to achieve their weekly exercise objective. In addition, participants prepared coping plans describing strategies to overcome barriers that they anticipated would pose a problem. Methods for mapping out walking routes around home, recommendations about appropriate community exercise programs (same sites recommended as usual care²¹) and recommendations regarding home exercise equipment were discussed. During group teleconferences, participants reviewed their recent activity, identified any barriers to exercise maintenance they had experienced and brainstormed solutions as a group.

Facilitators received training in the intervention by the principal investigator (RR) and a clinician (JH, physiotherapist and lead of Heartwise Exercise community program²¹). Intervention components were

codified in a treatment manual; scripts and checklists were developed to ensure the intervention was delivered as originally conceptualized. Facilitators also participated in quarterly case discussions /booster sessions on the phone as a group (sometimes including JH), to maintain their skill over time. During these sessions, any challenging situations or difficulties adhering to the script were discussed.

Treatment Fidelity

We audio-recorded a random sub-sample of 10% of scheduled exercise facilitator sessions completed at each site. An independent auditor (JH) rated each session for the presence or absence of pre-identified session elements using a standardized scoring rubric.

Statistical Analysis

Analyses were performed by RR, with support from SAP and the Cardiovascular Methods Centre at UOHI. Prior to analyses, accelerometer data were prepared. Wear time was determined by subtracting non-wear time from 24 hours. For participants with >7 valid days (i.e., ≥ 10 hours of wear time), the first day was removed (to minimize reactivity), and the subsequent 7 days used for the average. Participants had to have ≥ 4 valid days for inclusion (at baseline, this was met by 89.5% of participants).

Activity counts of 2690 per minute and 6167 per minute were the thresholds for moderate and vigorous level activity, respectively²³. Weekly minutes spent in activity of moderate, vigorous, or moderate and vigorous intensity combined were calculated by multiplying the daily average minutes per day above these thresholds by seven. Activity occurring in sustained bouts of 10 minutes or more was also calculated.

Treatment effects on MVPA, exercise capacity, CHD risk factors, and quality of life were evaluated with sex-specific linear mixed models with repeated measures using SPSS version 25 (IBM Corporation, Armonk, New York). A $p < .05$ was considered statistically significant. In these analyses, the outcome of interest was used as dependent variable and the fixed effect matrix included treatment

group (UC and EFI), time point (1 to 3), and site (1 to 3). The proportion of participants enrolled in community exercise programs was compared between groups using logistic regression. Baseline differences for important predictors of outcome were controlled for in the analyses.

In accordance with the intention-to-treat principle, all patients were included in the group to which they were randomly assigned. In addition, a pre-specified efficacy analysis that included only patients who completed at least 66% of the intervention contacts was conducted (i.e., 6/9 contacts; per-protocol). Missing outcome data were imputed using multiple imputation procedures.

RESULTS

Participant Flow

Figure 1a displays the flow of female participants during the trial; Figure 1b displays the male. Of the 1066 women who completed CR, 417 met initial inclusion criteria and 135 were randomized: 67 to the UC group and 68 to the EFI. Of the 1603 men who completed CR, 775 met initial inclusion criteria and 314 were randomized: 156 to the UC group and 158 to EFI.

Eleven Toronto participants in the intervention arm (5 men, 6 women) and 8 in UC (5 men, 3 women) enrolled in maintenance CR. Sensitivity analyses revealed no effect on overall results.

At 52 weeks, complete outcome data were available for 94 women (69.6%) and 219 men (69.9%).

Attrition rates were similar between groups for both women (EFI 33.8%, UC 28.4%; $p=.41$) and men (EFI 36.1%, UC 28.2%; $p=.10$; Figure 1). There were no harms or unintended effects of the intervention.

Participant Characteristics

Baseline sociodemographic and clinical characteristics of women and men in the UC and EFI groups are shown in Supplementary Table S1. Among women, participants in UC had higher BMI scores and

were more likely to have dyslipidemia compared to those in the EFI. Among men, participants had similar characteristics regardless of group.

Supplementary Table S2 shows the differences in baseline characteristics between those retained versus lost to follow-up, by arm. As shown, in the EFI group, retained participants were older. Retained participants in UC were more educated than those lost to follow-up. Importantly, participants in the EFI arm were more active at baseline than those lost to follow-up; there were no such differences in the UC group.

Intervention Adherence

Women attended an average of 6.4 ± 2.3 (standard deviation) of 9 scheduled EFI sessions and men completed an average of 6.8 ± 1.9 ($p=.19$). Six participants (2 women, 4 men) assigned to the EFI group did not attend any sessions. For female and male participants, 48/68 (70.6%) and 123/158 (77.8%) completed 6 or more of the 9 scheduled treatment sessions, respectively (for per-protocol analyses). Among men in the intervention group, those that were adherent to the intervention were older (64.3 vs. 57.7 years; $p=.002$) and had lower diastolic BP (72.4 vs. 76.2 mmHg; $p=.05$) and low-density lipoprotein (1.59 vs. 1.90 mmol/L; $p=.03$) levels at baseline compared to those that were non-adherent. No other differences were observed.

Treatment Fidelity

Counselors delivered the EFI intervention with high fidelity. For each audited group telephone call, counselors covered a mean of 20.8/23 (90.4%) indicated elements. For each audited individual call, counselors covered a mean of 18.5/21 (87.9%) indicated elements.

Effect of Treatment on Physical Activity

At 52 weeks, 81 (37.9%) men and 30 (31.9%) women were engaging in guideline-recommended levels of MVPA (i.e., ≥ 150 minutes). With regard to mode, men ($n=198$, 88.0%) and women ($n=91$, 93.8%)

most commonly reported walking individually, followed by cardio machines (men n=106, 47.1%; women n=30, 30.9%), group exercise (men n=72, 32.0%; women n=41, 42.3%), weight training (men n=84, 37.3%; women n=36, 37.1%), and swimming (men n=33, 14.7%; women n=23, 23.7%). “Other” responses included cycling, yoga/stretching, dancing, skiing, skating or snowshoeing, rowing/paddling, hockey, and golf. Using raw self-reported data, men in the EFI group reported engaging in a mean of 238.72 ± 163.45 minutes of MVPA /week, men in UC 190.58 ± 163.86 ($t=2.143$, $p=.03$), women in EFI 187.21 ± 179.41 and women in UC 170.03 ± 172.56 ($t=.47$, $p=.64$).

Time and treatment effects for MVPA in women and men are presented in Table 1a and 1b, respectively. In the primary intent-to-treat analysis of women (Supplementary Table S3a), there were no significant effects for treatment or time on MVPA. In the planned secondary analysis that considered only women that were adherent to the EFI (per-protocol), MVPA levels were higher in those assigned to the EFI group compared to UC ($P=0.013$; Table 2a).

In the intent-to-treat analysis of men (Supplementary Table S3b), MVPA tended to decline over time ($P=0.052$). The decline (~30-35 minutes per week) was similar between arms; there was no effect of treatment assignment. Similar results were observed in secondary analyses considering only men adherent to EFI.

Secondary Outcomes

In the intention-to-treat analyses for women, a treatment group main effect was observed for BMI, however there was lack of equivalence at baseline which likely explains this effect (Supplementary Table S2a). There were no significant interaction effects or treatment group differences for any other outcomes following intention-to-treat analyses. There was an effect of time, with significant increases in systolic BP (trend for treatment effect). There was a trend for an EFI treatment effect for exercise capacity; while caution is warranted in over-interpretation, this is promising given the smaller sample

size for this outcome, however the change would not be considered clinically-meaningful. There were no treatment group differences for participation in community exercise programs at 52 weeks (EFI n=33, 67.3% vs UC n=27, 55.1%; $p=.21$).

Per-protocol analyses in women (Table 1a) revealed again no significant interaction effects. The BMI treatment effect was again observed. There was a significant treatment and time effect for systolic BP, with values increasing significantly over time in both groups, but values being significantly lower in EFI participants. EFI only was associated with significant improvements in exercise capacity from baseline to 52 weeks ($P=0.019$; which again would not be considered clinically-meaningful). There were again no effects on use of community exercise programs ($p=.17$).

In the intention-to-treat analyses for men (Supplementary Table S3b), there was a significant treatment effect on WC favoring UC. There were significant increases in quality of life (trend for treatment effect) and systolic BP over time, regardless of group. There were no treatment group differences for participation in community exercise programs at 52 weeks (EFI n=54, 49.1% vs UC n=58, 50.4%; $p=.84$).

Per-protocol analyses in men (Table 1b) replicated the significant treatment effect on WC favoring UC and the significant increases in systolic BP over time. The trend for a treatment effect on quality of life was also present. No other differences were observed ($p=.57$ for community exercise program use).

DISCUSSION

Although there is substantial epidemiological evidence that higher levels of MVPA are associated with better medical outcome and quality of life in patients with CHD,²⁴ there is considerably less evidence about interventions that can help patients maintain activity levels following completion of CR⁷. In the present trial, a 50-week, home and community-based, remotely-delivered EFI was shown to beneficially impact MVPA in women who adhered to the intervention sessions (almost 3/4s of the

women) compared to UC; the intervention was ineffective in men, who were already quite active.

There was no impact on participation in community exercise programs, contrary to hypotheses.

There have been calls for greater emphasis on sex and gender considerations in CHD research.²⁵ We analyzed results for women and men separately, given that women are less active than men during and after CR.⁴ The intervention may not have been effective in men given their high levels of MVPA at CR completion, and that they had good BP control and quality of life through program participation. The negative impact on WC may have been spurious (or perhaps men may have eaten more as they were partaking in an exercise intervention). The promising results in women suggest a fully-powered women-only trial is warranted (we did not meet the target sample size in women; there were 94 retained at 52 weeks of a planned 192) to determine the efficacy of the intervention. Results of planned tertiary analyses suggest the intervention may be impactful due to positive impacts on exercise task self-efficacy and PA intentions.¹⁰ The intervention was quite low-cost and feasible, given exercise professionals from the CR program were used or trainees. It may be important to re-visit the impact of the frequency and number of contacts on exercise maintenance, given intervention effects appeared more favorable in the first 6 months when there were more contacts with the exercise facilitator.

Consistent with our trial, previous studies have found exercise interventions post-CR can help individuals with CHD maintain PA in the long-term compared to controls, but there are variable effects of such interventions.⁷ This most recent review showed that although length of preceding CR did not impact intervention effectiveness (as was replicated herein; data not shown), the duration of intervention was important, with effective interventions lasting 12 weeks or longer, such as our EFI intervention. In a previous systematic review of PA interventions for individuals post-CR, Chase et al. found that interventions consisting of behavioral strategies and combined behavioral and cognitive strategies were more successful in PA behavior change than cognitive strategies alone, such as our EFI intervention.²⁶

Limitations

This was an open-label clinical trial. Participants in clinical trials are typically more motivated than non-participants. Our sample of women was small; we were unable to achieve our intended recruitment target of 192 women. A larger sample would have greater power to detect an overall treatment effect on MVPA. Men in our study were already very active. As in most longitudinal studies, there were missing data, although the mixed model analyses made use of all available data. Retained participants in the intervention group were more active at baseline than controls.

We used an objective measure of MVPA for our primary outcome. While this is a strength, objective measures can create a reactive response. Moreover, accelerometers respond poorly to activities like cycling, skating, load-carrying, and other non-standard activities, and must be removed for swimming. Given 56 (17.4%) participants reported some swimming (frequency unknown; no group differences, $p=.69$) and others reported cycling and skating, MVPA rates reported herein are likely somewhat under-estimated¹⁴ Indeed, self-reported MVPA was also reported for descriptive purposes, but is likely somewhat over-estimated.

Conclusions

In this study of CR completers, an EFI showed promise for women who adhered to the intervention, but was ineffective in men regardless of their adherence. Women had lower levels of MVPA at CR graduation, and hence greater room for improvement. Results of this trial, along with our recent meta-analysis⁷, point to future strategies which should be tried to ensure exercise maintenance, along with its' corresponding benefits, in CR graduates.

Contributions: RR, SC, CB, JH, SP and KM contributed to the overall concept and study design. EW, MM, GP, GG acquired study data. RR, SG, CB, MM, JH, GP, SP, KM and GG contributed to the

analysis and interpretation of study data. RR and SG drafted the manuscript. All authors critically reviewed and revised the manuscript to confirm accuracy. All authors gave final approval.

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Fig 1 a. Flow of Female Participants Through the ECO-PCR Trial

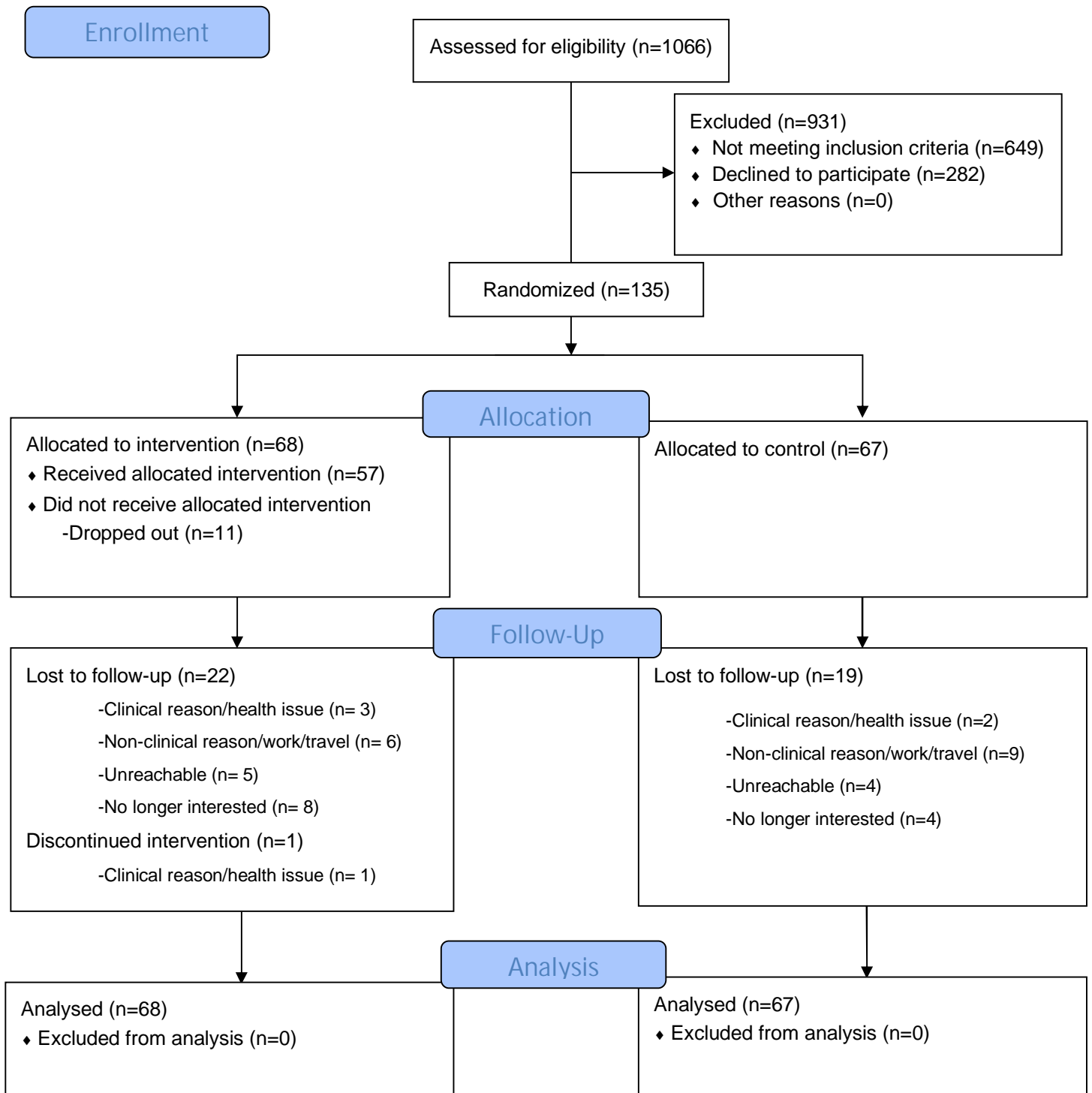


Fig 1 b. Flow of Male Participants Through the ECO-PCR Trial

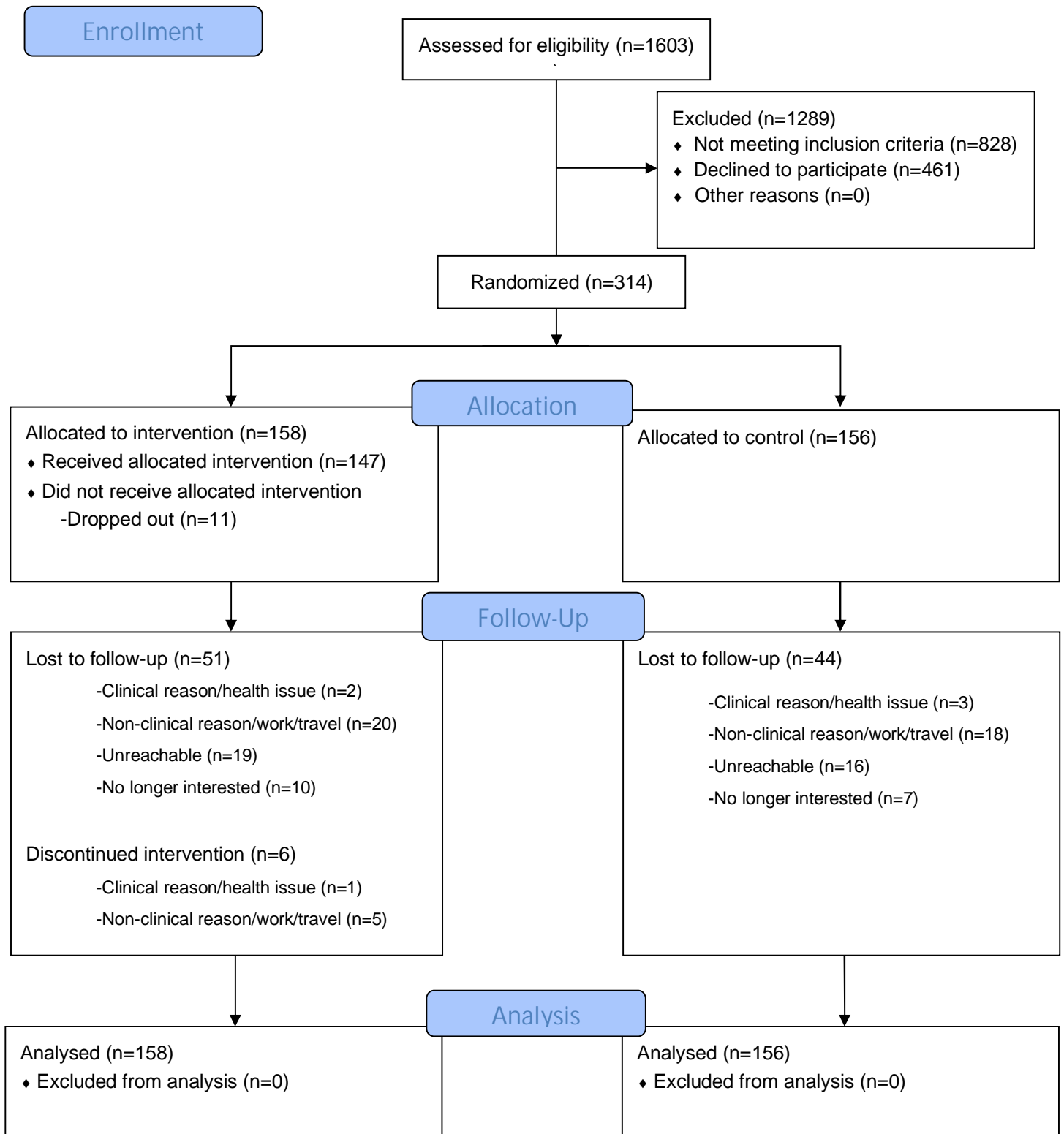


Table 1a: Primary and secondary outcomes in women adherent to the intervention (per protocol)

| Outcome | Post-CR Mean (SD) | 26 weeks Mean (SD) | 52 weeks Mean (SD) | Group effect p-value | Time effect p-value | Group*Time p-value |
|-----------------------------------------------|----------------------|-----------------------|-----------------------|-------------------------|------------------------|-----------------------|
| <i>Primary Outcome</i> | | | | | | |
| Weekly MVPA (in bouts of ≥ 10 min) | 130.3 (116.9) | 109.0 (116.2) | 111.8 (113.1) | 0.013 | 0.808 | 0.758 |
| Control | 156.5 (143.4) | 163.2 (185.4) | 150.0 (136.3) | | | |
| Intervention | | | | | | |
| Weekly MVPA (minutes) | | | | 0.107 | 0.563 | 0.998 |
| Control | 238.6 (167.1) | 240.2 (189.0) | 216.9 (179.8) | | | |
| Intervention | 272.9 (154.7) | 274.6 (200.0) | 248.1 (160.6) | | | |
| <i>Secondary Outcome</i> | | | | | | |
| Quality of life (VAS) | | | | 0.230 | 0.912 | 0.679 |
| Control | 79.1 (12.8) | 78.1 (11.6) | 78.9 (10.3) | | | |
| Intervention | 75.6 (13.4) | 77.8 (15.1) | 77.2 (14.7) | | | |
| Exercise capacity (ml O ₂ /kg/min) | | | | 0.019 | 0.605 | 0.323 |
| Control | 20.77 (4.19) | - | 20.32 (5.05) | | | |
| Intervention | 22.05 (5.10) | | 23.45 (4.88) | | | |

| | | | | | | |
|--------------------------------------|--------------|--------------|--------------|-------|-------|-------|
| Body mass index (kg/m ²) | | | | | | |
| Control | 28.94(5.67) | 29.14 (5.28) | 28.98 (5.02) | 0.002 | 0.897 | 0.975 |
| Intervention | 27.02 (5.59) | 27.35 (6.26) | 26.83 (5.73) | | | |
| Waist circumference (cm) | | | | | | |
| Control | 94.7 (13.5) | 95.4 (14.6) | 95.3 (12.0) | 0.173 | 0.466 | 0.592 |
| Intervention | 91.7 (13.1) | 95.5 (18.5) | 91.7 (13.6) | | | |
| Systolic blood pressure (mmHg) | | | | | | |
| Control | 121.8 (17.1) | 127.5 (17.7) | 127.2 (15.2) | 0.011 | 0.019 | 0.799 |
| Intervention | 117.5 (16.3) | 124.0 (17.0) | 120.7 (15.0) | | | |

MVPA: moderate to vigorous-intensity physical activity; SD: standard deviation; VAS: visual analog scale of EQ-5D; CR: cardiac rehabilitation.

-not assessed at this time point

Table 1b: Primary and secondary outcomes in men adherent to the intervention (per protocol)

| Outcome | Post-CR Mean (SD) | 26 weeks Mean (SD) | 52 weeks Mean (SD) | Group effect p-value | Time effect p-value | Group*Time p-value |
|-----------------------------------------------|----------------------|-----------------------|-----------------------|-------------------------|------------------------|-----------------------|
| <i>Primary Outcome</i> | | | | | | |
| Weekly MVPA (in bouts of ≥ 10 min) | 187.6 (137.4) | 152.2 (146.5) | 152.8 (148.9) | 0.741 | 0.059 | 0.438 |
| Control | 178.7 (150.1) | 175.7 (155.6) | 149.3 (149.3) | | | |
| Intervention | | | | | | |
| Weekly MVPA (non-bouted minutes) | 331.0 (207.4) | 294.9 (208.7) | 284.8 (202.3) | 0.946 | 0.112 | 0.557 |
| Control | 314.1 (195.9) | 316.8 (193.1) | 282.9 (206.9) | | | |
| Intervention | | | | | | |
| <i>Secondary Outcome</i> | | | | | | |
| Quality of life (VAS) | | | | 0.078 | 0.059 | 0.407 |
| Control | 79.1 (12.4) | 77.8 (12.7) | 80.2 (11.7) | | | |
| Intervention | 75.6 (14.6) | 76.7 (14.7) | 79.5 (12.0) | | | |
| Exercise capacity (ml O ₂ /kg/min) | | | | 0.243 | 0.802 | 0.637 |
| Control | 26.49 (7.26) | - | 27.41 (8.19) | | | |

| | | | | | | |
|--------------------------------------|--------------|--------------|--------------|-------|-------|-------|
| Intervention | 26.16 (6.32) | | 25.67 (6.26) | | | |
| Body mass index (kg/m ²) | | | | | | |
| Control | 28.27(4.77) | 28.90 (5.15) | 29.04 (5.39) | 0.364 | 0.412 | 0.764 |
| Intervention | 28.93 (4.37) | 28.94 (4.84) | 29.30 (4.48) | | | |
| Waist circumference (cm) | | | | | | |
| Control | 100.0 (12.9) | 101.6 (12.8) | 102.0 (14.2) | 0.018 | 0.255 | 0.941 |
| Intervention | 102.5 (12.0) | 103.9 (11.2) | 103.7 (12.4) | | | |
| Systolic blood pressure (mmHg) | | | | | | |
| Control | 120.1 (17.1) | 126.2 (17.7) | 126.2 (15.2) | 0.568 | <.001 | 0.819 |
| Intervention | 120.4 (15.8) | 124.7 (19.0) | 125.4 (14.8) | | | |

MVPA: moderate to vigorous-intensity physical activity; SD: standard deviation; VAS: visual analog scale of EQ-5D; CR: cardiac rehabilitation.

-not assessed at this time point

Supplemental Table S1: Characteristics of the Sample Post-Cardiac Rehabilitation

| n (%) or mean (SD) | Female Participants | | Male Participants | |
|-----------------------------------------|---------------------|-------------|-------------------|-------------|
| | EFI (n=68) | UC (n=67) | EFI (n=158) | UC (n=156) |
| Sociodemographic characteristics | | | | |
| Age (years) | 65.3 (10.3) | 66.1 (10.5) | 63.0 (9.8) | 63.2 (9.4) |
| White ethnocultural background | 55 (80.9) | 56 (83.5) | 124 (78.4) | 118 (75.6) |
| Married or cohabiting | 33 (48.5) | 34 (50.7) | 114 (72.1) | 115 (73.7) |
| Employed full-time | 14 (20.5) | 10 (14.9) | 46 (29.1) | 47 (30.1) |
| Current smoker | 1 (1.5) | 1 (1.5) | 2 (1.2) | 3 (2.0) |
| Body mass index | 27.0 (5.1) | 28.9 (5.7)* | 29.0 (4.8) | 28.3 (4.8) |
| Medical History | | | | |
| Hypertension, | 36 (52.9) | 47 (70.1) | 94 (59.5) | 83 (53.2) |
| Dyslipidemia | 33 (48.5) | 48 (71.6)* | 99 (63.9) | 99 (63.5) |
| Diabetes mellitus | 13 (19.1) | 14 (20.8) | 28 (17.7) | 29 (18.5) |
| Prior cardiac history | 7 (10.3) | 5 (7.5) | 15 (9.5) | 24 (15.4) |
| Peripheral vascular disease | 2 (2.9) | 2 (3.0) | 4 (2.5) | 1 (0.6) |
| Heart failure | 0 (0.0) | 1 (1.5) | 1 (0.6) | 2 (1.3) |
| Chronic kidney disease | 1 (1.5) | 0 (0.0) | 4 (2.5) | 4 (2.6) |
| Left ventricular ejection fraction | 57.5 (9.0) | 59.8 (7.3) | 51.8 (11.7) | 54.3 (11.2) |
| Indication for Cardiac Rehab | | | | |
| Coronary artery bypass surgery | 12 (17.6) | 17 (25.4) | 48 (30.4) | 39 (25.0) |
| Percutaneous coronary intervention | 43 (63.2) | 38 (56.7) | 102 (64.6) | 100 (64.1) |
| Myocardial infarction | 36 (52.9) | 30 (45.5) | 78 (49.7) | 71 (45.8) |
| Angina | 6 (9.1) | 10 (15.6) | 10 (6.8) | 13 (9.0) |
| Medications | | | | |

| | | | | |
|------------------------------------------|-----------|-----------|------------|------------|
| Angiotension-converting enzyme inhibitor | 33 (48.5) | 33 (49.3) | 92 (58.2) | 83 (53.2) |
| Angiotensin receptor blocker | 14 (20.6) | 18 (26.9) | 13 (8.3) | 15 (9.6) |
| Beta-blocker | 49 (72.1) | 54 (80.6) | 121 (76.6) | 121 (77.6) |
| Calcium channel blocker | 13 (19.1) | 11 (16.4) | 19 (12.0) | 24 (15.4) |
| Diuretic | 7 (10.3) | 10 (14.9) | 17 (10.8) | 9 (5.8) |
| Diabetes medication | 6 (8.8) | 11 (16.4) | 28 (17.7) | 21 (13.4) |
| Nitrates | 24 (35.2) | 32 (47.8) | 63 (40.1) | 55 (35.3) |
| Aspirin | 60 (88.2) | 60 (89.6) | 149 (94.3) | 149 (95.5) |
| Other anti-platelet medication | 29 (42.6) | 25 (37.3) | 65 (41.1) | 60 (38.5) |
| Statin | 60 (88.2) | 61 (91.0) | 151 (95.6) | 145 (92.9) |
| Psychotropic medication | 14 (20.6) | 16 (23.9) | 15 (9.6) | 15 (9.6) |

SD: standard deviation; EFI: exercise facilitator intervention; UC: usual care

Supplemental Table S2: Sociodemographic and clinical characteristics of participants at baseline (post-cardiac rehab) by arm and 1 year retention status

| | Retained | Lost to Follow-Up | Total |
|---------------------------------------|-------------|-------------------|-------------|
| Variable | 347 (77.3%) | 102 (22.7%) | N=449 |
| Site | | | |
| Ottawa | 244 (70.7) | 61 (60.4) | 306 (68.2) |
| Toronto | 101 (29.3) | 40 (39.6) | 143 (31.8) |
| <u>Sociodemographic</u> | | | |
| Age, mean years (SD) | | | |
| Control | 64.0 (9.5) | 64.0 (11.1) | 64.0 (9.8) |
| Intervention | 64.5 (9.2) | 61.3 (11.5) | 63.7 (9.9)* |
| Sex, n (% male) | | | |
| Control | 126 (69.0) | 29 (70.0) | 155 (69.8) |
| Intervention | 114 (69.5) | 41 (70.7) | 155 (69.8) |
| Ethnocultural background, n (% white) | | | |
| Control | 146 (85.4) | 27 (90.0) | 174 (86.1) |
| Intervention | 138 (86.3) | 41 (91.1) | 179 (87.3) |
| Working full-time, n (%) | | | |
| Control | 49 (28.7) | 8 (26.7) | 57 (28.2) |
| Intervention | 43 (26.9) | 17 (39.5) | 60 (29.6) |
| Married (or equiv.), n (%) | | | |
| Control | 128 (74.4) | 21 (70.0) | 149 (73.4) |
| Intervention | 116 (73.4) | 31 (68.9) | 147 (72.4) |
| ≥ University education, n (%) | | | |
| Control | 99 (57.9) | 10 (33.3) | 110 (54.5)* |
| Intervention | 75 (47.5) | 17 (38.6) | 92 (45.5) |

ClinicalCR discharge VO₂, mean

ml/kg/min (SD)

| | | | |
|---------|------------|------------|------------|
| Control | 25.2 (6.9) | 23.8 (7.3) | 24.9 (7.0) |
|---------|------------|------------|------------|

| | | | |
|--------------|------------|------------|------------|
| Intervention | 24.7 (6.0) | 24.8 (7.7) | 24.7 (6.4) |
|--------------|------------|------------|------------|

QALY, mean (SD)

| | | | |
|---------|-----------|-----------|-----------|
| Control | 0.9 (0.1) | 0.9 (0.1) | 0.9 (0.1) |
|---------|-----------|-----------|-----------|

| | | | |
|--------------|-----------|-----------|-----------|
| Intervention | 0.9 (0.1) | 0.9 (0.1) | 0.9 (0.1) |
|--------------|-----------|-----------|-----------|

Risk Factors

Current smoker, n (%)

| | | | |
|---------|---------|---|---------|
| Control | 4 (2.4) | 0 | 4 (2.0) |
|---------|---------|---|---------|

| | | | |
|--------------|---------|---------|---------|
| Intervention | 2 (1.4) | 1 (2.3) | 3 (1.5) |
|--------------|---------|---------|---------|

BMI, mean kg/m² (SD)

| | | | |
|---------|------------|------------|------------|
| Control | 28.5 (4.9) | 28.4 (5.5) | 28.5 (5.0) |
|---------|------------|------------|------------|

| | | | |
|--------------|------------|------------|------------|
| Intervention | 28.3 (4.8) | 28.8 (5.2) | 28.4 (4.9) |
|--------------|------------|------------|------------|

WC, mean cm (SD)

| | | | |
|---------|-------------|-------------|-------------|
| Control | 99.1 (13.0) | 95.5 (13.8) | 98.4 (13.2) |
|---------|-------------|-------------|-------------|

| | | | |
|--------------|-------------|-------------|-------------|
| Intervention | 99.0 (13.4) | 99.4 (14.0) | 99.1 (13.5) |
|--------------|-------------|-------------|-------------|

SBP, mean mmHg (SD)

| | | | |
|---------|--------------|--------------|--------------|
| Control | 120.8 (17.0) | 119.9 (20.1) | 120.6 (17.6) |
|---------|--------------|--------------|--------------|

| | | | |
|--------------|--------------|--------------|--------------|
| Intervention | 119.7 (16.3) | 122.9 (14.3) | 120.6 (15.8) |
|--------------|--------------|--------------|--------------|

Hypertension, n (%)

| | | | |
|---------|------------|-----------|------------|
| Control | 111 (61.7) | 68 (37.8) | 130 (58.3) |
|---------|------------|-----------|------------|

| | | | |
|--------------|-----------|-----------|------------|
| Intervention | 96 (57.5) | 71 (42.5) | 167 (57.5) |
|--------------|-----------|-----------|------------|

DM-Type 1 or 2, n (%)

| | | | |
|---------|-----------|----------|-----------|
| Control | 34 (19.3) | 9 (21.4) | 43 (19.6) |
|---------|-----------|----------|-----------|

| | | | |
|--------------|-----------|-----------|-----------|
| Intervention | 28 (16.9) | 13 (23.6) | 41 (18.6) |
|--------------|-----------|-----------|-----------|

| | | | |
|------------------------------------------|------------|-----------|------------|
| Dyslipidemia, n (%) | | | |
| Control | 117 (65.4) | 29 (69.0) | 147 (66.2) |
| Intervention | 98 (59.8) | 34 (57.6) | 132 (59.2) |
| <i>Cardiac Rehabilitation Indication</i> | | | |
| PCI, n (%) | | | |
| Control | 110 (61.1) | 28 (66.7) | 138 (61.9) |
| Intervention | 106 (63.5) | 39 (66.1) | 145 (64.2) |
| CABG, n (%) | | | |
| Control | 48 (26.7) | 8 (19.0) | 56 (25.1) |
| Intervention | 44 (26.3) | 16 (27.1) | 60 (26.5) |
| <i>Comorbidities</i> | | | |
| Cancer, n (%) | | | |
| Control | 15 (8.3) | 8 (19.0) | 23 (10.3) |
| Intervention | 14 (8.4) | 9 (15.5) | 23 (10.2) |
| Depression or anxiety, n (%) | | | |
| Control | 35 (20.0) | 9 (27.3) | 44 (21.1) |
| Intervention | 25 (15.6) | 10 (21.7) | 35 (17.0) |
| MSK/Joint replacement / arthritis, n (%) | | | |
| Control | 60 (34.7) | 14 (45.2) | 74 (36.1) |
| Intervention | 53 (33.3) | 17 (36.2) | 70 (34.0) |
| Peripheral vascular disease, n (%) | | | |
| Control | 2 (1.1) | 1 (2.4) | 3 (1.3) |
| Intervention | 4 (2.4) | 2 (3.4) | 6 (2.7) |
| <i>Pertinent Medications</i> | | | |
| Beta-Blocker, n (%) | | | |
| Control | 140 (77.8) | 34 (81.0) | 175 (78.5) |
| Intervention | 123 (73.7) | 47 (79.7) | 170 (75.2) |

| | | | |
|------------------------------|---------------|---------------|-----------------|
| Anti-depressant, n (%) | | | |
| Control | 23 (12.8) | 8 (19.0) | 31 (13.9) |
| Intervention | 21 (12.6) | 8 (13.8) | 29 (12.9) |
| <i>Primary Outcome</i> | | | |
| MVPA-Bouts, mean min/wk (SD) | | | |
| Control | 172.3 (129.5) | 156.7 (158.4) | 170.0 (133.8) |
| Intervention | 182.9 (152.6) | 98.9 (103.1) | 164.0 (146.9)** |

CABG = coronary artery bypass graft; CR = cardiac rehabilitation; BMI = body mass index; DM = diabetes mellitus; MI = myocardial infarction; MSK = musculoskeletal; MVPA = moderate to vigorous-intensity physical activity; PCI = percutaneous coronary intervention; QALY= quality-adjusted life year; SD = standard deviation; SBP = systolic blood pressure; WC = waist circumference

*p<.05, **p<.01, ***p<.001

Supplemental Table S3a: Primary and secondary outcomes in women (intention-to-treat)

| Mean (SD) | Post-CR | 26 weeks | 52 weeks | Group effect p-value | Time effect p-value | Group*Time p-value |
|-----------------------------------------------|---------------|---------------|---------------|-------------------------|------------------------|-----------------------|
| <i>Primary Outcome</i> | | | | | | |
| Weekly MVPA (in bouts of ≥ 10 min) | 130.3 (116.9) | 109.0 (116.2) | 111.8 (113.1) | 0.116 | 0.824 | 0.436 |
| Control | 132.7 (138.3) | 158.2 (188.3) | 132.6 (135.2) | | | |
| Intervention | | | | | | |
| Weekly MVPA (non-bouted minutes) | 238.6 (167.1) | 240.2 (189.0) | 216.9 (179.8) | 0.523 | 0.435 | 0.884 |
| Control | 242.1 (152.4) | 266.3 (204.7) | 225.2 (163.0) | | | |
| Intervention | | | | | | |
| <i>Secondary Outcomes</i> | | | | | | |
| Quality of life (VAS) | | | | 0.195 | 0.802 | 0.607 |
| Control | 79.1 (12.8) | 78.1 (11.6) | 78.9 (10.3) | | | |
| Intervention | 75.1 (15.0) | 77.4 (15.6) | 77.7 (14.5) | | | |
| Exercise capacity (ml O ₂ /kg/min) | | | | 0.088 | 0.482 | 0.234 |
| Control | 20.8 (4.2) | - | 20.3 (5.1) | | | |

| | | | | | | |
|--------------------------------------|--------------|--------------|--------------|-------|-------|-------|
| Intervention | 21.2 (5.2) | | 22.9 (4.9) | | | |
| Body mass index (kg/m ²) | | | | | | |
| Control | 28.94 (5.7) | 29.14 (5.3) | 28.98 (5.0) | 0.002 | 0.896 | 0.986 |
| Intervention | 27.02 (5.1) | 27.43 (6.0) | 27.06 (5.7) | | | |
| Waist circumference (cm) | | | | | | |
| Control | 94.7 (13.5) | 95.4 (14.6) | 95.3 (12.0) | 0.235 | 0.448 | 0.633 |
| Intervention | 91.7 (12.3) | 95.6 (17.4) | 92.8 (13.7) | | | |
| Systolic blood pressure (mmHg) | | | | | | |
| Control | 121.8 (17.1) | 127.5 (17.7) | 127.2 (15.2) | 0.059 | 0.033 | 0.862 |
| Intervention | 119.5 (16.3) | 124.3 (16.4) | 122.5 (15.7) | | | |

MVPA: moderate to vigorous-intensity physical activity; SD: standard deviation; VAS: visual analog scale of EQ-5D; CR: cardiac rehabilitation.

-not assessed at this time point

Supplemental Table S3b: Primary and secondary outcomes in men (intention-to-treat)

| Mean (SD) | Post-CR | 26 weeks | 52 weeks | Group effect p-value | Time effect p-value | Group*Time p-value |
|-----------------------------------------------|---------------|---------------|---------------|-------------------------|------------------------|-----------------------|
| <i>Primary Outcome</i> | | | | | | |
| Weekly MVPA (in bouts of ≥ 10 min) | 187.6 (187.6) | 152.2 (146.5) | 152.8 (148.9) | 0.745 | 0.052 | 0.379 |
| Control | 178.1 (149.1) | 176.8 (157.9) | 148.4 (149.1) | | | |
| Intervention | | | | | | |
| Weekly MVPA (non-bouted minutes) | 331.0 (207.4) | 294.9 (208.7) | 284.8 (202.3) | 0.851 | 0.085 | 0.627 |
| Control | 318.5 (193.9) | 316.0 (195.4) | 284.5 (205.3) | | | |
| Intervention | | | | | | |
| <i>Secondary Outcomes</i> | | | | | | |
| Exercise capacity (ml O ₂ /kg/min) | | | | 0.192 | 0.998 | 0.266 |
| Control | 26.5 (7.3) | - | 27.4 (8.2) | | | |
| Intervention | 26.3 (6.1) | | 25.4 (6.2) | | | |
| Body mass index (kg/m ²) | | | | | | |

| | | | | | | |
|--------------------------------|--------------|--------------|--------------|-------|-------|-------|
| Control | 28.27(4.8) | 28.90 (5.8) | 29.04 (5.4) | 0.286 | 0.461 | 0.725 |
| Intervention | 29.02 (4.8) | 29.01 (5.2) | 29.31 (4.6) | | | |
| Waist circumference (cm) | | | | | | |
| Control | 100.0 (12.9) | 101.6 (12.8) | 102.0 (14.2) | 0.034 | 0.243 | 0.950 |
| Intervention | 102.2 (12.9) | 103.6 (11.9) | 103.5 (12.7) | | | |
| Systolic blood pressure (mmHg) | | | | | | |
| Control | 120.1 (17.1) | 126.2 (17.7) | 126.2 (15.2) | 0.793 | <.001 | 0.731 |
| Intervention | 121.1 (15.7) | 125.3 (19.2) | 125.3 (14.5) | | | |
| Quality of life (VAS) | | | | | | |
| Control | 79.1 (12.4) | 77.8 (12.7) | 80.2 (11.7) | 0.091 | 0.034 | 0.371 |
| Intervention | 75.7 (14.3) | 76.6 (14.6) | 79.9 (12.1) | | | |

MVPA: moderate to vigorous-intensity physical activity; SD: standard deviation; VAS: visual analog scale of EQ-5D; CR: cardiac rehabilitation.

-not assessed at this time point