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ORIGINAL ARTICLE

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Efficiency of the home cardiac rehabilitation program for adults with complex congenital heart disease

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Abstract

Objective: We aimed to study the efficiency and safety of once-a-week outpatient rehabilitation followed by home program with tele-monitoring in patients with complex cyanotic congenital heart disease.

Design: Prospective nonrandomized study.

Method: Patients who have been diagnosed either Eisenmenger's syndrome or inoperable complex cyanotic heart disease and able to attend 12-week cardiac rehabilitation program were included. Training with treadmill walking and bicycling under supervision at cardiac rehabilitation unit once-a-week in the first 6 weeks followed by home-based exercise program (bicycle and walking) with a target at 40%-70% of maximum heart rate (HRmax) at pretraining peak exercise for another 6 weeks was performed in the intervention group. Video and telephone calls were scheduled for evaluation of compliance and complication. Data from cardiopulmonary exercise testing (CPET) on cycle ergometry including peak oxygen consumption (peakVO_2), oxygen pulse (O_2 pulse), ventilatory equivalent for carbon dioxide (VE/CO_2 at anaerobic threshold), constant work-rate endurance time (CWRET) at 75% of peak VO_2, and 6-minute walk distance (6MWD) were compared between baseline and after training by paired *t* test.

Result: Of the 400 patients in our adult congenital heart disease clinic, 60 patients met the inclusion criteria. Eleven patients who could follow program regularly were assigned home program. There was a statistically significant improvement of CWRET, O_2 pulse, and 6MWD after finishing the program (*P* = .003, .039, and .001, respectively). The mean difference of 6MWD change in the home-program group was significantly higher than in the control group (69.3 ± 47.9 meters vs. 4.1 ± 43.4 meters, *P* = .003). No serious adverse outcomes were reported during home training.

Conclusion: Once-a-week outpatient hospital-based exercise program followed by supervised home-based exercise program showed a significant benefit in improvement of exercise capacity in adults with complex cyanotic congenital heart disease without serious adverse outcomes.

KEYWORDS
adult congenital heart disease, complex cyanotic congenital heart disease, Eisenmenger's syndrome, home-based cardiac rehabilitation

1 | INTRODUCTION

The advance in surgical technique and medical treatment has reduced the mortality of children who were born with congenital heart defects. Thus, the prevalence of adult congenital heart disease (ACHD) has been increasing with complex lesions in more than half of these cases.[1] Many abnormalities in complex congenital heart disease such as ventricular dysfunction, pulmonary hypertension, and muscle weakness have contributed to an impairment of physical fitness. Exercise intolerance in ACHD has also led to a poor quality of life.[2,3] Therefore, improving exercise capacity is important in the care of patients with ACHD.

The benefit of cardiac rehabilitation has been proved in patients with heart failure and coronary artery disease.[4,5] In patients with congenital heart disease, cardiac rehabilitation has shown some benefits in not only an increase in exercise capacity but also an improvement of quality of life without serious adverse outcomes. However, most of the studies were performed in pediatric and young adult patients with specific types of disease, mainly in post-Fontan operation and post total repaired tetralogy of Fallot (TOF),[6] whereas most of ACHD patients in developing countries consists of unrepaired complex cyanotic heart disease and Eisenmenger's syndrome.

Even though the recent guideline from European Society of Cardiology has suggested that ACHD patients should receive individual exercise prescription,[7] the full cardiac rehabilitation program is commonly divided into three or four phases[8,9] and requires in-hospital monitoring during the initial phase, especially in complex ACHD. This has made cardiac rehabilitation program in many developing countries difficult to be followed due to a long period of admission. With an improvement of communication technology, telemedicine has become an adjunctive method to a conventional treatment. Systematic review of telemedicine in cardiac rehabilitation showed benefit in improving exercise capacity over standard treatment.[10] We then aimed to study the efficiency and safety of once-a-week outpatient hospital-based exercise program, followed by a supervised home-program with tele-monitoring in patients with complex cyanotic ACHD using cardiopulmonary exercise testing (CPET) parameters and 6-minute walk distance (6MWD) as the outcome measurements.

2 | METHODS

2.1 | Population

Patients with complex cyanotic congenital heart disease as defined by ACC/AHA guideline management for ACHD[11] were identified from Ramathibodi ACHD clinic. Inclusion criteria were; (i) age >18 years old, (ii) inoperable diseases, and (iii) New York Heart Association functional class II-III with stable clinical function at least 3 months without medical adjustment prior to inclusion. Patients who were mentally retarded, clinically unstable, and had uncontrolled arrhythmia were excluded.

To compare the effect of cardiac rehabilitation between patients who underwent the cardiac rehabilitation program (training group) and who did not participate (control group), patients in the control group were defined as patients who met the inclusion criteria but could not attend a 12-week training program and had 6MWD data available at 12-week interval in outpatient clinic. Flowchart of the study is illustrated in Figure 1.

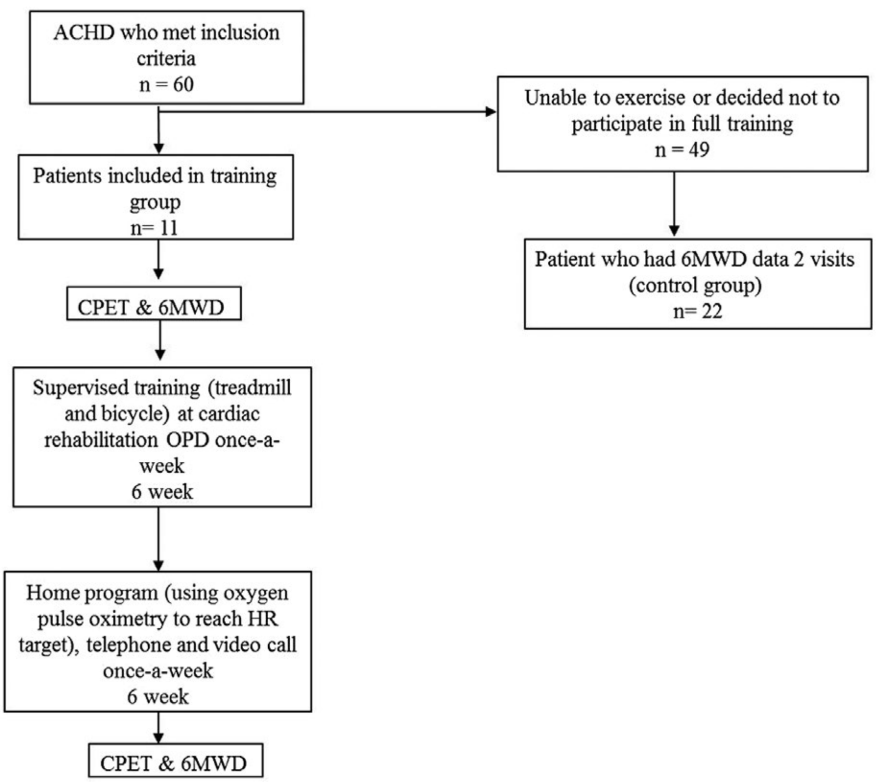

FIGURE 1 Flowchart of the study. Abbreviations: ACHD, adult congenital heart disease; CPET, cardiopulmonary exercise testing; HR, heart rate; OPD, outpatient department; 6MWD, 6-minute walk distance

The study protocol was reviewed and approved by ethical committee of Faculty of Medicine Ramathibodi Hospital, Mahidol University [ID 01-60-10]. Informed consent was given by each patient prior to enter the program.

2.2 | Cardiac rehabilitation program

2.2.1 | Hospital-based phase (total duration of 6 weeks)

The patients received training using once-a-week treadmill walking and bicycling with target heart rate (HR) at 40%-70% of HR at peak oxygen consumption (peakVO_2) determined from CPET. Training intensity started at the heart rate of 40% of the maximal HR in patients with pulmonary hypertension (PHT) and titrated up later, whereas the target heart rate of 70% of the maximal HR was aimed in non-PHT patients. Training was performed at the cardiac rehabilitation center under a supervision of well-trained physicians.

2.2.2 | Home-based phase (total duration of 6 weeks)

After finishing hospital-based training program, home-based exercise program with the same target heart rate as hospital-based phase, 5 days per week and 30 min per period were assigned. All participants received home pulse oximeters and were asked to use it during exercise in order to reach the target HR as prescribed individually. Once-a-week telephone call by ACHD nurses and video call by cardiology fellow were scheduled for monitoring the compliance of exercise training and checking the complications of exercise.

3 | OUTCOMES ASSESSMENT

3.1 | Cardiopulmonary exercise testing and 6MWD

CPET and 6MWD were performed in all patients in the training group before and after finishing 12-week program. The CPET machine, V-Max Encore 229d (VIASYS Healthcare, Conshohocken, Pennsylvania), was used for exercise testing on a cycle ergometry. An exercise protocol consisted of 2-minute resting, 2-minute unloaded cycling, followed by an exercise with the incremental work rate of 5-10 watts/min until the maximum as patients tolerated. The recovery period was 2 minutes or longer in order to ensure that the HR returned to near baseline. Peak VO_2, VO_2 at anaerobic threshold (AT), heart rate (HR), VE/VCO_2 at anaerobic threshold (VE/VCO_2 at AT) and O_2 pulse were measured. One hour after incremental CPET, patients were asked to perform an exercise with a constant work-rate protocol at the work rate (WR) of 75% of the peak WR from the incremental test to obtain the constant work-rate exercise time (CWERT). After 12 weeks of training, patients were asked to perform similar incremental exercise protocol and a constant work-rate exercise test (WR at 75% of the pre-training peak WR Electrocardiogram, blood pressure and pulse oximetry were continuously monitored throughout the exercise period. Exercise was terminated if patients were not able to maintain the cadence rate despite encouragement or had exhausted sensation. Six-minute walk distance (6MWD) was measured at the cardiac rehabilitation outpatient clinic by a well-trained technician who did not involve in the study.

3.2 | Safety outcome

Adverse outcomes were defined as syncope, cardiac arrhythmia with hypotension or required emergency treatment, death, and hospitalization.

4 | STATISTICAL ANALYSIS

The data were analyzed by SPSS version 23 (IBM, Armonk, New York). All data were tested for normality. Results were reported as mean ± SD or median with interquartile range (range). The Paired *t* test and Wilcoxon rank-sum test were used to analyze the difference of CPET parameters and CWRET before and after training. Student's *t* test was used to compare the change of 6MWD between the training group and the control group.

5 | RESULTS

5.1 | Demographic data

Of the 400 patients in ACHD clinic, 60 patients met the inclusion criteria. Eleven patients who could attend 12 weeks of training program were assigned into the training group, 45.5% of whom were female. Mean age was 30.9 ± 10.2 years. Mean body mass index was 18.3 ± 3.7 kg/m^2. All of the patients had cyanotic heart disease, four patients (36%) were diagnosed Eisenmenger's syndrome, and three patients (27.7%) had ventricular dysfunction. Baseline characteristics data are shown in Table 1.

5.2 | CPET and 6MWD data

Data of CPET and 6MWD before and after training program are shown in Table 2. Of these parameters, the O_2 pulse, CWRET and 6MWD significantly increased from the baseline (P = .039, .003, and .001, respectively). The peak VO_2 and VE/VCO_2 at AT did not significantly increase after training (Figure 2).

Compared with the control group, there were no statistical differences in age, sex, 6MWD, BMI, diagnosis, and number of patients with PHT between both groups as shown in Table 3. After finishing 12-week cardiac rehabilitation program, the changing of 6MWD in the training group was significantly higher than in the control group (P = .003) as shown in Figure 3.

5.3 | Safety outcomes

Two patients had dizziness and palpitation during home training but had no significant hypotension or arrhythmia. No serious adverse outcomes were reported.

6 | DISCUSSION

This is a prospective nonrandomized clinical trial investigating the effect of once-a-week outpatient hospital-based exercise program followed by home training under tele-monitoring in complex cyanotic ACHD patients. Compared with other studies from the Western countries which included mainly post total repaired TOF and Fontan operation,[6] our patients mainly consisted of Eisenmenger's syndrome and unrepaired complex congenital heart disease. The baseline peak VO_2 in our study was 13.3 ml/kg/min which is lower than previous studies (23.4 ml/kg/min).[12] Despite the worse baseline clinical characteristics, our result showed a significant improvement in exercise capacity as measured by 6MWD and CWRET. In addition, when compared with the control group, the improvement of 6MWD is significantly higher.

TABLE 1 Baseline clinical characteristic in training group

Characteristics	Training group (n = 11)
Age (years), mean ± SD	30.9 ± 10.2
Female, n (%)	5 (46)
BMI (kg/m²), mean ± SD	18.3 ± 3.7
6MWD (m), mean± SD	356.6 ± 47
Diagnosis, n (%)	
Eisenmenger's syndrome	4 (36)
TOF with palliative shunt	1 (9)
Single ventricle	2 (18)
Other (truncus arteriosus type IV, pulmonary atresia with VSD, ccTGA with VSD)	4 (36)
Pulmonary HT, n (%)	7 (64)
Ventricular dysfunction, n (%)	3 (27)
Medication, n (%)	
Beta-blocker	6 (55)
ACEI	3 (27)
Sildenafil	3 (27)

Abbreviations: ACEI, angiotensin converting enzyme inhibitor; BMI, body mass index; ccTGA congenitally corrected transposition of the great arteries; HT, hypertension; 6MWD, 6-minute walk distance; VSD, ventricular septal defect.
Values were presented as mean ± SD or as n (%).

Nowadays, cardiopulmonary exercise testing (CPET) has been widely accepted as a gold standard for evaluation of functional capacity prior to starting cardiac rehabilitation program. There are a number of data sets obtained from CPET that has been proved as a prognostic factors in ACHD[12,13] such as peak oxygen uptake (peak VO_2) which is a gold standard for evaluation of exercise capacity; ventilation-carbon dioxide (VE/VCO_2) relationship which represents ventilatory efficiency; peak oxygen pulse (O_2 pulse) which has been used as an indicator of stroke volume. Constant work-rate exercise time (CWRET) has been reported the most responsive test to evaluate an improvement in exercise capacity in patients with COPD after rehabilitation intervention and has been evaluated in one ACHD trial.[14,15] Six-minute walk distant (6MWD) is also commonly used in ACHD clinic and has shown a close correlation to peak VO_2 in one study.[16] Our study showed there were significant improvements of the O_2 pulse, CWRET, and 6MWD from the baseline (P = .039, .003, and .001, respectively). Improvement of exercise capacity after training can be explained by both central (improved cardiac function) and peripheral (musculoskeletal or oxygen delivery pathway) adaptation.[6,12] The increasing of oxygen pulse is the result of combination of increasing stroke volume and oxygen extraction. We did echocardiography to measure the cardiac function before and after training and found that there was no change of stroke volume and left ventricular ejection fraction in the patients who had improvement of posttraining peak O_2 pulse; therefore, peripheral adaptation is the major benefit of exercise program in our study.

This study failed to show a significant improvement in peak VO_2 and VE/VCO_2 after training. When analyzing the data individually, we found that there were three patients who showed a deterioration of peak VO_2 after training. The first patient was subsequently found a significant stenosis of Blalock-Taussig shunt. Thus, the decline of her peak VO_2 during training could be explained by the shunt stenosis. She was scheduled for catheterization 3 months after finishing training program and her oxygenation significantly increased after

TABLE 2 Comparison CPET, CWRET, and 6MWD data between pre- and posttraining

Parameters	Pretraining	Posttraining	Change after training	P
CPET				
Peak VO_2 (ml/kg/min), mean ± SD	13.3 ± 4.1	13.6 ± 3.0	0.27 ± 0.72	.72
Peak O_2 pulse (ml/min), mean ± SD	4.8 ± 1.1	5.3 ± 1.3	0.5 ± 0.68	.039
VE/VCO_2 at AT, mean ± SD	54.0 ± 11.4	51.4 ± 9.1	2.54 ± 5.6	.164
CWRET (min), median (range)	3.6 (2.2-17.7)	4.5 (2.8-29.8)	2.3 (0-4.6)	.049
6MWD (m), mean ± SD	356.6 ± 47.1	426 ± 71.9	69.4 ± 47.9	.001

Abbreviations: AT, anaerobic threshold; CPET, cardiopulmonary exercise testing; CWRET, constant work-rate endurance time; 6MWD, 6-minute walk distance; VE/VCO_2, ventilatory equivalent for carbon dioxide; VO_2, oxygen consumption.

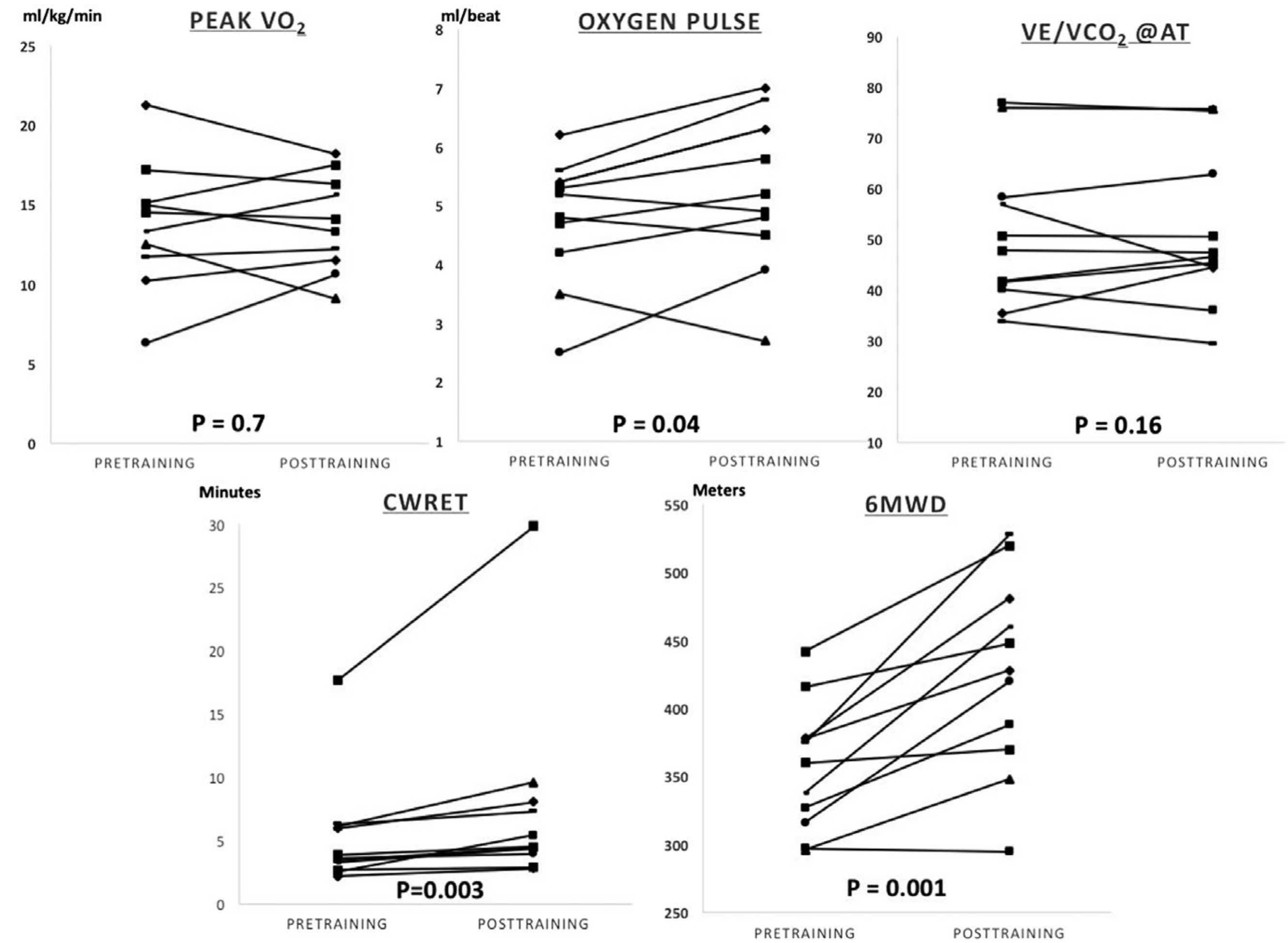

FIGURE 2 Changes of CPET parameters and 6MWD in individual patient pre- and posttraining. Abbreviations: CPET, cardiopulmonary exercise testing; 6MWD, 6-minute walk distance.

TABLE 3 Comparison of baseline characteristics between training and control group

Variables	Training group (*n* = 11)	Control group (*n* = 22)	*P*
Age (yr), mean ± SD	30.9 ± 10.2	38.1 ± 13	.11
Female, *n* (%)	5 (46)	15 (68)	.22
BMI (kg/m^2), mean ± SD	18.3 ± 3.7	19.4 ± 4.2	.47
6MWD (m), mean ± SD	356.6 ± 47	335.9 ± 51.3	.27
Diagnosis, *n* (%)			.999
Eisenmenger's syndrome	4 (36)	8 (36)	
TOF with palliative shunt	1 (9)	2 (9)	
Single ventricle	2 (18)	1 (9)	
Other	4 (36)	10 (45)	
Pulmonary HT, *n* (%)	7 (64)	13 (59)	.999

Abbreviations: BMI, body mass index; HT, hypertension; 6MWD, 6-minute walk distance.
Values were presented as mean ± SD or as n (%).

dilating the shunt (from 65% to 77%). The second patient had unexplained lower maximum heart rate (130 bpm) during post-training CPET measurement, compared with pretraining HR (170 bpm). The respiratory quotient (RQ) also decreased from 1.33 to 1.16 which represented the lower effort of posttraining exercise. The third patient also showed lower maximum heart rate during CPET measurement despite adequate effort of exercise. Inadequate chronotropic response which is not uncommon in adult congenital heart disease even after cardiac surgery[17] has been speculated in both patients. In term of VE/VCO_2, our data showed mixed results, both increased and decreased VE/VCO_2 slope individually. We postulated that the VE/VCO_2 slope was affected by different pulmonary blood flow in our patients. Patients with low pulmonary blood flow have a physiological dead-space CO_2 ventilation which will decrease the VCO_2, hence the VE/VCO_2 slope increases. We then evaluated the ratio of pulmonary to systemic blood flow (Qp:Qs) in each patients, using the data from either cardiac MRI or right heart catheterization prior to training, and found that patients whose VE/VCO_2 slope increased after exercise training had lower Qp:Qs ratio compared with patients whose VE/VCO_2 slope decreased after training (1.13 ± 0.29 vs. 1.36 ± 0.56) although it did not reach statistically significance

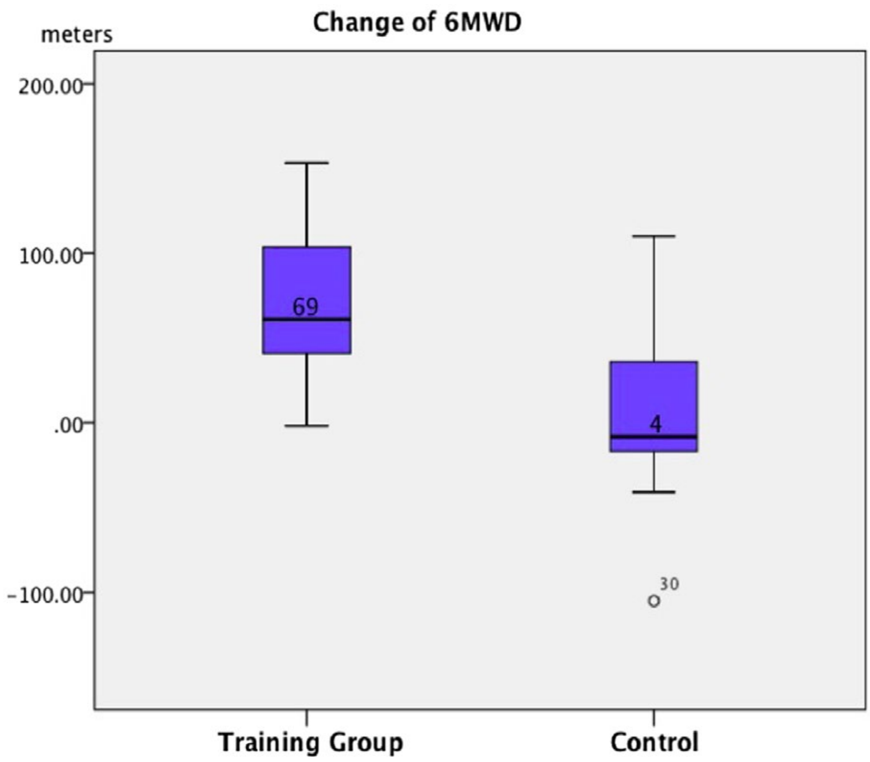

FIGURE 3 Box plot showing the changes of 6MWD between the training group and the control group, the changing of 6MWD in the training group was significantly higher than in the control group (P = .003). Abbreviation: 6MWD, 6-minute walk distance [Colour figure can be viewed at wileyonlinelibrary.com]

(P = .46). The other explanation for no significant change of VE/VCO_2 slope in our study maybe explained by the systemic deoxygenated venous blood in cyanotic patients which is the strong ventilation stimulus as suggested by Strieder et al study.[18] Therefore, the baseline VE/VCO_2 slope in cyanotic patient is significantly higher than other type of congenital heart disease[13] and this parameter may not change significantly after rehabilitation.

The two keys to success home program cardiac rehabilitation are achieving target heart rate (moderate to high intensity in this study) and good compliance. Martínez-Quintana et al[19] performed OPD-based rehabilitation program (twice per week for 3 months) in 4 patients. They found that the 6MWD did not change after 1-year follow-up. Our data showed a different result, with increasing 6MWD from 356.6 to 426 m. We hypothesized that tele-monitoring can encourage patients to exercise regularly with confidence.

Adverse effects are the most concerning issue. We have demonstrated the efficiency of tele-monitoring, using video call adds on telephone for early detection of adverse effects. Proper recommendation about exercise program can also be done by our nurse during tele-monitoring. With the help of technology, we have shown that no serious adverse events occurred during home-based exercise program in complex cyanotic ACHD patients in our study. Instead of prolonged admission for inpatient cardiac rehabilitation as recommended in current guideline, we have demonstrated that once-a-week outpatient rehabilitation followed by home program with tele-monitoring can significantly increase exercise capacity in this group of patients.

7 | LIMITATIONS

Small numbers of patients participating in the study and lack of randomization are our limitations. Future trials with randomization design and with a larger number of participants are warranted.

8 | CONCLUSION

Once-a-week outpatient hospital-based exercise program followed by supervised home-based exercise program showed significant benefit in improvement of exercise capacity in adults with complex congenital heart disease without serious adverse outcomes.

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CONFLICT OF INTEREST

The authors have no conflict of interest to report.

AUTHOR CONTRIBUTIONS

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