Innovations in Care

Randomized Trial of a Virtual Cardiac Rehabilitation Program Delivered at a Distance via the Internet

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Goals and Vision of the Program
With an aging population in many Western countries and increases in risk factors such as obesity, the number of patients with cardiovascular diseases (CVDs) is increasing.1 These patients are at greater risk of subsequent events, comorbidities, and premature mortality, therefore effective and ongoing management is needed to reduce this risk. Cardiac rehabilitation programs (CRPs) are effective at improving lifestyle behaviors and reducing risk factors in patients with CVD, as well as reducing CVD events and premature mortality, while being cost-effective.2,3 As a result, the American Heart Association, and others, have highlighted participation in CRP as an essential element of secondary prevention in patients with CVD.4-6

Despite the known benefits of CRP, as little as 10% to 30% of eligible patients attend these programs.9-13 The majority of these programs are limited to hospitals in large urban areas with geographical accessibility as one of the main barriers to attendance.14,15 Lack of access is more pronounced for patients in rural areas that do not have CRP,16,17 although risk factors such as smoking and obesity are higher in rural populations18 resulting in a greater rate of hospitalizations than urban populations.19 Home-based CRP have been developed to address the accessibility issue, and a review of these studies found no difference to hospital-based CRP with respect to improvements in CVD risk.20 However, these programs generally consist of a mix of on-site exercise sessions, clinic or home visits, telephone calls from staff, and diaries, which still 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.

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 healthcare services as it is ubiquitous, requires little infrastructure and cost, and is readily scalable to large populations. Despite the enthusiasm for technology supported healthcare services, the evidence to support such use in cardiac rehabilitation is limited to pilot studies.21-24 As a result, a recent American Heart Association Presidential Advisory has called for more robust research to test the feasibility and effectiveness of Internet-based CRP.25 Our goal therefore, was to test the clinical effectiveness of a virtual CRP (vCRP) delivered exclusively using Internet-based technology.

Local Challenges in Implementation
A common challenge to the implementation of CRP is the cost of their implementation despite having been demonstrated to be cost-effective.3 This challenge also holds true for technology-based solutions. Although several communication technology mediums exist (telephone, video-conferencing, and 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.

A potential barrier of using Internet-based technology is that access has been found to be lower in older age groups.26 To assess this, we conducted a survey of cardiac inpatients in our target hospitals in which we found that as many of 66% had home Internet access.27 Of these patients, >70% reported using the Internet to access health-related information. It has also been suggested that the lower access in this population 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 continue. This is reflected by Internet access increasing as adults in their 50s and 60s get older, their use of the Internet will continue. This is reflected by Internet access increasing as adults in their 50s and 60s get older, their use of the Internet will continue. This is reflected by Internet access increasing as adults in their 50s and 60s get older, their use of the Internet will continue.

Design of the Initiative
To address the above challenges and gaps in access to CRP, we developed and conducted a 12-week pilot study of the vCRP in 8 cardiac patients on the waitlist for our hospital-based CRP.

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Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00683813.
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This allowed us to assess the ease of use, as well as patient safety in an environment whereby we could bring patients immediately into our CRP if needed. The results of our pilot indicated the vCRP was safe, had high user acceptance, and demonstrated improvements in exercise capacity and risk factor reduction similar to a standard hospital-based CRP. Based on these findings, we further developed the vCRP to be evaluated in patients living in small urban and rural communities without access to standard CRP.

The vCRP was revised with input from physicians and allied health professionals with experience in delivering CRP and expanded to 16 weeks to mimic a standard hospital-based CRP. The vCRP included online intake forms (medical, risk factor, and lifestyle forms), scheduled one-on-one chat sessions with the program nurse case manager, exercise specialist and dietitian (3x each during the 16 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.

On initiation, participants were provided 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. A 30-minute in-person training session on the use of the vCRP, heart rate monitor, and blood pressure monitor was also provided. When logging in, participants were directed to the webpage that corresponded to their week in the vCRP on logging in. 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. These sessions lasted ≥1 hour; however, participants could also access the vCRP health staff via email. 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 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 on to the vCRP. In addition, they were to enter their weight, pre- and postexercise 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. In addition, the family physicians of participants were sent a letter at the start of the vCRP informing them of their patient’s participation and indicating under what circumstances the vCRP nurse and patient may contact them with regard to their care if further medical management was warranted. The vCRP remains the intellectual property of lead author Lear and it is not yet in the public domain. Questions on its use can be directed to the corresponding author.

The vCRP was evaluated in a 16-month randomized controlled trial with blinded outcome assessment consisting of a 4-month vCRP with a 12-month sustainability follow-up on exercise capacity and risk factor reduction compared with usual care. To do so, consecutive cardiac inpatients from either a tertiary care hospital in Vancouver, British Columbia, or the regional hospital in Northern British Columbia were screened for study eligibility. Participants must have resided in either the region serviced by the Northern Health Authority of British Columbia, which has just >300,000 people living in an area the size of France, or the Coast Garibaldi region, which is inaccessible by road, and residents must travel by either air or ferry to reach the Vancouver area. These areas are geographically isolated from the metropolitan areas, comprise of significant rural areas and scattered communities, have no outpatient CRP, and at the time of the study there were no cardiologists serving these areas. Patients must have been admitted for either acute coronary syndrome or revascularization procedure, be at low or moderate risk based on the American Association of Cardiovascular and Pulmonary Rehabilitation guidelines at the time, had regular Internet access (home, work, or other environment), no physical limitations to regular physical activity, and be fluent in English. Patients with previous experience with cardiac rehabilitation, depression, uncontrolled diabetes mellitus, 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 Healthcare and Northern Health Authority Research Ethics Boards All participants provided informed consent.

**Primary Outcome**

The primary outcome of exercise capacity was determined through a symptom-limited maximal treadmill exercise test using the Bruce protocol and reported as maximal time in seconds as a proxy indicator. As participants were recruited across diverse geographical locations in the province, a total of 4 sites were used to assess exercise capacity. Each participant completed all 3 of their assessments at the same site and the stress test technicians were blinded to the participant’s group assignment.

The study was powered to detect a clinically relevant difference (Δ) of 60 seconds between the groups considering both the 4- and 16-month time points. This difference corresponds approximately to 1 to 1.5 metabolic equivalents on the Bruce protocol, which translates to a predicted 12% to 50% mortality reduction. Using a SD of 77 seconds from our pilot, a power of 0.80, a total of 33 participants were required in each group. Accounting for a drop-out rate of 15%, a total of 38 participants were needed in each group for a total study cohort of 76.

**Secondary Outcome Measures**

Total cholesterol, high-density lipoprotein cholesterol, triglycerides, and blood glucose were assessed from fasting blood samples collected in the morning. Low-density lipoprotein cholesterol was calculated using the Friedewald equation. Blood pressure was assessed using the BpTRU (model BPM-200, VSM MedTech Ltd.) oscillometric office blood pressure monitor and taken as the average of 5 measures in the left arm after 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 meters squared.
Weight was assessed with participants in light street clothing, footwear removed, and pockets emptied. Waist circumference was recorded in centimeters as the average of 2 measures taken at the point of maximal narrowing against the skin after a normal expiration. Leisure time physical activity (LTPA) was determined by the 4-week modified Minnesota LTPA questionnaire after removing the categories on lawn and garden and home repair activities as well as any household or work-related activities and reported as the average weekly kilocalories (kcal/wk) expended. Diet was reported as percent daily kilocalories fat, protein, and carbohydrates using a 3-day food record 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 (A.I.) 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).

**Study Procedures**

A baseline assessment consisting of participant demographics, medical history, exercise stress test, and all other outcome measures was conducted before randomization. Participants were then randomized (1:1) to either usual care or the vCRP (as described above). Randomization was stratified by site using variable block sizes of 2, 4, and 6. The random allocation was computer generated by a statistician unassociated with the trial who was the only one to have access to the list during the study. The list was incorporated into a telephone randomization system to which the randomization research coordinator called for treatment allocation. The randomization research coordinator informed the participants of their group assignment.

Usual care consisted of patients receiving care from their primary care physician and participants 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 from both groups returned for a follow-up assessment after 4 months. After this time, participants in the vCRP group were graduated from the program and returned to usual care. vCRP participants underwent a semistructured, open-ended interview at the end of the intervention to assess patient satisfaction and attitudes. Interviews were conducted by a trained research coordinator using questions developed in consultation with the research team and key stakeholders. Interviews were digitally recorded and transcribed verbatim. The computer-aided data analysis software program NVIVO8 (QSR, n.d) was used to facilitate the management and storage of the interview transcripts. In line with the qualitative descriptive approach, interview data were analyzed and coded. Emerging data and codes were compared using the constant comparison technique and common descriptive themes were identified. Peer checking of the ongoing analysis was undertaken to promote accuracy and rigor. The final number of interviews was driven by the prospective discovery of factors (or concepts) that may affect patients’ satisfaction with care provided through the vCRP. After another 12 months, all participants returned for a subsequent final assessment.

**Statistical Analyses**

Distributions of continuous variables are reported as median and interquartile ranges (25th and 75th percentiles), whereas counts and percentages are reported for the categorical variables. The primary outcome of interest, maximal time on Figure 1. Diagram of participant flow through the study.
the treadmill, was normally distributed. However, some of the secondary outcomes required natural log transformation before analyses. 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 (ie, 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. That is, participants who completed ≥1 follow-up assessment contributed to the analyses based on their assigned allocation. As there were no significant differences in baseline characteristics based on follow-up status, it was assumed data were missing at random.

Age and sex were identified a priori as covariates, and baseline differences in type 2 diabetes mellitus and Internet use for health information were included as these differences were considered clinically relevant. Comparisons of dichotomous outcomes between groups were made using the Fisher exact test. P values <0.05 were considered statistically significant. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC).

### Implementation of the Initiative

Potentially eligible participants were recruited from February 2009 to April 2011. During this time, 78 participants were recruited and randomized to usual care (n=40) or the vCRP (n=38). Figure 1 outlines the participant flow for recruitment and follow-up for the study. The participants were well balanced with respect to the demographic variables except for family history of CVD and current diagnosis of type 2 diabetes mellitus (Table 1). Internet access and use at baseline were similar between the 2 groups apart from a higher rate of accessing the Internet for health information in the vCRP group (Table 2). The baseline values of the primary outcome of maximal time on the treadmill and the secondary outcomes were clinically similar between the groups (Table 3).

Adherence to the vCRP intervention was based on website usage from the 34 completing vCRP participants. The median number of website logins per person was 27 (range, 0–140), whereas the median values for exercise sessions and blood pressure measures uploaded were 22 (range, 0–138) and 3 (range, 0–9), respectively. One participant did not log on to the website at all during the intervention. A total of 41% of vCRP participants uploaded ≥32 exercise reports equating to an average of 2 exercise bouts per week. A total of 26% of vCRP participants uploaded the required 8 blood pressure reports. There were 122 one-to-one private chat sessions...
Table 3. Baseline Risk Factors of the 2 Study Groups

<table>
<thead>
<tr>
<th></th>
<th>Usual Care (n=40)</th>
<th>Intervention (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time on exercise stress test, s</td>
<td>543 (430, 581)</td>
<td>545 (446, 578)</td>
</tr>
<tr>
<td>Total cholesterol, mmol/L</td>
<td>3.47 (2.96, 4.39)</td>
<td>3.60 (2.95, 4.47)</td>
</tr>
<tr>
<td>LDL-C, mmol/L</td>
<td>1.81 (1.51, 2.21)</td>
<td>1.84 (1.33, 2.31)</td>
</tr>
<tr>
<td>HDL-C, mmol/L</td>
<td>1.02 (0.82, 1.30)</td>
<td>1.00 (0.86, 1.26)</td>
</tr>
<tr>
<td>Triglycerides, mmol/L</td>
<td>1.26 (0.96, 1.61)</td>
<td>1.50 (0.96, 2.35)</td>
</tr>
<tr>
<td>Total cholesterol/HDL-C</td>
<td>3.22 (2.70, 4.36)</td>
<td>3.38 (2.78, 4.11)</td>
</tr>
<tr>
<td>Blood glucose, mmol/L</td>
<td>5.5 (5.0, 6.1)</td>
<td>5.8 (5.2, 6.5)</td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td>115 (109, 130)</td>
<td>122 (109, 133)</td>
</tr>
<tr>
<td>Diastolic blood pressure, mmHg</td>
<td>76 (69, 83)</td>
<td>76 (69, 85)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>10 (25%)</td>
<td>12 (32%)</td>
</tr>
<tr>
<td>Former</td>
<td>28 (70%)</td>
<td>23 (61%)</td>
</tr>
<tr>
<td>Current</td>
<td>2 (5%)</td>
<td>3 (8%)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>29.7 (27.3, 33.6)</td>
<td>29.9 (26.2, 33.1)</td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td>103.7 (96.4, 111.1)</td>
<td>102.9 (95.5, 114.2)</td>
</tr>
<tr>
<td>Leisure time physical activity, kcal/wk</td>
<td>1130 (583, 2169)</td>
<td>1300 (724, 2761)</td>
</tr>
<tr>
<td>Dietary intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbohydrate, % kcal/d</td>
<td>43.4 (40.5, 48.3)</td>
<td>49.2 (45.4, 52.5)</td>
</tr>
<tr>
<td>Protein, % kcal/d</td>
<td>17.8 (16.0, 20.9)</td>
<td>17.8 (15.1, 21.4)</td>
</tr>
<tr>
<td>Fat, % kcal/d</td>
<td>35.0 (31.4, 42.1)</td>
<td>30.2 (26.3, 34.5)</td>
</tr>
<tr>
<td>Saturated fat, % kcal/d</td>
<td>10.9 (8.0, 12.0)</td>
<td>8.3 (6.2, 11.0)</td>
</tr>
</tbody>
</table>

HDL-C indicates high-density lipoprotein cholesterol; and LDL-C, low-density lipoprotein cholesterol.

between the vCRP participants and the nurse, dietitian, or exercise specialist, which averages to 3.6 per participant. The average participant used 2.4, 2.6, and 2.7 hours of nursing, dietitian, and exercise specialist time, respectively.

Success of the Initiative

Table 4 shows the simple distributions of the primary and secondary outcomes at each time point for participants included in the analyses in the 2 groups. In unadjusted analyses, total cholesterol (−7.3%; P=0.026), low-density lipoprotein cholesterol (−11.9%; P=0.022), and dietary saturated fat (−1.4% kcal/d; P=0.018) were lower in the vCRP group, whereas dietary protein (1.6% kcal/d; P=0.044) was higher. The lower saturated fat and higher protein intake remained significant after adjusting for confounders, 1.5% kcal/d (P=0.03) and 1.9% kcal/d (P=0.018), respectively.

For the primary outcome, after adjustment for the maximal time on the treadmill at baseline, age, sex, type 2 diabetes mellitus, and Internet use for health information, participants in the vCRP had a greater increase in maximal time on the treadmill by 45.7 (95% confidence interval, 1.04–90.48) seconds compared with the usual care group during the 16 months (P=0.045; Figure 2).

There was a nonsignificantly greater number of unique patients with ≥1 emergency room visit or major event in the usual care group compared with the vCRP (30% versus 18%; P=0.275; Table 5). Taking into account all events (including multiple events for the same participant), there were 22 events in the usual care group compared with 8 in the vCRP group.

A total of 19 vCRP participants underwent exit 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. Sample quotes related to these findings are highlighted:

“Convenience of fitting into your lifestyle is big. Access to numerous experts in one location is also handy.” [participant 107]

“… I knew that by becoming involved with this program that I was going to learn a lot more than if I just had the operation and was left on my own” [participant 208]

“I am becoming more educated on preventative health, so it’s not about, dealing with things after the fact … I looked at it as a gift … I was worried about what it was going to be like after, who I was going to see. This gave me a place to sort of have a central body of information” [participant 208]

Summary of the Experience, Future Directions, and Challenges

The vCRP was safe and superior to usual care in reducing CVD risk and sustaining this reduction. Specifically, we report significant improvements in exercise capacity and dietary quality, with reductions in cholesterol levels. As exercise capacity has a strong association with CVD mortality and is a stronger prognostic indicator than other traditional risk facts,32,33 it provides a robust primary outcome. Previous studies have found that an increase in 60 seconds on the Bruce protocol is approximately an increase of 1 to 1.5 metabolic equivalent,31 which is associated with a 12% to 50% reduction in mortality.32,33 However, our finding of an improvement of 46 seconds above and beyond that of the usual care group is slightly less than this value. These findings were reinforced by patients reporting that the vCRP improved their access to healthcare, provided greater awareness of their condition, and supported self-management. We also observed a nonsignificantly lower event rate. Although this study was appropriately powered with respect to the primary outcome of maximal time on an exercise stress test, it is a small clinical trial and that further study is warranted to determine the reproducibility in a larger population or different settings.

Only a small number of studies have investigated the remote delivery of cardiac rehabilitation, but these studies have been limited to developmental, pilot, and nonrandomized feasibility studies.21,22,39,40 To our knowledge, only 1 randomized study previously investigated the use of the Internet for cardiac rehabilitation remotely,23 which comprised online chats between patients and nurses/dietitians, online educational resources, and financial incentives for participation. After 6 months,
there was no difference in exercise capacity and the only parameter to improve compared with the control group was weight reduction. These results may reflect the limited nature of their program; there was no formal multifactorial 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.

Of importance is that the benefits of the vCRP were sustained for a 12-month period after removal of the 4-month intervention. This is a key finding because recidivism in cardiac rehabilitation is commonplace after completion of a program, and indeed, the drop-out rates in these programs are as high as 35%. In our study, <10% of participants withdrew from the intervention; however, as with traditional CRP, the level of engagement with the vCRP varied with 1 participant not logging on to the website at all during the 4 months to

![Figure 2. Maximal time on the treadmill exercise stress test during the 16-month study for the virtual cardiac rehabilitation program (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).](image-url)
 Asking about the role of technology in the delivery of healthcare may be needed to this important risk factor.44

Index and this is, unfortunately, common in CRP so more counseling in the vCRP, there was no change in body mass index was not. Despite the inclusion of behavioral risk factors such as lipid, glucose, and blood pressure levels at baseline were within desired ranges for many participants, others logging on 8 times times per week. There was similar variability in the number of exercise sessions uploaded. Taken together, the vCRP was delivered with a minimal use of health human resources, which was calculated as <8 hours of staff time per patient, compared with a standard of 40 to 60 hours of onsite time for a standard 12- to 16-week CRP. It is likely that this low amount of human resources reflects the low participation of some of the vCRP participants, and as engagement increases so would the requirement for human resources.

The adoption of technology in the delivery of healthcare has been slow to come to fruition. To date, much of the focus and funding for uses of technology have been targeted toward administrative uses such as electronic medical records, and store and forward of medical imaging, with limited attention to patient-focused uses. This may be in part because of the lack of robust evidence to support the use of technology in delivering healthcare, privacy concerns, the slow process of policy changes, and some resistance to moving to a more consumer-based focus of healthcare. With the increasing prevalence of cardiovascular and chronic diseases, the uptake of technology will be required to ensure the sustainability of healthcare and efforts are needed to change the culture to accept the role of technology in providing patient-focused healthcare.

Although the gold standard for measuring exercise capacity is through direct assessment of VO2 max, it was not feasible to conduct this test because of lack of facilities in the remote areas. We therefore chose to use maximal time on the treadmill exercise test as a proxy for assessing exercise capacity. In addition, only 1 exercise test was conducted per participant at each time period and the exercise tests were conducted in multiple sites; however, these sites were all trained in the appropriate conduct of exercise stress testing and each participant was assessed at the same site throughout the study period. Although our reported increase in exercise capacity because of the vCRP is less than what we,43 and others have reported from hospital-based CRP,33 the model of the vCRP, in which patients are exercising on their own in small urban and rural communities, is much different than the standard, medically supervised CRPs in which patients attend onsite sessions with access to a variety of exercise equipment. Of note is that we observed limited improvement in other risk factors, whereas risk factors such as lipid, glucose, and blood pressure levels at baseline were within desired ranges for many participants, body mass index was not. Despite the inclusion of behavioral counseling in the vCRP, there was no change in body mass index and this is, unfortunately, common in CRP so more attention may be needed to this important risk factor.44

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. This occurred requiring minimal health human resources; less than an average of 8 hours of staff time were needed per patient making this model of care cost efficient and readily sustainable. These results are promising and suggest that a low-cost technology such as the Internet can be used safely and effectively in remotely delivering cardiac rehabilitation; however, future studies are needed to assess reproducibility in other populations and the impact on CVD events.

Table 5. Occurrence of Cardiovascular-Related Emergency Room and Major Events in Unique Patients

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Usual Care (n=37)</th>
<th>Intervention (n=34)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency room events</td>
<td>8 (22%)</td>
<td>4 (12%)</td>
<td>0.349</td>
</tr>
<tr>
<td>Major events†</td>
<td>6 (16%)</td>
<td>3 (9%)</td>
<td>0.482</td>
</tr>
<tr>
<td>Total events</td>
<td>11 (30%)</td>
<td>6 (18%)</td>
<td>0.275</td>
</tr>
</tbody>
</table>

Event count categorized on the basis of ≥1 event vs no events per person.

* Determined by Fisher exact test.
† Revascularization, unstable angina requiring hospitalization, stroke, and death of any kind.

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Disclosures

None.

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