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State of the Art Review

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Remote Cardiac Rehabilitation With Wearable Devices

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AUTHOR'S SUMMARY

Cardiac rehabilitation (CR) for cardiovascular patients in improving exercise tolerance and prognosis are well known. A remote CR device, in which vital information is transmitted to the hospital via a remote CR app linked to a wearable device and telemonitored by CR staff, is attracting attention as a program medical device. The effects of remote CR on improving exercise capacity were proven. However, the effects of remote CR on preventing cardiac events and death were still controversial. Safe and effective remote CR requires exercise risk stratification of each patient, telenursing by skilled staff, and multidisciplinary intervention, but issues such as cost-effectiveness remain.

ABSTRACT

Although cardiac rehabilitation (CR) has been shown to improve exercise tolerance and prognosis in patients with cardiovascular diseases, there remains low participation in outpatient CR. This may be attributed to the patients' busy schedules and difficulty in visiting the hospital due to distance, cost, avoidance of exercise, and severity of coronary disease. To overcome these challenges, many countries are exploring the possibility of remote CR. Specifically, there is increasing attention on the development of remote CR devices,

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The data generated in this study is available from the corresponding author upon reasonable request.

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Conceptualization: Nakayama A, Ishii N, Marukawa M, Ohno K, Yoshida A, Hasegawa E, Kawahara T, Ikemage T, Isobe M; Data curation: Mantani M, Samukawa K, Tsuneta R, Sakamoto J, Hori K, Kawahara T; Formal analysis: Nakayama A; Funding acquisition: Nakayama A; Investigation: Nakayama A, Ishii N, Mantani M, Samukawa K, Tsuneta R, Sakamoto J, Hori K, Takahashi S, Komuro K, Hiruma T, Abe R, Norimatsu T, Shimbo M, Tajima M, Nagasaki M; Methodology: Nakayama A, Marukawa M, Ohno K, Yoshida A, Hasegawa E, Sakamoto J, Hori K, Kawahara T; Project administration: Nakayama A, Isobe M; Supervision: Nanasato M, Ikemage T, Isobe M; Writing - original draft: Nakayama A; Writing - review & editing: Nakayama A.

which allow transmission of vital information to the hospital via a remote CR application linked to a wearable device for telemonitoring by dedicated hospital staff. In addition, remote CR programs can support return to work after hospitalization. Previous studies have demonstrated the effects of remote CR on exercise tolerance. However, the preventive effects of remote CR on cardiac events and mortality remain controversial. Thus, safe and effective remote CR requires exercise risk stratification for each patient, telenursing by skilled staff, and multidisciplinary interventions. Therefore, quality assurance of telenursing and multi-disciplinary interventions will be essential for remote CR. Remote CR may become an important part of cardiac management in the future. However, issues such as cost-effectiveness and insurance coverage still persist.

Keywords: Remote medicine; Cardiac rehabilitation; Wearable devise

INTRODUCTION

Cardiac rehabilitation (CR) should progress smoothly across the acute, recovery, and maintenance phases; however, it is plagued with low participation rates, especially in outpatient CR service which was medical option in recovery or maintenance phases, even when CR is provided during hospitalization. Specifically, participation rate of acute myocardial infraction in outpatient CR is much lower in Asia, including Japan (4–8%),[1] than in United States (US, 35%) or in Europe (23–29%) where exercise is widely accepted as part of medical care. This low participation in outpatient CR could be attributed to the lack of recommendation by doctors, a general dislike or apathy for exercise, need for family support to visit the hospital, and not wanting to bother others. Additionally, some cardiovascular patients cannot participate in outpatient CR because they live far away from the hospital and have poor transport connections,[2] are busy with work,[3] cannot afford the rehabilitation cost, and do not want to run the risk of coronavirus disease 2019 (COVID-19) infections for group exercise. Moreover, reasons for low participation among women include housework and childcare taking priority over their own health.[4] In Japan, cardiopulmonary exercise testing (CPET) is required as part of the CR course in order to prescribe exercise. However, there are a limited number of facilities capable of providing outpatient CR given the small number of facilities that can perform CPET. Additionally, patients with severe heart failure require detailed exercise and lifestyle advice. However, their condition may impede frequent hospital visits, leading to aggravate medical conditions and repeated readmissions. With the onset of the COVID-19 pandemic, there has been a rapid increase in the demand for remote CR services since 2020. In 2020, there were 3,997 cardiovascular facilities, including clinics and hospitals, in Japan.[5] According to a national survey in Japan, 1,065 (69%) out of 1,533 major institutions, which mainly included large cardiovascular centers, could provide CR services,[6] suggesting that only 1,065 out of 3,997 (27%) cardiovascular institutions could provide CR services to cardiovascular patients, because most of the small volume hospitals or clinics could not provide CR services, which require safety, space, and multidisciplinary staff. Due to the COVID-19 pandemic, there has been a marked tendency to avoid potentially dense group CR, resulting in fewer facilities that can provide CR. In 2020, a Japanese nationwide survey found that out of 37 CR facilities that responded, 70% had stopped providing outpatient CR because of the state of emergency declared during the COVID-19 pandemic.[7] Additionally, an international survey of 330 overseas centers reported that half of the CR programs were suspended due to the COVID-19 pandemic; however, each country subsequently sought a remote program, with the telephone being the most common means of communication (113 centers, 85%).[8]

As a solution to the barriers to participation in outpatient CR, remote CR, which allows participation without a hospital visit, has the advantages of eliminating the time required for hospital visits, solving access problems for patients living far away from the hospital, potentially reducing costs, avoiding the risk of infection during group exercises, and conferring the advantages of information technology (IT) equipment. There has been increasing attention in the application of IT advances in remote CR services. Meta-analyses have shown that remote CR can effectively improve exercise tolerance and prognosis.[9]

However, there remain challenges to remote medication. It is important that the quality of remote medical care should not be much lower than that of face-to-face medical care; further, quality assessment is necessary when implementing remote CR. The safety of remote CR should be ensured through risk stratification and selection of appropriate patients, and security measures for protecting personal information should be mandatory. Furthermore, it is important to seriously consider legal issues that may arise in terms of the management of accidents that occur during remote CR.

HISTORY OF REMOTE CARDIAC REHABILITATION

Remote CR can be defined as comprehensive remote cardiac management, including exercise coaching, nutritional advice, smoking cessation education, psychological counseling, and disease education, based on monitored vital signs. As advances in telemedicine devices, many countries have attempted to implement remote CR. Large-scale randomized trials on remote management were initially conducted among patients with heart failure. In 2005, a large-scale, randomized, open-label, multicenter trial (the Trans-European Network-Home-Care Management System: TEN-HMS) conducted in Europe allocated 426 patients with heart failure with reduced ejection fraction (mean age: 67 years; ejection fraction <40%) to a standard treatment group (n=65) with outpatient visits every 4 months without telemonitoring or telenursing, a telenursing without telemonitoring group (n=168), and a telenursing with telemonitoring group (n=173) (**Table 1**, **Figure 1**).[10] Notably, there was no difference in the mortality rate between the telenursing with and without telemonitoring groups. This could be attributed to the fact that remote devices during that era (2005) may not have accurately captured the vital signs of daily activities; moreover, telemonitoring without telenursing would have been insufficient to improve patient outcomes. However, the telenursing with telemonitoring group required fewer days of rehospitalization than the telenursing without telemonitoring group (10.9 days vs. 14.8 days), suggesting the possibility of superior cost-effectiveness in telemonitoring group.

A subsequent randomized trial of remote heart failure management (the Better Effectiveness After Transition - Heart Failure: BEAT-HF) conducted in the US in 2015 also tested the effectiveness of telenursing with remote monitoring in 1,473 patients with heart failure (median age: 73 years; female patients [47%]) assigned to the remote group (n=715) or standard treatment group (n=722) (**Table 1**).[11] In the remote group, telenursing was provided by nurses 9 times over 180 days. There was no significant between-group difference in the rate of readmission for any reason within 180 days after discharge. However, there was a significant between-group difference in the quality of life within these 180 days. This observed lack of effectiveness of teleintervention may be attributed to the different levels of the nurses in charge of telenursing and the lack of active intervention by physicians.

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Table 1. Randomized trials of remote heart management for patients with heart failure

Trial (year)	TEN-HMS (2005)[10]			BEAT-HF (2015)[11]		TIM-HF2 (2018)[12]	
	Telenursing with telemonitoring	Telenursing without telemonitoring	Usual care	Remote group	Usual care	Remote group	Usual care
Patient's background							
Number	168	173	85	715	722	765	773
Age (years)	67	67	68	73	74	70	70
Female (%)	20	28	18	46.6	47.1	30	31
EF (%)	25	25	24	-	-	41	41
NYHA (%)							
I	22	18	18	0	1	0	1
II	46	44	36	23	26	52	51
III	23	30	42	66	64	47	47
IV	8	9	4	11	10	0	0
Intervention for remote management							
Telenursing	+	+	−	+	−	+	−
Telemonitoring	+	−	−	+	−	+	−
Output (%)							
Total death	120 days, 9 240 days, 18	120 days, 12 240 days, 18	120 days, 18 240 days, 26	30 days, 3.4 80 days, 5.4	30 days, 14.0 180 days, 15.8	8	12
Cardiac death	-	-	-	-	-	5	8
Quality of life score, MLHFQ	-	-	-	30 days, 30.28 180 days, 28.50	30 days, 32.21 180 days, 32.63	−3.08 (change from baseline to 12 months)	−1.98 (change from baseline to 12 months)
Dropout rate (%)							
Withdraw rate during intervention	7	0	-	15	-	2	-

BEAT-HF = Better Effectiveness After Transition - Heart Failure; EF = ejection fraction; MLHFQ = Minnesota Living with Heart Failure Questionnaire; NYHA = New York Heart Association; TEN-HMS = Trans-European Network-Home-Care Management System; TIM-HF2 = Telemedical Interventional Management in patients with Heart Failure.

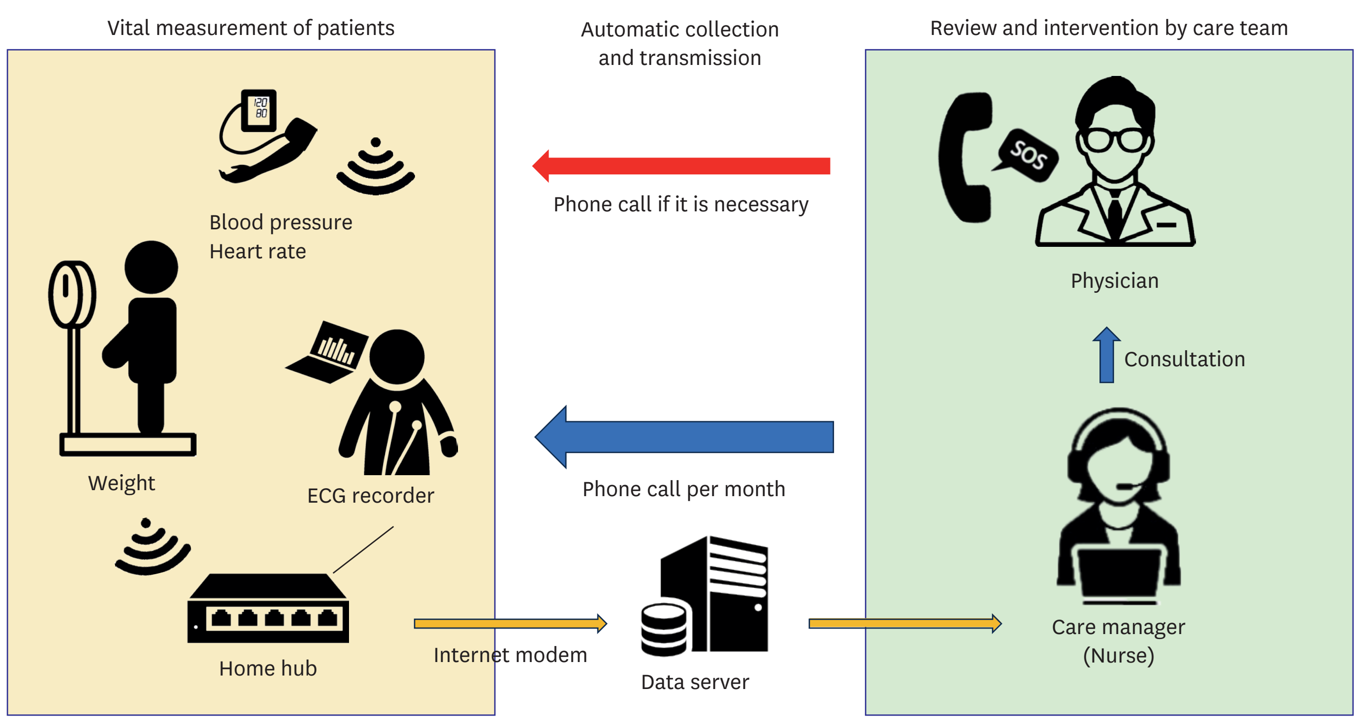

Figure 1. Classical remote heart management for patients with heart failure. A remote device is installed in a patient's home and monitored by a doctor, nurse, or other healthcare professional.
ECG = electrocardiogram.

In a 2018 German randomized trial (Telemedical Interventional Management in patients with Heart Failure: TIM-HF2), 1,571 patients with heart failure (New York Heart Association class II and III) were randomized to receive remote monitoring (n=765) or standard treatment (n=773).[12] Various telemedicine devices (blood pressure monitor, weight scale, SpO_2 monitor, electrocardiogram (ECG) monitor, and emergency call mobile phone) were provided to the remote group along with 24-hour monitoring with physician guidance, which significantly improved the prognosis of patients with heart failure (**Table 1**). All-cause mortality was significantly improved in remote CR compared to standard treatment (hazard ratio [HR], 0.70; 95% confidence interval [CI], 0.50, 0.96; p=0.028). However, cardiovascular mortality (HR, 0.67; 95% CI, 0.45, 1.01; p=0.056) and change in QOL score from baseline to 12 months were not significantly improved by remote CR program. This better prognosis in the remote group by TIM-HF2 could be attributed to the comprehensive life support provided by monthly telenursing and 24-hour physician-led medical support for patient management, as well as a longer 12-month follow-up period.

The aforementioned 3 large-scale randomized trials on telecardiac management showed that telemanagement resulted in high rates of program adherence (**Table 1**) and that improved outcomes required both telenursing and active physician intervention. In all 3 studies, program retention with telemanagement was ≥80%, which is surprisingly high since the dropout rate for outpatient CR is approximately 30%.[13] Additionally, these findings suggested that telecardiac management requires telephone intervention from the healthcare provider to the patient since telemonitoring by itself could not effectively improve the prognosis, and comprehensive lifestyle management contributes to improved prognosis.

A meta-analysis of remote CR for heart failure patients published in 2021[14] included 17 major studies involving 2,206 patients with heart failure and compared the effectiveness of remote CR and standard treatment. Remote CR effectively improved functional capacity during the 6-minute walk test (mean difference [MD], 15.86; 95% CI, 7.23, 24.49; I^2=74%) and maximal oxygen uptake (peakVO_2) (MD, 1.85; 95% CI, 0.16, 3.53; I^2=93%). Moreover, remote CR improved the patient quality of life (Minnesota Living with Heart Failure Questionnaire: MD, −6.62; 95% CI, −11.40, −1.84; I^2=99%). There were no serious adverse events during home exercises; however, it was concluded that there remained poor evidence regarding the impact of remote CR on reducing re-admissions and cardiac deaths.

Limited to Asia, telecardiac management lags behind that in the West. In Japan, there has been reluctance regarding telemedicine due to the restrictions of Japanese Law which stipulates that medical treatment is based on a face-to-face encounter between the physician and the patient. Moreover, despite the incorporation of telemedicine into the 1997 regulatory reform and its promotion in 2015, telemedicine had not become widespread due to low insurance coverage as well as concerns regarding personal information and safety. Similar to that in other countries, the game changer for telemedicine in Japan occurred during the COVID-19 pandemic. Various restrictions, such as limiting telemedicine to the patient's doctor, were lifted after the COVID-19 outbreak.

A single-center study conducted by Nakayama et al.[15] in 2018 found that telenursing management of patients with severe heart failure prevented rehospitalization and significantly improved Hospital Anxiety and Depression Scale scores compared with standard care and outpatient CR. In this study, patient’s demand for this remote system to avoid virus infection, which was introduced before the COVID-19 pandemic, rapidly increased during the

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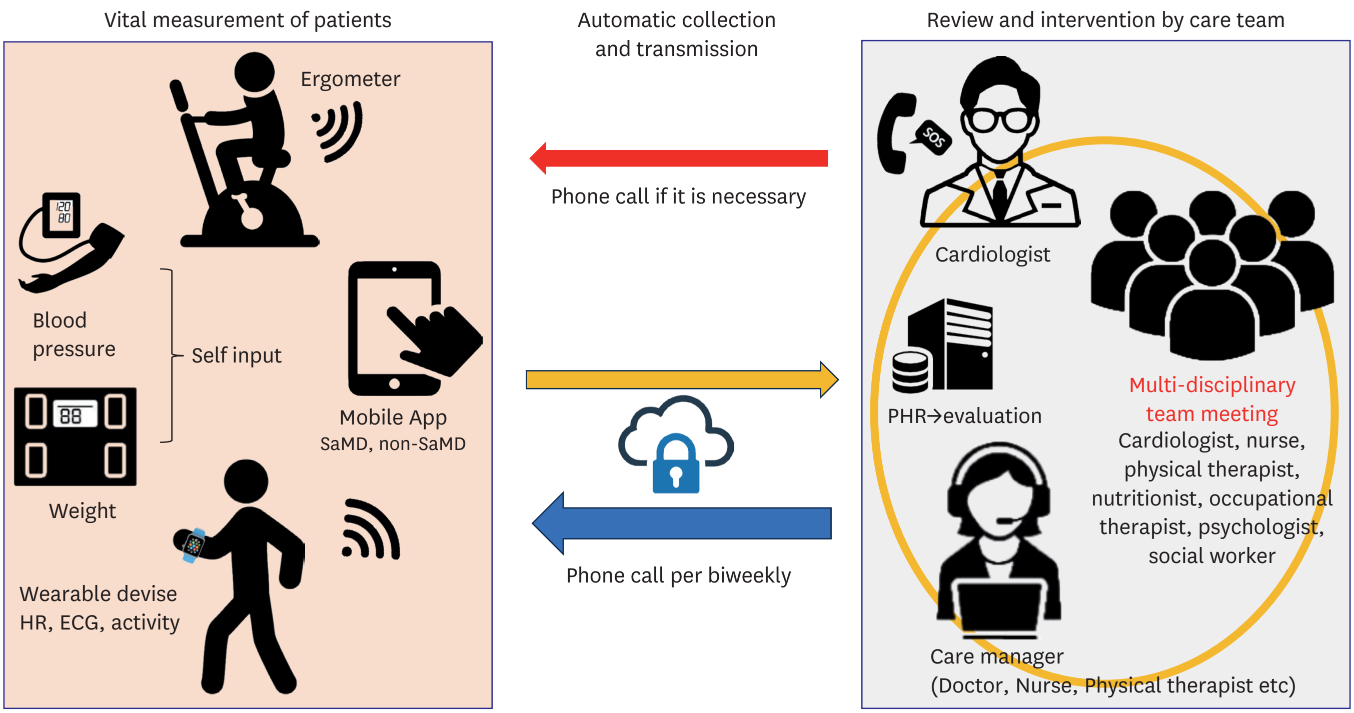

Figure 2. Recent remote heart management for cardiovascular patients. Remote devices are becoming increasingly sophisticated, smaller, and less expensive. Vital information during exercise at home was transferred to the medical center, which was then used by a multidisciplinary team for intervention.
ECG = electrocardiogram; HR = heart rate; PHR = personal health record; SaMD = Software as a Medical Device.

COVID-19 pandemic. Subsequently, telemedicine devices have become smaller and cheaper; additionally, home ergometers and wearable devices such as the Apple Watch (Apple Inc., Cupertino, CA, USA) have been developed, as well as implantable biochips that can measure biometric information, including pulse rate.

The classical telecardiac management system (**Figure 1**) was simple, and vital data could only be obtained after the patient exercised and transmitted its vital data. However, recent advances in telecardiac management using wearable devices allow patients to wear a smartwatch or smartband that can automatically obtain 24-hour vital signs, which can then be used to manage more appropriate exercise intensity (**Figure 2**). In addition, it is now possible for a multidisciplinary team to perform comprehensive remote cardiac management, including exercise guidance by a physical therapist (PT), nutritional guidance by a dietician, psychological counseling by a psychologist, and employment support by a social worker, which allows comprehensive CR similar to outpatient CR. Moreover, rather than complete remote management without hospital visits, hybrid management combining outpatient CR and remote CR has been explored to overcome their individual limitations.[16]

REMOTE CARDIAC REHABILITATION DEVICES

There are 2 main types of remote devices used for remote CR: ergometers and wearable watches (**Figure 3**). The implementation of remote CR systems requires ingenuity in each device since safety during exercise is considered the most important factor, followed by cybersecurity. Remote CR using an ergometer involves installation of the ergometer and relay device for Internet connection in the patient's home, which are monitored in real time during

Telemonitoring devise for cardiovascular patients	Ergometer	Wearable watch or band
Devise		
Easy to use the remote system	●●	●●
Easy to explain how to use	●●	●●
Real-time monitoring	●●●	●
Daily monitoring	●	●●●
Versatility for other patients, hospital, and program	●	●●
Cardiac rehabilitation staff		
Reducing the burden on cardiac rehabilitation staff	●	●●●
Multi-disciplinary intervention	●●	●●
Patients		
Availability for severe heart disease	●●	●
Availability for elderly	●●●	●●
Availability for female	●●	●
Others		
Evidence of effectiveness	●●	●
Security, protect health information	●●	●●
Cost effectiveness	●	●●●
Availability of personal health records for big data	●	●●●

Advantage level	
●	Mild
●●	Moderate
●●●	Strong

Figure 3. Comparison between ergometer device and wearable device for remote exercise monitoring. Two typical remote devices were compared: ergometers and wearable watches.

exercise by medical staff.[17)] This allows safe monitoring of the exercise where the medical staff check the patients' facial expressions and physical condition on a video screen. However, real-time monitoring is burdensome for the medical staff, space is required for installing ergometer devices at the patient's home, and the patient should be familiar with the devices. For some patients, the use of remote devices may be difficult and expensive; therefore, there have been concerns regarding their widespread use. Additionally, in ergometer-based remote management, vital information is only obtained when the ergometer is used, and it may be difficult to obtain vital information on a day-to-day basis. Therefore, the use of wearable devices to monitor exercise therapy will potentially allow widespread use of remote CR since they are easy to use and becoming less expensive. However, elderly and female patients, who are considered to have low IT literacy, may face significant hurdles in using health apps. Accordingly, for these patients, there is a need to build easy-to-understand health apps that work with wearable devices. Furthermore, remote CR apps should ensure strict adherence to personal data protection while considering versatility and future applicability. Wearable devices are superior in terms of data collection and analysis; moreover, wearable devices are versatile with respect to extensibility, such as functional improvements and add-on new functions for apps. The Apple Watch (Apple Inc.) is a widely used wearable watch globally, and various other wearable devices have been recently marketed, including Fitbit® (Fitbit Inc., San Francisco, CA, USA)[18)] and HeartGuide® (Omron Corp., Kyoto, Japan) which is a cuff-type wearable blood pressure monitor.[19)] Nowadays, cuffless wearable blood pressure monitors are being developed, but the accuracy of their measurements is still insufficient, therefore, European Society of Hypertension Guidelines on BP Measurement (2021) does not recommend them for clinical use.[20)] However, if an accurate wearable blood pressure monitor is developed in the future and incorporated into a health app, its contribution to human health has unlimited potential.

A South Korean report suggested that a home CR program using a portable ECG data transmitter (HeartCallTM®) improved the exercise tolerance and quality of life of

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participants.[21] Moreover, there have been other South Korean studies on the development and clinical effectiveness of remote CR using smart devices and sensors.[22)23]

Since the use of remote CR apps is mainly tied to the hospitals or medical institutes, they could be considered as a programmed medical device called Software as a Medical Device (SaMD) and cannot be easily downloaded by general users. Several remote CR apps, including TeleRehab® at Sakakibara Heart Hospital,[24] have been investigated in the research phase before being approved as a medical device.

REMOTE CARDIAC REHABILITATION USING SOFTWARE AS A MEDICAL DEVICE

Regarding remote CR, SaMD[25] refers to the use of software applications or platforms that allow individuals with cardiac conditions to perform rehabilitation exercises while being monitored from a remote location. To facilitate remote CR, these SaMD solutions typically offer personalized exercise plans, real-time monitoring, educational resources, and communication tools such as telenursing (**Figure 4**).

SaMD platforms support tailored exercise programs based on an individual's medical history or exercise perception as per the CPET. Data are transmitted to the platform during the exercise sessions in real time, which allows healthcare professionals to remotely monitor the patient's progress and make adjustments as needed. SaMD can provide instructional videos, animations, and written guidelines for helping users to understand the importance of recording their exercise sessions and monitoring their progress over time. Many SaMD platforms have features that allow direct communication between patients and healthcare providers, including virtual consultations and messaging. This facilitates ongoing guidance, support, and adjustments to the rehabilitation protocol based on the patient's progress and feedback. SaMD applications often incorporate gamification elements, challenges, and rewards to motivate and engage patients during their rehabilitation process.

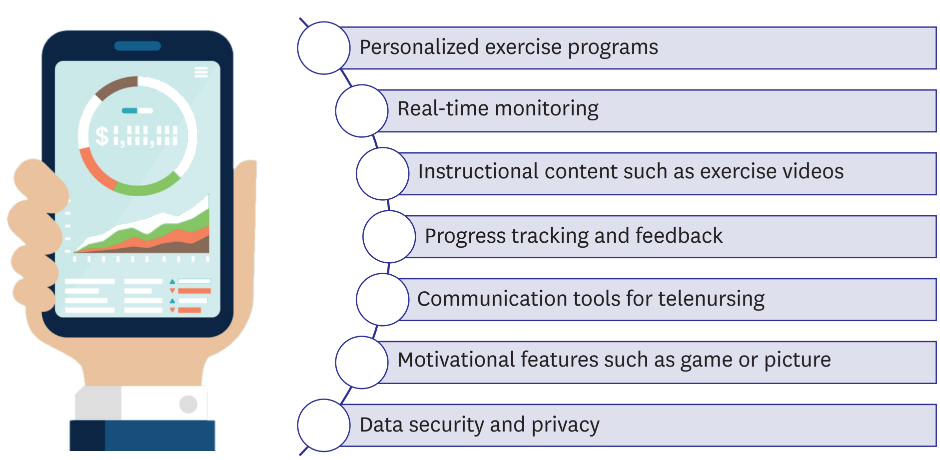

Figure 4. Software as a Medical Device for remote cardiac rehabilitation. Health apps are intangible, but are recognized as medical devices and can be used as monitors, programs, communication tools, and personal health data gatherers.

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SaMD platforms should adhere to strict data protection measures, including encryption, secure data storage, and compliance with the relevant healthcare data regulations. Additionally, SaMD solutions can be integrated with electronic health record systems, which allows seamless sharing of personal health record (PHR) with healthcare providers.

Notably, SaMD platforms for remote CR should be developed in compliance with medical device regulations; furthermore, healthcare professionals should be actively involved in guiding patients through the rehabilitation process and making informed decisions based on data collected by the SaMD platform.

In addition to SaMD, which requires registration as a conventional medical device, there is a growing expectation for non_SaMD, which does not require registration as a medical device and is easier to bring to market, but is a high-quality health promotion application. In the US, SaMD is covered by the Health Insurance Portability and Accountability Act (HIPAA), and the Department of Health and Human Services has promoted the use of health data based on the Health Level 7 - Fast Healthcare Interoperability Resources (LH7-FHIR) standard. LH7-FHIR is a standard for health information exchange that enables access to data distributed across multiple systems, databases, and devices. In contrast, non-SaMD, which is exempt from HIPAA, has been under the jurisdiction of the Federal Trade Commission, which is responsible for consumer protection. However, the lack of strict standards in the development and operation of non-SaMD has sometimes caused problems, including several reported violations of privacy laws in the US. As a result, non-SaMD may be required similar privacy and cybersecurity measures as SaMD in the future.

PATIENT RISK STRATIFICATION AND SAFETY OF REMOTE CARDIAC REHABILITATION

To date, trials on remote CR have not reported significant risks; however, it is important to carefully examine and identify appropriate patients for remote CR implementation (**Table 2**).

For example, patients with physical conditions requiring assistance are unsuitable for remote CR since their main focus should be disuse rehabilitation under careful watch by face-to-

Table 2. Candidate patients for remote CR

1	Geographically remote patients	Individuals living in rural or underserved areas with limited access to outpatient-CR programs.
2	Patients with mobility limitations	Individuals with physical disabilities or limitations that make traveling to a rehabilitation center difficult.
3	Busy patients	People with demanding work schedules who might find it challenging to attend in-person sessions.
4	Patients who have developed exercise habits	Individuals who already have exercise habits can quickly start the remote CR program.
5	Patients with anxiety or depression	Those experiencing psychological distress following a cardiac event or diagnosis may benefit from a flexible, at-home rehabilitation approach.
6	IT equipment literate patients	Individuals or patients' families who can use IT devices. Platforms or apps with intuitive interfaces that require minimal technical skills are required.
7	Patients who have hospital backup	It is essential to have hospital backup to deal with patients when they are unwell and to provide remote program interventions.
8	Patients without frail or sarcopenia	Physical ability who can exercise themselves are required.
9	Patients without hearing loss	Individuals with difficulty hearing by phone or bidirectional video.
10	Patients without cognitive impairment	Cognition that can understand the method of the remote CR is required.
11	Patients without exercise risks	Cardiovascular patients who have risks of chest pain or arrhythmias during exercise should be avoid remote CR program, as first aid is delayed.
12	Patients without CIEDs*	Wearable devices do not guarantee complete safety in patients with CIEDs.

CIED = cardiac implantable electronic devices; CR = cardiac rehabilitation; FDA = Food and Drug Administration; IT = information technology.

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face. Moreover, elderly or female patients may have difficulty using communication devices; additionally, remote CR may be unsuitable for patients with dementia or severe hearing loss who cannot answer the telephone. In addition, remote CR is unsuitable for patients at high exercise risk, including those who develop arrhythmias such as ventricular tachycardia and ventricular fibrillation during exercise, given the delay in first aid. Conversely, patients suitable for remote CR include those who are young and able to manage exercise, too busy or too far away to make frequent hospital visits, and do not like to exercise in a group setting. Although some wearable devices do not guarantee complete safety in patients after pacemaker or implantable cardioverter-defibrillator implantation, smartwatches and their chargers were reported to rarely interfere with proper cardiac implantable electronic devices (CIEDs) function and have been used in practice.[26] As long as the Food and Drug Administration recommendations of keeping smartphones and accessories at least 6 inches away from CIEDs are followed, the risk of a clinically significant event is unlikely.

Patients with heart failure as well as those who have undergone catheterization and heart bypass who used to exercise before treatment have been considered good candidates for remote CR. However, patients who have undergone valvular disease treatment, including transcatheter aortic valve implantation or transcatheter mitral valve repair, are more suitable for outpatient CR due to disuse syndrome or the appearance of exercise-induced arrhythmias. Furthermore, patients who have undergone aortic dissection are considered more suitable for outpatient management given the need for strict monitoring of blood pressure during exercise. Nevertheless, remote CR remains in its early stage of implementations, and cardiologists should fully examine the indications for the safe implementation of remote CR from many perspectives.

Ensuring safety before exercise is important. In our remote CR program, cardiologists conducted CPET before the start of the CR program; prescribed appropriate exercise; and instructed patients not to exceed the Borg13 exercise load, which suggests the anaerobic threshold level of exercise load. On a daily basis, patients in the remote CR program should be instructed that they could only exercise if they had no problems with the 12 items presented in the application (**Table 3**). Further, in case of appearance of chest symptoms during exercise, the patient is instructed to stop exercising and contact the hospital. The real-time interactive system with the ergometer allows immediate assessment, while the remote system with wearable devices allows direct contact with the hospital since a smartphone is linked to the watch.

Table 3. Self checklist before starting exercise of remote cardiac rehabilitation

1	Severe leg and foot pain
2	Fever
3	Feeling tired
4	Nausea or feeling sick
5	Headache or dizziness
6	Ringing in the ears
7	Feeling ill with sleep deprivation
8	Loss of appetite
9	Diarrhea, constipation, or stomach pain
10	Have a cold
11	Heart palpitations and shortness of breath with low levels of exercise
12	Chest pain with low levels of exercise

If patients have above symptoms, they are recommended to stop exercise. If their condition is worse than usual and do not improve, patients are recommended to go to hospital.

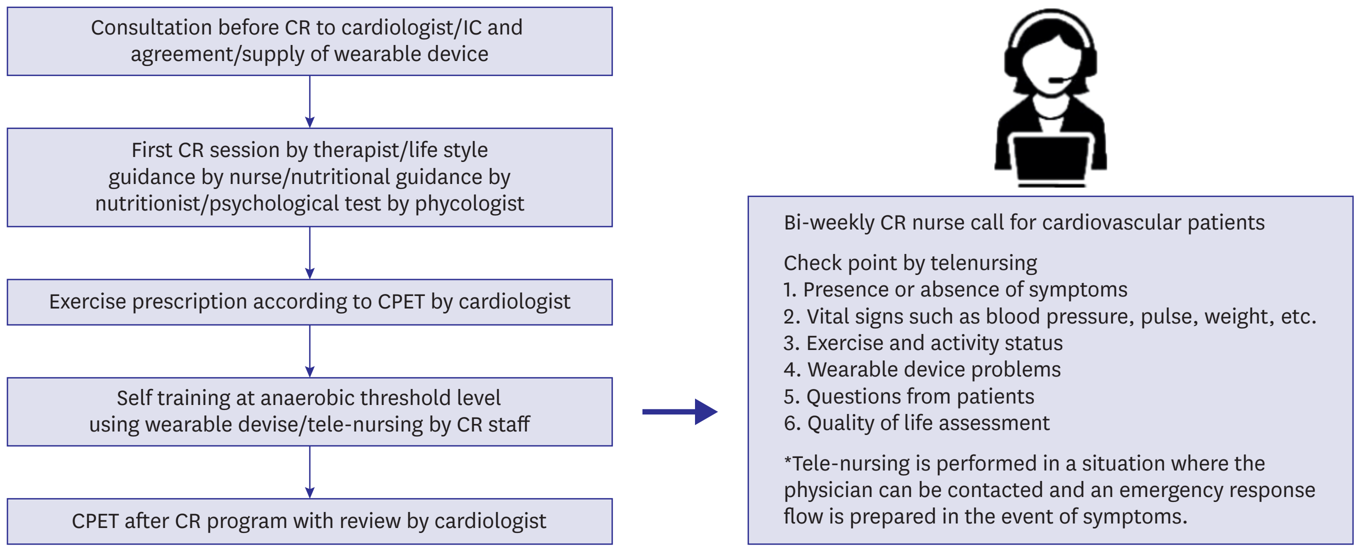

Figure 5. Flowchart of remote heart management by a multi-disciplinary team. A flow of telenursing and multi-professional interventions must be developed in advance to collect data efficiently.
CPET = cardiopulmonary exercise testing; CR = cardiac rehabilitation; IC = informed consent.

QUALITY ASSURANCE OF TELENURSING AND MULTIDISCIPLINARY INTERVENTION

Supervision of lifestyle guidance through telenursing is not limited to nurses; rather, it can be provided by doctors, physiotherapists, nutritionists, occupational therapists, psychologists, and social workers. However, there remain no established guidelines indicating the medical professionals qualified for telenursing supervision in Japan. Since the supervision is not always in a face-to-face basis, the supervisor should be skilled in efficient communication and ability to accurately detect signs from the patient without relying on facial expressions, which are then transmitted to the doctor and multidisciplinary conferences.

Data obtained from wearable devices and applications play an important role as objective indicators of safe exercise therapy. Accordingly, both the patient and telenursing supervisor should be able to appropriately utilize information and communication technology. Further, to efficiently obtain patient information within a limited time through telephone interviews, questions regarding symptoms, vital signs, exercise, problems related to wearable device equipment, and quality of life scores should be prepared in advance and recorded in the medical records (**Figure 5**).

For example, in remote CR department of Sakakibara Heart Institute, telenursing takes 10–30 minutes per person; further, a weekly multidisciplinary meeting is held, which must be considered as an effort of the medical staff for social implementation. If the telenursing supervisor recognizes signs of heart failure or chest pain, a doctor is consulted; if a patient's anxiety or depressive symptoms are suspected, a clinical psychologist is consulted; and if employment support is deemed necessary, a social worker is contacted. Regarding whether a license is required for telenursing practitioners, it is importance to consider the extent of telemedicine implementation and labor availability as well as seek reasonable strictness but ensured quality. In Japan, medical qualifications such as Certified Heart Failure Educator or Registered Instructor of Cardiac Rehabilitation could be proposed for telenursing supervision. Multidisciplinary cooperation is important in telenursing for comprehensive CR; accordingly, it is important to establish a system that facilitates this multidisciplinary cooperation within a limited time without the need for face-to-face contact.

In July 2023, American Heart Association has initiated a certification system to maintain the quality of telemedicine, and the academic society is considering directions to ensure the accuracy and reliability of telemedicine.[27] Such certification system would also be required in other countries.

TIMING OF REMOTE CARDIAC REHABILITATION INTERVENTIONS

The appropriate phase for remote CR intervention is the recovery or maintenance phase after assessment of the exercise-related risk.[9] However, the lack of data regarding acute remote CR impedes evaluation of its effectiveness during hospitalization. In the recovery and maintenance phases, remote CR could be considered for allowing home-based exercise therapy since exercise therapy should be incorporated in the daily routine. Employment support for patients with cardiovascular disease is often provided during the recovery and maintenance phases; therefore, remote employment support is being explored.

MEDICAL INSURANCE FOR REMOTE CARDIAC REHABILITATION IN THE WORLD

Japan has a universal health insurance system; further, remote medical consultation using communication devices is currently covered by insurance. However, remote CR is yet to be covered by insurance; therefore, research funds are required for remote CR applications such as TeleRehab®.[24] Additionally, further evidence is required to inform the inclusion of remote CR in the insurance coverage.

In the US, telemedicine has been introduced, and a telemedicine system has been established by the government since it is cheaper than visiting a medical institution and can be used at any time. There are 2 main public health insurance schemes in the US. The first one is Medicare, a health insurance scheme for the elderly patients and patients with disability aged ≥65 years, which is administered by the federal government. The second one is Medicaid, which covers low-income individuals and is administered by the state and federal governments. Telemedicine services covered by the Centers for Medicare and Medicaid Services include telemedicine by doctors, nurses, psychologists, PTs, and occupational therapists using videoconferencing systems. Moreover, telecoaching by medical staff is covered for the same amount as face-to-face treatment.[28] However, remote CR is not covered by public insurance in the US.

In China, there has been a shortage of doctors. To address regional disparities, Ping An Good Doctor®, China's largest online medical application, provides a one-stop service for health consultations, medical appointments, and online medication prescription.[29] Moreover, AI analysis is conducted using data obtained from over 100 million users to inform healthcare interventions. The onset of the COVID-19 pandemic led to a rapid response to insurance reimbursement for online medical services by both public medical institutions and private companies.

In Europe, online medical applications covered by national health insurance are used in several countries. In the United Kingdom (UK), the number of consultations on the online medical system eConsult® has rapidly increased as a result of the National Health Service, which is free-of-charge in principle, switching to online medical care, requesting support to expand the introduction of online medical care, and encouraging online collaboration among medical professionals in response to the COVID-19.[30)]

RETURN TO WORK SUPPORT THROUGH REMOTE CARDIAC REHABILITATION

Japan has become an aging society with a super-low birth rate, and the working population (age 15–64 years) has already begun to decline. One of the government's measures for reforming the work culture is promoting employment among the elderly and balancing work with disease treatment. Traditionally, CR teams have provided comprehensive support for patients with cardiovascular disease through multidisciplinary interventions, including lifestyle modifications such as exercise, nutritional guidance, smoking cessation, psychological counseling, disease education, and social support. The CR team comprises doctors, nurses, PTs, chartered psychologists (clinical psychologists), dietitians, social workers, speech therapists, and occupational therapists. Outpatient CR is a comprehensive multidisciplinary intervention that is effective in supporting patients who need to return to work. A systematic review with meta-analysis conducted in 2021 concluded that CR interventions, including outpatient CR, are effective in supporting employment.[31)] Specifically, multidisciplinary support through outpatient CR is considered effective since it is not possible to detect and address employment support issues during hospitalization; moreover, long-term social support in outpatient settings is required for some patients after discharge.

In Sakakibara Heart Institute, which is among the largest CR centers in Japan that handles 34,000 cases of CR annually, remote CR with wearable devices has become a routine practice. In addition to consultation with specialized cardiologists for CR and CPET, biweekly telenursing for vital signs is conducted using the remote CR application for comprehensive cardiac management, with implementation of hybrid CR. CR nurses responsible for telenursing identify patients requiring employment support in the remote CR program, which is provided using the same process using for patients receiving outpatient CR. In this institute, psychological assessment is performed using the Patient Health Questionnaire 9 and the Hospital Anxiety and Depression Scale during the first remote CR interview. A case of long-term telesupport was described in a patient treated for myocardial infarction who needed psychological support. The patient's return-to-work problems occurred gradually after discharge. Eventually, he was able to return to work after extensive discussion with a psychologist about the possibility of remote support or recommending medical consultation; in addition, the patient received psychological counseling during the biweekly telenursing.[32)]

COST-EFFECTIVENESS OF REMOTE CARDIAC REHABILITATION

Few studies have examined the cost-effectiveness of CR in East Asia; however, there have been several reports from other countries. In 1992, Ades et al.[33)] conducted the first study on the cost-effectiveness of CR. Specifically, in a study on 580 patients who experienced myocardial infarction or cardiac bypass surgery, the outpatient-CR group (n=230) showed a mean cost saving of $739 compared with the non-CR group (n=380). A meta-analysis conducted in 1997 reported that CR was more cost-effective than other interventions such as cardiac bypass surgery or drugs for hyperlipidemia, with a survival benefit of 0.202 years over a 15-year follow-up period.[34] Since 2014, health economic evaluation methods have been established and the cost-effectiveness of CR has been actively studied. After 2016, many studies on the economic effectiveness of remote CR have been published abroad. Frederix et al.[35] reported that remote CR was cost-effective compared with outpatient CR (incremental cost-effectiveness ratio [ICER] $26,300/EuroQol-5 Dimension quality-adjusted life-year [QALY]). Contrastingly, a randomized trial on 151 patients found that there was no difference between the cost-effectiveness of outpatient and remote CR, which had an implementation cost of €392 for a remote device (rented devices for 3 months) and a monthly cost of €5,709, resulting in $710,000/QALY.[36] An Australian randomized trial on ergometer-based remote CR found that remote CR was more effective than standard care (estimated relative gain of 5.7 QALYs); however, remote CR was more costly (an extra $650,000 per 1,000 patients over 5 years) than standard practice.[37]

Since the assessed remote CR methods varied across studies, their costs cannot be compared uniformly, given the differences in the cost of remote CR telemonitoring performed in real time or non-real time, using ergometry or wearable devices to transmit biometric data. Telemonitoring remote CR, which requires renting or purchasing of an expensive remote device, incurs installation and maintenance costs; therefore, wearable devices with lower prices are likely to cost less. Cost-effectiveness analysis could inform insurance coverage for remote CR. To be considered cost-effective, the ICER must be lower than the limit, which varies across countries, with the limit being 5 million yen/QALY in Japan (Central Social Insurance Medical Council), 30,000 pounds/QALY in the UK, and 50,000 dollars/QALY in the US.

CONCLUSION

Although there are various available remote devices, it remains unclear whether remote CR using wearable devices can replace outpatient CR. Rather than using wearable devices as mere remote monitors, telenursing and multidisciplinary intervention via remote CR applications could be used to improve outcomes. Furthermore, available PHR-based analyses from wearable devices have the potential to help improve patients' quality of life.

In the future, it will be important to implement practical, versatile, and advanced remote CR solutions.

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