COST-EFFECTIVENSS OF EXERCISE FACILITATION POST-CARDIAC REHABILITATION

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Abstract

Background: Physical activity declines post-cardiac rehabilitation (CR) suggests the need for an exercise maintenance intervention. The study objectives were to assess (1) health-care resource utilization, (2) QALYs, and (3) intervention cost-effectiveness.

Methods: A randomized controlled trial of post-CR participants allocated to: (a) exercise facilitator intervention, or (b) usual care. Participants were randomized and asked to complete a baseline and follow-up surveys.

Results: Overall, 297 (16.7%) graduates consented (50.2% intervention), of which 276 (92.9%) were retained at the 26 week and 264 (88.9%) were retained at 52 weeks. At 26 weeks, there were significant differences in emergency department mean visits (0.33±0.71 [control], 0.22±0.51 [intervention]) and hospitalizations (0.16±0.39[control], 0.07±0.28[intervention]). At 52 weeks, interventional participants had higher hospitalizations ($p<0.05$). There were minimal differences in quality of life (QoL) means score and QALYs throughout the trial among groups.

Conclusion: These results suggest that there was an early cost-benefit associated with the intervention from a societal perspective, but this was not sustained at 52 weeks.

Dedication

I would like to dedicate this to my family, for I could not have come this far without their love and support.

Acknowledgments

I would like to firstly thank my supervisor Dr. Sherry Grace and my thesis committee, Drs. Alison Macpherson and Ellen G. Schraa, for all their support and guidance during the past 2 years. In addition, I would like to thank everyone at the Ottawa site for their collaboration. Finally, I would like to thank all my colleagues for their shared memories.

Table of Contents:

List of Tables:

List of Figures:

1.0 Introduction

Cardiac rehabilitation (CR) is a secondary prevention program designed to achieve multi-factorial cardiovascular risk reduction. Despite evidence for the benefits of exercise for secondary prevention of cardiovascular diseases (CVDs), physical activity (PA) declines dramatically post-CR. There is a need for an intervention with broad reach to promote exercise maintenance in CVD patients, to optimize secondary prevention.

A randomized controlled trial (RCT) of an intervention to increase PA maintenance is currently underway. An exercise 'facilitator' assists the transition of patients from structured, supervised exercise, to self-managed home- or appropriate community-based exercise programs in the 1 year post-CR. The objectives of this thesis are to: i) compare cardiac-related health care usage in CR graduates receiving the exercise facilitator intervention versus usual care; ii) compare quality-adjusted life years (QALYs) in CR graduates receiving the exercise facilitator intervention versus usual care; and iii) assess the cost-effectiveness of exercise facilitation. It is hypothesized that those in the facilitator intervention will utilize cost-driving health care resources (i.e., hospitals and emergency services) less frequently than those receiving usual care and greater QALYs than the usual care group over the 1-year time horizon. It is also hypothesized that the facilitator intervention will be cost-effective from both a societal and health care perspective over this time frame.

2.0 Literature Review

2.1 BURDEN OF CVD

CVDs are currently the leading cause of mortality worldwide [1,2], with coronary artery disease (CAD), a CVD characterized by plaque formation within the coronary vessels, increasingly prevalent since the 1990s[3]. Globally in 2008, approximately 17.3 million deaths were due to CVDs, of which 42% were due to CAD[4].

Of those that survive a myocardial infarction, approximately 15% are readmitted within 30 days of discharge, and almost 25% require repeat revascularization procedures[5]. With CAD mortality rates projected to increase to 10 million in 2030 from 7 million globally in 2005, more financial and healthcare resources will be required to control this disease[6].

2.2 MEDICAL CARE COSTS FOR CVD

According to a Conference Board of Canada report, an estimated $20.9 billion was attributable to CVD care costs in 2005, and this figure is expected to increase to $28.3 billion by the year 2020[7]. In the United States (US), direct cardiovascular care costs as of 2010 were $273 billion, with indirect costs close behind at approximately $195 billion[8].

In addition to North America, other countries such as India, China, the United Kingdom (UK), and Saudi Arabia have also seen increasing CVD care costs[9]. Annually, in 2005, an estimated €104.7 billion was spent on CVD-related procedures in Europe[10], $5.9 billion in Australia[11] and approximately US$ 10 million in Saudi Arabia[12]. With scarce resources and financial constraints, there are many governmental and third-party administrators looking to allocate these financial resources to more cost-effective approaches.

Since CVD is a chronic disease, once coronary artery blood flow is restored there is a need to regress or stabilize the underlying atherosclerosis via secondary prevention[13]. Indeed clinical practice guidelines on secondary prevention have been issued by learned medical societies. According to the

US Preventative Services Task Force, the goals are lipid reduction, normalizing blood pressure, modification of lifestyle behaviour, while also providing patient support and education[14].

2.3 CARDIAC REHABILITATION

CR is a chronic disease management program aimed at reducing cardiovascular risk. In Canada, the average program lasts from several weeks to a full year[15], and in Ontario, the average program is 5 months with a frequency of two classes weekly[16]. According to the most recent standards by the British Association for Cardiovascular Prevention and Rehabilitation (BACPR), there are 7 core components of CR[17]. These are: lifestyle risk factor management, psychosocial health, health behaviour change and education, pharmacotherapy, medical risk factor management, long-term management, and audit and evaluation[18]. One of the chief elements of the health behaviour change component is exercise. Canadian guidelines recommend 30-60 minutes of moderate to vigorous PA on most, preferably, all days of the week for patients with CAD[19].

According to the most recent Cochrane meta-analysis, participation in CR is related to decreased long-term (≥12 month) cardiovascular mortality (OR 0.74; 95% CI 0.63-0.87) , and total mortality (OR 0.87; 95%CI 0.75-0.99) when compared to usual care[20]. Jolliffe et al. [21] had previously examined the effects of exercise-based versus comprehensive CR. Participants in exercise-only CR showed a decrease in total mortality (OR 0.73; 95% CI 0.54-0.98), which was not observed with comprehensive CR (OR 0.87; CI 0.71-1.05). However, cardiac mortality was reduced substantially in both the exercise-only and comprehensive CR groups (OR 0.69; 95% CI 0.51-0.94), (OR 0.74; CI 0.57-0.96), respectively. CR has also been documented to decrease re-hospitalizations[22,23], improve risk factor control[20], while enhancing quality of life (QoL)[24].

The beneficial effects observed from participation in CR arguably stem primarily from an improvement in cardiometabolic fitness. These improvements are the result of the effects of exercise training on cardiovascular risk factors, vascular biology, and the atherosclerotic process itself. Exercise training has been documented to reduce C-reactive inflammatory protein concentrations[25], increase cardiovascular functional capacity[26], decrease myocardial oxygen demand, maintain lipid

control[27], have a blood pressure lowering effect, aid weight control, and improve insulin sensitivity[28,29].

Few CR programs have incorporated strategies to assist patients in making a successful transition from supervised to self-managed home- and/or community-based exercise. In most CR programs, long-term maintenance is addressed briefly or not at all. Effective transition to post-CR care, focused on maintaining and enhancing gains in levels of activity experienced during CR, would protect and augment the investment in exercise adoption.

2.4 HEALTH ECONOMICS AND CARDIAC CARE

Healthcare resources are scarce, and with an increase in patient demand for CVD care, there is a need to allocate these resources in a manner which maximizes health benefits and minimizes opportunity costs (i.e., the cost of an alternative that has been foregone). Health economic evaluations help us allocate these scarce resources. Three economic evaluation methods are cost-effectiveness (CEA), cost-benefit and a cost-utility analysis (CUA)[30]. CEA focuses on the cost or input in an outcome measured in natural units (for example, an increase or decrease in hospital admissions) while a cost-benefit analysis reports outcomes measured in natural units in monetary values. Cost-utility is similar to cost-effectiveness, but varies in how the outcome variable is reported. Instead of using natural units, cost-utility combines QoL and time span, and reports outcomes in QALYs. QALYs are defined as a measure of health output that combines the increase in QoL over the duration a treatment or while a program is being administered. The concept of a CUA from a governmental or third-party holder is preferred over a CEA since the results achieved from this analysis can be used to compare different programs [30]. These three analyses seek to maximize health gains in a given program, by assessing whether it is worthwhile compared to a standard program, and aid in decision-making.

As a result of limited healthcare resources, clinicians are under increased pressure from the government to adopt policies and programs that are more cost-effective [31]. Compared to an unmanaged fee-for-service model, offering CR programs, which facilitate inter-provider coordination of care and optimal secondary prevention, can reduce healthcare costs [32].

A systematic review of CR economic evaluations by Wong et al.[33] included 9 studies, governmental and societal perspective studies, which illustrated that implementing CR is cost-effective as the cost/QALY was in a reasonable willingness-to-pay (WTP) threshold. The WTP threshold is often used to decide whether the amount one is investing in a QALY or outcome is in an acceptable range. All summarized societal studies, in particular the study by Ades et al.[34] found that CR is cost-effective since there are reduced hospitalizations costs compared to other medical interventions [CR (US $ 4950/ Life-year gained (LYG)) and coronary artery angioplasty (US $ 126 400/LYG)]. In this paper, LYG was defined as the increase in life expectancy calculated by using previously-reported decreasing mortality rates attributable to CR[35]. The most recent governmental perspective study included in the review examined the effect of CR on dialysis patients[36]. It was found that CR was very effective, as the incremental cost-effectiveness ratio (ICER) was $13,887 per year of life saved in favor of CR. The ICER represents the additional cost for an outcome (QALY) when compared to another program or intervention.

In two other studies that assessed total healthcare costs of CR components, and the cost-effectiveness of implementing CR programs in EUROASPIRE III countries, CR was deemed very cost-effective [37,38]. De Smedt et al.[38] assessed the costs of different interventions (smoking cessation, cholesterol treatment and lifestyle intervention) to optimize CVD prevention in EUROASPIRE III. The majority of the European countries found all therapies to be cost-effective since much of the costs were below the $30,000 WTP threshold value. Dendale et al.[37] studied the long-term effects of comprehensive CR on the risk of recurrent CVD complications and their associated health costs. It was found that since total health care costs at 4.5 years follow-up in the CR group was lower [€4,862 /patient] than the usual care group [€5,498 /patient], CR was cost-effective.

2.5 DECLINE IN PHYSICAL ACTIVITY POST-CR

The long-term benefits of CR lie in the patient's ability to maintain their health behaviour changes, and most importantly PA, over the long-term. Numerous studies have reported that graduates are failing to maintain adequate levels of PA (150 minutes of moderate/vigorous physical activity

weekly)[39–41] despite education and counselling in CR[42,43]. Willmer et al.[44] compared how PA at one and five years post-CR varied in patients that had engaged in an exercise maintenance program versus those that had not. Regardless of their membership in an exercise maintenance program, both groups engaged in fewer minutes of PA (maintenance program at 1 and 5 years (140 and 120 minutes per week respectively), no maintenance program at 1 and 5 years (138 and 105 minutes per week respectively)), and less frequently met the recommended 30 minutes of PA per day.

In another study by Stahle et al.[45], graduates were randomized to either to CR or usual care and then followed 12 months post-program. Patients who were randomized to CR at 3 and 12 months post-CR had a reduced exercise capacity [measured in Watts (W)] compared to those in usual care [CR group (120 W & 100 W at 3 and 12 months respectively]. In addition to exercise capacity, patient's self-reported PA (self-reported on a scale from 1 to 7) had also decreased to similar levels as those who never attended CR (CR group (4.3 and 3.6 at 3 and 12 months post-CR respectively), usual care (3.8 and 3.5 at 3 and 12 months post-CR respectively)). Overall, the literature suggests that only 38-56% of CR participants are adequately active 1 year after CR program completion[46,47].

2.6 EXERCISE FACILITATION POST-CR

Given PA declines, interventions to increase PA levels post-CR have been tested. To our knowledge, there have been 10 published RCTs of interventions to improve exercise maintenance post-CR[48–56]; 8 of these RCTs have shown beneficial results[48–50, 53–56]. Interventions that improved PA levels or helped maintain CR induced benefits (e.g., improvements in cardiometabolic fitness), incorporated a mix of self-regulatory skills training on exercise planning;[54] exercise consultation;[49] an exercise diary and quarterly group meetings;[48] a home walking program and daily activity log [51]; written action and coping plans[55,56]; and self-monitoring of vital measurements, and pedometer-measured PA with personal feedback.[50] Only one study was undertaken in Canada; it did not improve exercise maintenance 52 weeks post-CR.[52]

There are substantial limitations to the literature assessing interventions for exercise maintenance. One of the most critical limitations is the lack of an economic evaluation; previous

studies[48,51,54,57] that have assessed interventions for increasing PA levels did not consider incorporating community resources for exercise to facilitate sustainability and affordability.

A three-site, RCT titled *Ecologically Optimizing Exercise Maintenance in Men and Women Post-Cardiac Rehabilitation: A Randomized Controlled Trial of Efficacy with Economics (ECO-PCR)* was proposed to investigate the cost-effectiveness of an exercise facilitator intervention to increase long-term exercise maintenance in CAD patients post-CR. Given the components of previously successful RCTs that improved PA levels post-CR (e.g., exercise consultation, self-regulatory skills in exercise planning), the facilitator intervention aimed to assist the transition from CR, a supervised and structured program, to a home or community exercise program (i.e., *Heart Wise Exercise* programs; www.heartwiseexercise.ca). The ECO-PCR trial includes an economic analysis of the intervention as part of the RCT. Effectiveness of the intervention was defined as a decline in cost driving health care resources such as visits to the emergency department or hospital admissions; visits to a cardiologist or physician was seen as preventative as these do not pose a major financial burden as the emergency department visits or hospital admissions. Effects of the intervention were analyzed to test whether it is economically viable, which may convince health policy-makers that the intervention should be implemented.

There are three objectives to this thesis. The first objective is to compare how cardiac-related health care resources (emergency department and hospital visits) were utilized among patients in the intervention compared to those in usual care. The second objective is to assess the impact of the intervention on QALYs, when compared to usual care. The third objective is to assess the cost-effectiveness of implementing this intervention.

2.7 CANDIDATE'S ROLE

The candidate's role in this study primarily involved follow-up assessments for the Toronto participants in ECO-PCR trial at the 52 time-point. This involved administering surveys, chart extraction, accelerometer data collection and assessment and documentation of vital sign measurements. Any out-of-range vital sign findings were documented and reported to the qualified

clinical investigator. The candidate also followed up with participants via mail and telephone to ensure each assessment was complete. Finally, the candidate undertook blinded data entry, as well as data cleaning and analysis related to this thesis.

3.0 Methods

3.1 DESIGN

This study was a randomized (Appendix A), controlled, allocation-sealed, superiority study that aimed to evaluate the effectiveness of an exercise facilitator intervention on exercise maintenance and health care resource utilization. The trial was registered with clinicaltrials.gov (Identifier: NCT01658683), and was reported according to the CONSORT guidelines[58]. The study was funded by the Heart and Stroke Foundation for 5 years. The study protocol was also approved by Research Ethics Boards of participating hospitals and York University.

3.2 PROCEDURE

Potential participants were approached during their second last and last CR classes. Study coordinators explained the study to potential participants and obtained informed written consent (Appendix B) before any clinical data was collected.

The study coordinator extracted from medical databases and charts, participant information about medical history, bloodwork, risk factors, disease severity indicators, co-morbidities, medications, and CR attendance using a standardized case report form (Appendix C). Resting heart rate, blood pressure, body weight, and waist circumference were measured using a BPTru machine (calibrated annually by University of Ottawa Heart Institute (UOHI)), a digital scale (calibrated annually by University Health Network (UHN)), and a tape measure, respectively. Participants were also asked to complete a self-report survey (Appendix D).

All participants were asked to return to the study centers for follow-up assessments at 26 and 52 weeks after randomization (Appendix E & F). Both the 26 and 52 week follow-up time points

coincided with the mid- and end-point of the facilitator intervention. Resting heart rate, blood pressure, body weight, and waist circumference were again measured using calibrated instruments. Participants were also instructed to bring any medications they were currently taking to be documented. Participants were also asked to complete a questionnaire assessing QoL, out-of-pocket expenses (e.g., exercise-related products and services, taxi fares, parking fees), and items related to productivity, including lost work days, home care expenses due to reduced function or cardiac disability(Appendix G & H).

3.3 SETTING

The trial was conducted at three sites: UOHI in Ottawa, the Peter Munk Cardiac Centre (PMCC) and Toronto Rehabilitation Institute (TRI) of the UHN in Toronto. The UOHI and UHN CR programs served a mixture of rural and urban patients from large ethnic communities. The length of CR programs ranged from 8-24 weeks in duration.

Participants underwent medical and coronary risk factor assessments during their CR exercise sessions 2-3 times each week, and received personalized exercise prescriptions. Participants in Ottawa also had the opportunity of attending up to three nutrition workshops. Participants in Toronto had risk factor modification discussions during each exercise visit and the opportunity to attend some workshops and seminars that included a nutritional aspect. At all sites, services such as psychological and depression counselling, stress management, smoking cessation and nutritional counselling were available on an as-needed referral basis. At all sites, discharge summaries were provided to primary care providers, and other providers upon the request of the participant.

3.4 PARTICIPANTS

The ECO-PCR trial had a target enrollment of 416 participants (224 men and 192 women) based on sample size calculations from pilot work. The inclusion criteria were:

1. Currently participating in an on-site CR program of ≥ 8-week duration
2. Patient has graduated from CR
3. Has a documented diagnosis of CAD
4. 18 years of age or older
5. Able and willing to provide informed consent

6. Able to walk unaided at 2 miles per hour.

The exclusion criteria were as follows:

1. Has New York Heart Association class III or IV heart failure[59]
2. Pregnant, lactating or planning to become pregnant during the study period
3. Unable to read and understand English or French
4. Planning to leave the province or region in the next 12 months
5. Member of the participant's household is already participating in the study
6. Unable, in the opinion of the qualified investigator, to participate in unsupervised exercise.

3.5 RANDOMIZATION AND BLINDING

Participants were randomized in a 1:1 ratio through the aid of a statistical consultant. Participants were stratified by site and gender through sequences that was computer-generated in permutated blocks of 4, 8, and 10. The computer-generated sequences were placed in sealed, numerically identified opaque envelopes to ensure that treatment allocation was concealed until after baseline data collection. Post-baseline data collection, study coordinators were given the next available computer-generated sequence; patient randomization sequences were then filed after the participant was notified of their allocated group.

Follow-up assessments for the 26 and 52 week time points were performed by research assistants who were blinded to the participant's treatment allocation. Participants were instructed not to reveal their treatment allocation, and questionnaires were only identifiable through a numeric research ID.

3.6 INTERVENTION

Upon randomization to the exercise facilitator group, participants received a booklet that contained information about exercise regimens and routines to be completed during the intervention, a pedometer, and an activity workbook that was to be used to record the date, time, location, mode, duration and intensity of their physical activities. Appendix I outlines the exercise facilitator intervention format, duration, timing, and the content over the 52-week intervention period. As shown, the intervention consisted of an introductory face-to-face session (this happened two weeks post-randomization), and consisted of both individual and group teleconferences.

The facilitator intervention was based on the socio-ecological model[60]. This model highlighted the importance of individual variability on behaviour in response to the changing social or physical environment[61]. The model posits that there are individual (e.g. knowledge, attitudes, and skills), social environmental (e.g., friends, family, and social networks) and physical environmental (e.g. home, neighbourhood and community characteristics, weather) factors that influence physical activity[62, 63]. Each of factors mentioned has both an independent and interdependent effects on PA maintenance.

Intervention participants were formed into small groups (5-8 participants). During the teleconferences, the importance of exercise maintenance to maintain improvements in cardiometabolic fitness from CR was emphasized. The recommended standard for exercise maintenance in patients with CAD was reiterated (i.e., 150 minutes of moderate to vigorous- intensity PA per week[64]). The facilitator also helped participants develop plans for adhering to this exercise standard. Suggestions for mapping out walking routes and the use of exercise equipment in the home, community and workplace were also discussed.

Small group counseling teleconferences were held 1, 13, 26, 39 and 50 weeks after randomization. During each of the group teleconferences, all participants were encouraged to discuss any barriers they had faced to date. With each identified barrier, solutions were brainstormed as a group. In addition, the facilitator reviewed their activity diaries and general goals. Approximately, every 2-3 weeks for the duration of the intervention period, or as requested by the participant, exercise facilitators conducted community program demonstrations at *Heart Wise Exercise* programs and other community exercise facilities in Ottawa and Toronto. There are > 75 and > 25 Heart Wise Exercise programs within a 45-minute radius of the Ottawa and Toronto sites, respectively. Participants were also informed of the date and time of all demonstrations by e-mail or telephone.

As per protocol, the facilitator contacted participants 20, 34 and 45 weeks after CR program completion for their individual telephone calls. During each call, the facilitator reviewed the participant's interventional journal, previous goals, and finally assessed their confidence and motivation with respect to exercise maintenance. Barriers and solutions were discussed as appropriate. Attendance records were also kept for all contacts.

Facilitators received training prior to initiating any teleconferences with the participant. The facilitators also participated in quarterly case discussions (teleconferences between the Ottawa and Toronto exercise facilitators) and booster sessions to maintain skills over time. Facilitators were required to record their training hours and time spent during in-person community demonstrations and teleconferences. To ensure consistent delivery of the intervention at both sites, facilitators recorded a random subset of individual and group calls, which were then audited.

Participants in the usual care group had access to the activities and strategies available to CR graduates at both the UOHI and UHN sites. All participants in their respective sites were provided with an updated individualized exercise prescription and exercise maintenance strategies by a program staff during CR. The usual care at UHN also had access to an alumni/maintenance program that offer group exercise sessions for CR graduates.

3.7 MEASURES

Socio-demographic characteristics (i.e., age, gender, ethnic background, living arrangements, education, income, employment and marital status) were assessed via self-report (see Appendix D, section A). Clinical characteristics (i.e., referral indication, body mass index, hypertension and dyslipidemia) were extracted from the CR charts, while smoking history and functional status (Duke Activity Status Index[65]) were gathered through self-report. The purpose of this assessment was to describe the study population and assess if there were any differences among the two randomized groups (independent variable).

To assess societal costs, all participants were requested to complete a monthly diary to record time for counselling and physical activities, out-of-pocket expenses (e.g., exercise-related products and services, taxi fares, parking fees), and items related to productivity, including lost work days, home care expenses due to reduced function or disability associated with their cardiac conditions. This diary aimed to facilitate patient recall in completion of the costing items in the 26 and 52 week surveys (see Appendix J).

To assess cardiac-related health care resource usage, investigator-generated items on care and costs developed based on Oliveira et al.[66] was administered in both the 26 and 52 week surveys (see Appendix G & H, section N). These questions assessed the frequency of cardiac-related emergency room visits and hospital admissions in the past 26 weeks. In addition to these visits, the number of heart conditions and procedures performed in the last 26 weeks were assessed. Reported usage of health care resources was then translated into a monetary value in order to perform a cost-benefit analysis. This analysis took into account the differential costs between each health care procedure and / or visits. In accordance with a previous Canadian study[67], costs for cardiac-related emergency visits were assigned a unit cost of $224 CAD and for cardiac-related hospital admission $2,248 CAD. The mean number of visits was then multiplied by its appropriate visit costs to compute a cost-benefit analysis.

QALYs, a measure that takes into account health-related improvements over a specified time horizon[68], was derived for all participants based on the Euro-QoL (EQ-5D) questionnaire (see Appendix G, section C[69]). The EQ-5D assesses 5 dimensions of health (i.e., mobility, self-care, usual activity, pain/discomfort, and anxiety/depression), and respondents were asked to rate the degree of severity (i.e., no problem, moderate problem, and extreme problem). Each state got a 5 digit score, with 1 representing 'no problem' and 3 representing the worst health state. Based on the Canadian tariffs by Bansback et al. (2012), a constant (0.111) was subtracted for any dysfunction, with further reductions for other poor health states as indicated by the tariffs. The EQ-5D has been documented to have good construct validity and satisfactory internal consistency reliability, as documented by Cronbach's alpha co-efficient of 0.73-0.74[71,72].

Health-related QoL weights were derived from participants' responses to the EQ-5D at baseline, 26 and 52 weeks. By using the area-under-the-curve method [68] which effectively weights time by QoL values, QALYs were calculated for each time point. Upon calculating incremental costs and incremental QALYs associated with the intervention, an ICER was calculated.

To assess the cost-effectiveness of the intervention, data on the resources used for each intervention, including training time for facilitators, equipment, and phone used for teleconference

counselling and community program demonstrations were collected. Costs were then calculated by multiplying the quantities of resources used by their appropriate unit costs.

3.8 STATISITICAL ANALYSES

All analyses were performed using IBM's Statistical Package for Social Sciences (SPSS) Version 22[73]. Descriptive statistics were performed to describe socio-demographic and clinical characteristics of the participants. Recruitment, consent and retention rates were described. The equivalence of socio-demographic and clinical characteristics of participants in each group were confirmed using chi-square or independent samples t-tests, as applicable. The baseline socio-demographic and clinical characteristics of those retained at 26 and 52 weeks to those who were lost to follow-up were compared using chi-square or analysis of variance (ANOVA), as applicable. A significance cut-off of $p<0.05$ was used.

To assess the first objective, cardiac-related health care usage was compared by group using chi-square analyses and t-tests, as applicable. To assess the second objective, QoL for both groups was first plotted. By using the area-under-the-curve method which effectively weights time by QoL values, QALYs were calculated over each participant's period of follow-up.

To assess the third objective, upon calculation of total costs for the intervention and the incremental QALYs gained over the trial, cost-per QALY were compared to a WTP threshold of $50,000. Although this is a commonly-used benchmark [74], an acceptable range of WTP threshold ranges from $20,000 to $100,000 [75]. A comparative analysis was then used to assess the cost-effectiveness of this intervention compared to usual care.

4.0 Results

4.1 RESPONDENT CHARACTERISITCS

A study flow diagram is shown in Figure 1. Of the 634 eligible patients, 297 participants were randomized (16.7% consent rate). Of these, 291 (98.2%) completed the baseline survey.

Table 1 displays participant socio-demographic and clinical characteristics by group at baseline. The Duke Activity Status Index score indicates that most patients had high functional capacity. Interventional participants had approximately double the amount of joint replacements than controls (p=0.06). There were no statistical significant differences in participant characteristics by group however.

Overall, 276 (92.9% retention) participants were retained at 26 weeks and 264 (88.9% retention) were retained at the 52 week follow-up. Reasons for loss to follow-up are shown in Figure 1. In terms of survey completion, 229 (82.9%) participants completed the 26 week survey and 150 (54.3%) completed the 52 week survey.

As shown in Table 2, participants retained at 26 weeks were less likely to have someone at home who required caregiving than those lost to follow-up; this difference was also observed at 52 weeks as shown in Table 3. In addition to the above, as shown in Table 3, those retained at 52 weeks were also more likely to report that they had other comorbidities and were less likely to live with family than those lost to follow-up. No other differences in the sociodemographic and clinical characteristics were observed between the retained and non-retained participants.

Participants were asked to report their occupation at the time of their first cardiac event in the 26 week survey. Overall, 84 (37.2%) reported being retired, 54 (23.9%) a professional, 30 (13.3%) being a manager or administrator, 17 (7.5%) in sales occupations, 7 (3.1%) being in a clerical related career, 6 (2.7%) not working, 4 (1.8%) being in service occupations, 4 (1.8%) each reported being vehicle or equipment operators and laborers, 3 (1.3%) in skilled crafts and 1 (0.4%) in the military. A total of 21 (7.1%) participants had reported that their heart disease lead them to retirement or disability.

4.2 HEALTHCARE UTILIZATION AND QALYS

Cardiac-related healthcare service encounters participants reported in the 26 and 52 week post-CR surveys (during the preceding six months) are shown in Table 4. With regard to objective 1, participants in the facilitator intervention were significantly less likely to report being admitted to the hospital and visiting the emergency department at 26 weeks. At 52 weeks however, we observed that

the intervention were more likely to be admitted to the hospital than the control group while emergency department visits were reported to be similar to findings at 26weeks. No other differences were observed at either assessment point.

Cardiac events and procedures participants reported in the 26 and 52 week post-CR survey (during the preceding six months) are shown in Table 5 by group. “Other” procedures and conditions reported by participants included atrial fibrillation and description of symptoms such as sharp pain. There were no significant differences by group.

At 26 and 52 weeks, participants reported paying a mean of $493.24 ± 423.07 and $601.15 ± 415.66 of their own money to attend these healthcare visits (Table 6), respectively (e.g., transportation, parking, food). This did not differ by group (p=0.18 and p=0.43) at either 26 or 52 weeks, respectively. Participants in the intervention group reported being accompanied on these healthcare visits by no one (n=131, 70.8%), a partner (n=59, 32.1%), sibling (n=2, 1.1%), or a child 2 (1.1%).The person that accompanied the participant was most often a female (n=45, 75.0%), aged 63.1 ± 9.6.

At 52 weeks, 15 (19.2%) participants reported they had difficulty working due to their heart disease, and that they missed 4.4±17.9 days of work since graduating from CR (p=0.44). Four (5.2%) participants reported they were unable to do household chores, and 4 (5.2%) reported there were unable to participate in their usual leisure activities due to CVD. Throughout the duration of the study, a total of 67 (22.6%) of participants bought equipment related to their CVD, such as treadmill and running shoes. A total of 2 (1.3%) participants reported using community services for CVD at 52 weeks. No differences between the time points among the groups were observed (Table 7).

Overall QoL measured at the 26 week and 52 week follow-up was quite high (Figure 2). QoL did not differ significantly by group or by time. To assess effectiveness, QALYs were tracked over the 52 weeks. The interventional group had gained 0.919 QALYS while those in the usual care had gained 0.921 QALYs 52 weeks post-CR.

4.3 COST- BENEFIT ANALYSIS

From a health care perspective, the benefits were translated into monetary values as shown in Table 8. Decreases in cardiac-related emergency department visits and hospital admissions were assigned appropriate costs[67], and then compared with the cost of the intervention. At 26 weeks, the intervention group consumed $43.10 worth of less health care resources; this effect however was opposite at 52 weeks. At 52 weeks, since the intervention had more hospital admissions, this resulted in the intervention group consuming $144.62 worth of more health care resources. From a societal perspective, our conclusion remained the same as there was no significant difference among the direct and indirect costs for patients in both groups throughout the 52 weeks (Table 7).

4.4 COST-UTILITY ANALYSIS

Costs for implementing the intervention for 52 weeks were computed, and are shown in Table 9. Facilitator training took 15 hours. Intervention delivery required 5.6 facilitator hours per participant. The overall intervention cost as shown in Table 9, was $28,310.13 Canadian dollars (CAD); this averaged to $190.00 CAD per patient. From a health care perspective, the usual care was assumed to have no cost in comparison to the intervention since the study absorbed any costs for transportation, and the usual care had no interaction with the exercise facilitator. Using a theoretical approach, the cost of the intervention per patient was divided by the incremental QALYs to result in a cost effectiveness ratio of - $95,000.00 CAD per decrease in one QALY (calculation not shown).The difference in QALYs however was minute to provide insight into the real cost-effectiveness of the intervention. Given a decrease in health care resources at 26 weeks, and some decline at 52 weeks, the intervention does have some indicators of being a cost-effective intervention.

5.0 Discussion

The ECO-PCR trial is the first Canadian study to investigate the economics of an exercise facilitator intervention post-CR for reducing health care costs. Cardiac rehabilitation graduates randomized to the intervention reported fewer cardiac-related hospital admissions and emergency

department visits at 26 weeks. At 52 weeks, only fewer emergency department visits were observed than those in the control group, however there were no significant differences in heart-related events or procedures. Our hypothesis with respective to objective 1 was thus partially confirmed. Since QoL scores had a ceiling effect, the only differences in QALYs between the two groups were 0.002 QALYs. Given the results from our cost-benefit analysis, our hypothesis that the intervention was cost-effective was only sustained at 26 weeks.

Our preliminary finding that exercise facilitation post-CR may reduce healthcare utilization is consistent with previous research[76]. A randomized controlled trial by Jannsen et al.[76] assessed the effects of a CR exercise maintenance intervention where group sessions were designed to encourage goal-setting, self-reward strategies and generate alternative pathways to goal attainment. The intervention was shown to reduce cardiac-related hospital admissions by 20% over a 15 month follow-up when compared to usual care. These findings were similar to what was observed in our interventional group at 26 weeks for both hospital admissions and emergency department visits. At 52 weeks post-CR however, the intervention group reported higher hospital admissions, suggesting that our intervention had an early cost-benefit that was not sustained. This association may be spurious however, due to inflated error from multiple comparisons.

Since our cost-benefit analysis suggested an early interventional benefit that was then diminished at 52 weeks, a cost-utility analyses was then used as a hallmark to further robust our findings. In general, when a cost-utility value is below the WTP threshold of $50,000, a standard in North America[77], the intervention is deemed cost-effective. Our interventional study resulted in a negative cost-utility ratio, suggesting that the intervention may not be cost-effective. The negative cost-utility stemmed from the minute differential QALYs between both groups, and one explanation to this may be the ceiling effect from the EQ-5D questionnaire.

The decision of which QoL questionnaire to use has sparked some debate since QoL is closely tied with the decision as to whether a trial is cost-effective. One of commonly reported limitations in using the EQ-5D questionnaire is its ceiling effect[78]. Some studies suggest that the EQ-5D has been shown to successfully discriminate between different health states while other have shown that EQ-5D

has been shown to result in higher utility values than EQ-5D[79]. While the EQ-5D questionnaire has been successfully administered to a CR population [80], it is possible that this questionnaire might not have been sensitive enough to detect any differences in QoL gained from our interventional study.

5.1 IMPLICATIONS AND DIRECTIONS FOR FUTURE RESEARCH

Should the intervention be shown to effectively promote exercise maintenance as well (primary outcome of the trial), the implications of these preliminary findings are that offering an exercise facilitator intervention for 26 weeks post-CR, may be cost-effective for the health care system. An excellent model of broad and standardized provision of post-CR exercise maintenance is the BACPR Phase IV model[81]. Phase IV CR is a long-term maintenance program offered in established community settings with the aim of shifting the responsibility on the individual to keep physical active[82]. BACPR offers standardized Phase IV exercise instructor training. In Ontario, the Heartwise Exercise program (http://heartwise.ottawaheart.ca/) serves as another model to more broadly facilitate exercise maintenance post-CR. CR graduates are provided a list of local community programs where the facilities meet the 6 principles established for safely exercising. The exercise instructors at these settings also receive training (albeit informal) on safe exercise for patients with cardiac disease.

A ceiling effect was observed with the EQ-5D-3L. This was likely due to the benefits of CR participation, particularly as patients who were highly adherent to the program were selected for inclusion in this trial. In future studies, administration of direct QoL questionnaires should be considered, such as the time trade-off scale[83,84].

At the end of this trial, the data will be linked to the health administrative data housed at the Institute for Clinical Evaluative Sciences to ascertain health care utilization. Health effects will be measured in terms event-free time from a cardiac event or revascularization procedure, and then translated into overall QALYs. The analysis will take the societal perspective, with a time horizon of 78 weeks. Upon obtaining data for emergency department visits, hospitalizations, day procedures, general and specialist visits, a more comprehensive cost-effectiveness analysis of the intervention will be performed by using CAD associated Canadian resource intensity weights.

5.2 LIMITATIONS

Caution is warranted in interpreting our results. First, since the primary objective of this study was to assess PA levels with the facilitator intervention, one of the biggest limitations was that the trial was not powered to test differences in the outcomes tested herein. Healthcare use is a relatively rare event, and hence lack of associations may merely be a function of the sample size, not a true lack of association. Second, results regarding whether the intervention successfully increased PA levels post-CR are not yet available, as the trial is ongoing. This limits capacity to interpret the effects observed herein. Third, despite administering a QoL questionnaire, it seems as this questionnaire might not be sufficient to fully understand and assess the intervention benefits in a population with already high QoL. Fourth, generalizability is limited to patients who gain access to CR programs and complete them. Fifth, given majority of the data was collected through self-reported measures from follow-up surveys, this invited the possibility of having social desirability bias. Sixth, despite providing participants costing diaries to record expenses through the 52 weeks of the study, these diaries were not widely used, such that inaccurate recall may have resulted. Finally, the health care cost items were investigator-generated, and despite the fact that they were previously administered in oncology patients[85], the validity and reliability of the items in cardiac patients is unknown.

6.0 Conclusion

In conclusion, cardiac patients receiving exercise facilitation for 52 weeks following CR reported lower usage of costly health care services due to their cardiac condition at the 26 and 52 week follow-up compared to control patients; one exception to this observed effect was that the intervention group had reported more hospital admissions than the control at 52 weeks. Patients in both groups had a high QoL throughout the course of the study, and this did not differ by group. The cost-benefit analysis suggests that the intervention appears to be promising from a societal perspective. This study provides insight into potential savings, particularly related to reductions in costly emergency department visits with patient use of outpatient visits instead, even though a comprehensive cost-utility analysis was not possible due to a ceiling effect in QoL. Ongoing research is needed to assess the

association between an exercise facilitator intervention and QoL, to better assess cost-utility. In conjunction with planned future analyses using administrative data and pending determination of intervention effectiveness for exercise maintenance, our results could be used to inform policy-makers regarding the economic benefits of delivering exercise facilitation for patients post-CR.

7.0 References

1. World Health Organization. The top 10 causes of death. *WHO website*. 2014.
2. Lozano R, Naghavi M, Foreman K, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380(9859):2095-2128. doi:10.1016/S0140-6736(12)61728-0.
3. Moran AE, Forouzanfar MH, Roth GA, et al. The global burden of ischemic heart disease in 1990 and 2010: the Global Burden of Disease 2010 study. *Circulation*. 2014;129(14):1493-1501. doi:10.1161/CIRCULATIONAHA.113.004046.
4. World Health Organization. *Global Atlas on Cardiovascular Disease Prevention and Control*.; 2011:44.
5. Curtis JP, Schreiner G, Wang Y, et al. All-cause readmission and repeat revascularization after percutaneous coronary intervention in a cohort of medicare patients. *J Am Coll Cardiol*. 2009;54(10):903-907. doi:10.1016/j.jacc.2009.04.076.
6. World Health Organization. *THE GLOBAL BURDEN OF DISEASE*.; 2004:40.
7. Theriault L, Stonebridge C, Sabrina B. *The Canadian Heart Health Strategy: Risk Factors and Future Cost Implications*. Canada; 2010:25.
8. Laslett LJ, Alagona P, Clark BA, et al. The worldwide environment of cardiovascular disease: prevalence, diagnosis, therapy, and policy issues: a report from the American College of Cardiology. *J Am Coll Cardiol*. 2012;60(25 Suppl):S1-49. doi:10.1016/j.jacc.2012.11.002.
9. Yusuf S, Reddy S, Ounpuu S, Anand S. Global Burden of Cardiovascular Diseases: Part I: General Considerations, the Epidemiologic Transition, Risk Factors, and Impact of Urbanization. *Circulation*. 2001;104(22):2746-2753.
10. Perk J, Mathes P, Gohlke H, et al. *Cardiovascular Prevention and Rehabilitation*. Vol Springer-V. Printed in Singapore: Springer; 2007:517.
11. *Cardiovascular Disease Australian Facts 2011*.; 2011:220. http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737418530.
12. Osman AM, Alsultan MS, Al-Mutairi MA. The burden of ischemic heart disease at a major cardiac center in Central Saudi Arabia. *Saudi Med J*. 2011;32(12):1279-1284. http://www.ncbi.nlm.nih.gov/pubmed/22159384. Accessed September 21, 2014.
13. Golia E, Limongelli G, Natale F, et al. Inflammation and cardiovascular disease: from pathogenesis to therapeutic target. *Curr Atheroscler Rep*. 2014;16(9):435. doi:10.1007/s11883-014-0435-z.
14. Force UPT. *Guide to Clinical Services*. Baltimore: Williams & Wilkins; 1996:290+.
15. Canadian Coordinating Office for Health Technology Assessment. *Exercise-Based Cardiac Rehabilitation Programs for Coronary Artery Disease: A Systematic Clinical and Economic Review.*; 2003:83.
16. Polyzotis PA, Tan Y, Prior PL, Oh P, Fair T, Grace SL. Cardiac rehabilitation services in Ontario: components, models and underserved groups. *J Cardiovasc Med*. 2012;13(11):727-734.
17. BACPR. *Cardiovascular Disease Prevention and Rehabilitation 2012*.; :28.
18. Buckley JP, Furze G, Doherty P, et al. BACPR scientific statement: British standards and core components for cardiovascular disease prevention and rehabilitation. *Heart*. 2013;99(15):1069-1071. doi:10.1136/heartjnl-2012-303460.
19. Medicine AC of S and. *ACSM's Guidelines for Exercise Testing and Prescription*. Vol 8th editio. Lippincott Williams & Wilkins; 2009:400.
20. Heran BS, Chen JM, Ebrahim S, et al. Exercise-based cardiac rehabilitation for coronary heart disease. *Cochrane database Syst Rev*. 2011;(7):CD001800. doi:10.1002/14651858.CD001800.pub2.
21. Jolliffe JA, Rees K, Taylor RS, Thompson D, Oldridge N, Ebrahim S. Exercise-based rehabilitation for coronary heart disease. *Cochrane database Syst Rev*. 2001;(1):CD001800. doi:10.1002/14651858.CD001800.

22. Lawler PR, Filion KB, Eisenberg MJ. Efficacy of exercise-based cardiac rehabilitation post-myocardial infarction: a systematic review and meta-analysis of randomized controlled trials. *Am Heart J*. 2011;162(4):571-584. doi:10.1016/j.ahj.2011.07.017.
23. Mampuya WM. Cardiac rehabilitation past, present and future: an overview. *Cardiovasc Diagn Ther*. 2012;2(1):38-49. doi:10.3978/j.issn.2223-3652.2012.01.02.
24. Joep Perk, Peter Mathes HG and CM. Cardiovascular Prevention and Rehabilitation. In: Vol 2007th ed. Verlag London: Springer; 2007:517.
25. Balen S, Vukelić-Damijani N, Persić V, et al. Anti-inflammatory effects of exercise training in the early period after myocardial infarction. *Coll Antropol*. 2008;32(1):285-291. http://www.ncbi.nlm.nih.gov/pubmed/18494215. Accessed September 21, 2014.
26. Fletcher GF, Balady G, Blair SN, et al. Statement on Exercise: Benefits and Recommendations for Physical Activity Programs for All Americans: A Statement for Health Professionals by the Committee on Exercise and Cardiac Rehabilitation of the Council on Clinical Cardiology, American Heart Associ. *Circulation*. 1996;94(4):857-862. doi:10.1161/01.CIR.94.4.857.
27. King AC, Haskell WL, Young DR, Oka RK, Stefanick ML. Long-term Effects of Varying Intensities and Formats of Physical Activity on Participation Rates, Fitness, and Lipoproteins in Men and Women Aged 50 to 65 Years. *Circulation*. 1995;91(10):2596-2604. doi:10.1161/01.CIR.91.10.2596.
28. Rosenthal M, Haskell WL, Solomon R, Widstrom A, Reaven GM. Demonstration of a Relationship Between Level of Physical Training and Insulin-stimulated Glucose Utilization in Normal Humans. *Diabetes*. 1983;32(5):408-411. doi:10.2337/diab.32.5.408.
29. King DS, Dalsky GP, Clutter WE, et al. Effects of exercise and lack of exercise on insulin sensitivity and responsiveness. *J Appl Physiol*. 1988;64(5):1942-1946. http://www.ncbi.nlm.nih.gov/pubmed/3292505. Accessed November 15, 2014.
30. Drummond M, Sculpher M, Torrance G, O'Brien B, Stoddart G. *Methods for Economic Evaluation of Health Care Programmes*. Vol 3rd ed. Oxford University Press; 2005:379.
31. Drummond M, Stoddart G, Labelle R, Cushman R. Health economics: an introduction for clinicians. *Ann Intern Med*. 1987;107(1):88-92. http://www.ncbi.nlm.nih.gov/pubmed/3109298. Accessed September 21, 2014.
32. Wise CG, Bahl V, Mitchell R, West BT, Carli T. Population-based medical and disease management: an evaluation of cost and quality. *Dis Manag*. 2006;9(1):45-55. doi:10.1089/dis.2006.9.45.
33. Wong WP, Feng J, Pwee KH, Lim J. A systematic review of economic evaluations of cardiac rehabilitation. *BMC Health Serv Res*. 2012;12:243.
34. Ades PA, Pashkow FJ, Nestor JR. Cost-effectiveness of cardiac rehabilitation after myocardial infarction. *J Cardiopulm Rehabil*. 17(4):222-231. http://www.ncbi.nlm.nih.gov/pubmed/9271765. Accessed November 24, 2014.
35. Oldridge N, Furlong W, Feeny D, et al. Economic evaluation of cardiac rehabilitation soon after acute myocardial infarction. *Am J Cardiol*. 1993;72(2):154-161. http://www.ncbi.nlm.nih.gov/pubmed/8328376. Accessed June 24, 2011.
36. Huang Y, Zhang R, Culler SD, Kutner NG. Costs and effectiveness of cardiac rehabilitation for dialysis patients following coronary bypass. *Kidney Int*. 2008;74(8):1079-1084. doi:10.1038/ki.2008.381.
37. Dendale P, Hansen D, Berger J, Lamotte M. Long-term cost-benefit ratio of cardiac rehabilitation after percutaneous coronary intervention. *Acta Cardiol*. 2008;63(4):451-456. doi:10.2143/AC.63.4.2033043.
38. De Smedt D, Kotseva K, De Bacquer D, et al. Cost-effectiveness of optimizing prevention in patients with coronary heart disease: the EUROASPIRE III health economics project. *Eur Heart J*. 2012;33(22):2865-2872. doi:10.1093/eurheartj/ehs210.
39. Warburton DER, Katzmarzyk PT, Rhodes RE, Shephard RJ. Evidence-informed physical activity guidelines for Canadian adultsThis article is part of a supplement entitled Advancing physical activity measurement and guidelines in Canada: a scientific review and evidence-based

foundation for the future of Canadian. *Appl Physiol Nutr Metab*. 2007;32(S2E):S16-S68. doi:10.1139/H07-123.
40. Kesäniemi A, Riddoch CJ, Reeder B, Blair SN, Sørensen TI. Advancing the future of physical activity guidelines in Canada: an independent expert panel interpretation of the evidence. *Int J Behav Nutr Phys Act*. 2010;7:41. doi:10.1186/1479-5868-7-41.
41. American Heart Association. American Heart Association Recommendations for Physical Activity in Adults. 2014. http://www.heart.org/HEARTORG/GettingHealthy/PhysicalActivity/FitnessBasics/American-Heart-Association-Recommendations-for-Physical-Activity-in-Adults_UCM_307976_Article.jsp. Accessed November 16, 2014.
42. Moore SM, Ruland CM, Pashkow FJ, Blackburn GG. Women's patterns of exercise following cardiac rehabilitation. *Nurs Res*. 1998;47(6):318-324.
43. Bock BC, Carmona-Barros RE, Esler JL, Tilkemeier PL. Program Participation and Physical Activity Maintenance after Cardiac Rehabilitation. *Behav Modif*. 2003;27(1):37-53. doi:10.1177/0145445502238692.
44. Willmer KA, Waite M. Long-term benefits of cardiac rehabilitation: a five-year follow-up of community-based phase 4 programmes. *Br J Cardiol*. 16(2):5.
45. Ståhle A, Mattsson E, Rydén L, Unden A, Nordlander R. Improved physical fitness and quality of life following training of elderly patients after acute coronary events. A 1 year follow-up randomized controlled study. *Eur Heart J*. 1999;20(20):1475-1484. doi:10.1053/euhj.1999.1581.
46. Bock BC, Carmona-Barros RE, Esler JL, Tilkemeier PL. Program participation and physical activity maintenance after cardiac rehabilitation. *Behav Modif*. 2003;27(1):37-53. http://www.ncbi.nlm.nih.gov/pubmed/12587259. Accessed November 17, 2014.
47. Izawa KP, Yamada S, Oka K, et al. Long-term exercise maintenance, physical activity, and health-related quality of life after cardiac rehabilitation. *Am J Phys Med Rehabil*. 2004;83(12):884-892. http://www.ncbi.nlm.nih.gov/pubmed/15624566. Accessed November 17, 2014.
48. Arrigo I, Brunner-LaRocca H, Lefkovits M, Pfisterer M, Hoffmann A. Comparative outcome one year after formal cardiac rehabilitation: the effects of a randomized intervention to improve exercise adherence. *Eur J Cardiovasc Prev Rehabil*. 2008;15(3):306-311. doi:10.1097/HJR.0b013e3282f40e01.
49. Hughes AR, Mutrie N, Macintyre PD. Effect of an exercise consultation on maintenance of physical activity after completion of phase III exercise-based cardiac rehabilitation. *Eur J Cardiovasc Prev Rehabil*. 2007;14(1):114-121. doi:10.1097/HJR.0b013e3280116485.
50. Izawa KP, Watanabe S, Omiya K, et al. Effect of the self-monitoring approach on exercise maintenance during cardiac rehabilitation: a randomized, controlled trial. *Am J Phys Med Rehabil*. 2005;84(5):313-321. http://www.ncbi.nlm.nih.gov/pubmed/15829777. Accessed October 28, 2014.
51. Johnson NA, Lim LL-Y, Bowe SJ. Multicenter randomized controlled trial of a home walking intervention after outpatient cardiac rehabilitation on health-related quality of life in women. *Eur J Cardiovasc Prev Rehabil*. 2009;16(5):633-637. doi:10.1097/HJR.0b013e32832e8eba.
52. Lear SA, Ignaszewski A, Linden W, et al. The Extensive Lifestyle Management Intervention (ELMI) following cardiac rehabilitation trial. *Eur Heart J*. 2003;24(21):1920-1927. http://www.ncbi.nlm.nih.gov/pubmed/14585250. Accessed October 28, 2014.
53. Moore SM, Charvat JM, Gordon NH, et al. Effects of a CHANGE intervention to increase exercise maintenance following cardiac events. *Ann Behav Med*. 2006;31(1):53-62. doi:10.1207/s15324796abm3101_9.
54. Scholz U, Knoll N, Sniehotta FF, Schwarzer R. Physical activity and depressive symptoms in cardiac rehabilitation: long-term effects of a self-management intervention. *Soc Sci Med*. 2006;62(12):3109-3120. doi:10.1016/j.socscimed.2005.11.035.

55. Sniehotta FF, Scholz U, Schwarzer R. Action plans and coping plans for physical exercise: A longitudinal intervention study in cardiac rehabilitation. *Br J Health Psychol*. 2006;11(Pt 1):23-37. doi:10.1348/135910705X43804.
56. Sniehotta FF, Scholz U, Schwarzer R, Fuhrmann B, Kiwus U, Völler H. Long-term effects of two psychological interventions on physical exercise and self-regulation following coronary rehabilitation. *Int J Behav Med*. 2005;12(4):244-255. doi:10.1207/s15327558ijbm1204_5.
57. Luszczynska A. An implementation intentions intervention, the use of a planning strategy, and physical activity after myocardial infarction. *Soc Sci Med*. 2006;62(4):900-908. doi:10.1016/j.socscimed.2005.06.043.
58. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med*. 2008;148(4):295-309.
59. American Heart Association A. Classes of Heart Failure. 2014. http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp. Accessed November 18, 2014.
60. Trost SG, Owen N, Bauman AE, Sallis JF, Brown W. Correlates of adults' participation in physical activity: review and update. *Med Sci Sports Exerc*. 2002;34(12):1996-2001. doi:10.1249/01.MSS.0000038974.76900.92.
61. Sallis JF, Bauman a, Pratt M. Environmental and policy interventions to promote physical activity. *Am J Prev Med*. 1998;15(4):379-397. http://www.ncbi.nlm.nih.gov/pubmed/9838979.
62. Booth ML, Owen N, Bauman A, Clavisi O, Leslie E. Social-cognitive and perceived environment influences associated with physical activity in older Australians. *Prev Med (Baltim)*. 2000;31(1):15-22. doi:10.1006/pmed.2000.0661.
63. King AC, Castro C, Wilcox S, Eyler A a., Sallis JF, Brownson RC. Personal and environmental factors associated with physical inactivity among different racial-ethnic groups of U.S. middle-aged and older-aged women. *Heal Psychol*. 2000;19(4):354-364. doi:10.1037//0278-6133.19.4.354.
64. CSEP. *Canadian Physical Activity Guidelines*.; 2014:2. http://www.csep.ca/CMFIles/Guidelines/CSEP_PAGuidelines_adults_en.pdf.
65. Hlatky MA, Boineau RE, Higginbotham MB, et al. A brief self-administered questionnaire to determine functional capacity (the Duke Activity Status Index). *Am J Cardiol*. 1989;64(10):651-654. http://www.ncbi.nlm.nih.gov/pubmed/2782256. Accessed November 17, 2014.
66. De Oliveira C, Bremner KE, Ni A, Alibhai SMH, Laporte A, Krahn MD. Patient time and out-of-pocket costs for long-term prostate cancer survivors in Ontario, Canada. *J Cancer Surviv*. 2014;8(1):9-20. doi:10.1007/s11764-013-0305-7.
67. Rinfret S, Kennedy WA, Lachaine J, et al. Economic Impact of Same-Day Home Discharge After Uncomplicated Transradial Percutaneous Coronary Intervention and Bolus-Only Abciximab Regimen. *JACC Cardiovasc Interv*. 2010;3(10):1011-1019. doi:10.1016/j.jcin.2010.07.011.
68. Whitehead SJ, Ali S. Health outcomes in economic evaluation: the QALY and utilities. *Br Med Bull*. 2010;96:5-21. doi:10.1093/bmb/ldq033.
69. Kind P. *The EuroQol Instrument: An Index of Health Related Quality of Life. Quality of Life and PharmacoEconomics in Clinical Trials.* Vol 2nd editio. (B.Spiker, ed.). Lippincott-Raven Publishers; 1996.
70. Bansback N, Tsuchiya A, Brazier J, Anis A. Canadian valuation of EQ-5D health states: preliminary value set and considerations for future valuation studies. *PLoS One*. 2012;7(2):e31115. doi:10.1371/journal.pone.0031115.
71. Savoia E, Fantini MP, Pandolfi PP, Dallolio L, Collina N. Assessing the construct validity of the Italian version of the EQ-5D: preliminary results from a cross-sectional study in North Italy. *Health Qual Life Outcomes*. 2006;4:47. doi:10.1186/1477-7525-4-47.
72. Kontodimopoulos N, Pappa E, Niakas D, Yfantopoulos J, Dimitrakaki C, Tountas Y. Validity of the EuroQoL (EQ-5D) instrument in a Greek general population. *Value Health*. 2008;11(7):1162-1169. doi:10.1111/j.1524-4733.2008.00356.x.

73. IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.
74. Weinstein M. How Much Are Americans Willing to Pay for a Quality-Adjusted Life Year? *Editoral*. 2008.
75. Cape JD; Beca JM; Hoch JS. Introduction to cost-effectiveness analysis for clinicians. *UTMJ*. 2013;90(3):103-105.
76. Janssen V, De Gucht V, van Exel H, Maes S. A self-regulation lifestyle program for post-cardiac rehabilitation patients has long-term effects on exercise adherence. *J Behav Med*. 2014;37(2):308-321. doi:10.1007/s10865-012-9489-y.
77. Weinstein MC. How much are Americans willing to pay for a quality-adjusted life year? *Med Care*. 2008;46(4):343-345. doi:10.1097/MLR.0b013e31816a7144.
78. Bharmal M, Thomas J. Comparing the EQ-5D and the SF-6D descriptive systems to assess their ceiling effects in the US general population. *Value Health*. 9(4):262-271. doi:10.1111/j.1524-4733.2006.00108.x.
79. Moock J, Kohlmann T. Comparing preference-based quality-of-life measures: results from rehabilitation patients with musculoskeletal, cardiovascular, or psychosomatic disorders. *Qual Life Res*. 2008;17(3):485-495. doi:10.1007/s11136-008-9317-6.
80. Sandström L, Ståhle A. Rehabilitation of elderly with coronary heart disease – Improvement in quality of life at a low cost. *Adv Physiother*. 2005;7(2):60-66. doi:10.1080/14038190510010287.
81. BACPR. *The BACPR Standards and Core Components for Cardiovascular Disease Prevention and Rehabilitation 2012*.; 2012:28.
82. Thow M. *Exercise Leadership in Cardiac Rehabilitation: An Evidence-Based Approach*. Vol (Thow M, ed.). Great Britain: TJ International Ltd; 2006:228.
83. Attema AE, Edelaar-Peeters Y, Versteegh MM, Stolk EA. Time trade-off: one methodology, different methods. *Eur J Health Econ*. 2013;14 Suppl 1:S53-64. doi:10.1007/s10198-013-0508-x.
84. Guo J, Konetzka RT, Dale W. Using time trade-off methods to assess preferences over health care delivery options: a feasibility study. *Value Health*. 2014;17(2):302-305. doi:10.1016/j.jval.2013.11.010.
85. De Oliveira C, Bremner KE, Ni A, Alibhai SMH, Laporte A, Krahn MD. Patient time and out-of-pocket costs for long-term prostate cancer survivors in Ontario, Canada. *J Cancer Surviv*. 2014;8(1):9-20. doi:10.1007/s11764-013-0305-7.

Figure 1: **ECO-PCR Study Flow Diagram**

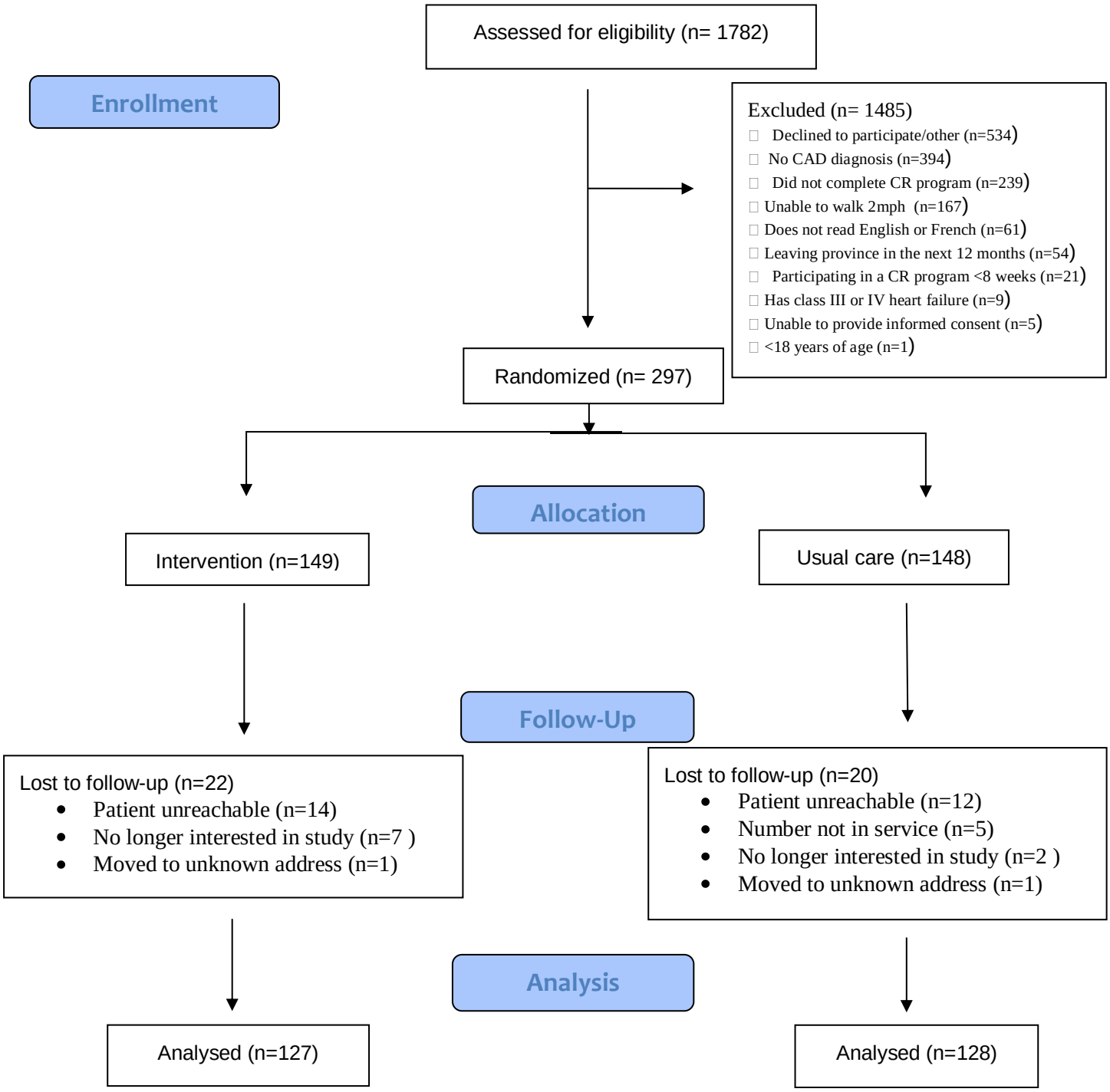
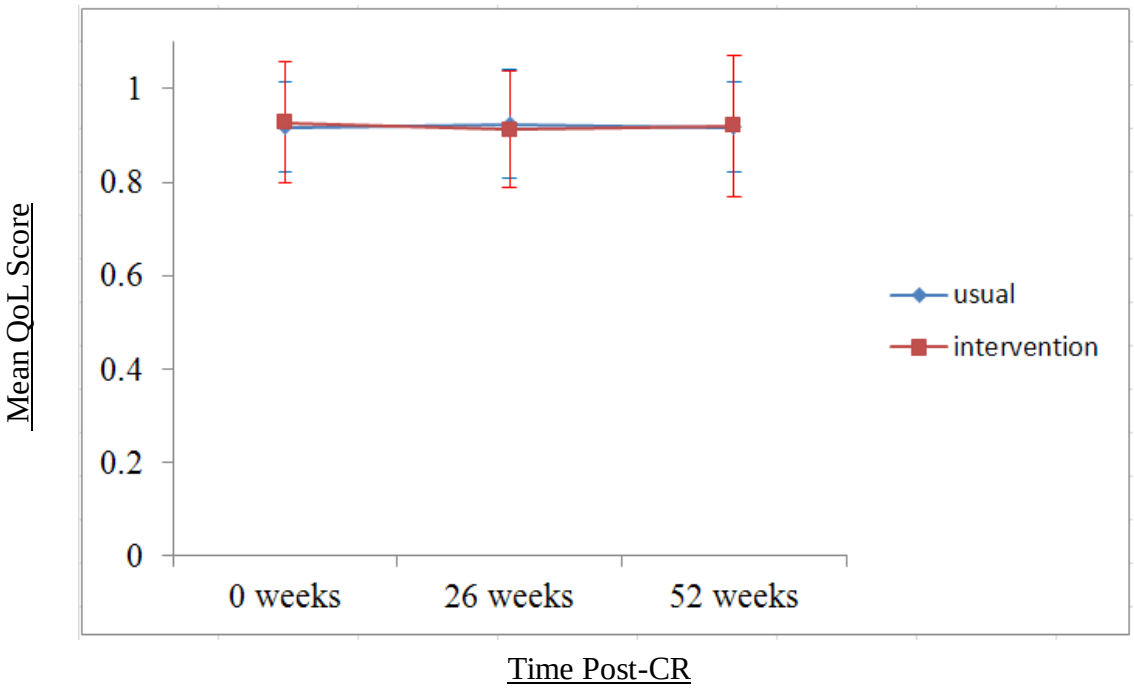


Figure 2: **Quality of Life (QoL) score by group over time**



* p>0.05 for change in QoL scores for both groups throughout the duration of the study, and for differences by groups at each time point. Quality adjusted life years (QALYs) were computed by finding the area under each graph.

Table 1: **Participant sociodemographic and clinical characteristics post-CR by group**

Characteristics	Usual Care n= 148 (49.8%)	Intervention Group n= 149 (50.2%)	p	Total N=297
Sociodemographic				
Age (mean ± SD)	63.1 ± 9.7	63.7 ± 9.6	0.87	63.4 ± 9.7
Sex (% Male)	111 (75.0%)	113 (76.3%)	0.45	224 (75.7%)
Racial/Ethnic Background (% White/Caucasian)	117 (85.4%)	120 (91.6%)	0.15	237 (88.4%)
Living Arrangements (% with Family)	101 (73.7%)	100 (75.8%)	0.54	201 (74.7%)
Living with Someone Who Requires Caregiving	10 (7.4%)	10 (7.6%)	0.56	20 (7.5%)
Employment Status (% Retired)	64 (46.7%)	66 (50.0%)	0.88	130 (48.3%)
Marital Status (% Married/Equivalent)	97 (73.7%)	97 (74.6%)	0.96	198 (74.2%)
Highest Education (% University or greater)	72 (52.6%)	59 (45.0%)	0.49	131 (48.9%)
Annual Income (<$50,000 CAD/year)	59 (46.1%)	58 (47.2%)	0.35	117 (46.7%)
Referral Indication				
PCI	91 (61.5%)	98 (66.2%)	0.23	189 (63.9%)
MI	75 (51.0%)	74 (50.0%)	0.48	149 (50.5%)
CABG Surgery	34 (23.1%)	42 (28.4%)	0.19	76 (25.8%)
Risk Factors (% yes)				
Family history of heart disease	99 (73.3%)	104 (79.4%)	0.16	203 (76.3%)
Dyslipidemia	70 (47.6%)	60 (40.5%)	0.13	130 (41.0%)
Hypertension	57 (38.8%)	64 (38.8%)	0.46	121 (41.0%)
History of physical activity	52 (38.2%)	43(32.8%)	0.21	95 (35.6%)
Smoking (% current)	3 (2.2%)	1 (0.8 %)	0.38	4 (1.7 %)
Body Mass Index (Mean ± SD)	28.4 ± 4.8	28.1 ± 4.8	0.84	28.3 ± 4.8
Comorbidities				
Other	90 (60.8%)	86 (58.1%)	0.15	176 (59.5%)
Cancer	17 (11.5%)	19 (12.8%)	0.43	36 (12.2%)
Joint Replacement	10 (6.7%)	19 (12.8%)	0.06	29 (9.8%)
Depression	17 (11.5%)	11 (7.4%)	0.16	28 (9.5%)
Cardiac Medications				
ASA	140 (94.6%)	138 (93.2%)	0.40	278 (93.9%)
Statins	133 (89.9%)	138 (93.2%)	0.20	271 (91.6%)
Other	127 (85.8%)	129 (87.8%)	0.37	256 (86.8%)
Beta Blocker	120 (81.1%)	111 (75.0%)	0.13	231 (78.0%)
ACE Inhibitors	90 (60.1%)	85 (57.4%)	0.32	175 (59.0%)
Nitrates (not PRN)	62 (41.9%)	63 (42.6%)	0.50	125 (42.2%)
Clopidrogel/Ticlopidine	56 (37.8%)	68 (45.9%)	0.10	124 (41.9%)
Calcium Antagonists	24 (16.2%)	20 (13.5%)	0.31	44 (14.9%)
Anti-depressants	20 (13.5%)	19 (12.8%)	0.50	39 (13.2%)
Oral hypoglycemic	16 (10.8%)	16 (10.8%)	0.57	32 (10.8%)
Diuretics	15 (10.1%)	15 (10.1%)	0.58	30 (10.1%)
Anti-Platelets	18 (12.1%)	11 (7.4%)	0.12	29 (9.8%)
ARBs	11 (7.4%)	14 (9.5%)	0.34	25(8.4%)
Coumadin	9 (6.1%)	8 (5.4%)	0.50	17 (5.7%)
Nicotine Replacement	7 (4.7%)	3 (2.0%)	0.17	10 (3.4%)
Insulin	3 (2.0%)	6 (4.0%)	0.25	9 (3.0%)
Anti-Coagulants	3 (2.0%)	4 (2.7%)	0.50	7 (2.4%)
Anti-Arrhythmias	2 (1.4%)	2 (1.4%)	0.70	4 (1.4%)
HRT	3 (2.0%)	1 (0.7%)	0.31	4 (1.4%)
Peak VO_2† (ml.kg-1.min-1)	25.1±7.3	24.9±6.5	0.12	25.0±6.9
Resting heart rate (bpm)	64.7±10.9	66.3±11.2	0.71	65.5±11.1
Systolic blood pressure (mmHg)	120.2±18.2	127.8±82.6	0.35	124.0±60.0
Diastolic blood pressure (mmHg)	71.8±9.3	72.9±9.9	0.30	72.4±9.6
Duke Activity Status Index (Mean ± SD)	46.7±12.7	47.1±11.1	0.17	46.3±11.8

CR= Cardiac Rehabilitation; CAD= Canadian Currency; PCI- Percutaneous Coronary Intervention; MI- Myocardial Infarction; CABG- Coronary Artery Bypass Graft; PVD- Peripheral Vascular Disease; SD- Standard Deviation; PRN- "when necessary"; BPM- beats per minute
†275 available in random sub-sample of 297 participants.

Table 2: **Post-CR (baseline) sociodemographic and clinical characteristics by retention at 26 week follow-up**

Characteristics	Retained† n= 276 (92.9%)	Lost to follow-up n= 21(7.1%)	p
Sociodemographic			
Age (mean ± SD)	63.5 ± 9.8	63.0 ± 8.6	0.35
Sex (% Male)	207 (75.3%)	17 (80.9%)	0.39
Racial/Ethnic Background (% White/Caucasian)	225 (88.9%)	12 (80.0%)	0.10
Living Arrangements (% with Family)	186 (73.2%)	15 (71.4%)	0.07
Living with Someone Who Requires Caregiving	15 (5.9%)	5 (33.3%)	<0.01
Employment Status (% Retired)	122 (48.0%)	8 (53.3%)	0.57
Marital Status (% Married/Equivalent)	184 (74.2%)	14 (93.3%)	0.26
Highest Education (% University or greater)	124 (49.0%)	7 (46.7%)	0.61
Annual Income (<$50,000 CAD/year)	110 (46.4%)	7 (50.0%)	0.83
Referral Indication			
PCI	177 (64.4%)	12 (57.1%)	0.33
MI	140 (51.1%)	9 (42.9%)	0.31
CABG surgery	71 (25.9%)	5 (23.8%)	0.53
Risk Factors (% yes)			
Family history of heart disease	192 (76.5%)	11 (73.3 %)	0.49
Hypertension	114 (41.6%)	7 (33.3 %)	0.72
Dyslipidemia	123 (44.9%)	7 (33.3%)	0.21
History of physical activity	90 (35.7%)	5(33.3%)	0.55
Smoking (% current)	4 (1.6%)	0 (0%)	0.89
Body Mass Index (Mean ± SD)	28.4 ± 4.8	28.1 ± 4.8	
Comorbidities			
Other	167 (60.7%)	9 (42.9%)	0.36
Cancer	33 (12.0%)	3 (14.2%)	0.48
Joint Replacement	26 (9.5%)	3 (14.2%)	0.34
Depression	26 (9.4%)	2 (9.5%)	0.61
Cardiac Medications			
ASA	260 (94.5%)	18 (85.7%)	0.13
Statins	253 (92%)	18 (85.7%)	0.26
Beta Blocker	213 (77.4%)	18 (85.7%)	0.28
Other	238 (86.9%)	18 (85.7%)	0.50
ACE Inhibitors	161 (58.5%)	14 (66.7%)	0.31
Nitrates (not PRN)	116 (42.2%)	9 (42.9%)	0.56
Clopidrogel/Ticlopidine	118 (42.9%)	6 (28.6%)	0.15
Diuretics	26 (9.4%)	4 (19.0%)	0.15
Oral hypoglycemic	28 (10.2%)	4 (19.0%)	0.18
Anti-depressants	36 (13.1%)	3 (14.3%)	0.54
Anti-Coagulants	5 (1.8%)	2 (9.5%)	0.08
Calcium Antagonists	42 (15.3%)	2 (9.5%)	0.37
Anti-Platelets	28 (10.2%)	1 (4.8%)	0.37
Anti-Arrhythmias	3 (1.1%)	1 (4.8%)	0.26
ARBs	24 (8.7%)	1 (4.8%)	0.45
Coumadin	16 (5.8%)	1 (4.8%)	0.66
Insulin	8 (2.9%)	1 (4.8%)	0.49
Nicotine Replacement	10 (3.6%)	0 (0%)	0.47
HRT	4 (1.5%)	0 (0%)	0.74
Peak VO_2† (ml.kg-1.min-1)	25.1±7.0	23.2±4.0	0.06
Resting heart rate (bpm)	65.2±11.1	68.5±11.0	0.94
Systolic blood pressure (mmHg)	124.5±62.1	118.4±12.7	0.54
Diastolic blood pressure (mmHg)	72.4±9.6	72.1±9.4	0.84
Duke Activity Status Index (Mean ± SD)	46.2±12.4	47.1±10.2	0.68

CR= Cardiac Rehab; CAD= Canadian Currency; PCI- Percutaneous Coronary Intervention; MI- Myocardial Infarction; CABG- Coronary Artery Bypass Graft; PVD- Peripheral Vascular Disease; SD- Standard Deviation; PRN- "when necessary"; BPM- beats per minute
*p<.05
†276 available in random sub-sample of 297 participants.

Table 3: Post-CR socio-demographic and clinical characteristics by retention at 52 week follow-up

Characteristics	Retained n= 264 (88.9%)	Lost to follow-up n= 33 (11.1%)	p
Sociodemographic			
Age (mean ± SD)	63.7 ± 9.8	61.5 ± 8.8	0.68
Sex (% Male)	196 (74.5%)	28 (84.8%)	0.14
Racial/Ethnic Background (% White/Caucasian)	214 (88.4%)	23 (88.5%)	0.53
Living Arrangements (% with Family)	176 (72.4%)	25 (96.1%)	0.02
Living with Someone Who Requires Caregiving	13 (5.4%)	7 (26.9%)	<0.001
Employment Status (% Retired)	117 (48.1%)	13 (50.0%)	0.87
Marital Status (% Married/Equivalent)	174 (72.2%)	24 (92.3%)	0.14
Highest Education (% University or greater)	121 (50.0%)	10 (38.5%)	0.08
Annual Income (<$50,000 CAD/year)	105 (46.1%)	7 (50.0%)	0.84
Referral Indication			
PCI	172 (65.4%)	17 (51.5%)	0.09
MI	136 (51.9%)	13 (39.4%)	0.12
CABG surgery	67 (25.5%)	9 (28.1%)	0.45
Risk Factors (% yes)			
Family history of heart disease	183 (76.3%)	20 (76.9%)	0.58
Dyslipidemia	118 (45.0%)	12 (36.4%)	0.23
Hypertension	111 (42.4%)	10 (30.3%)	0.38
History of physical activity	87 (36.1%)	8 (30.8%)	0.38
Smoking (% current)	4 (1.7%)	0 (0 %)	0.80
Body Mass Index (Mean ± SD)	28.2 ± 4.8	28.7 ± 4.9	0.80
Comorbidities			
Other	163 (62.2%)	13 (39.4%)	<0.05
Cancer	30 (11.4%)	6 (18.2%)	0.20
Joint Replacement	26 (9.9 %)	3 (9.0%)	0.59
Depression	26 (9.9%)	2 (6.1%)	0.37
Cardiac Medications			
ASA	248 (94.3%)	30 (90.9%)	0.32
Statins	241 (91.6%)	30 (90.9%)	0.55
Beta Blocker	202 (76.8%)	29 (87.8%)	0.11
Other	230 (87.8%)	26 (78.8%)	0.12
ACE Inhibitors	156 (59.3%)	19 (57.6%)	0.50
Nitrates (not PRN)	112 (42.6%)	13 (39.4%)	0.44
Clopidrogel/Ticlopidine	114 (43.3%)	10 (30.3%)	0.11
Oral hypoglycemic	26 (9.9%)	6 (18.2%)	0.13
Diuretics	25 (95.1%)	5 (15.2%)	0.23
Calcium Antagonists	40 (15.2%)	4 (12.1%)	0.43
Anti-depressants	36 (13.7%)	3 (9.0%)	0.34
Coumadin	15 (5.7%)	2 (6.0%)	0.59
Insulin	7 (2.7%)	2 (6.0%)	0.26
Anti-Coagulants	5 (1.9%)	2 (6.1%)	0.18
Nicotine Replacement	9 (3.4%)	1 (3.0%)	0.70
Anti-Arrhythmias	3 (1.1%)	1 (3.0%)	0.38
ARBs	24 (9.1%)	1 (3.0%)	0.20
Anti-Platelets	28 (10.6%)	1 (3.3%)	0.14
HRT	4 (1.5%)	0 (0%)	0.62
Peak VO_2† (ml.kg-1.min-1)	25.0±7.0	24.6±4.7	0.10
Resting heart rate (bpm)	65.3 ± 11.2	67.3 ± 10.4	0.75
Systolic blood pressure (mmHg)	125.0±63.4	116.6±15.1	0.55
Diastolic blood pressure (mmHg)	72.6±9.6	67.3±10.4	0.75
Duke Activity Status Index (Mean ± SD)	46.9±11.3	48.0±10.3	0.78

CR= Cardiac Rehab; CAD= Canadian Currency; PCI- Percutaneous Coronary Intervention; MI- Myocardial Infarction; CABG- Coronary Artery Bypass Graft; PVD- Peripheral Vascular Disease; SD- Standard Deviation; PRN- "when necessary"; BPM- beats per minute
†264 available in random sub-sample of 297 participants.

Table 4: **Cardiac-related health care resource use (mean number of visits ± standard deviation) by group**

	Usual Care n=148 (49.8%)	**Intervention n=149 (50.2%)**	**p**	**Total N=297**
26 weeks post-CR				
Family Physician	2.53 ± 2.04 (n=104)	2.82 ± 3.00 (n=100)	0.09	2.67 ± 2.50
Cardiac Specialist	1.33 ± 1.19 (n=89)	1.27 ± 1.24 (n=81)	0.70	1.30 ± 1.21
Emergency Department	0.33 ± 0.71 (n=27)	0.22 ± 0.51 (n=18)	<0.01*	0.27 ± 0.62
Admitted to Hospital	0.16 ± 0.39 (n=17)	0.07 ± 0.28 (n=6)	<0.01*	0.11 ± 0.35
52 weeks post-CR				
Seen your family doctor	2.41 ± 2.0 (n=70)	2.36 ± 3.2 (n=62)	0.67	2.39 ± 2.7
Seen a heart specialist	1.04 ± 0.81 (n=59)	0.88 ± 0.90 (n=44)	0.44	0.97 ± 0.85
Went to emergency department	0.26 ± 0.52 (n=17)	0.14 ± 0.43 (n=8)	<0.01*	0.20 ± 0.48
Been admitted to the hospital	0.05 ± 0.22 (n=4)	0.19 ± 0.99 (n=13)	0.02*	0.12 ± 0.70

CR= Cardiac Rehabilitation;
*p<.05 between usual and intervention group

Table 5: **Procedures and heart conditions by group**

	Usual Care n=148 (49.8%)	**Intervention n=149 (50.2%)**	**p**	**Total N=297**
26 weeks Post-CR				
Other	13 (11.7%)	14 (12.7%)	0.49	27 (12.2%)
Angina	13 (11.7%)	12 (10.9%)	0.51	25 (11.3%)
Percutaneous Coronary Intervention	5 (4.5%)	3 (2.7%)	0.37	8 (3.6%)
None of the Above	86 (76.1%)	77 (70.0%)	0.19	163 (73.1%)
52 weeks Post-CR				
Angina	5 (6.5%)	8 (11.6%)	0.22	13 (9.0%)
Other	4 (5.3%)	2 (2.9%)	0.39	6 (4.1%)
None of the above	65 (87.8%)	55 (84.6%)	0.38	120 (86.3%)

Table 6: Out-of-pocket patient costs for medications and health care visits by group

Medication Costs			
Post-CR	**Control**	**Intervention**	**p**
26 weeks	$ 580.33 ± 559.37	$ 584.15 ± 623.43	0.74
52 weeks	$ 448.02 ± 469.09	$ 549.54 ± 446.56	0.78
Health Care Visit Costs			
Post-CR	**Control**	**Intervention**	**p**
26 weeks	$ 570.68 ± 405.02	$ 493.24 ± 423.07	0.18
52 weeks	$ 544.23 ± 388.63	$ 601.15 ± 415.66	0.43

Table 7: Societal costs by group at 52 weeks

	N (%)		
	Intervention	**Usual Care**	**p**
Did you buy any items for a problem related to heart disease? (equipment, aids, devices)	15 (19.2%)	9 (12.5%)	0.18
Difficulty working at your paid employment due to treatment or problems to heart disease?	3 (2.8%)	2 (4.2%)	0.44
Unable to do chores around the house (housecleaning, running errands) due to heart disease	4 (5.2%)	4 (5.2%)	0.58
Unable to participate in leisure activities due to heart disease?	4 (5.2%)	5 (6.9%)	0.44
Did you use any community services in the last 6 months due to heart disease?	1 (1.4%)	1 (1.3%)	0.73
Have you ever seen a health professional or seek treatment for heart disease outside Ontario?	5 (6.4%)	2 (2.8%)	0.26
	mean ± standard deviation		
	Intervention	**Usual Care**	p
How many days of work did you miss since you graduated from cardiac rehabilitation?	4.4 ± 17.9	5.8 ±13.9	0.44
In you are not currently working, how many days were you unable to perform your usual activities?	5.7 ± 24.4	6.3 ± 19.4	0.9

Table 8: Translating intervention benefits into monetary values

	Usual Care		Intervention	
	N=114	N=115	N=79	N=71
Time Post-CR	26 weeks	52 weeks	26 weeks	52 weeks
Hospital admissions	$361.28	$112.90	$429.02	$270.94
ER Visits	$73.92	$58.24	$49.28	$44.80
Total	$435.20	$171.14	$478.30	$315.76

Note: amounts shown in Canadian dollars.
CR=Cardiac Rehabilitation

* costs based on Rinfret et al.[67]

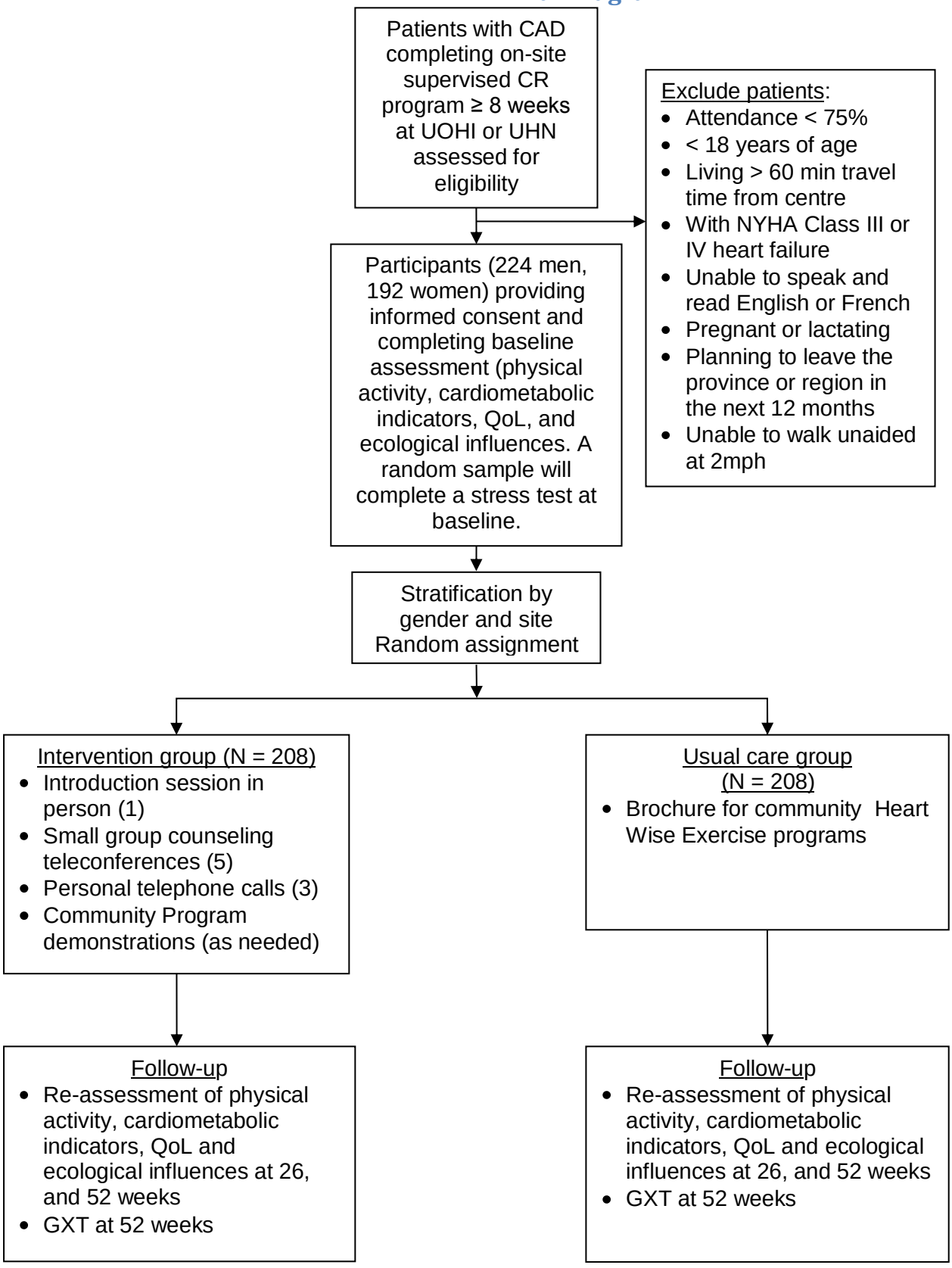
Table 9: Micro-costing from health care perspective for the intervention group

Item	Unit Price	Total Cost
Training Exercise Facilitator (Includes training and patient call times)	$25.41	$21,318.99
Teleconference Calls	$220.47	$2645.64
Pedometer Costs	$13.00	$1755.00
Workbook Costs	$23.55	$2590.50

Note: amounts shown in Canadian dollars.

8.0 APPENDICES

APPENDIX A: Trial Diagram



CAD- Coronary Artery Disease
UOHI – University of Ottawa Heart Institute
UHN-University Health Network
QoL-Quality of Life
GXT-Graded stress test
NYHA-New York Heart Association

APPENDIX B: CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title:	**Ecologically Optimizing Exercise Maintenance in Men and Women Following Cardiac Rehabilitation: A Randomized Controlled Trial of Efficacy with Economics**
Sponsor	**Heart and Stroke Foundation of Ontario**

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

Physical activity is an important contributor to fitness for patients with heart disease. Canadian guidelines recommend 30-60 minutes of moderate to vigorous physical activity most, preferably, all days of the week.

Participation in an outpatient cardiac rehabilitation program is the usual first step toward developing an exercising lifestyle after a heart problem is diagnosed. About 70-85% of people report achieving recommended guidelines for physical activity during the time they are participating in cardiac rehab. Unfortunately, these levels of physical activity are often not maintained after participation in the program ends.

You have been asked to take part in this research study because you have completed at least 75% of a supervised cardiac rehabilitation program at the University Health Network.

We have developed a new intervention to promote the continuation of exercise following cardiac rehab. It incorporates an exercise "facilitator" to transition patients from structured, supervised exercise to home walking or approved community-based exercise programs (also known as Heart Wise Exercise Programs).

This research study will examine whether the facilitator intervention is related to more exercise maintenance over the year following cardiac rehab, which elements of the process affected your exercise, your clinical profile, and the cost of in the intervention, including whether patients are less likely to use the healthcare system.

About 416 people from Ottawa and Toronto will be in the study. About 139 people will come from the University Health Network (Toronto Western Hospital and the Toronto Rehabilitation Institute cardiac rehab programs).

Study Design

This study is a one and a half year study that that will compare an intervention group (exercise facilitator) with a control group (usual care). Whether you assigned to the intervention or the control group will be decided randomly (by chance) like flipping a coin or rolling dice. The number of people getting study intervention will be 208 and the number of people in the control group will be 208.

Study Procedures

Questionnaires

You will be asked to complete four (4) survey questionnaires: one at the beginning of the study, one at 26 weeks (6 months), one at 52 weeks (1 year) and one at 78 week (1.5year). The questionnaires will ask you about your demographics (age, gender, education), lifestyle (exercise behaviours, cardiac risk factors, medications), as well as questions about your health and emotional well-being. Completion of the questionnaires will require approximately 45 minutes of your time.

Intervention Group

Participants in the intervention group will receive five small group counselling teleconferences, be invited to multiple community exercise program demonstrations, and three personal telephone calls from a trained exercise facilitator over a 50-week (almost 1 year) intervention period.

- Small group teleconferences will take place in study weeks: 3, 13, 26, 39 and 50. These sessions are 60 minutes long.
- Personal (individual phone calls) will take place in study weeks: 20, 34 and 45. These sessions are 15-30 minutes long.
- A random sub-sample of these calls would be audio taped with your permission so we can audit the consistency of the session content the facilitator is providing.
- The above activities will actively explore and review your exercise behaviours and barriers.

Usual Care Group

The usual care group will receive the usual exercise advice provided to patients exiting cardiac rehabilitation at the study centers. Patients in both programs are provided with an updated exercise prescription and a home-based walking program prior to program completion and exercise maintenance strategies are reviewed with program exercise staff. There is no further patient contact after program completion at either program.

Follow-up

Participants in both groups will have their follow-up continue through to 78 weeks (1.5 years later).

- Results from your exit assessments will be collected from your cardiac rehab charts.
- Measures will be taken at 26 weeks (6 months), 52 weeks (1 year) and 78 weeks (1.5 years) after randomization.
    - You will be asked to come on site for these assessments, and complete a survey measuring your thoughts and feelings about exercise. It will take approximately 45 minutes to complete.

- In order to measure your health, we would also like to test your blood pressure and measure your waist.
- You will be asked wear an accelerometer device to measure your physical activity for 9 days. You will be provided with a pre-paid addressed envelope to return the accelerometer.

- A randomly-chosen subsample of patients will be asked to do a physician-supervised, symptom-limited cardiopulmonary test at the 1-year final assessment only. Cardiac rehab graduates from the Toronto Rehabilitation Institute program are asked to do this as a standard part of the program, so if this information is available we would simply want to get the results.

As part of the study, we will review your medical records to obtain information about your diagnosis and your medical history, including the nature of your cardiac problem, heart history and medications. We will also collect the information obtained as part of your rehab program, which includes test results, blood pressure and waist measurements, cholesterol levels, as well as your participation level and dates of attendance.

Economic Measures

Finally, we would also like permission to link your information gathered from this program with a provincial database to determine your health care use and health outcomes over time. This would not require any paperwork on your behalf.

Reminders

While you are in this study you should continue with everything your family doctor or cardiac specialist has recommended. You will still receive your usual care from your family doctor and cardiac specialist. You do not have to stop or change anything.

Potential Risks and Benefits

It is very unlikely that participation in this research study will result in any side effects. The Cardiopulmonary stress test will require you to walk (starting at a low level with the speed and grade slowly increasing throughout the test) on a treadmill with electrodes on your chest in order to see how the heart works during exercise. It will help us measure your heart minimal and maximal exercise capacity. This test is based on your own efforts and you can stop at any time throughout the procedure. There will be a full medical staff supervising the stress test.

You will be revealing personal information about yourself; however this information will remain private.

Benefits to Being in the Study

You may receive direct benefit from being in this study by receiving further support to maintain exercise. Your participation will also help us improve the care of future cardiac patients following cardiac rehab participation.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name
- address
- email address
- OHIP number
- new or existing medical records (including types, dates and results of medical tests or procedures)

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee.
- University Health Network Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for any of the procedures (i.e. stress test) involved with this study. You will be reimbursed for your parking costs for your 4 on-site visits to complete study assessments (initial, 26, 52 and 78 weeks). You will not be paid for participation in this study.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: _____ or the Study Coordinator at _____.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) at _____or please call the Toronto Rehab Research Ethics Board Office at _____.The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

APPENDIX C: Case Report Form (CRF)

ECO-PCR CASE REPORT FORM: 26 WEEK FOLLOW UP

Date assessed: _____ (dd/mm/yy)

Basic Measures
1) Weight(kg): _____ 2) Waist circumference (cm): _____ 3) BP: syst:_____/ diast:_____ Heart Rate: _____

Current Medications *(check all that apply)*		
Medication	**Name**	**Dose**
☐ 4) ACE Inhibitors		
☐ 5) Anti-coagulants		
☐ 6) ASA		
☐ 7) Ca^{2+} antagonists		
☐ 8) Statin		
☐ 9) LL – fibrate		
☐ 10) LL – nicotinic acid		
☐ 11) LL – resin drugs		
☐ 12) Diuretics		
☐ 13) Clopidogrel or ticlopidine		

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APPENDIX D: ECO-PCR Study Initial Survey

Heart Wise Exercise · Corps à cœur ·

Instructions for completing the survey questions appear at the beginning of each section.

Please seal your completed questionnaire in the envelope provided, and

return it to the study coordinator.

DATE COMPLETED:(dd/mm/yyyy)_____ Participant #_____

SECTION A: ABOUT YOU

Instructions: The information within this section is needed to help understand the characteristics of the people participating in this study. For this reason, it is very important information. **Be assured that it will remain confidential.**

1. What do you consider to be your racial/ethnic background? Please check ☑ one (1) of the following boxes:

- ☐ Aboriginal (includes Inuit, Métis peoples of Canada, First Nations)
- ☐ Arab (includes Egyptian, Kuwait, Libyan)
- ☐ West Asian (includes Afghan, Assyrian and Iranian)
- ☐ Black (includes African, Nigerian, Somali)
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Latin American (includes Chilean, Costa Rican, Mexican)
- ☐ South Asian (includes Bengladeshi, Punjabi, Sri Lankan)
- ☐ South East Asian (includes Vietnamese, Cambodian, Malaysian)
- ☐ White (Caucasian)
- ☐ Other (**specify:** _____)
- ☐ Multiple cultural backgrounds (**specify**_____)

2. Who do you live with?

- ❑ Family (spouse, children, etc.)
- ❑ Alone
- ❑ Other (specify:_____)

3. How many people live in your house hold? _____

4. Do you live with someone who requires caregiving (e.g., ill spouse, grandchildren)?

- ☐ Yes
- ☐ No

5. Which option best matches your work status?

- ❑ Employed Full-time (that is 35 or more hours per week)
- ❑ Employed Part-time (that is less than 35 hours per week)
- ❑ Self-employed (primary occupation)
- ❑ Unemployed, but looking for work
- ❑ Student
- ❑ Retired
- ❑ Not in the paid workforce (homemaker, unemployed, not looking for work)

6. What is your marital status?

- ❑ Single

- ❑ Married or equivalent (i.e., common law, same sex)
- ❑ Separated or equivalent
- ❑ Widowed

7. What is the highest level of education you have completed?

- ❑ Less than high school (no certificates, diplomas or degrees)
- ❑ High school graduation certificate
- ❑ Trades certificate
- ❑ College certificate or diploma: a certificate from a community college, CEGEP, school of nursing, theological college or private college
- ❑ University: a certificate below the bachelor's level, bachelor's degree, certificate above the bachelor level, master's degree, earned doctorate or a professional degree in medicine, dentistry, veterinary medicine or optometry

8. How much did you earn before taxes and other deductions, during the past 12 months?

- ❑ Less than $5,000
- ❑ $5,000 through $11,999
- ❑ $12,000 through $15,999
- ❑ $16,000 through $24,999
- ❑ $25,000 through $34,999
- ❑ $35,000 through $49,999
- ❑ $50,000 through $74,999
- ❑ $75,000 through $99,999
- ❑ $100,000 and greater

APPENDIX E: 26-week cover-letter

Date:

Participant Name
Address

RE: ECO-PCR Study: Exercise Maintenance in Men and Women Post-Cardiac Rehabilitation

Dear Salutation –Participant Name,

I am writing to request that you complete the enclosed survey for our research study on exercise after cardiac rehabilitation in patients with coronary artery disease (CAD), the study that you consented to participate in 6/18 months ago at the end of your cardiac rehabilitation program. We very much appreciate the time and effort you have put into helping us with this study and hope that you will be willing to complete this questionnaire.

This survey, like the previous one, requests information about your physical activity, quality of life, risk factors and health care costs. Enclosed is a pre-addressed and stamped envelope in which you can return the completed survey.

If you have any questions regarding the survey or the study please feel free to contact the study coordinator at _____.

We want to stress that your participation in this study is completely voluntary, and will not impact the care or services you or your family receive. Please know that your help would be greatly appreciated and any information you could give us would further aid us in improving the quality of life for patients after cardiac rehabilitation, such as yourself.

Thank you for your consideration.

Sincerely,

ECO-PCR Study Investigator
York University & University Health Network

APPENDIX F: 52-week telephone script

ECO-PCR Telephone Script
12 month Assessment
Hello, my name is < insert name >, and I am contacting you regarding the ECO-PCR study from the University Health Network. Is <participant name> available?
Hello. I am calling about the ECO-PCR study, where we have been tracking the exercise patterns of our cardiac rehab graduates. It is time for your final 52 week assessment. This involves a stress test, filling out a survey, and wearing an accelerometer for 9 days.
I mailed a "pulse check" form to you. **The main purpose of this form is to allow you to get a free stress test. The doctor needs to verify that there are no health concerns in doing the stress test.**
Have you received the form in your mail?
If yes: Great. Have you been able to schedule an appointment to see your doctor to get the form completed? Then the doctor can fax it to the cardiac rehab program. The fax number is on the form.

> **If yes:** The cardiac rehab program will contact you by phone when they receive the faxed form. They will schedule the stress test with you. They will let me know when you are coming in, and I will meet with you as well. Just like your 6 month assessment, I will take your blood pressure, heart rate, weight, height and waist circumference. I will also provide you a final survey to complete, and provide you with an accelerometer to wear for the following 9 days.

Please bring a few things along with you:

1. You medication bottles, so we can record your medication
2. The "costing diary" if you received one
3. Your "participant journal" if you received one
4. Your pedometer that was provided at the beginning of the study.

We will pay for your parking.
<If patient is from _____: give them directions to the _____and explain about parking>
If patient says no: My apologies. I will mail you the form right away.
Do you have an email address?

> If yes: I could scan and email it to you.
> If no: let me just confirm your mailing address with you.

If you have any question, please contact me at _____. Do you have a pen handy? I can repeat that number. If you prefer to reach me via email, my email address is _____.
Thank you for your time and have a nice day.

Voice Mail Script
This is <researcher name > call from the ECO-PCR study at University Health Network, about exercise after cardiac rehab. I am calling to arrange your final 12 month assessment. I mailed you a "pulse check" form that you can take to your doctor to sign for your free stress test. I am calling to see if you received it, and if you had any questions about the assessment process. Do you have a pen handy? I can be reached at _____. REPEAT PHONE NUMBER AND EMAIL ADDRESS.
Thank you.

---

52 Wk Assessment Reminder Call
Hello, my name is < insert name >, and I am contacting you regarding the ECO-PCR study from the University Health Network. Is <participant name> available?
Hello. I am calling about the ECO-PCR study, where we have been tracking the exercise patterns of our cardiac rehab graduates. This is a reminder that your stress test and final assessments are scheduled on <day of week> <month> <day of month> at <time>. I will be there as well to take your measures and give you your survey and pedometer.
Please remember to bring:

1. You medication bottles, so we can record your medication

2. The “costing diary” if you received one
3. Your “participant journal” if you received one
4. Your pedometer that was provided at the beginning of the study.

Did you have any questions?
If they say they need to re-schedule, provide contact information: _____.
Okay. Thanks in advance, and I will look forward to meeting with you on <day>.

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APPENDIX G: ECO-PCR Study Follow-up (26-week) Survey

Heart Wise Exercise · Corps à cœur ·

Instructions for completing the survey questions appear at the beginning of each section.

Please seal your completed questionnaire in the envelope provided, and

return it to the study coordinator.

DATE COMPLETED:(dd/mm/yyyy)_____ Participant #_____

SECTION C: YOUR QUALITY OF LIFE

Instructions: By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today. [2]

1. Mobility

- ❑ I have no problems in walking about
- ❑ I have some problems in walking about
- ❑ I am confined to bed

2. Self-Care

- ❑ I have no problems with self-care
- ❑ I have some problems washing or dressing myself
- ❑ I am unable to wash or dress myself

3. Usual Activities (*e.g. work, study, housework, family or leisure activities)*

- ❑ I have no problems with performing my usual activities
- ❑ I have some problems with performing my usual activities
- ❑ I am unable to perform my usual activities

4. Pain/Discomfort

- ❑ I have no pain or discomfort
- ❑ I have moderate pain or discomfort
- ❑ I have extreme pain or discomfort

5. Anxiety/Depression

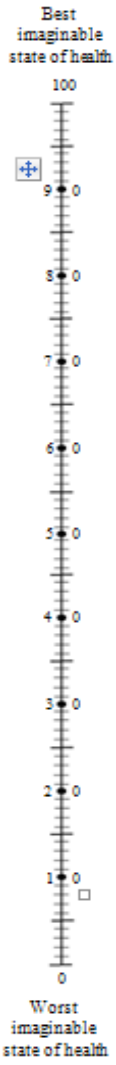
- ❑ I am not anxious or depressed
- ❑ I am moderately anxious or depressed
- ❑ I am extremely anxious or depressed

[2] *P.Kind. The EuroQol instrument: An index of health related quality of life. Quality of life and PharmacoEconomics in clinical trials. Second edition, edited by B.Spiker. Lippincott-Raven Publishers. Philadelphia 1996.*

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

YOUR HEALTH TODAY = ☐



SECTION M: YOUR MEDICATIONS

Please record **all medications**, prescribed by a health professional or bought over-the-counter, that you used **DURING THE LAST 6 MONTHS FOR CARDIOVASCULAR HEALTH.**
Include medications taken for heart disease and its problems (e.g., pain), or problems caused by treatment (e.g. loss of sexual function).

Write the dose used each time (e.g. two 5 mg pills=10 mg) and the number of times used each day. If you used it less often than once per day (e.g., an injection once every 4 weeks), please write this in the space after "Times taken/used per day". If you used more than 6 medications, please write them on the back page. We suggest that you put the medications you have at home in front of you while you answer these questions. Remember to include herbal medicine, skin creams, drops, needles, etc., as well as pills.

- ❑ I used **NO** medications during the last 6 months.

1. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

2. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

3. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

4. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

5. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

6. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

7. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

8. How much **of your own money** did you spend in the last **12** months, with **no reimbursement**, for **all** of your medications? $ _____

SECTION N: CARE & COSTS

We would like to know about the health professionals you saw during **the last 6 months** **BECAUSE OF YOUR CARDIOVASCULAR HEALTH.** It will be easier to answer if you refer to a calendar or appointment list on which you record your appointments. If you did not keep a record, try to remember if any appointments were on or near special days, such as your birthday, or the day of a social event. Please answer the questions below by entering the number of times in the past 6 months that you have:

1. How much did you earn before taxes and other deductions, during the past 12 months?

- ❑ Less than $5,000
- ❑ $5,000 through $11,999
- ❑ $12,000 through $15,999
- ❑ $16,000 through $24,999
- ❑ $25,000 through $34,999
- ❑ $35,000 through $49,999
- ❑ $50,000 through $74,999
- ❑ $75,000 through $99,999
- ❑ $100,000 and greater

		Number of times
2.	Seen your family doctor	_____
3.	Seen a heart specialist	_____
4.	Gone to the Emergency Department	_____
5.	Been admitted to the hospital	_____

6. Have you experienced any of the following heart problems or procedures **in the last 6 months**? (Please check ☑ all that apply):

- ❑ Heart Attack
- ❑ Angina
- ❑ Angioplasty (stent)
- ❑ Bypass Surgery
- ❑ Valve Surgery
- ❑ Heart Failure
- ❑ Heart transplant
- ❑ Pacemaker or implantable cardiovascular defibrillator
- ❑ Stroke
- ❑ Peripheral Vascular Disease
- ❑ Ablation
- ❑ Left ventricular assist device
- ❑ Other, please specify: _____
- ❑ None of the above

7. Have you experienced any of the following diagnostic tests **in the last 6 months**? (Please check ☑ all that apply):

- ❑ X-Ray
- ❑ Electrocardiogram (ECG)
- ❑ Blood test
- ❑ Urine test
- ❑ CT Scan
- ❑ Echocardiogram
- ❑ Stress Test
- ❑ Other, please specify: _____
- ❑ None of the above

8. How much **of your own money**, in total, did you pay for these health care visits (eg., transportation, parking, food, lodging), including the money paid by anyone who accompanied you?

- ❑ None **OR** enter amount: $_____

9. How much time was associated with these health care visits (include travel, waiting, etc.)?

_____hours in total

10. In the last **6 months,** who USUALLY accompanied you on these health care visits? Check (√) all that apply**.**

- ❑ Nobody; I usually went by myself
- ❑ Partner
- ❑ Son, daughter, or grandchild
- ❑ Sister, brother, friend, or neighbour
- ❑ Volunteer
- ❑ Paid homemaker or caregiver
- ❑ Other, please specify_____

10b. This person's age is: _____years.

10c. This person is: ☐ Male OR ☐ Female

11. Please describe your current smoking status:

a. Have you ever smoked cigarettes daily? ☐ Yes ☐ No (if no, move to Q12)

b. At the present time, do you smoke cigarettes? ☐ Every day ☐ Occasionally ☐ Not at all

c. If not at all, when did you stop smoking? _____ (month and year)

12. In the past 6 months, have you had a change in your:

(a) Place of Residence? ☐ Yes ☐ No If yes, please describe: _____

(b) Work Status? ☐ Yes ☐ No If yes, please describe: _____

13. What best describes your occupation at the time of your heart diagnosis?

☐ Professional, technical and related (teachers, lawyers, physicians, engineers)

- ☐ Managers, administrators or proprietors (manager, real estate agent, postmasters)
- ☐ Clerical and related (secretaries, clerks, mail carriers)
- ☐ Sales occupations (sales person, demonstrator, agent or broker)
- ☐ Service occupations (police, cook, hairdresser)
- ☐ Skilled crafts, repairer and related (carpenters, telephone line workers)
- ☐ Equipment or vehicle operators and related (drivers, brakemen)
- ☐ Laborers (helpers, longshoremen, warehouse workers)
- ☐ Farmers (owners, managers, operators, tenants)
- ☐ Military
- ☐ Homemaker
- ☐ Not working
- ☐ Retired
- ☐ Other, please describe: _____

14. Did heart disease or its treatment lead you to retirement or disability?
    - ☐ Yes
    - ☐ No
    - ☐ Not applicable

15. How many days of work did you miss since you graduated from cardiac rehabilitation? _____ days

16. If you are not currently working, how many days were you unable to perform your usual activities? ____ days

17. Have you EVER seen a health professional or had treatment for heart disease OUTSIDE of Ontario?

☐NO - Go to Question 18
☐YES ……continue below

Where (city, province, state, country):_____
When (month and year): From_____ to_____

Type(s) of health professional seen:_____
_____

Treatment(s) you received:_____
_____

If you had other heart disease treatment outside of Ontario, please tell us about it on the back of this page. Describe where, when, who and treatments received.

18. Equipment (aids, devices, household items) bought during the last 6 months

Please list all items you bought during the last 6 months for a problem related to heart disease, and the amount of your own money, if any, that you paid for each.

☐I bought **NO** equipment in the last 6 months because of heart disease.
Please go to Question 19.

1. Item_____ Cost to you: $_____

2. Item_____ Cost to you: $_____

3. Item_____ Cost to you: $_____

4. Item_____ Cost to you: $_____

5. Item_____ Cost to you: $_____

6. Item_____ Cost to you: $_____

19. **Community services used during the last 6 months**

Please list any community services (e.g., home care, meals-on-wheels, transportation) you used in the last 6 months because of a disability RELATED TO YOUR HEART DISEASE. Please record the number of times that you used each and how much you paid of your own money for each service.

□I used **NO** community services in the last 6 months because of heart disease.
Please go to Question 20.

OR list the services you used IN THE LAST 6 MONTHS below

1. Service_____ Times used____ Total Cost to you: $_____

2. Service_____ Times used_____ Total Cost to you: $_____

3. Service_____ Times used_____Total Cost to you: $_____

4. Service_____ Times used_____Total Cost to you: $_____

5. Service_____ Times used_____Total Cost to you: $_____

20. Difficulty working

During the past 6 months, did you have any difficulty working at your paid employment **because of your heart disease or its treatment?**

□ I was unemployed or retired during the past 6 months.
Please go to Question 21.

□ NO, no difficulty working because of heart disease
Please go to Question 21.

□ **YES,** I had difficult working
Total time you had difficulty working: _____days and/or _____ hours

By approximately what percent was your working capacity reduced during this time?
_____%

21. Household chores

During the past 6 months, were you unable to do chores around the house (such as housecleaning, shovelling snow, running errands) **because of your heart disease?**

□ I cannot do chores because of another illness or disability, **or** I do not have any household chores to do

Please go to Question 22.

□ NO, I had no problem doing chores.
Please go to Question 22.

□**YES**, I was unable to do chores because of heart disease.

Total time you could not do chores: _____days and/or _____hours
Total amount of time that other people did chores for you in the last 6 months, **without** pay from you:
□ None **OR** _____days and/or _____hours

Total amount of **your own money** you paid people to do chores for you in the last 6 months:
□ None **OR** $ _____

22. Leisure activities
During the past 6 months, did you have any problems participating in your usual leisure activities **because of your heart disease or its treatment**?

□ NO, I had no problems with leisure activities because of heart disease in the last 6 months
Please go to Question 23

□ **YES,** I had problems with leisure activities because of heart disease in the last 6 months :

Total amount of time you had difficulty with leisure activities in the last 6 months:
_____days and/or _____hours.

23. Do you have any health care or medical insurance other than that provided by OHIP or the Ontario Drug Benefit Plan?

□ YES □ NO

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APPENDIX H: ECO-PCR Study Follow-Up (52-week) Survey

Heart Wise Exercise
Corps à cœur

Instructions for completing the survey questions appear at the beginning of each section.

Please seal your complete questionnaire in the envelope provided, and

return it to the study coordinator.

DATE COMPLETED: (dd/mm/yyyy) _____

Participant #_____

SECTION C: YOUR QUALITY OF LIFE

Instructions: By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today. [2]

1. Mobility

- ❑ I have no problems in walking about
- ❑ I have some problems in walking about
- ❑ I am confined to bed

2. Self-Care

- ❑ I have no problems with self-care
- ❑ I have some problems washing or dressing myself
- ❑ I am unable to wash or dress myself

3. Usual Activities (*e.g. work, study, housework, family or leisure activities)*

- ❑ I have no problems with performing my usual activities
- ❑ I have some problems with performing my usual activities
- ❑ I am unable to perform my usual activities

4. Pain/Discomfort

- ❑ I have no pain or discomfort
- ❑ I have moderate pain or discomfort
- ❑ I have extreme pain or discomfort

5. Anxiety/Depression

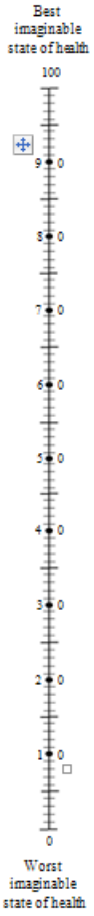
- ❑ I am not anxious or depressed
- ❑ I am moderately anxious or depressed
- ❑ I am extremely anxious or depressed

2 P.Kind. The EuroQol instrument: An index of health related quality of life. Quality of life and PharmacoEconomics in clinical trials. Second edition, edited by B.Spiker. Lippincott-Raven Publishers. Philadelphia 1996.

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

YOUR HEALTH TODAY =



SECTION M: YOUR MEDICATIONS

Please record **all medications**, prescribed by a health professional or bought over-the-counter, that you used **DURING THE LAST 6 MONTHS FOR CARDIOVASCULAR HEALTH.**
Include medications taken for heart disease and its problems (e.g., pain), or problems caused by treatment (e.g. loss of sexual function).

Write the dose used each time (e.g. two 5 mg pills=10 mg) and the number of times used each day. If you used it less often than once per day (e.g., an injection once every 4 weeks), please write this in the space after "Times taken/used per day". If you used more than 6 medications, please write them on the back page. We suggest that you put the medications you have at home in front of you while you answer these questions. Remember to include herbal medicine, skin creams, drops, needles, etc., as well as pills.

- ❑ I used **NO** medications during the last 6 months.

1. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

2. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

3. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

4. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

5. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

6. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

7. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

8. How much **of your own money** did you spend in the last **6** months, with **no reimbursement**, for **all** of your medications? $ _____

SECTION N: CARE & COSTS

We would like to know about the health professionals you saw during **the last 6 months** **BECAUSE OF YOUR CARDIOVASCULAR HEALTH.** It will be easier to answer if you refer to a calendar or appointment list on which you record your appointments. If you did not keep a record, try to remember if any appointments were on or near special days, such as your birthday, or the day of a social event. Please answer the questions below by entering the number of times in the past 6 months that you have:

1. How much did you earn before taxes and other deductions, during the past 12 months?

- ❑ Less than $5,000
- ❑ $5,000 through $11,999
- ❑ $12,000 through $15,999
- ❑ $16,000 through $24,999
- ❑ $25,000 through $34,999
- ❑ $35,000 through $49,999
- ❑ $50,000 through $74,999
- ❑ $75,000 through $99,999
- ❑ $100,000 and greater

		Number of times
2.	Seen your family doctor	_____
3.	Seen a heart specialist	_____
4.	Gone to the Emergency Department	_____
5.	Been admitted to the hospital	_____

6. Have you experienced any of the following heart problems or procedures **in the last 6 months**? (Please check ☑ all that apply):

- ❑ Heart Attack
- ❑ Angina
- ❑ Angioplasty (stent)
- ❑ Bypass Surgery
- ❑ Valve Surgery
- ❑ Heart Failure
- ❑ Heart transplant
- ❑ Pacemaker or implantable cardioverter defibrillator
- ❑ Stroke
- ❑ Peripheral Vascular Disease
- ❑ Ablation
- ❑ Left ventricular assist device
- ❑ Other, please specify: _____
- ❑ None of the above

7. Have you experienced any of the following diagnostic tests **in the last 6 months**? (Please check ☑ all that apply):

- ❑ X-Ray
- ❑ Electrocardiogram (ECG)
- ❑ Blood test
- ❑ Urine test
- ❑ CT Scan
- ❑ Echocardiogram
- ❑ Stress Test
- ❑ Other, please specify: _____
- ❑ None of the above

8. How much **<u>of your own money</u>**, in total, did you pay for these health care visits (eg., transportation, parking, food, lodging), including the money paid by anyone who accompanied you?

- ❑ None **OR** enter amount: $_____

9. How much time was associated with these health care visits (include travel, waiting, etc.)?

_____hours in total

10. In the last **6 months,** who <u>USUALLY</u> accompanied you on these health care visits? Check (√**)** all that apply**.**

- ❑ Nobody; I usually went by myself
- ❑ Partner
- ❑ Son, daughter, or grandchild
- ❑ Sister, brother, friend, or neighbour
- ❑ Volunteer
- ❑ Paid homemaker or caregiver
- ❑ Other, please specify_____

10b. This person's age is: _____years.

10c. This person is: ☐ Male OR ☐ Female

11. **a**. Have you ever smoked cigarettes daily? ☐ Yes ☐ No (if no, move to Q12)

b. At the present time, do you smoke cigarettes? ☐ Every day ☐ Occasionally ☐ Not at all

c. If not at all, when did you stop smoking? _____ (<u>month</u> and <u>year</u>)

12. In the past 6 months, have you had a change in your:

(a) Place of Residence? ☐ Yes ☐ No If yes, please describe: _____

(b) Work Status? ☐ Yes ☐ No If yes, please describe: _____

13. What best describes your occupation at the time of your heart diagnosis?

- ☐ Professional, technical and related (teachers, lawyers, physicians, engineers)
- ☐ Managers, administrators or proprietors (manager, real estate agent, postmasters)

- ☐ Clerical and related (secretaries, clerks, mail carriers)
- ☐ Sales occupations (sales person, demonstrator, agent or broker)
- ☐ Service occupations (police, cook, hairdresser)
- ☐ Skilled crafts, repairer and related (carpenters, telephone line workers)
- ☐ Equipment or vehicle operators and related (drivers, brakemen)
- ☐ Laborers (helpers, longshoremen, warehouse workers)
- ☐ Farmers (owners, managers, operators, tenants)
- ☐ Military
- ☐ Homemaker
- ☐ Not working
- ☐ Retired
- ☐ Other, please describe: _____

14. Did heart disease or its treatment lead you to retirement or disability?
    - ☐ Yes
    - ☐ No
    - ☐ Not applicable

15. How many days of work did you miss since you graduated from cardiac rehabilitation? _____ days

16. If you are not currently working, how many days were you unable to perform your usual activities?

_____ days

17. Have you EVER seen a health professional or had treatment for heart disease OUTSIDE of Ontario?

☐NO - Go to Question 18
☐YES ……continue below

Where (city, province, state, country):_____
When (month and year): From_____ to_____

Type(s) of health professional seen:_____
_____

Treatment(s) you received:_____
_____

If you had other heart disease treatment outside of Ontario, please tell us about it on the back of this page. Describe where, when, who and treatments received.

18. Equipment (aids, devices, household items) bought during the last 6 months

Please list all items you bought during the last 6 months for a problem related to heart disease, and the amount of your own money, if any, that you paid for each.

☐I bought **NO** equipment in the last 6 months because of heart disease.
Please go to Question 19.

1. Item_____ Cost to you: $_____

2. Item_____ Cost to you: $_____

3. Item_____ Cost to you: $_____

4. Item_____ Cost to you: $_____

5. Item_____ Cost to you: $_____

6. Item_____ Cost to you: $_____

19. **Community services used during the last 6 months**

Please list any community services (e.g., home care, meals-on-wheels, transportation) you used in the last 6 months because of a disability RELATED TO YOUR HEART DISEASE. Please record the number of times that you used each and how much you paid of your own money for each service.

□I used **NO** community services in the last 6 months because of heart disease.
Please go to Question 20.

OR list the services you used IN THE LAST 6 MONTHS below

1. Service_____ Times used____ Total Cost to you: $_____

2. Service_____ Times used_____ Total Cost to you: $_____

3. Service_____ Times used_____Total Cost to you: $_____

4. Service_____ Times used_____Total Cost to you: $_____

5. Service_____ Times used_____Total Cost to you: $_____

20. Difficulty working

During the past 6 months, did you have any difficulty working at your paid employment **because of your heart disease or its treatment?**

□I was unemployed or retired during the past 6 months.
Please go to Question 21.

□ NO, no difficulty working because of heart disease
Please go to Question 21.

□ **YES,** I had difficult working

Total time you had difficulty working: _____days and/or _____ hours

By approximately what percent was your working capacity reduced during this time?
_____%

21. Household chores

During the past 6 months, were you unable to do chores around the house (such as housecleaning, shovelling snow, running errands) **because of your heart disease?**

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HEART INSTITUTE
INSTITUT DE CARDIOLOGIE
DE L'UNIVERSITÉ D'OTTAWA

Tracking my Health and Expenses

Instructions: *We would like to know information regarding your health and related expenses. In the table below, please record the date, event details, if the event required you to spend any of your own money, and the amount of your time which was spent. We are especially interested in hearing about:*

- *Visits to your family doctor, heart specialist, or the hospital and if any diagnostic tests were performed*
- *Any changes to your work status*
- *Missed work days due to your cardiovascular health*
- *Days you were unable to perform your usual activities or household chores due to your cardiovascular health*
- *Equipment purchases related to your cardiovascular health (i.e. aids, devices, household items, exercise equipment)*
- *Community services used due to your cardiovascular health (i.e. food delivery services, exercise classes)*

Date	**Event Details**	**Cost to you**	**Time Spent**
Ex: Sept 10, 2012	Visited the Ottawa Heart Institute and completed a stress test on the treadmill	13$ for parking	1 hour

APPENDIX J: Intervention Summary Table

Contact	Format	Duration (min)	Timing relative to CR completion (weeks)	Content	Targeted barriers/facilitators
1	Introduction Session (in person)	60	Baseline	• Introduction to intervention tools and counseling teleconferences • Establish standards and identify potential barriers for exercise adherence • Complete action/coping planning exercise (Goal Setting) • Complete exercise activity inventory • Provide activity diary (Self-Monitoring) • Provide pedometer (Self-Monitoring) • Create awareness for PCR community programs and provide list for Heart Wise exercise programs in community • Exercise safety	• Knowledge/Awareness • Confidence • Motivation • Action planning • Linkages with approved community programs • Social Support • Home exercise equipment • Self-monitoring
2	Small group counseling teleconference	60	1 - 3	• Review activity diary • Identify barriers to exercise adherence experienced to date • Brainstorm solutions to barriers in group • Complete coping planning exercise • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Action planning • Social support • Physical symptoms
3	Community Program Demonstrations (multiple opportunities)	60-90	Every 2-3 weeks for 52 weeks	• Facilitator-lead tour of community exercise facility and orientation to *Heart Wise Exercise* programs occurring at that location • Demonstration of individual exercise opportunities using facility equipment • Overview of program registration procedures • Facilitation of physician referral for interested participants	• Motivation • Social support • Convenient exercise options

				for program or facility enrollment • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	
4	Small group counseling teleconference	60	13	• Review activity diary • Identify barriers to exercise adherence experienced to date • Brainstorm solutions to barriers in group • Complete coping planning exercise • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Action planning • Social support • Physical symptoms
5	Personal telephone call	15-30	20	• Review activity diary • Assess confidence and motivation • Discuss barriers and solutions • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Social support • Physical symptoms
6	Small group counseling teleconference	60	26	• Review activity diary • Identify barriers to exercise adherence experienced to date • Brainstorm solutions to barriers in group • Complete coping planning exercise • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Action planning • Social support • Physical symptoms
7	Personal telephone call	15-30	34	• Review activity diary • Assess confidence and motivation • Discuss barriers and solutions • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Social support • Physical symptoms
8	Small group counseling teleconference	60	39	• Review activity diary • Identify barriers to exercise adherence experienced to date • Brainstorm solutions to barriers in group	• Confidence • Motivation • Action planning

				• Complete coping planning exercise • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Social support • Physical symptoms
9	Personal telephone call	15-30	45	• Review activity diary • Assess confidence and motivation • Discuss barriers and solutions • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Social support • Physical symptoms
10	Small group counseling teleconference	60	50	• Review activity diary • Identify barriers to exercise adherence experienced to date • Brainstorm solutions to barriers in group • Complete coping planning exercise • Discuss past successes and failures • Elicit personal views and discuss benefits of exercise for CAD management	• Confidence • Motivation • Action planning • Social support • Physical symptoms

CAD – Coronary Artery Disease