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Clinical Research

A Randomized Controlled Trial of an Exercise Maintenance Intervention in Men and Women After Cardiac Rehabilitation (ECO-PCR Trial)

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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 with 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 and 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 enrollment in community-based exercise programs. Effects were tested with the use of linear mixed models.

RÉSUMÉ

Contexte : Des interventions visant à favoriser la poursuite d'un programme d'activité physique s'imposent pour aider les patients ayant terminé leur programme de réadaptation cardiaque (RC) à continuer de faire de l'activité physique d'intensité modérée à vigoureuse (APMV). Nous avons évalué séparément chez les hommes et les femmes l'efficacité d'une intervention par un facilitateur d'activité physique (IFAP) pour promouvoir la poursuite d'un programme d'activité physique comparativement aux soins usuels.

Méthodologie : Nous avons mené un essai de supériorité avec répartition aléatoire (selon un rapport de 1:1) et groupes parallèles dans trois centres (essai ECO-PCR). Les patients ayant terminé un programme de RC ont été stratifiés selon le centre et le sexe avant d'être soumis à une répartition aléatoire (à l'insu). Sur une période de 50 semaines, les participants du groupe IFAP ont assisté à une séance d'introduction en personne ainsi qu'à 5 téléconférences de counselling

Cardiac rehabilitation (CR) is a 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 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 problem,[4] which 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 after CR

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Results: A total of 449 CR graduates (135 women, 314 men) were randomised (n = 226 EFI, n = 223 UC). In the intention-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 ≥ 66% of sessions; per-protocol), bouted MVPA (ie, in sustained bouts of ≥ 10 min) was higher in women in the EFI group (mean = 132.6 ± 135.2 min/wk at 52 weeks) compared with UC (111.8 ± 113.1; $P = 0.013$). Regarding 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) favouring EFI; no other differences were observed.

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

Résultats : Au total, 449 patients ayant terminé un programme de RC (135 femmes et 314 hommes) ont été répartis aléatoirement (IFAP : n = 226; soins usuels : n = 223). Les résultats de l'analyse de la population en intention de traiter (hommes et femmes pris séparément) ne révèlent aucun effet significatif du traitement ou du temps sur l'APMV. À l'issue d'une analyse secondaire planifiée portant uniquement sur les sujets ayant adhéré à l'IFAP (au moins 66 % des séances d'exercices prévues effectuées, selon le protocole), la durée totale des séances d'APMV (c.-à-d. d'une durée d'au moins 10 minutes consécutives) était plus élevée chez les femmes du groupe IFAP (moyenne : 132,6 ± 135,2 minutes/semaine à la 52e semaine) que chez celles du groupe soins usuels (111,8 ± 113,1; $p = 0,013$). En ce qui concerne les résultats au chapitre des critères d'évaluation secondaires, un effet principal en faveur du groupe IFAP a été observé chez les femmes quant à la pression artérielle ($p = 0,011$) et à la capacité à l'effort ($p = 0,019$; selon le protocole dans les deux cas); aucune autre différence n'a été relevée.

Conclusions : Au cours de cet essai portant sur les patients ayant terminé un programme de RC, l'IFAP s'est révélée prometteuse chez les femmes, mais inefficace chez les hommes.

helped participants maintain physical activity (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 hypothesised that compared with usual care, patients completing CR who receive support over a 50-week period from a trained exercise facilitator would be engaging in more MVPA 52 weeks after the completion of CR.

Methods

Trial design and procedure

Ecologically-**O**ptimising Exercise Maintenance in Men and Women **P**ost—**C**ardiac **R**ehabilitation (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] are reported elsewhere9,10). Women and men who had completed CR underwent baseline measurements on site with the research coordinators (E.A.W., M.M.) 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 midway through (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 functional class III or IV heart failure,[11] inability to walk unaided at 3.2 km/h, 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 every participant. The first participant was randomised 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 min/wk 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 socio-demographic characteristics on a questionnaire, and clinical characteristics were extracted from CR charts. The outcomes

described below (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, FL). 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 Questionnaire[13] 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 treadmill[15] 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 from post-CR to 52 weeks later (equivalent to approximately 3.5 mL O_2/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 nonstretchable standard tape measure according to World Health Organisation protocol.[18] Blood pressure (BP) was measured in a seated position after a 5-minute rest period with the use of an automated noninvasive BP monitor (BPTru, Coquitlam, BC)[19] that averaged 6 measurements.

Quality of life. Quality of life was measured with the use of the EuroQol 5D[20] questionnaire visual analog scale. Respondents self-rated their health on a 0-100 vertical scale, where the end points 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 move CR participants to self-care after program completion; they were very similar. 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. The Toronto sites had a maintenance program; use of these programs was noted and sensitivity analyses undertaken.

EFI. 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 are summarised elsewhere.[8] A combination of face-to-face, group teleconference, and individual telephone counselling sessions was offered. Attendance records were kept for all contacts.

The EFI was designed using an ecological perspective encompassing "individual" (eg, knowledge, attitudes, skills), "social-environmental" (eg, friends, family, and social networks), and "physical-environmental" (eg, home, neighbourhood and community characteristics, climate) factors known to influence exercise behavior.[22,23] The recommended standard for exercise maintenance in patients with CHD ($\geq$ 150 min/wk MVPA in bouts of $\geq$ 10 minutes) was the behavioural objective of the intervention. The facilitator helped participants develop plans for adhering to this exercise standard. At each intervention session, participants prepared 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 care[21]) and recommendations regarding home exercise equipment were discussed. During group teleconferences, participants reviewed their recent activity, identified any barriers to exercise maintenance hat they had experienced, and brainstormed solutions as a group.

Facilitators received training in the intervention from the principal investigator (R.D.R.) and a clinician (J.H., a physiotherapist and lead of Heart Wise Exercise community program[21]). Intervention components were codified in a treatment manual; scripts and checklists were developed to ensure the intervention was delivered as originally conceptualised. Facilitators also participated in quarterly case discussions/booster sessions on the phone as a group (sometimes including J.H.), 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 subsample of 10% of scheduled exercise facilitator sessions completed at each site. An independent auditor (J.H.) rated each session for the presence or absence of preidentified session elements with the use of a standardised scoring rubric.

Statistical analysis

Analyses were performed by R.D.R., with support from S.A.P. and the Cardiovascular Methods Centre at the University of Ottawa Heart Institute. Before analyses, accelerometer data were prepared. Wear time was determined by subtracting nonwear time from 24 hours. For participants

with > 7 valid days (ie, ≥ 10 h/d wear time), the first day was removed (to minimise 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, respectively.[23] 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 7. Activity occurring in sustained bouts of ≥ 10 minutes was also calculated.

Treatment effects on MVPA, exercise capacity, CHD risk factors, and quality of life were evaluated by means of sex-specific linear mixed models with repeated measures using SPSS version 25 (IBM Corp, Armonk, NY). A P value of < 0.05 was considered to be 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 by means of 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 prespecified efficacy analysis that included only patients who completed at least 66% of the intervention contacts was conducted (ie, 6/9 contacts; per-protocol). Missing outcome data were imputed using multiple imputation procedures.

Results

Participant flow

Figure 1A shows the flow of female participants during the trial, Figure 1B the male. Of the 1066 women who completed CR, 417 met initial inclusion criteria and 135 were randomised: 67 to the UC group and 68 to EFI. Of the 1603 men who completed CR, 775 met initial inclusion criteria and 314 were randomised: 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%; $P = 0.41$; Fig. 1) and men (EFI 36.1%, UC 28.2%; $P = 0.10$; Fig. 2). 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 presented in Supplemental Table S1. Among women, participants in UC had higher BMIs and were more likely to have dyslipidemia compared with those in the EFI. Among men, participants had similar characteristics regardless of group.

Supplemental Table S2 presents the differences in baseline characteristics by arm between those retained versus those lost to follow-up. 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 completed an average of 6.4 ± 2.3 (SD) of 9 scheduled EFI sessions and men completed an average of 6.8 ± 1.9 ($P = 0.19$). 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%), respectively, completed ≥ 6 of the 9 scheduled treatment sessions (for per-protocol analyses). Among men in the intervention group, those who were adherent to the intervention were older (64.3 vs 57.7 y; $P = 0.002$) and had lower diastolic BP (72.4 vs 76.2 mm Hg; $P = 0.05$) and low-density lipoprotein levels (1.59 vs 1.90 mmol/L; $P = 0.03$) at baseline compared with those that were nonadherent. No other differences were observed.

Treatment fidelity

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

Effect of treatment on physical activity

At 52 weeks, 81 men (37.9%) and 30 women (31.9%) were engaging in guideline-recommended levels of MVPA (ie, ≥ 150 min). Regarding mode, 198 men (88.0%) and 91 women (93.8%) most commonly reported walking individually, followed by cardio machines (106 men [47.1%], 30 women [30.9%]), group exercise (72 men [32.0%], 41 women [42.3%]), weight training (84 men [37.3%], 36 women [37.1%]), and swimming (33 men [14.7%], 23 women [23.7%]). "Other" responses included cycling, yoga/stretching, dancing, skiing, skating or snowshoeing, rowing/paddling, hockey, and golf. According to raw self-reported data, men in the EFI group reported engaging in a mean 238.72 ± 163.45 min/wk of MVPA, men in UC 190.58 ± 163.86 ($t = 2.143$, $P = 0.03$); women in the EFI group reported 187.21 ± 179.41 and women in UC 170.03 ± 172.56 ($t = .47$; $P = 0.64$).

Time and treatment effects for MVPA in women and men are presented in Tables 1 and 2, respectively. In the primary intent-to-treat analysis of women (Supplemental Table S3), 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 with UC ($P = 0.013$; Table 1).

In the intention-to-treat analysis of men (Supplemental Table S4), MVPA tended to decline over time ($P = 0.052$). The decline (~30-35 min/wk) was similar between arms; there was no effect of treatment assignment. Similar results

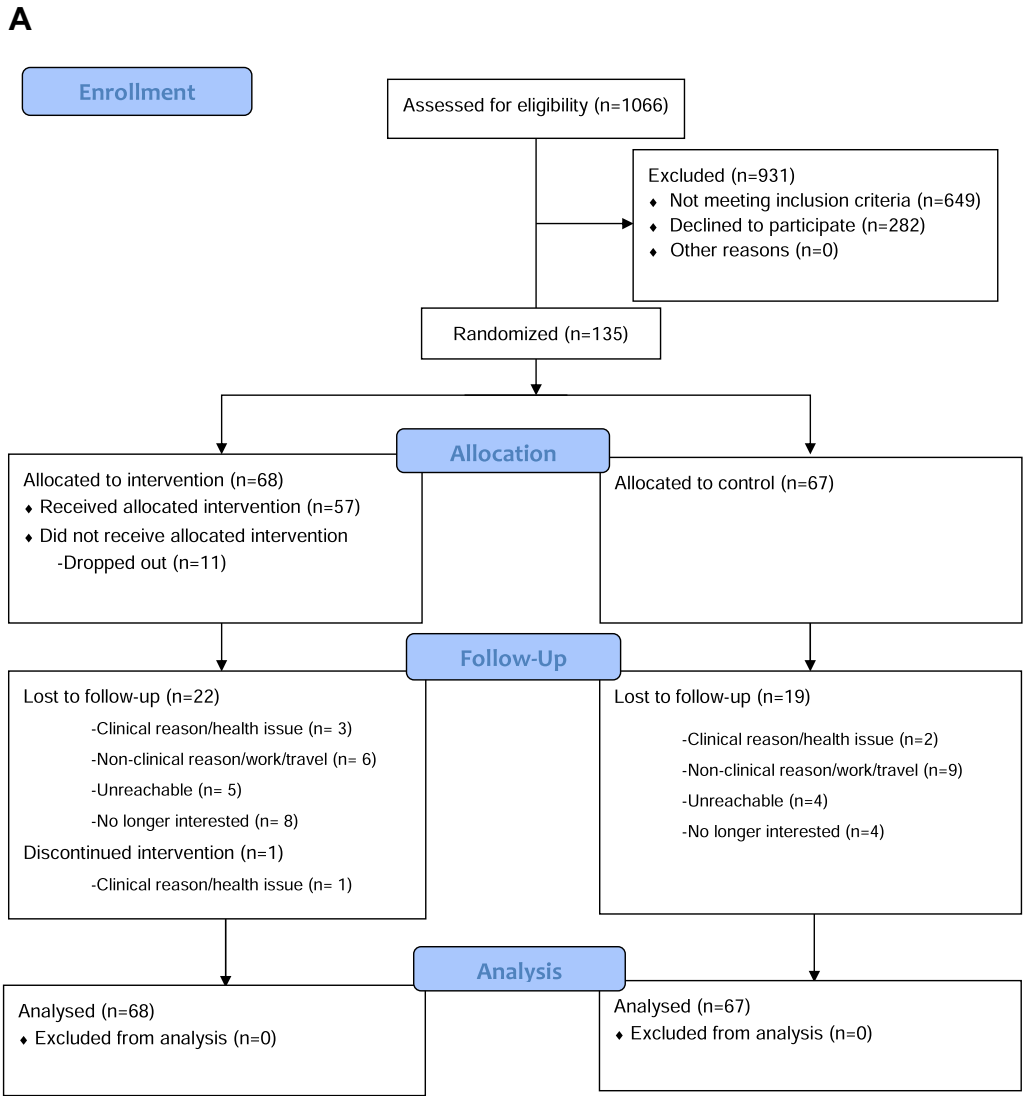

Figure 1. Flow of female participants through the ECO-PCR trial.

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, but a lack of equivalence at baseline likely explained that effect (Supplemental Table S3). There were no significant interaction effects or treatment group differences for any other outcomes after 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, which, though caution is warranted in overinterpretation, is promising given the smaller sample size for this outcome, although 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%; UC: n = 27, 55.1%; $P = 0.21$).

Per-protocol analyses in women (Table 1) also revealed 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 no effects on use of community exercise programs ($P = 0.17$)

In the intention-to-treat analyses for men (Supplemental Table S4), there was a significant treatment effect on WC favouring 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%; UC: n = 58, 50.4%; $P = 0.84$).

Per-protocol analyses in men (Table 2) replicated the significant treatment effect on WC favouring UC and the significant increases in systolic BP over time. The trend for a

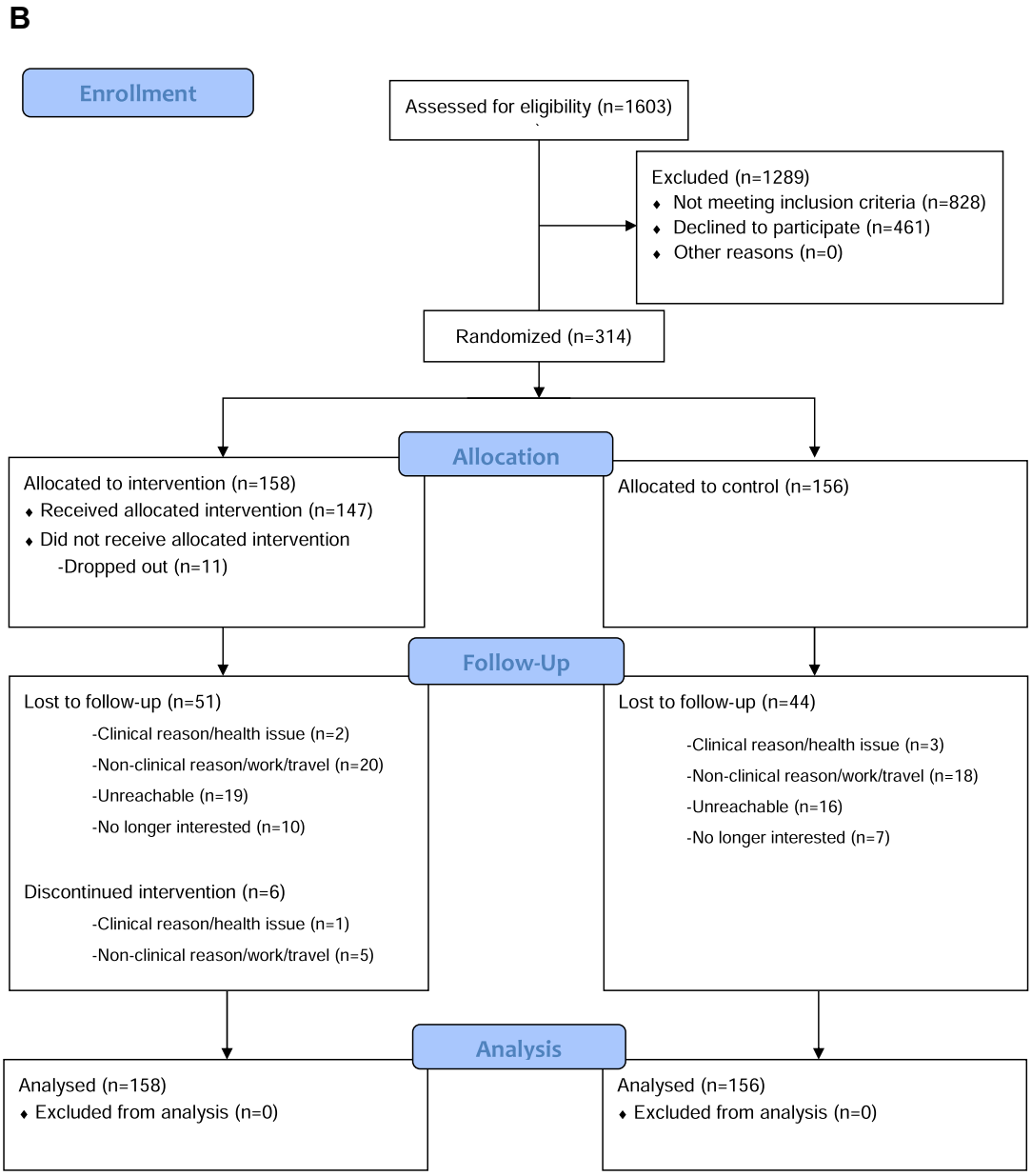

Figure 2. Flow of male participants through the ECO-PCR trial.

treatment effect on quality of life was also present. No other differences were observed ($P = 0.57$ 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 after completion of CR.[7] In the ECO-PCR trial, a 50-week home- and community-based, remotely delivered EFI was shown to beneficially affect MVPA in women who adhered to the intervention sessions (almost three-fourths of the women) compared with 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 already at CR completion and that they had good BP control and quality of life throughout the 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 that a fully powered women-only trial is warranted (we did not meet the target sample size in women, with 94

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

Outcome	Post-CR	26 wk	52 wk	*P*, group effect	*P*, time effect	*P*, group × time
Primary outcome						
Weekly MVPA (in bouts of ≥ 10 min)				0.013	0.808	0.758
Control	130.3 (116.9)	109.0 (116.2)	111.8 (113.1)			
Intervention	156.5 (143.4)	163.2 (185.4)	150.0 (136.3)			
Weekly MVPA (total min)				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)			
Secondary outcomes						
Quality of life (VAS, mm)				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)				0.002	0.897	0.975
Control	28.94 (5.67)	29.14 (5.28)	28.98 (5.02)			
Intervention	27.02 (5.59)	27.35 (6.26)	26.83 (5.73)			
Waist circumference (cm)				0.173	0.466	0.592
Control	94.7 (13.5)	95.4 (14.6)	95.3 (12.0)			
Intervention	91.7 (13.1)	95.5 (18.5)	91.7 (13.6)			
Systolic blood pressure (mm Hg)				0.011	0.019	0.799
Control	121.8 (17.1)	127.5 (17.7)	127.2 (15.2)			
Intervention	117.5 (16.3)	124.0 (17.0)	120.7 (15.0)			

Results are presented as mean (SD).
CR, cardiac rehabilitation; MVPA, moderate to vigorous-intensity physical activity; VAS, visual analog scale of EuroQol-5D.
*Not assessed at this time point.

retained at 52 weeks instead of the 192 planned) to determine the efficacy of the intervention. Results of planned tertiary analyses suggest that the intervention may be effective owing to positive impacts on exercise task self-efficacy and PA intentions.[10] The intervention was quite low-cost and feasible, given that exercise professionals or trainees from the CR program were used. It may be important to revisit the impact of the frequency and number of contacts on exercise maintenance, given that intervention effects appeared more favourable in the first 6 months when there were more contacts with the exercise facilitator.

Consistent with our trial, previous studies have found that exercise interventions after CR can help individuals with CHD maintain PA in the long term compared with control subjects, but there are variable effects of such interventions.[7] The most recent review showed that although length of

Table 2. Primary and secondary outcomes in men adherent to the intervention (per protocol)

Outcome	Post-CR	26 wk	52 wk	*P*, group effect	*P*, time effect	*P*, group × time
Primary outcome						
Weekly MVPA (in bouts of ≥ 10 min)				0.741	0.059	0.438
Control	187.6 (137.4)	152.2 (146.5)	152.8 (148.9)			
Intervention	178.7 (150.1)	175.7 (155.6)	149.3 (149.3)			
Weekly MVPA (total min)				0.946	0.112	0.557
Control	331.0 (207.4)	294.9 (208.7)	284.8 (202.3)			
Intervention	314.1 (195.9)	316.8 (193.1)	282.9 (206.9)			
Secondary outcomes						
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)				0.364	0.412	0.764
Control	28.27(4.77)	28.90 (5.15)	29.04 (5.39)			
Intervention	28.93 (4.37)	28.94 (4.84)	29.30 (4.48)			
Waist circumference (cm)				0.018	0.255	0.941
Control	100.0 (12.9)	101.6 (12.8)	102.0 (14.2)			
Intervention	102.5 (12.0)	103.9 (11.2)	103.7 (12.4)			
Systolic blood pressure (mm Hg)				0.568	< 0.001	0.819
Control	120.1 (17.1)	126.2 (17.7)	126.2 (15.2)			
Intervention	120.4 (15.8)	124.7 (19.0)	125.4 (14.8)			

Results are presented as mean (SD).
CR, cardiac rehabilitation; MVPA, moderate to vigorous-intensity physical activity; VAS, visual analog scale of EuroQol-5D.
*Not assessed at this time point.

preceding CR did not affect intervention effectiveness (as was replicated in the present trial; data not presented), the duration of intervention was important, with effective interventions lasting 12 weeks or longer, as with our EFI intervention. In an earlier systematic review of PA interventions for individuals after CR, Chase found that interventions consisting of behavioural strategies and combined behavioural and cognitive strategies, as with our EFI intervention, were more successful in PA behaviour change than cognitive strategies alone.[26]

Limitations

This was an open-label clinical trial. Participants in clinical trials are typically more motivated than nonparticipants. 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 than control participants at baseline.

We used an objective measure of MVPA for our primary outcome. Although this is a strength, objective measures can create a reactive response. Moreover, accelerometers respond poorly to activities like cycling, skating, load carrying, and other nonstandard activities and must be removed for swimming. Given that 56 participants (17.4%) reported some swimming (frequency unknown; no group differences: $P = 0.69$) and others reported cycling and skating, MVPA rates reported herein are likely somewhat underestimated[14] Indeed, self-reported MVPA was also reported for descriptive purposes, but is likely somewhat overestimated.

Conclusion

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 thus greater room for improvement. Results of this trial, along with our recent meta-analysis,[7] point to future strategies which should be tried to ensure exercise maintenance, along with its corresponding benefits, in CR graduates.

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Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at https://doi.org/10.1016/j.cjca.2020.10.015.