Enhancing Quality of Life through a Supervised Cardiac Rehabilitation Program along with a conventional conditioning exercise program at home in Cardiovascular Disease Patients.

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Abstract

Aims & Objective: Debilitating day-to-day practices, including a sedentary lifestyle, increased unhealthy food consumption habits, no exercise, smoking, remarkably low HDL, and high cholesterol levels, lead to increased obesity, diabetes, and cardiovascular diseases (CVD), affecting the quality of life. Supervised, steady, and long-term aerobic exercise training benefits cardiorespiratory fitness, psychological status, and quality of life. Therefore, the study’s objective was to determine the effect of cardiac rehabilitation program (CRP) on heart rate (HR), systolic and diastolic blood pressure (SBP and DBP), and quality of life (QOL) in CVD patients. Methodology: The study followed a two-arm parallel group randomized comparative design. Thirty participants (n=15/group) with CVD were randomly allocated to two groups. CRP Group received the CRP and a conventional conditioning exercise program at home and the Control Group received the conventional program at home. The outcomes, HR, SBP, DBP, and QOL, were assessed using a sphygmomanometer and short-form 36 (SF-36) questionnaire’s physical component summary (PCS) and mental component summary (MCS) scale, respectively. Results: The mean scores comparison of the outcomes, HR, PCS, and MCS, were found significant (95% CI, p<0.05) within CRP and Control groups; however, SBP and DBP mean scores were found insignificant (95% CI, p>0.05) within both groups, except DBP mean score which was found significant (p<0.05) within CRP Group. Comparing the outcomes mean scores between the groups at four-week post-intervention, except PCS and MCS (95% CI, p<0.05), HR, SBP, and DBP were found to be insignificant (p>0.05). Conclusions: The CRP and conventional CEP at home together and conventional CEP at home alone were equally effective in decreasing HR and improving QOL in CVD patients. However, the CRP and conventional CEP at home together showed more effectiveness than the conventional CEP at home in improving the QOL in CVD patients.

Keywords: Cardiac rehabilitation program, conditioning exercise program, Hypertension, Quality of life, cardiovascular disease.
Introduction

Cardiovascular disease is a group of disorders that affect the heart and blood vessels. It includes coronary artery disease, heart failure, arrhythmias, and valvular heart disease.\[1\] These conditions can cause various symptoms, including chest pain, shortness of breath, fatigue, and weakness, leading to serious complications such as heart attack and stroke.\[2\] Cardiac rehabilitation programs are designed to help patients with cardiovascular disease manage their condition and improve their overall health and well-being.\[3,4\] These programs typically include exercise training, education on healthy lifestyle choices, and support for managing risk factors such as high blood pressure, high cholesterol, and diabetes.\[5\] Cardiac rehabilitation programs are recommended for patients with various cardiovascular conditions, including those who have had a heart attack, heart surgery, or a heart-related procedure such as angioplasty or stenting.\[6,7\] Cardiac rehabilitation aims to help patients improve their exercise capacity, reduce their symptoms, and improve their overall quality of life.\[4,8,9\] Studies have shown that participation in a cardiac rehabilitation program can significantly improve exercise capacity, reduce the risk of future cardiovascular events, and improve overall health outcomes for patients with cardiovascular disease.\[10-12\] As such, cardiac rehabilitation programs are an important part of managing cardiovascular disease and are recommended by healthcare professionals worldwide.\[9-12\]

Quality of life (QOL) is an important outcome measure in CVD patients. Patients with CVD often experience a reduced QOL due to symptoms such as chest pain, shortness of breath, and fatigue.\[9,12\] Psychological factors such as anxiety and depression can also negatively impact QOL in these patients.\[13\] Improving QOL can help patients to manage their symptoms better, adhere to their treatment plans, and enjoy a more fulfilling life.\[13,14\] Cardiac rehabilitation programs can play a key role in improving QOL in CVD patients. These programs typically include exercise training, education on CVD risk factors and lifestyle modifications, and psychological support.\[3-7\] By improving QOL, cardiac rehabilitation can help to reduce morbidity and mortality in patients with CVD.\[1,9,14\]

The growing body of evidence supports cardiac rehabilitation programs’ beneficial effects on cardiovascular disease patients’ quality of life.\[7-12\] Cardiac rehabilitation programs are designed to help patients with cardiovascular disease improve their physical and psychological well-being through exercise, education, and counseling. While these programs have been shown to reduce the risk of cardiovascular events and improve overall survival rates, the precise mechanisms by which they achieve these benefits are not yet fully understood.15-18 Therefore, to better understand the underlying mechanisms that contribute to the positive outcomes associated with these programs and identify ways to optimize their effectiveness. This study hypothesized that there would be a significant difference in the quality of life in CVD patients following a cardiac rehabilitation program.

Moreover, the results of this study will be particularly relevant given the rising incidence of cardiovascular disease worldwide, as well as the increasing recognition of the importance of lifestyle modifications in its management. Ultimately, this research can help inform the development of more tailored and effective cardiac rehabilitation programs that can improve the health and well-being of cardiovascular disease patients.

Methodology

The study was based on a two-arm parallel group randomized comparative design. The study followed the standard ethical guidelines for conducting human research by the local ethical body. This study was conducted per the declaration of Helsinki (2010). The participants from each group returned with a signed, completed informed-consent form before the beginning of the study. Computer software G*Power 3.1.9.4 was used to estimate the effective sample size. A priori t-test (independent means): computer required sample size- given α (0.05), power (0.95), and effect size (mean 1 ± SD = 259.7 ± 39.17, mean 2 ±4 6.29, d = 1.55). Assuming a 20% sample attrition, a total of twenty-four participants (15/group) were required to satisfy the effective power of the study. The outcomes score of the physical component summary (PCS) of the SF-36 questionnaire was used to calculate the intervention’s effect size.
The CVD patients were approached to participate in the study at the outpatient physiotherapy department, where a consultant physician referred them to receive the cardiac rehabilitation program. The participants were informed of the present study through in-campus posters hanging inside the physician chamber, the physiotherapy department, and outside the hospital premises. The COVID-19 pandemic safety measures were strictly followed to safeguard the study’s participants, assessors, and therapists’ safety. The study was completed within thirteen months, from June 2021 to August 2022.

The study’s participants were screened and recruited based on inclusion and exclusion criteria. The inclusion criteria were as follows: CVD patients, including essential hypertension not greater than 140-159/90-94 mmHg, post coronary artery bypass grafting, Myocardial infarction, peripheral vascular disease, a chronic cerebrovascular accident within 6 to 12 months, and chronic heart disease, aged within 45 to 65 years, ejection fraction greater than 45%, and must pass the exercise stress tests. The exclusion criteria were as follows: participants with uncontrolled diabetes and metabolic disturbances, poorly controlled hypertension, acute cerebrovascular accident, neurological/muscular disorders, uncontrolled arrhythmias, hemodynamically unstable, and showed non-cooperation in the study.

The study utilized a simple random sampling method for randomization, employing a lottery technique to allocate participants into two groups. Participants were randomly assigned to either the experimental group, which received both the Cardiac Rehabilitation Program (CRP) and the Conventional Conditioning Exercise Program (CEP) at home, or the control group, which was limited to the CEP at home. Prior to the commencement of the study, all participants provided signed informed consent forms. A CONSORT (2010) flow diagram presents the study procedures, including enrolment, randomization, allocation, follow-up, and analysis, in Figure 1.

Figure 1: A CONSORT (2010) flow diagram presents the study’s procedures, including enrolment, randomization, allocation, follow-up, and analysis.
The Cardiac Rehabilitation Program (CRP)\textsuperscript{[16–18]}, employed a structured exercise regime for participants, which began with a 10-minute warm-up phase. This phase included simple neck movements, deep breathing exercises, upper limb free exercises, trunk mobility exercises, and knee marching in a standing position with hand support. The conditioning phase, lasting 20 minutes, involved light-weight resistance exercises using 0.5 kg weight cuffs for both upper and lower limbs. Participants completed ten repetitions of each movement per session, supplemented by aerobic training on a treadmill with zero elevation and an intensity set at 70\% of the maximum heart rate for ten minutes per session, as detailed in reference.\textsuperscript{[17]} The session concluded with a 10-minute cool-down phase, incorporating stretching and flexibility exercises for the targeted limbs and muscles. Additionally, participants were advised to engage in regular walking at their own pace for 30 minutes daily.

Concurrently, the Conventional Conditioning Exercise Program (CEP) \textsuperscript{[20]} was implemented for the same duration. This regimen included exercises like simple neck movements, deep breathing exercises, upper limb free exercises, and trunk mobility exercises, with each exercise performed for 10 repetitions, twice daily.

Both the CRP and CEP were followed for three alternate days each week over a 4-week period. Vital parameters such as heart rate, respiratory rate, oxygen saturation, and blood pressure were monitored every 10 minutes during the training sessions to prevent adverse effects, as per the protocol in study.\textsuperscript{[17]} Blood pressure was also recorded at the end of each exercise session in a sitting position. To ensure participant comfort and safety, intermittent rest periods of 5 minutes were provided as needed.

The protocols were explained by a specialist physiotherapist who was not blind to the participants’ group distribution. The participants from the CRP group performed a cardiac rehabilitation program under the supervision of a specialist physical therapist and were instructed to perform conventional CEP at home. However, the participants from the control group were instructed to perform only conventional CEP at home. The stipulated exercise protocol for both groups was advised to continue until three alternate days a week for four weeks. The assistant physiotherapist, who was kept blind to the group allocation, took the outcomes scores at baseline and 4 weeks post-intervention. Two readings were recorded for each outcome score, and the average score of the two readings was taken for the data analysis. The study outcome measures, such as Heart Rate (HR) and Blood Pressure (BP), was measured by a sphygmomanometer; QOL was measured by a short-form 36 questionnaire.\textsuperscript{[19]} Individual subscales and two summary scores, physical component summary (PCS) and mental component summary (MCS) was computed.\textsuperscript{[16,18]} The required data were collected for the given variables and evaluated statistically.

A statistical package for social science version 26 (IBM SPSS Inc. Armonk, USA) was used to analyze the study’s data. A Shapiro-Wilk test of normality was performed to check the normal distribution of the data within each group. An unpaired t-test was used to analyze the between-group comparison for the mean HR, SBP, and DBP scores post-intervention. The between-group factor was time and outcomes, measured at baseline and after 4 weeks for all four dependent variables. A paired t-test was used to analyze the outcomes scores within-group across the two-time points. A non-parametric Wilcoxon-signed test and the Wilcoxon rank-sum test were used to quantify the intervention effects on participants’ QOL within and between groups. For all the statistical analyses, the confidence interval alpha (\(\alpha\)) was set at 95\% to be considered a significant value (\(p<0.05\)).

**Results**

A Shapiro-Wilk normality test revealed a normal distribution for the participants’ characteristics and the baseline scores for all the outcomes. The within-group comparison revealed insignificant differences (95\% CI, \(p>0.05\)) for the outcomes (HR, SBP, and DBP) except PCS and MCS (95\% CI, \(p<0.05\)) when comparing the baseline scores with 4-week post-intervention scores within CRP Group, presented in Table 2. However, except SBP scores (95\% CI, \(p>0.05\)), all the outcomes (HR, DBP, PCS, and MCS) showed significant differences (95\% CI, \(p<0.05\)) within the Control Group compared to the baseline scores with 4-week post-intervention scores, presented in Table 1.
The between-group comparison revealed insignificant differences (95% CI, p>0.05) for all the outcomes (HR, SBP, and DBP) except PCS and MCS (95% CI, p<0.05) compared to the scores between the groups at 4-week post-intervention (CRP vs. Control), presented in Table 2.

Table-1: Within-group comparison for the mean HR, SBP, DBP, PCS & MCS scores.

<table>
<thead>
<tr>
<th>Group</th>
<th>Variable</th>
<th>Mean±SD N=15</th>
<th>Mean±SD N=15</th>
<th>t-test</th>
<th>Wilcoxon Signed-Rank test</th>
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<td><strong>P</strong></td>
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<tr>
<td>Experimental</td>
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<tr>
<td>HR (/m)</td>
<td>87.13 ± 14.71</td>
<td>82.06 ± 14.48</td>
<td>3.134</td>
<td>.007*</td>
<td>--</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>123.66 ± 12.61</td>
<td>120.46 ± 8.13</td>
<td>1.045</td>
<td>.314</td>
<td>--</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>81.33 ± 5.81</td>
<td>78.66 ± 8.54</td>
<td>1.586</td>
<td>.135</td>
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<tr>
<td>PCS</td>
<td>162.27 ± 37.8</td>
<td>297.8 ± 40.32</td>
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<td>3.408</td>
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<tr>
<td>MCS</td>
<td>188.06 ± 82.4</td>
<td>307.98 ± 48.36</td>
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<td>3.409</td>
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<tr>
<td>Control</td>
<td></td>
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<tr>
<td>HR (/m)</td>
<td>84.33 ± 9.80</td>
<td>81.86 ± 7.72</td>
<td>2.581</td>
<td>.022*</td>
<td>--</td>
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<tr>
<td>SBP (mmHg)</td>
<td>123.66 ± 9.67</td>
<td>121.13 ± 8.23</td>
<td>1.363</td>
<td>.194</td>
<td>--</td>
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<tr>
<td>DBP (mmHg)</td>
<td>84.73 ± 10.26</td>
<td>78.33 ± 10.80</td>
<td>2.469</td>
<td>.027*</td>
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</tr>
<tr>
<td>PCS</td>
<td>131.72 ± 31.24</td>
<td>188.76 ± 50.38</td>
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<td>--</td>
<td>3.351</td>
</tr>
<tr>
<td>MCS</td>
<td>130.18 ± 26.99</td>
<td>189.17 ± 55.91</td>
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<td>3.296</td>
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</tbody>
</table>

Key: * - Significant value if p<0.05; HR: heart Rate/minute; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; PCS: Physical Component Summary Scale; MCS: Mental Component Summary Scale; SD: Standard Deviation; /m: per minute; mmHg: millimeter of mercury.

Table-2: Differences between groups at baseline, three weeks, and three months of treatment for three different treatment regimens.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experimental Group Mean±SD N=15</th>
<th>Control Group Mean±SD N=15</th>
<th>t-test</th>
<th>Wilcoxon Signed-Rank test</th>
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<tr>
<td>HR (/m)</td>
<td>82.06 ± 14.48</td>
<td>81.86 ± 7.72</td>
<td>.047</td>
<td>.963</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>120.46 ± 8.13</td>
<td>121.13 ± 8.23</td>
<td>2.23</td>
<td>.825</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>78.66 ± 8.54</td>
<td>78.33 ± 10.80</td>
<td>.094</td>
<td>.926</td>
</tr>
<tr>
<td>PCS</td>
<td>297.8 ± 40.32</td>
<td>188.76 ± 50.38</td>
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</tr>
</tbody>
</table>

Key: * - Significant value if p<0.05; HR: heart Rate/minute; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; PCS: Physical Component Summary Scale; MCS: Mental Component Summary Scale; SD: Standard Deviation; /m: per minute; mmHg: millimeter of mercury.

This study aimed to determine CRP’s effect on CVD participants’ quality of life. During baseline readings, CRP and Control Groups were demographically identical without significant differences in their descriptive statistics.

It has been demonstrated that intense physical activities and fitness minimize the causes of mortality and mortality rate of CVD. Therefore, for health promotion, exercising regularly within intensities ranging from 40 to 90% of the maximum volume of oxygen uptake per minute per kilogram (VO2 max) is endorsed among patients with CVD. However, aerobic, or conditioning exercise programs are often conducted at low to moderate intensities. A previous study has revealed a significant contrary relationship between participation in CRP and reduced progression of CAD.[18]

The results of this randomized controlled study demonstrated that with aerobic exercise training at low to moderate intensities, the enhancement in quality of life was evident in both the groups: the CRP group and the Control group, after a 4-week cardiac rehabilitation program. Within-group analysis (CRP group) revealed a statistically significant result in heart rate (p=.007) and QOL (p=.001). Similar statistically significant results were obtained from the Control
group in heart rate (p=.022) and QOL (P=.000). Strikingly, there was a significant p-value for DBP (p=.022). Heart rate, oxygen saturation, and perceived exertion rate were measured during the running/walking. [21]

The present study is one of the few reported on a four-week multidisciplinary cardiac rehabilitation program. It has been significant in improving the participants’ quality of life. A similar study was conducted for ten weeks, and four weeks of CRP involving CVD patients, including MI and CABG (n=60), and reported that the CRP significantly enhanced the general health, life well-being, and exercise capacity following the CRP within-group. However, insignificant differences were detected between-group analyses. [22] This is consistent with the current study's findings, where no significant results were found in the between-group analysis. But indeed, these data advocate that short-term courses of CRP are advantageous to CVD patients in improving their quality of life and promoting more widespread use of the CRP.

The baseline heart rate and blood pressure readings in all the subjects (n=30) were similar without significant differences. With the improvement in the quality of life, a significant decline in HR was revealed in both groups (p<0.05). Significant changes were seen in the DBP (p=.027) of the Control group in contrast to the CRP group during within-group analysis. In the CRP group, heart rate and blood pressure increased during strength training sessions but returned to their resting levels once the session was over. The increase in SBP during the strength training in the CRP group was due to circulatory changes in response to the training session. There was an increased metabolic demand due to muscle work and improved muscle flow. Arterial vasoconstriction and increased cardiac output, too, resulted in increased heart rate and blood pressure values. [23,24]

A previous study reported that no between-group differences were detected in subjects under a 4-week and 10-week cardiac rehabilitation. [22] These results aligned with the current study, where heart rate and blood pressure declined with no between-group differences. Reduction in blood pressure was also seen in patients with hypertension who underwent short-term endurance training programs after CABG. [25] The decline in blood pressure can be explained due to the relative increase in vagal activity and reduction in sympathetic activity. [25]

In contrast, another study reported on the early short-term intensive cardiac rehabilitation program (2-3 months) in an intervention group (n=105) and control group came up with puzzling results. [26] Smoking cessation influenced the body weight of the experimental group, which was relatively profound. No changes in blood lipid levels were present. It became clear that exercise alone does not impact total or LDL cholesterol except when associated with robust diet modifications. The resting systolic and diastolic pressure was significantly higher. They postulated that the deceptive increase in blood pressure was possible because of the impulsive retrieval of the left ventricular function post-CABG and acute MI. [26]

Quality of life was the main outcome measure of CVD patients in this study. The prime goal of inclusive CRP is to encourage positive lifestyle adaptations and supports CVD patients in incorporating these behaviors into their daily lives. CRP has revealed an improvement in functional capacity and quality of life. [27] The cardiac rehabilitation program has been practiced primarily in supervised institution-based settings. But recently, home-based aerobic exercises have been advocated to be as effective as institution-based cardiac rehabilitation in improving short-term functional capacity, health-related quality of life (HQRL), and perceived social support (PSS) in CVD patients. [28]

The promising effects of the short-term CRP on the PCS and MCS score of SF36 remained significantly higher than the baseline in both groups (p<.05). Both the groups revealed significantly higher physical HRQOL.
per the PCS of the SF36 at baseline and after the completion of the study.

These results of this study are similar to a previous study finding which revealed that if a designated CRP is continued until six months, its observed effects on the study outcomes, including cardiovascular fitness and psychological and vocational status, would be maintained for the next 12 months in the home group while declined in the hospital group. Also supported by another study that revealed maintaining the intervention effects for 1-5 years. Though the current study's duration was relatively small, the results of the above-mentioned studies complied with the current study regarding improved exercise capacity and quality of life in both groups. However, since this study aimed to see the improvement in the participants' quality of life, these findings only strongly support that both the groups maintained a higher PCS and MCS statistically after the between-group analysis was done.

The current study was limited to a relatively short intervention duration and assessment/follow-up program to observe CRP's long-term effects on CVD patients. A Hindi version of the SF 36 questionnaire was not introduced as it could guide more efficiently in matching/ticking the actual problems with the real question, which could bias the results. The study's report generalizability could limit to a particular geographical area as the study sample was taken from one hospital representing a particular local area. Furthermore, educational awareness was not provided on weight management and smoking cessation. Future studies should consider these limitations to observe the long-term effect of the cardiac rehabilitation program, make more aware of weight management and smoking cessation, economic evaluation in terms of cost-effectiveness for each program session, and generalize the reports globally. It should also evaluate the cost-effectiveness of each program session.

**Conclusion**

The cardiac rehabilitation and conventional conditioning exercise program at home together and the conventional conditioning exercise program at home alone were equally effective in reducing heart rate and improving quality of life in cardiovascular diseases patients. However, the cardiac rehabilitation and conventional conditioning exercise program at home together showed more effectiveness than the conventional conditioning exercise program at home alone in improving the quality of life in cardiovascular disease patients. Physical therapists should consider either the cardiac rehabilitation and conventional conditioning exercise program at home together or the conventional conditioning exercise program at home alone, depending on the treatment goals based on the individuals’ assessment.

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**Conflict of interest**

All authors declare no conflict of interest in this study.

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