

Short Communication

Remote Cardiac Rehabilitation in Older Cardiac **Disease: A Randomized Case Series Feasibility Study**

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Abstract

Background: Cardiac rehabilitation (CR) in the long term is fundamental to achieve better outcomes. However, most patients may find it difficult to maintain healthy lifestyle behavior after ambulatory CR program. We aimed to investigate the feasibility on remote CR support program (Remote-CR) in older patients with cardiac disease.

Methods: Between October 2020 and February 2021, we enrolled older patients with cardiac disease after at least over 5 months of ambulatory CR program. The study was conducted as a randomized controlled case series to compare Remote-CR vs. center-based CR (CB-CR) after ambulatory CR in older patients with cardiac disease. The core component of Remote-CR is a web application, which evaluates vital sign and receives feedback through real-time video consultation once a week. We evaluated the satisfaction of Remote-CR, and impact of Remote-CR on adherence to exercise and physical activity management. Moreover, we assessed the change in functional status using handgrip strength, usual gait speed, short physical performance battery (SPPB), and Kihon checklist (KCL) before the intervention,

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at the end of the 4-week intervention, and cardiovascular-related hospital discharge within 6 months after completion of ambulatory CR.

Results: Eleven patients were enrolled (six for Remote-CR and five for CB-CR). All participants completed the intervention without serious adverse event in each group. After the on-site initial remote system set up, all the patients completed the Remote-CR session without on-site assistance. Patients' satisfaction with Remote-CR was generally high. Remote-CR helps to maintain healthy lifestyle behavior. In addition, Remote-CR and CB-CR seem to be equally successful in maintaining functional status and preventing cardiovascular-related hospital readmission.

Conclusions: This trial suggested the Remote-CR comprising a hybrid of information and communication technology and strategy for health behavior change may be a feasible and safe intervention option in selected older patients with cardiac disease after completion of ambulatory CR.

Keywords: Remote; Cardiac rehabilitation; Older; Functional status; Prognosis

Introduction

Cardiac rehabilitation (CR) is a multidisciplinary, comprehensive program to improve exercise capacity and quality of life (QoL), and reduce risk of hospital readmission [1]. CR is usually provided through group-based program in CR center, which induces therapeutic exercise and self-management education on secondary prevention. Maintaining unsupervised CR in the long term even after completion of outpatients CR program is fundamental to achieve better outcomes. However, its long-term benefits are less promising because most patients may find it difficult to maintain CR [2].

Currently, CR program should provide a variety of delivery option for patients according to their need or preferences. The remote systems using the internet enable patients to participate in the home setting [3], which has contributed to improving CR adherence [2]. Several systematic reviews also

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suggested that real-time remote exercise-based CR has comparable favorable effects on functional status, QoL, and reduced morbidity as compared with center-based CR (CB-CR) [4-6]. However, there are few studies to examine the effect of remote CR support program (Remote-CR), which evaluates vital sign and provides feedback through real-time video consultation due to strategy for health behavior change in older patients with cardiovascular disease, particularly in Japan [7].

Functional decline or deterioration in physical activity was observed after CR completion in older subjects, even in a short period of time [8, 9]. Marchionni et al suggested that continuously reinforced intervention after CR completion maintained long-term benefits [10]. To our knowledge, there is no study to investigate the feasibility on Remote-CR in adherence of unsupervised CR and maintaining functional status after CR completion in older patients with cardiac disease. This study aimed to assess whether Remote-CR after completion of ambulatory CR is able to assist health behavior change, and is effective in maintaining their functional status and short-term prognosis after CR completion in older patients with cardiovascular disease.

Materials and Methods

Participants

The study was conducted at Juntendo University Hospital, Tokyo, Japan. Study subjects were older patients enrolled in ambulatory CR program. Inclusion criteria were as follows: 1) aged 65 years or older; 2) stable adult patients with cardiac disease, defined as completed ambulatory CR program for at least over 5 months without adverse cardiac events; 3) internet access at home; and 4) patients with family or caregiver to support remote CR. Exclusion criteria were as follows: 1) unable to complete the basic course of treatment with poor adherence or inability to follow-up; and 2) severe cognitive impairment or lack of digital literacy which prohibits them to operate Remote-CR system.

The study was a randomized clinical trial (RCT) performed according to the CPONSORT statement [11]. The RCT was conducted from October 20, 2020 to February 30, 2021, in the CR Center at the Juntendo University Hospital, Japan. The study was conducted as an open label, randomized, controlled study. Patients were randomized with an allocation ratio of 1:1, based on a computer-generated list of random numbers. Allocation concealment was ensured since allocation information was protected in opaque sealed envelopes and kept by an investigator who was involved in patient recruitment. The trial was approved by the ethic committee of Department of Physical Therapy, Faculty of Health Science, Juntendo University (20-156) and registered with the University Hospital Medical Information Network (UMIN) clinical trial registry (UMIN 000042275), and the study was conducted in accordance with the principles of the Declaration of Helsinki. All participants gave written consent to participation after explaining the study procedures. We have done sample size power calculation, and a sample size of 46 patients was chosen based on the recommended methods. The present was terminated before it had

reached a sufficient sample size due to the spread of coronavirus disease 2019 (COVID-19) and interruption of ambulatory CR program due to state of emergency and quarantine.

Study interventions

The patients received Remote-CR program and learned how to use the tablet computer (iPad, Apple, Cupertino, CA) and remote real-time telemedicine system (Nipro HeartLine[™], NIPRO). Videoconference was performed through Nipro HeartLine[™], which also enabled health providers to monitor the health condition of patient's vital sign in real time on a tablet device. Participants were asked to encourage unsupervised exercise using original exercise video file detailing the aerobic, resistance, balance, and flexibility exercises, and record their exercises or pedometer-assessed daily steps in a logbook. The electrocardiograph (Duranta, ZAIKEN, Japan), pulse oximeter (Mighty-SatTMRx, Masimo, USA) and electronic sphygmomanometer (NBP-1BLE, NIPROm Japan) were used with a Bluetooth connection to a tablet computer, and data were recorded in the remote monitoring system. Patients were asked to continue unsupervised exercises for three or more times a week for 4 weeks after completing the 12 weeks of ambulatory CR program. The exercise program was 20 - 30 min at Borg scale of 11 - 13. Patients and family or caregivers were asked to fill the exercise diary after each exercise training, pedometer-assessed daily steps, and disease management status (body weight, leg edema, fatigue, blood pressure, heart rate, short of breath, oxygen saturation, pedometer trend, appetite, healthy diet, medication adherence, and daily stress). The physical therapists with more than 20 years of professional experience were responsible for contacting patients via a remote real-time monitoring system weekly. In addition, physical therapists checked handwritten logbook including exercise diary, pedometer-assessed daily steps, and disease management status through the display of videoconference, and provided feedback to the patients (Fig. 1). The cost for telemedicine system is the US dollars (USD) and Eros (EUR) at the exchange rate on October 20, when this study started.

In the CB-CR group, patients visited CR Center, Juntendo University Hospital for 1 - 2 times a week for 4 weeks after completing the 12 weeks of ambulatory CR program. CB-CR program included individualized supervised progressive aerobic exercise and resistance exercise. In addition, secondary prevention education or guidance was instructed by health fitness programmer, nurses, or physician certified from the Japanese Association of Cardiac Rehabilitation (JACR) [1]. All participants were encouraged to home-based aerobic exercise for 20 - 30 min and resistance exercise at Borg scale of 11 - 13 for 1 - 2 times a week in addition to CB-CR session for total of at least three times a week.

A survey for feasibility

In this study, the following four questions were assessed on satisfaction and adherence to exercise or physical activity management with Remote-CR program, and a 5-point Likert

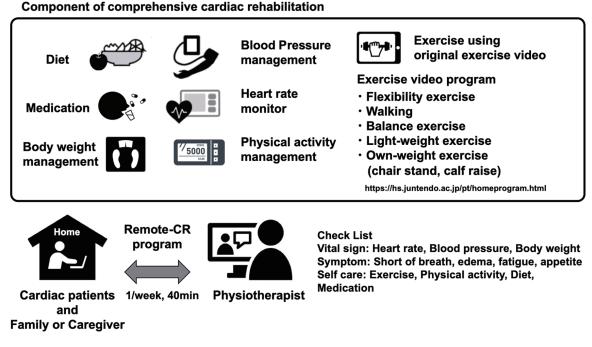


Figure 1. Schema of Remote-CR. Patients who participated in Remote-CR program were given tablet PC guides for exercise program staff; after completion of ambulatory CR, remote consultation program was provided to them by trained physiotherapist, once a week for 4 weeks. Remote-CR: remote cardiac rehabilitation support program.

scale ranging from 1 (strongly disagree) to 5 (strongly agree): "Remote-CR was an acceptable way to receive a CR program", "I have more time for exercise", "I have increased my physical activity", and frequency of video-based exercise application use with 4-point Likert scale ranging from 1 (never) to 4 (at least three times a week): "How many days per week did you use the video-based exercise application?"

Functional assessment

We assessed short physical performance battery (SPPB), handgrip strength, gait speed [12], and Kihon checklist (KCL), which is a self-reported comprehensive health checklist for evaluation of vulnerable to frailty. All baseline measures were collected during the ambulatory CR program before randomization. Follow-up physical functional assessment was collected by trained physical therapist, non-blinded assessors according to standardized protocols after completing the 4-week intervention.

Handgrip strength

Isometric handgrip strength was measured using the Jamar hand dynamometer, which measured strength in kilograms with a precision of 0.1 kg. Patients were instructed to sit on a straight-backed chair with both feet placed flat on the floor, shoulder adducted and neutrally rotated, elbow flexed at 90°, and forearm and wrist in neutral position, as recommended by Roberts et al [13]. Grip strength was measured twice per hand in each of the two handle positions. Patients were instructed

to apply maximum power for 3 s and work at maximum effort each trial.

Usual gait speed

During the 5-m walk test, time was recorded, and gait speed was determined in meter per second. Use of cane was acceptable. Participations were asked to walk 5 m at their comfortable speed without overexerting. Using a digital stopwatch that records time within 0.01 s, timing was manually started at the "go" instruction and stopped when the patients crossed the 5-m line [14].

SPPB

The SPPB is a highly standardized geriatric physical functioning test that consists of tests for balance, gait, strength, and endurance [12]. The standing balance test included side-by-side, semi-tandem, and tandem standing, and patients were timed until they lost balance or after 10 s. The gait test assessed the time taken to walk 4 m and was performed at patient's usual pace. The five-time chair-standing test, a pre-test, was also performed, wherein patients were asked to fold their arms across their chest and stand up from the chair. If the pre-test was successful, patients were asked to rise from the chair five times consecutively as quickly as possible. Each of the three subtests of SPPB was scored from 0 to 4 and summed for an SPPB score of 0 to 12 points. Higher scores indicated better physical function.

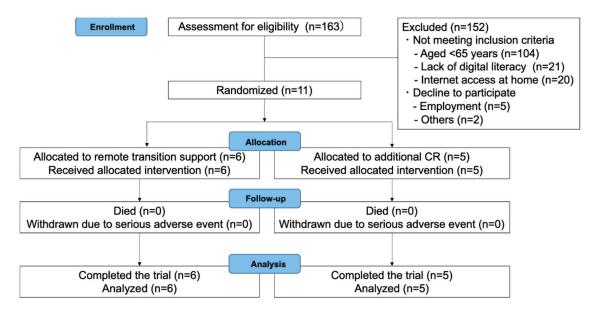


Figure 2. Trial flow chart. CR: cardiac rehabilitation.

KCL

The patients were also provided with KCL, which is a selfreported comprehensive health checklist for evaluation of vulnerable to frailty [15, 16]. The KCL consists of 25 items (yes/ no) divided into seven categories: instrumental activities of daily living, physical strength, nutrition, eating, socialisation, memory, and mood, each item is scored from 0 to 1 point, and the sum of all indices can be from 0 to 25. A total score of ≥ 8 points is classified as indicating frailty [16].

Outcomes

Our outcomes were feasibility of Remote-CR, change in functional status, and cardiovascular-related hospital discharge within 6 months after completion of ambulatory CR between study groups.

Statistical analysis

Clinical characteristics were summarized using medians with interquartile range (IQR) or proportions. To assess for differences of baseline data between two groups, the following tests were used: Fisher's exact test for dichotomy variables, Mann-Whitney test for non-normally distributed continuous variables, and Chi-square test for categorical variables. Within-group difference of changes in functional status between baseline and 4 weeks after intervention periods used Wilcoxon signed-rank test. To compare change in functional status between the two groups, the absolute difference during the intervention periods was calculated, and a Mann-Whitney test was performed. Statistical analysis was conducted using SPSS version 23.0 for Windows (IBM Corp., Armonk, New York).

Results

Participant flow

One hundred sixty-three patients were screened in the trial periods. Figure 2 reports patients not meeting inclusion criteria and patients meeting the exclusion criteria at baseline. Recruitment rates were extremely low due to patients not meeting the inclusion criteria due to no internet access at home. In addition, feasibility of the study was complicated by the spread of COVID-19. Included patients were allocated to Remote-CR group (n = 6) and CB-CE group (n = 5), and 11 (100%) completed the follow-up assessment. All participants completed one to two exercises during intervention periods in each group. There was no serious adverse event in both Remote-CR and CB-CR groups during 4-week intervention periods.

Baseline data

The baseline demographic and clinical characteristics of the patients in each group are summarized in Table 1. The median age was 73 years (range: 68 - 78 years), and three were female. A positive baseline frailty score was found in one patient in the CB-CR group (9%). A positive baseline low muscle strength was found in three patients in the Remote-CR group and in three in CB-CR group (55%). No patient had baseline slow gait speed in each group. We found no significant differences in baseline demographic and clinical characteristics between the two groups. At baseline, no between group difference was found in the handgrip strength (27.80 (22.75 - 33.00) vs. 33.00 (25.75 - 34.50) kg), gait speed (3.345 (2.303 - 3.788) vs. 3.080 (2.980 - 3.680) s), five-time chair stand test (8.220 (7.053 - 9.598) vs. 7.000 (6.535 - 7.625) s), SPPB score (11.50 (10.75

Table 1. Baseline Characteristics

| | Total (n = 11) | Remote-CR $(n = 6)$ | CB-CR (n = 5) | P-value |
|------------------------------------|--------------------|---------------------|--------------------|---------|
| Male, no. (%) | 8 (73) | 4 (67) | 4 (80) | 0.621 |
| Age, years | 74 (68 - 78) | 74 (72 - 80) | 68 (67 - 75) | 0.126 |
| Body mass index, kg/m ² | 22.3 (21.0 - 24.1) | 23.6 (21.2 - 25.1) | 22.3 (21.0 - 23.0) | 0.537 |
| Medical treatment, no. (%) | | | | 0.639 |
| Angina | 5 (45) | 2 (33) | 3 (42) | |
| Myocardial infarction | 3 (27) | 1 (17) | 2 (29) | |
| Cardiac surgery | 4 (36) | 2 (33) | 2 (29) | |
| Dilated cardiomyopathy | 1 (9) | 1 (17) | 0 (0) | |
| Comorbidity, no. (%) | | | | |
| Hypertension | 6 (55) | 4 (67) | 2 (40) | 0.376 |
| Diabetes mellitus | 3 (27) | 2 (33) | 1 (20) | 0.621 |
| Dyslipidemia | 7 (64) | 5 (83) | 2 (40) | 0.137 |
| LVEF, % | 63 (43 - 69) | 54 (33 - 72) | 63 (58 - 67) | 0.465 |
| Laboratory data | | | | |
| Hb, mg/dL | 13.9 (13.5 - 14.9) | 14.9 (12.9 - 16.2) | 13.9 (13.5 - 14.9) | 0.917 |
| Alb, mg/dL | 4.1 (4.1 - 4.2) | 4.2 (4.0 - 4.3) | 4.1 (4.1 - 4.1) | 0.459 |
| eGFR, mL/min/1.73 m ² | 72.1 (40.2 - 76.1) | 64.9 (34.9 - 78.0) | 67.6 (55.2 - 73.6) | 0.834 |
| BUN, mg/dL | 18.0 (11.0 - 23.5) | 20.0 (10.5 - 28.0) | 18.0 (16.0 - 20.5) | 1.000 |
| TG, mg/dL | 84 (50 - 143) | 136 (75 - 157) | 119 (50 - 132) | 0.175 |
| LDL, mg/dL | 64 (59 - 81) | 97 (81 - 111) | 64 (59 - 103) | 0.753 |
| HDL, mg/dL | 56 (54 - 60) | 51 (42 - 60) | 55 (50 - 58) | 0.841 |
| CRP, mg/dL | 0.06 (0.03 - 0.16) | 0.12 (0.06 - 0.13) | 0.05 (0.03 - 0.13) | 0.251 |
| Medication, no. (%) | | | | |
| Ca blocker | 5 (45) | 2 (18) | 3 (60) | 0.376 |
| Beta-blocker | 7 (64) | 4 (57) | 3 (60) | 0.819 |
| ACEI/ARB | 7 (64) | 3 (50) | 4 (80) | 0.303 |
| Diuretics | 3 (27) | 2 (33) | 1 (20) | 0.621 |
| Statin | 9 (82) | 5 (83) | 4 (80) | 0.347 |

CR: cardiac rehabilitation; LVEF: left ventricular ejection fraction; Hb: hemoglobin; eGFR: estimated glomerular filtration rate; BUN: blood urine nitrogen; Alb: albumin; TG: triglyceride; LDL: low-density lipoprotein; HDL: high-density lipoprotein; CRP: C-reactive protein; Ca: calcium; ACEI: angiotensin converting enzyme inhibitor; ARB: angiotensin II receptor blocker.

- 12.00) vs. 12.00 (12.00 - 12.00) points), or KCL score (4.00 (2.00 - 5.00) vs. 3.00 (2.00 - 5.00) points).

Survey for feasibility of Remote-CR

After the on-site initial remote system set up, all the patients completed the Remote-CR program session without on-site assistance. The percentage of the response opinions of satisfaction with Remote-CR program, adherence to the exercise or physical activity management are shown in Figure 3. Patients' satisfaction with Remote-CR program was generally high. Remote-CR program helps to maintain unsupervised exercise and physical activity. Most of the patients were walking round their homes and conducted resistance exercise program including in the exercise video outdoors. Therefore, only about 30% of the patients performed exercise at home at least three times a week using an exercise video. The initial cost for preparation of the telemedicine system was 520 USD or 440 EUR for a single health provider kit, and 4,260 USD or 3,620 EUR for a single patient kit.

Change in functional status

We also found no difference in each functional status when comparing the 4-week follow-up in each group. We found no difference in the change in handgrip strength (3.00 (0.00 - 4.70) kg), gait speed (-0.001 (-0.45 - 0.18) s), five-time chair stand test (-1.01 (-2.29 - 0.09) s), and SPPB score (0.00 (0.00 - 0.00) s).

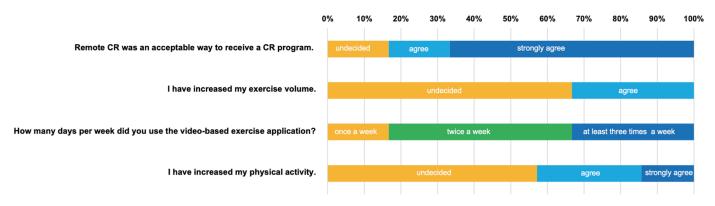


Figure 3. Questionnaire for the satisfaction and adherence to exercise or physical activity management via Remote-CR. Remote-CR: remote cardiac rehabilitation support program.

- 0.00) points) when comparing the Remote-CR and CB-CR, respectively (Table 2).

Cardiovascular-related hospital readmission

The rate of cardiovascular-related hospital readmission within 6 months after completion of ambulatory CR was comparable (Remote-CR group 0% vs. CB-CR group 0%).

Discussion

To our knowledge, this is the first study to evaluate the feasibility of Remote-CR by a trained physical therapist on adherence of healthy lifestyle behavior, maintaining of functional status and short-term prognosis after completion of CR in older patients with cardiac disease.

Only 3.8% of medical institutes in Japan could provide remote CR program as of 2020 [7]. Older subjects have shown to be strongly linked to low digital literacy [17]. Patients' ability to understand how to use digital devices is important to refer a Remote-CR program. However, we included patients with a certain level of digital literacy in this study. To control the selection bias and confounding bias, innovated user-friendly remote real-time monitoring system that can be used by every older patient is essential. All the patients were able to complete the session without on-site assistance. Five out of six patients agree or strongly agree with the item "I feel Remote-CR was an acceptable way to receive a comprehensive CR program". However, there was some feedback from patients about usability or connectivity problems. Improvement of user-friendly system and applications to support continued use would be needed for widespread clinical implementation.

Despite the short follow-up periods, our findings showed a positive effect on the maintenance of functional status, and

Table 2. Within and Between-Group Difference in the Functional Status

| | | | Within-group difference | Between-group difference* |
|-------------------|------------------------|-----------------------|-------------------------|---------------------------------|
| | Baseline, median (IQR) | 4 weeks, median (IQR) | Baseline vs. 4 weeks | Remote-CR vs. CB-CR |
| | | | P-value | Median (IQR), P-value |
| SPPB score | | | | |
| Remote-CR | 11.50 (10.75 - 12.00) | 11.50 (11.00 - 12.00) | P = 0.317 | 0.00 (0.00 - 0.00), P = 0.892 |
| CB-CR | 12.00 (12.00 - 12.00) | 12.00 (12.00 - 12.00) | P = 0.317 | |
| Handgrip strength | | | | |
| Remote-CR | 27.80 (22.75 - 33.00) | 30.50 (25.50 - 34.00) | P = 0.072 | 3.00 (0.00 - 4.70), P = 0.286 |
| CB-CR | 33.00 (25.75 - 34.50) | 36.00 (26.50 - 38.00) | P = 0.141 | |
| Gait speed | | | | |
| Remote-CR | 3.345 (2.303 - 3.788) | 3.220 (2.340 - 3.803) | P = 0.686 | -0.01 (-0.45 - 0.18), P = 0.273 |
| CB-CR | 3.080 (2.980 - 3.680) | 3.030 (2.690 - 3.330) | P = 0.138 | |
| KCL total score | | | | |
| Remote-CR | 4.00 (2.00 - 5.00) | 3.50 (1.50 - 4.00) | P = 0.083 | -1.00 (-1.00 - 0.00), P = 1.000 |
| CB-CR | 3.00 (2.00 - 5.00) | 2.00 (1.00 - 5.00) | P = 0.680 | |

*The change in functional status during intervention periods was determined as the absolute difference and compared the Remote-CR group with CB-CR group. IQR: interquartile range; SPPB: short physical performance battery; KCL: Kihon checklist; CR: cardiac rehabilitation; CB: center-based. short-term prognosis. The difficulty of maintaining healthy lifestyle behavior and its derived successful ageing has been suggested in older patients with cardiac disease [18]. Caregiver supervision or interaction and self-monitoring and its derived insight in the health status were reported as essential determinants for the long-term healthy lifestyle behavior changes [19]. Thus, we explained to patient's family to participate in the Remote-CR program. All the patients participated in the Remote-CR program with family or caregiver, which would be effective in maintaining the adherence to exercise or physical activity management. We think that one of the advantages of the Remote-CR program is that it involved the family or caregivers into CR program.

Generally, medical cost would be higher for remote CR program; however, it is not covered by National Health Insurance in Japan. Initial cost of telemedicine system demonstrated in this study, 520 USD or 440 EUR for single health provider kit including tablet computer, annual license of the telemedicine system, and 4,260 USD or 3,620 EUR for single patient kit including two tablet computers, electrocardiography, pulse oximeter, electronic sphygmomanometer, and data communication charge. All equipment was prepared by researchers and lent to each patient free of charge. Lack of financial burden may have contributed to satisfaction of Remote-CR program. Future studies should be encouraged to investigate how a cost-efficient Remote-CR program can be implemented.

Limitations

Several limitations of our present study should be noted. The present study was conducted as case series feasibility study with a small sample size at a single center. The limited number of patients does not allow for a statistical and robust conclusion. The benefit of conducting the Remote-CR on the adherence to healthy lifestyle behavior and patients' functional status, and prognosis should be further investigated with a large sample and long-term intervention. The results of satisfaction of Remote-CR showed the good feasibility of this system. However, the success of the Remote-CR is dependent on the digital literacy and internet networking environment, and application. In the future, we need develop a user-friendly telemedicine system that can be easily used by anyone, anywhere.

Conclusion

The Remote-CR after completion of ambulatory CR may be applicable as intervention option in selected stable older patients with cardiac disease. The results of this study should prompt further investigation of the usefulness of Remote-CR on functional status, QoL, prognosis, and cost-effectiveness in clinical setting.

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Financial Disclosure

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Conflict of Interest

The authors declare that they have no conflict of interest.

Informed Consent

All participants gave written consent to participation after explaining the study procedures.

Author Contributions

TT, TF and HD conceived the study and obtained grant funding. MS, TT, TM and MN-Y contributed to the conception and design of the work. MS, TT, TM, AH, AA and MN-Y contributed to the literature search. MS and TT contributed to the data analysis for the work. MS, TT, TM, NK, and TK contributed to the drafting the manuscript. MS, TT, TM, TM, TA, TF and HD critically revised the manuscript.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon request.

Abbreviations

CR: cardiac rehabilitation; QoL: quality of life; CB-CR: center-based CR; remote-CR: remote CR support program; RCT: randomized clinical trial; UMIN: University Hospital Medical Information Network; COVID-19: coronavirus disease 2019; USD: US dollars; EUR: Eros; JACR: Japanese Association of Cardiac Rehabilitation; SPPB: short physical performance battery; IQR: interquartile range

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