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Improving Access to Cardiac Rehabilitation Using the Internet: A Randomized Trial

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> ABSTRACT. Cardiac rehabilitation (CR) is essential for secondary prevention, yet only 10%-30% of eligible patients attend as geographical proximity is a major barrier. We evaluated a 'virtual' CR program (vCRP) delivered by the Internet to patients in small urban and rural areas. In our study, in-patients (n=78) with acute coronary syndrome or post-revascularization were randomized to usual care (UC) or vCRP. The vCRP was a four-month program that included heart rate monitoring; physiologic data capture; education sessions; ask-an-expert sessions; and chat sessions with a nurse, exercise specialist and dietitian. Participants were assessed at baseline and four months, and followed for another 12 months. The primary outcome was change in maximal time on the treadmill stress test (MTT) between groups adjusted for age, sex, diabetes status and Internet use for health information. The vCRP resulted in a greater increase in MTT by 45.7 seconds (95% CI: 1.0, 90.5) compared to usual care (p=0.045). Cholesterol levels and dietary quality improved in the vCRP compared to the UC group. Participants perceived the vCRP to be an accessible, convenient and effective way to received healthcare. Eleven (30%) and 6 (18%) participants in the UC and vCRP groups, respectively, had cardiovascular-related events (p=0.275). In conclusion, the vCRP was safe and effective and resulted in sustainable risk reduction without the requirement of face-to-face visits and directly monitored exercise.

Key Words. telemedicine, exercise, risk factors, cardiac rehabilitation

Introduction

Patients with cardiovascular diseases (CVD) are at greater risk of subsequent events, co-morbidities and premature mortality, therefore effective and ongoing management is needed to reduce this risk. Cardiac rehabilitation programs (CRP) are effective at improving lifestyle behaviours and reducing risk factors in CVD patients, as well as reducing CVD events and premature mortality, while being cost-effective [1-4].

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However, as little as 10% to 30% of eligible patients attend these programs [5-9] as the majority of CRP are limited to hospitals in large urban areas with geographical accessibility as one of the main barriers to attendance [10-11].

The proliferation of low-cost communications technology, such as the Internet, has opened up an array of opportunities for patient communication while bridging geographic distance. The Internet holds great promise in improving access to health care services as it is ubiquitous, requires little infrastructure and cost, and is readily scalable to large populations. Despite the enthusiasm for technology supported health care services, the evidence to support such use in cardiac rehabilitation is limited to feasibility and pilot studies [12-15]. We conducted a 16-month randomized controlled trial with blinded outcome assessment consisting of a four-month vCRP with a 12-month sustainability follow-up on exercise capacity and risk factor reduction compared to usual care in patients living in small urban and rural communities without access to standard CRP.

1. Methods

Cardiac in-patients (admitted for either acute coronary syndrome or revascularization procedure) from two hospitals in British Columbia were screened for study eligibility. To be eligible, participants must have resided in either Northern British Columbia, or the Coast Garibaldi region, as these areas are geographically isolated from the metropolitan areas, comprised of significant rural areas and scattered communities and have no outpatient CRP. Patients must have been at low or moderate risk [16], had regular Internet access (home, work or other environment), no physical limitations to regular physical activity and were fluent in English. Patients with previous experience with cardiac rehabilitation, depression, uncontrolled diabetes and other significant comorbidities that may interfere with effective cardiovascular management, pregnant women and those who the attending physician thought were unsuitable for participation were excluded. This study was registered at ClinicalTrials.gov (registration number: NCT00683813) and approved by the Simon Fraser University, Providence Health Care and Northern Health Authority Research Ethics Boards. All participants provided informed consent.

1.1 Outcome Measures

The primary outcome of exercise capacity was determined through a symptom-limited maximal treadmill exercise test using the Bruce protocol [17] and reported as maximal time in seconds as a proxy indicator. The study was powered to detect a clinically relevant difference (delta) of 60 seconds between the groups considering both the 4-month and 16-month time points. Total cholesterol, HDL-C, triglycerides and blood glucose were assessed from fasting blood samples collected in the morning. Blood pressure was assessed using the BpTRU (model BPM-200, VSM MedTech Ltd.) oscillometric office BP monitor [18] and taken as the average of five measures in the left arm following 10 minutes of seated rest. Smoking status was determined by self-report. Body mass index was calculated from weight in kilograms divided by height in metres squared. Weight was assessed with participants in light street clothing, footwear removed and pockets emptied. Waist circumference was recorded in centimetres as the average of two measures taken at the point of maximal narrowing against the skin

following a normal expiration. Physical activity was determined by the 4-week modified Minnesota LTPA questionnaire and reported as the average weekly kilocalories (kcal/wk) expended [19]. From this questionnaire we further determined leisure time physical activity by removing the categories regarding lawn and garden, and home repair activities as well as any household or work related activities. Diet was reported as percent daily kilocalories fat, protein and carbohydrates using a three-day food record [20] analyzed by a registered dietitian using the ESHA Food Processor SQL Software (Salem, OR). Hospital admissions and emergency room visits were identified by patient self report and confirmed through collection of medical records. These medical records were adjudicated by the study cardiologist (AI) blinded to the participant group assignment and categorized into emergency room visit events only and major cardiovascular events (revascularization, unstable angina requiring hospitalization, stroke and death of any kind).

1.2 Study Procedures

Following baseline assessment, participants were randomized (1:1) to either usual care or the 'virtual' cardiac rehabilitation program (vCRP). The randomization research coordinator informed the participants of their group assignment.

Participants randomized to usual care (care from their primary care physician) were given simple guidelines for safe exercising and healthy eating habits, and a list of Internet-based resources. Apart from the study follow-up assessments, there was no contact between the study personnel and the usual care participants for the duration of the study, nor was there any attempt to control for the level of patient care.

Participants randomized to the intervention were registered to the vCRP website with a unique username and password, and received an off-the-shelf heart rate monitor (Polar s610i) and a home blood pressure monitor (Lifesource UA779) for the intervention. Participants underwent a 30 minute in-person training session following their randomization on the use of the vCRP, heart rate monitor and blood pressure monitor. The vCRP included on-line intake forms (medical, risk factor and lifestyle forms), scheduled one-on-one chat sessions with the program nurse case manager, exercise specialist and dietitian (three times each during the 12 weeks), weekly education sessions in the form of interactive slide presentations, data capture for the exercise stress test and blood test results, progress notes (for health professionals), and monthly ask-an-expert group chat sessions.

Upon logging in participants were directed to the webpage that corresponded to their week in the vCRP. This page displayed the tasks that needed to be completed for each week. The one-on-one chat sessions were used to discuss progress, any change in symptoms, provide exercise prescription, dietary recommendations, and risk factor management. The heart rate monitor allowed for exercise heart rate data to be stored and downloaded to the patient's home computer and then uploaded to the vCRP webserver. Participants were asked to wear their heart rate monitors when exercising and upload their exercise data at least twice per week onto the vCRP. In addition, they were to enter their weight, pre- and post-exercise blood pressure, and random glucose (if diabetic) twice per week for 2 weeks, once per week for 2 weeks and once per month thereafter, unless instructed otherwise by the nurse case manager.

Participants from both groups returned for a follow-up assessment after four months. After this time, participants in the vCRP group were graduated from the program and returned to usual care. vCRP participants underwent a semi-structured, open-ended interview at the end of the intervention to assess patient satisfaction and attitudes. After another 12 months, all participants returned for a subsequent final assessment.

1.3 Statistical Analyses

Distributions of continuous variables are reported as median and interquartile ranges (25th and 75thpercentiles) while counts and percentages are reported for the categorical variables. In order to account for the correlations between multiple measures within an individual, linear mixed effects models were used to compare the group differences over time. Follow-up assessments (i.e. measures at 4 months and 16 months from baseline) were taken as the outcome while adjusting for the baseline value to capture the true intervention effect using intent-to-treat analysis. Age, sex, type 2 diabetes and Internet use for health information, were chosen for the multivariate models. These covariates were chosen due to their relationship with the primary outcome. Comparisons of dichotomous outcomes between groups were made using the Fisher's exact test. P-values less than 0.05 were considered statistically significant. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC).

2. Results

A total of 78 participants were recruited and randomized to usual care (n=40) or the vCRP (n=38). Participants were well balanced with respect to the demographic variables except for family history of CVD and current diagnosis of type 2 diabetes (Table 1).

	Usual Care	Intervention
	(n=40)	(n=38)
Age	58.4 (52.8, 64.7)	61.7 (51.3, 65.2)
Male	32 (80%)	34 (90%)
Education		
Less Than High School	9 (23%)	8 (21%)
High School	8 (20%)	10 (26%)
Some Post-Secondary	9 (23%)	9 (24%)
Post-Secondary Degree/Diploma	10 (25%)	9 (24%)
Post-Graduate Degree	4 (10%)	2 (5%)
Average Annual Household Income		
<\$20,000	2 (5%)	3 (8%)
\$20,000 to \$30,000	2 (5%)	1 (3%)
\$30,000 to \$40,000	2 (5%)	4 (11%)
\$40,000 to \$50,000	1 (3%)	0 (0%)
\$50,000 to \$60,000	5 (14%)	4 (11%)
>\$60,000	25 (68%)	25 (68%)
Marital Status		
Single	1 (3%)	2 (5%)
Common Law	1 (3%)	3 (8%)
Married	35 (88%)	29 (76%)
Divorced	1 (3%)	3 (8%)
Widowed	2 (5%)	1 (3%)
Family History	14 (35%)	20 (53%)

 Table 1. Baseline demographics and medical history of the two study groups.

Reason for Admission		
Myocardial Infarction	19 (48%)	17 (45%)
CABG	7 (18%)	11 (29%)
Angioplasty	24 (60%)	21 (55%)
Other Heart Condition	4 (10%)	11 (29%)
Diabetes Personal History	4 (10%)	11 (29%)
Post-menopausal (women)	6 (75%)	4 (100%)
Northern BC Recruitment Site	28 (70%)	27 (71%)

Note: continuous variables reported as median and inter-quartile ranges.

Internet access and use at baseline were similar between the two groups apart from a higher rate of accessing the Internet for health information in the vCRP group (data not shown). The baseline values of the primary outcome of maximal time on the treadmill and the secondary outcomes were clinically similar between the groups (Table 2).

	Usual Care	Intervention
	(n=40)	(n=38)
Total time on exercise stress test (seconds)	543 (430, 581)	545 (446, 578)
Total cholesterol (mmol/L)	3.47 (2.96, 4.39)	3.60 (2.95, 4.47)
LDL-C (mmol/L)	1.81 (1.51, 2.21)	1.84 (1.33, 2.31)
HDL-C (mmol/L)	1.02 (0.82, 1.30)	1.00 (0.86, 1.26)
Triglycerides (mmol/L)	1.26 (0.96, 1.61)	1.50 (0.96, 2.35)
Total cholesterol/HDL-C	3.22 (2.70, 4.36)	3.38 (2.78, 4.11)
Blood glucose (mmol/L)	5.5 (5.0, 6.1)	5.8 (5.2, 6.5)
Systolic blood pressure (mmHg)	115 (109, 130)	122 (109, 133)
Diastolic blood pressure (mmHg)	76 (69, 83)	76 (69, 85)
Smoking status		
Never	10 (25%)	12 (32%)
Former	28 (70%)	23 (61%)
Current	2 (5%)	3 (8%)
Body mass index (kg/m ²)	29.7 (27.3, 33.6)	29.9 (26.2, 33.1)
Waist circumference (cm)	103.7 (96.4, 111.1)	102.9 (95.5, 114.2)
Leisure time physical activity (kcal/week)	1130 (583, 2169)	1300 (724, 2761)
Dietary intake		
Carbohydrate (% kcal/day)	43.4 (40.5, 48.3)	49.2 (45.4, 52.5)
Protein (% kcal/day)	17.8 (16.0, 20.9)	17.8 (15.1, 21.4)
Fat (% kcal/day)	35.0 (31.4, 42.1)	30.2 (26.3, 34.5)
Saturated fat (% kcal/day)	10.9 (8.0, 12.0)	8.3 (6.2, 11.0)

Table 2. Baseline risk factors of the two study groups.

The median number of website logins per person was 27 (range: 0 to 140), while the median values for exercise sessions and blood pressure measures uploaded was 22 (range: 0 to 138) and 3 (range: 0 to 9), respectively. There were 122 one-to-one private chat sessions between the vCRP participants and either the nurse, dietitian or exercise specialist, which averages to 3.6 per participant. The average participant utilized 2.4, 2.6 and 2.7 hours of nursing, dietitian and exercise specialist time, respectively.

After adjustment for the maximal time on the treadmill at baseline, age, sex, type 2 diabetes and Internet use for health information, participants in the vCRP had a greater increase in maximal time on the treadmill by 45.7 (95% CI: 1.04, 90.48) seconds compared to the usual care group over the 16 months (p=0.045) (Figure 1). Total cholesterol and LDL-C were 7% (p=0.026) and 12% (p=0.022) lower, respectively, in

the vCRP group. These differences were no longer significant when adjusted for potential confounders. Participants in the vCRP group had 1.6% kcal/day higher dietary protein and 1.4% kcal/day lower dietary saturated fat compared to the usual care participants, p=0.04 and p=0.018, respectively, and these differences remained significant after adjusting for confounders, p=0.03 and p=0.018, respectively.

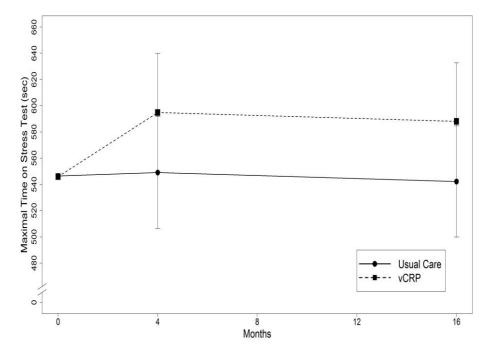


Figure 1. Maximal time on the treadmill exercise stress test over the 16-month study for the vCRP group (dashed line, square markers) and the usual care group (solid line, diamond markers). Data and 95% confidence intervals were determined from the linear mixed effect model (p=0.045 for difference between groups).

There was a non-significantly greater number of patients with at least one emergency room visit or major event in the usual care group compared to the vCRP (11 [30%] vs. 6 [18%], respectively, p=0.275). Taking into account all events (including multiple events for the same participant), there were 22 events in the usual care group compared to 8 in the vCRP group.

From the interviews, participants perceived the vCRP to be an accessible, convenient and effective way to deliver healthcare services. A key benefit was seen to be the easy access to vCRP health professionals. Participants reported greater awareness and motivation to manage their health condition and adopt healthier lifestyles through participation in the vCRP. As a result, many of the participants expressed feeling confident and reassured, and more attuned to self-management activities. The majority of participants reported that they felt their health had improved.

3. Discussion

The four-month vCRP was safe and superior to usual care in reducing CVD risk by improving exercise capacity, cholesterol and dietary factors. These findings were reinforced by patients reporting that the vCRP improved their access to health care, provided greater awareness of their condition and supported self-management. The vCRP was delivered with a minimal use of health human resources, which was calculated as less than eight hours of staff time per patient, compared to a standard of 40 to 60 hours of onsite time for a standard 12 to 16-week CRP.

Previous studies have found that an increase in exercise capacity of 1 metabolic equivalent (3.5 mL/kg *min) was associated with a 12% to 50% reduction in mortality.²²⁻²³ Given this association, our observation of an improvement of 46 seconds (approximately 0.77 metabolic equivalents or 2.7 mL/kg *min) on the exercise stress test greater than that of the usual care group is clinically relevant and translates to a 9% to 38% reduction in mortality. Of importance is that the benefits of the vCRP were sustained for a 12-month period after removal of the four-month intervention. This is a key finding as recidivism in cardiac rehabilitation is commonplace following completion of a program,²⁴ and indeed, the drop-out rates in these programs are as high as 35%.²⁵

To our knowledge, only one randomized study previously investigated the use of the Internet for cardiac rehabilitation remotely,¹⁴ which comprised of online chats between patients and nurses/dietitians, online educational resources and financial incentives for participation. After six months, there was no difference in exercise capacity and the only parameter to improve compared to the control group was weight reduction. These results may reflect the limited nature of their program; there was no formal multi-factorial intervention, nor did the intervention provide a structured, monitored exercise program. Our vCRP consisted of similar components but also included exercise data monitoring and exchange of other physiological markers making it more reflective of comprehensive CRP.

While a number of communication technology mediums exist (telephone, videoconferencing, telemonitoring), we chose to use a web-based program delivered through the Internet as it is 1) commonly available in people's homes, 2) requires less capital expense than more costly options such as telemonitoring devices, 3) is more convenient than video-conferencing programs that require patients to travel to a central location and 4) the technology is readily scalable to large patient populations without further incurring additional technology costs. While home Internet access has been found to be lower in older age groups it has been steadily increasing in this group.²⁶ Indeed the lower prevalence in older adults is likely a cohort effect rather than an age effect per se, such that as adults in their 50s and 60s get older, their use of the Internet will likely continue, making this modality a viable medium to reach a large patient population.

Conclusions

In our study, we found that a cardiac rehabilitation program delivered exclusively through the Internet to patients in small urban and rural locations was safe and effective at providing sustainable improvements in exercise capacity and reductions in CVD risk. Not only does our vCRP have the potential to improve patient access to proven care, it did so requiring minimal health human resources; less than an average of eight

hours of staff time were needed per patient making this model of care cost efficient and readily sustainable. These results indicate that a low-cost technology such as the Internet can be used safely and effectively in remotely delivering cardiac rehabilitation to patients without the requirement of face-to-face visits and directly monitored exercise.

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Disclosures

Clinical Trial Registration: www.ClinicalTrials.gov (registration number: NCT00683813).

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