



BMJ Open Role of the intelligent exercise rehabilitation management system on adherence of cardiac rehabilitation in patients with coronary heart disease: a randomised controlled crossover study protocol

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ABSTRACT

Introduction The benefits of cardiac rehabilitation (CR) on the reduction of cardiac and all-cause mortality are well documented. However, adherence remains suboptimal in China. It is clear that traditional CR does not meet the needs of many eligible patients and innovation is required to improve its application. Home-based CR (HBCR) is a cost-effective method that may be a valuable alternative for many individuals in China. In HBCR, it is often difficult to maintain an exercise intensity that is both effective and within safe limits, factors that are essential for patient safety. Mobile health interventions have the potential to overcome these obstacles and may be efficacious in improving adherence. The purpose of this study is to evaluate whether an Intelligent Exercise Rehabilitation Management System (IERMS)-based HBCR could improve adherence to CR and to assess the effects on exercise capacity, mental health, self-efficacy, quality of life and lifestyle-related risk factors.

Methods and analysis We propose a single-blinded, two-arm, randomised controlled crossover study of 70 patients with coronary heart disease (CHD). Participants will be randomly assigned in a 1:1 ratio to one of the two groups. Patients in group 1 will receive the IERMS intervention together with usual care for the first 6 weeks and usual care for the last 6 weeks, while patients assigned to group 2 will receive usual care for the first 6 weeks and will use IERMS in the last 6 weeks. The primary outcome is adherence to the programme and secondary outcomes include exercise capacity, psychological well-being, quality of life, self-efficacy and lifestyle-related risk factors. All secondary outcomes will be measured at baseline, 6 weeks and 12 weeks.

Ethics and dissemination This study has been approved by the Human Research Ethics Committee of the School of Nursing, Jilin University (HREC 2019120901). The results will be published in peer-reviewed journals and at conferences.

Trial registration number ChiCTR1900028182; Pre-results.

Strengths and limitations of this study

- Our home-based cardiac rehabilitation programme is technology-based and may improve adherence of cardiac rehabilitation (CR) in patients with coronary heart disease.
- The measurements of plantar pressure and heart rate used in this study are accurate in evaluating exercise type and intensity. This is essential for reminding patients to exercise appropriately within safe limits during CR sessions at home.
- The crossover study design allows us to observe the maintenance of effects after the 6-week Intelligent Exercise Rehabilitation Management System intervention.
- The study is of relatively short duration and long-term effectiveness will not be observed after 12 months.
- The study is limited to patients with smartphones and internet access.

BACKGROUND

Coronary heart disease (CHD) is the leading cause of mortality in China and has increased by 20.6% from 1990 to 2017.¹ Studies over the past few decades have shown an increased prevalence and incidence of CHD and it was estimated that about 11 million patients suffered from it in 2017.² Patients with CHD have severe physical and often psychological problems and show reduced health-related quality of life scores, which is associated with high mortality and additional cardiac events.^{3,4}

Cardiac rehabilitation (CR), an integral component of the continuum of care for patients with CHD,⁵ has been demonstrated to

reduce mortality by up to 37%^{6,7} to improve both physical functioning and quality of life,^{8–10} and is recommended by the American Heart Association (AHA)/American College of Cardiology (ACC) and the European Society of Cardiology guidelines for patients with CHD.^{11,12}

Despite proven benefits, the use of adherence to CR remains suboptimal, with participation rates between 10.3% and 16.3%¹³ and dropout rates between 40% and 55%.^{14,15} In China, access to CR services remains very low, with the estimated availability of CR programmes about two programmes per 100 million inhabitants.¹⁶ This may be due to the poor availability and problems with supplying CR in China, including lack of facilities, funding, staff training and reimbursements for participating patients.^{17,18} Drop-out or non-adherence may lead to undesirable outcomes in CHD.¹⁹ Therefore, innovation is needed to improve the implementation of CR in China.

Besides centre-based CR (CBCR), home-based CR (HBCR) is an alternative method recommended by AHA and ACC. HBCR may be more effective in the provision of CR to many patients in China²⁰ and has proved to be effective in improving adherence.²¹ However, while effective performance of the prescribed exercises is essential, difficulties, such as managing the exercise type, intensity and duration appropriately at home, occur with HBCR.²² With the development of new digital technologies, mobile health (m-health) interventions have emerged and have shown the potential to deliver HBCR safely and effectively.^{23–25} The m-health interventions could help patients to monitor exercise intensity, provide objective feedback data and encourage patients to track their own progress, which could help them to self-manage their CR and may be useful in improving their adherence. In addition, patients with CHD have shown great interest in using m-health at home, providing the clear potential for developing such interventions.²⁶

In HBCR, m-health that could accurately monitor the intensity and type of exercise is required to ensure both safety and effectiveness. The Intelligent Exercise

Rehabilitation Management System (IERMS) has been designed to meet these requirements. It introduces a closed-loop rehabilitation management system that supports the home-based management of prescribed CR and lifestyle-related risk factors for patients with CHD. The purpose of this study is to evaluate whether IERMS-based HBCR could improve adherence to CR and to assess its effects on exercise capacity, mental health, self-efficacy, quality of life and lifestyle-related risk factors. The results of the trial are expected to facilitate the development of effective m-health interventions for HBCR.

METHODS

Study design

A single-blinded, two-arm, randomised control crossover study will be conducted to evaluate the role of IERMS-based HBCR on adherence, exercise capacity, mental health, self-efficacy, quality of life and lifestyle-related risk factors. All participants will be recruited from the CR outpatient setting of a medical centre in Changchun, China. A total of 70 participants will be randomly assigned to one of two groups. Patients in group 1 will use IERMS in the first stage and receive usual care in the last stage, while patients in group 2 will receive usual care in the first stage and IERMS-based HBCR in the last stage. Each stage of the study will last for 6 weeks. As one of our main objectives is to assess whether there is an interaction at the end of the intervention and to observe the maintenance of the effects after the intervention, this study does not allow a wash-out period. An illustration of the study design is displayed in figure 1. The trial conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines²⁷ and is registered at ClinicalTrials.gov.

Eligibility and recruitment

Patients will be eligible to participate if they have: (1) a documented diagnosis of CHD and having had a hospitalisation incident within 6 months prior to randomisation;

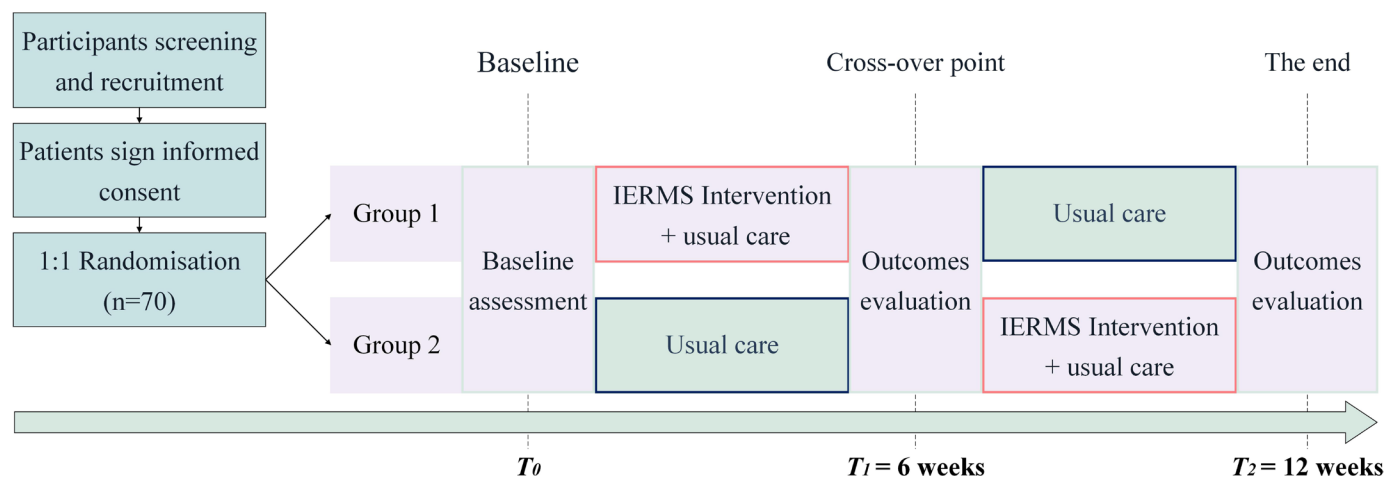


Figure 1 Illustration of the randomised controlled crossover study design. IERMS, Intelligent Exercise Rehabilitation Management System.

(2) been assessed as suitable by a cardiologist and a physical therapist to participate in their CR; (3) no contraindications to undergo a cardiopulmonary exercise test; (4) should own a smartphone and be willing and able to upload data and that they should have access to internet at home and (5) if they are willing and able to participate in the study and to provide written informed consent.

Exclusion criteria include: (1) severe heart failure (New York Heart Association (NYHA) class IV); (2) unstable angina; (3) unstable clinical status; (4) coronary artery bypass grafting within the last 3 months; (5) patients are unable to use the IERMS-enabled devices after instruction; (6) requiring a walking aid for mobility and (7) participation in another clinical trial.

Our research group has formed a team with experienced clinical nurses and rehabilitation therapists in the cardiovascular department at a medical centre in Changchun, China. Experienced clinical nurses and researchers in our team will be responsible for recruiting participants. Patients admitted with CHD and eligible for CR will be screened and those meeting the inclusion criteria will be invited to participate. Rehabilitation therapists will inform them of the study details, and if they agree to participate in the study, they will be asked to sign the consent form. If complex clinical problems are encountered, our researchers, nursing experts and rehabilitation therapists will work together to develop a solution.

Sample size calculation

This study selects the main outcome indicators of HBCR adherence as the calculation standard. A previous study has shown CR adherence rates of ~94% for technology-based HBCR and 68% for traditional CR.²⁸ We will use two sample rate calculation formula: $N = \left[\frac{Z_{\alpha/2} \sqrt{\pi_c(1-\pi_c)(Q_1^{-1} + Q_2^{-1})}}{\pi_1 - \pi_2} \right] + \left[\frac{Z_{\beta} \sqrt{\pi_1(1-\pi_1)/Q_1 + \pi_2(1-\pi_2)/Q_2}}{\pi_1 - \pi_2} \right]$ with 90% power (type I error=5%) to calculate the sample size, and a total sample size of 54 across both arms will be used in this study. Allowing for an estimated 20% loss to follow-up, a total of 70 participants will be recruited.

Randomisation, blinding and concealed allocation

After signing an informed consent, patients will complete a baseline assessment. They will then be randomised in a 1:1 ratio to either group 1 or group 2 by a computer-generated randomisation list, using block randomisation and randomly selected block sizes of 4, 6 or 8. This assignment will be done by independent individuals who will not participate in the recruitment process. Given the characteristics of the intervention, the participants or researchers implementing the intervention cannot be blinded. However, researchers evaluating the results will be unaware of patient assignments. To ensure hidden assignments and minimise selection bias, independent designated members of the School of Nursing, Jilin University, will assign random numbers based on local researcher requirements.

Usual care

Regardless of the IERMS intervention, all patients will receive usual care. Patients will receive health education about CR provided by a cardiologist and a physical therapist will give them personalised exercise prescriptions according to the results of their cardiopulmonary exercise test (CPET). Patients will be free to participate in any type of exercise classes, Tai Chi programmes, group dancing and available CR programmes after discharge from rehabilitation facilities. All patients will be required to upload exercise logs weekly at home, including exercise type, intensity and duration. Patients using IERMS will have exercise logs automatically recorded by the system and are required to upload them to the research team. Patients under usual care will record exercise logs in any form they like in the memorandum, and we will remind them to send them to us weekly through WeChat which is a popular social media site in China. In addition, all patients will receive follow-up calls at 6 weeks and 12 weeks.

Key components of IERMS

The IERMS is a closed-loop rehabilitation management system which can facilitate management of exercise prescription and lifestyle-related risk factors and consists of three main components: professional system, patient station and the cloud (figure 2). This system has been authorised as a China Invention Patent (Publication Patent Number : 201810114305.3).

Patient station

The patient station consists of one mobile application and two monitoring devices which include a pair of smart insoles and a heart rate (HR) monitor.

Smart insoles have been independently developed in this study and are able to measure gait parameters using inserted plantar pressure sensors and accelerometers during CR sessions. This has been shown to be accurate in identifying the type of exercise and in calculating energy expenditure.^{29,30} The data collected by the smart insoles will be uploaded to the cloud, and the cloud will analyse the metabolic equivalent through an algorithm which has been developed specifically for this study, and then present the results on the mobile application. The HR monitor used in this study is attached around the chest and can monitor HR in real-time.

The mobile application and these monitoring devices are connected by Bluetooth. The mobile application is thus able to synchronise the data collected by the sensors and provide real-time motivational feedback automatically generated from actual exercise performances. Furthermore, the mobile application can present educational materials and exercise prescriptions prescribed by professionals and upload patients' data to the professional system.

The cloud

The cloud is the core part of the data processing, which stores and analyses the data transmitted by the

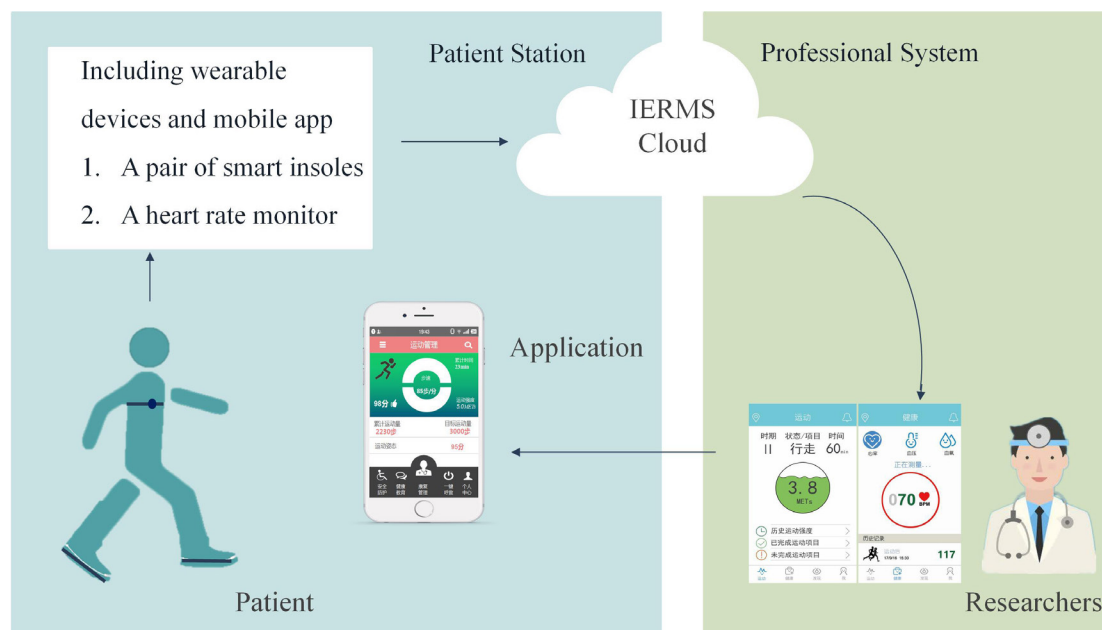


Figure 2 Components of the IERMS. IERMS, Intelligent Exercise Rehabilitation Management System.

monitoring devices and then distributes the results to the patient station and the professional system. The cloud will use deep neural network models to train and evaluate the data and generate feedback on the patient's exercise and send them to the mobile application on the patient station. The cloud will also send a report of the exercise performance of patients in CR sessions to the professionals allowing them to update the exercise prescription for reference.

Professional system

The professional system is a web-based tool for medical professionals, which can manage patients' CR exercise at home. Patient files are stored in the system, including the patient's medical history, past exercise prescriptions and lifestyle-related risk factors. The system can also synchronise the patient's exercise progress, weight, HR, Blood Pressure (and BP) and so on. The professionals can thus monitor the patient's health situations remotely through the system and perform continuity of care for patients.

Description of the IERMS intervention

Eligible and consenting participants will be enrolled prior to discharge from an outpatient ambulatory CR programme and will learn and practice all features of the system in the hospital. Participants will be given a pair of smart insoles and an HR monitor and a mobile application will be installed on their smartphones.

Tele-monitoring CR sessions

In order to ensure the patients' safety, a series of confirmations will be performed before CR sessions, including BP, HR and the presence or absence of cardiac symptoms, such as dyspnoea and chest distress. Patients will receive immediate feedback on whether they are safe to exercise at that time, and if not, the exercise time will be changed.

During the exercise sessions, patients will be asked to wear a pair of smart insoles and an HR monitor, which can monitor the intensity and type of exercise to ensure both safety and effectiveness. Endurance and resistance training are both included in CR sessions. The goal of the endurance training is to reach the individual, predefined target zone,³¹ which will make sure that the patient is safe while also allowing effective exercise. When the exercise intensity is not enough, the mobile application will automatically encourage the patients to speed up, and if the exercise intensity is excessive or the exercise type is not appropriate, the mobile application will remind the patients to slow down or change the type of training.

Encouraging self-management

The IERMS will provide an individualised exercise target according to the prescribed exercise programme developed by the physical therapists, which will be progressively updated weekly. The medical staff will be able to monitor the exercise frequency, intensity and type of exercise through the information collected by the monitoring devices and give feedback on the completion of the rehabilitation exercise and set goals, which can encourage patients to track their exercise progress. In addition, patients can communicate with the professionals via short message service built into the mobile application and receive feedback within 24 hours.

The IERMS encourages patients to upload BP, HR, weight, smoking situation and physical activity to the mobile application. This enables them to track their own progress to motivate them to quit smoking, lose weight, improve physical activity and reduce sedentary behaviours, which can, in turn, improve their self-monitoring, thereby increasing patients' adherence. Participants will also be encouraged to participate in other different types of physical activities, such as jogging, Tai Chi and group dancing.

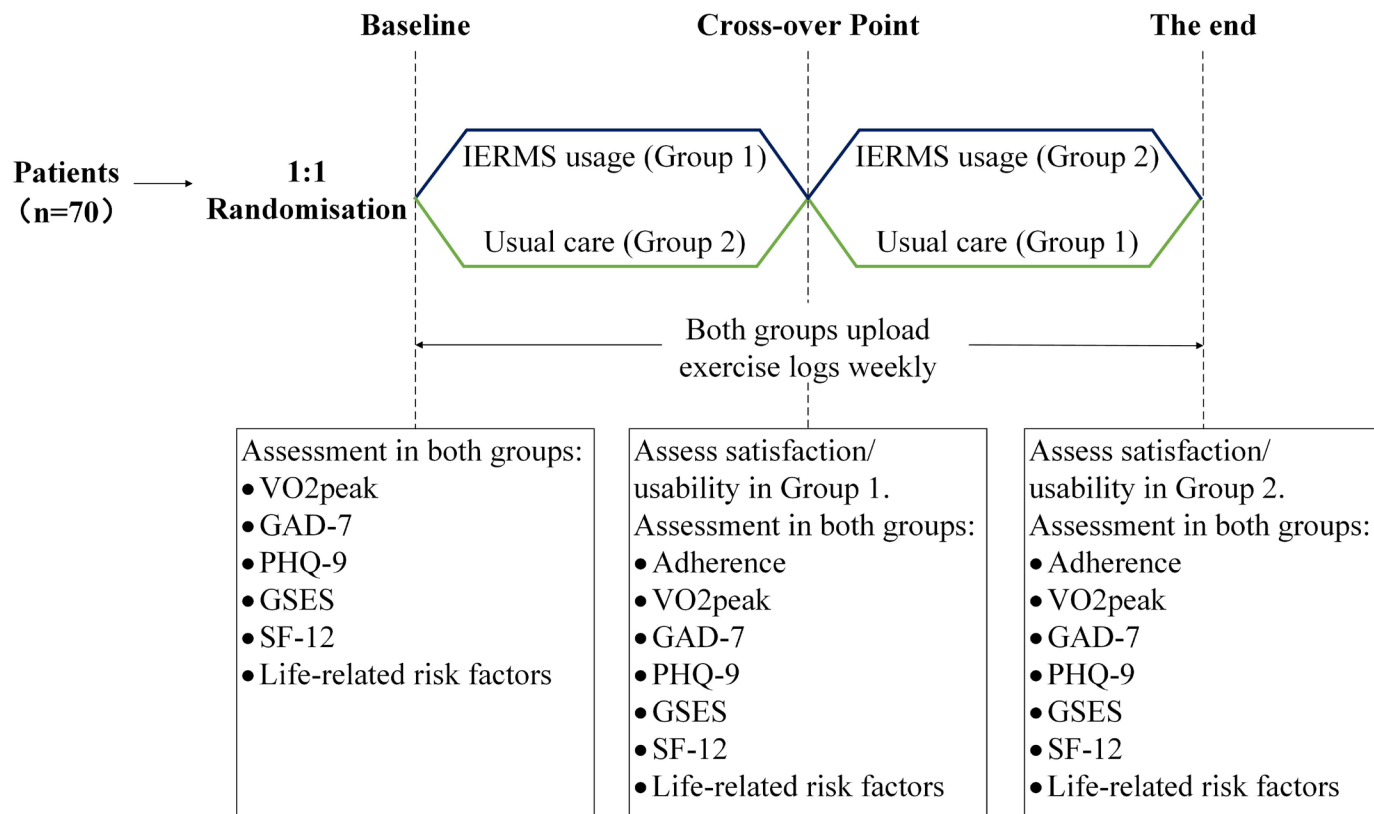


Figure 3 Assessment timepoints for primary and secondary outcomes. GAD-7, the Generalised Anxiety Disorder Scale-7; GSES, General Self-efficacy Scale; PHQ-9, Patients' Health Questionnaire Depression Scale-9; SF-12, the 12-Item Short form Health Survey; VO_{2peak}, peak oxygen uptake.

Outcome measures and data collection

Outcome measures will be analysed by researchers blinded to the group allocation. All assessments will be performed at baseline, 6 weeks and 12 weeks (figure 3). A summary of the outcome measures for the study is outlined in table 1.

Primary outcome

The primary outcome will be adherence for CR. Adherence is defined as attendance for 4 weeks (eight or more sessions) for usual care or uploading of 4 weeks' data for IERMS-based HBCR and attending 6 week assessments (both groups), as described in a similar study by Dalal *et al.*³² The participation information in the IERMS-based HBCR phase will be collected by the IERMS, while the adherence in the usual care phase will be analysed from the training log.

Secondary outcomes

The secondary outcome measures for the trial are outlined in figure 3. In general, all secondary outcomes will be measured at baseline, 6 weeks and 12 weeks. Secondary outcomes include VO_{2peak}, the Generalised Anxiety Disorder Scale-7 (GAD-7); Patients' Health Questionnaire Depression Scale-9 (PHQ-9); the 12-item Short Form Health Survey (SF-12); General Self-Efficacy Scale (GSES) and lifestyle-related risk factors, which include weight, smoking situation and physical activity. Satisfaction/usability will be measured at the end of the IERMS

intervention in each group, using a 5-point Likert scale specifically designed for this study.

Adverse events monitoring

We will report all adverse events that occurred during the 12 weeks study period in the final paper. Adverse events during exercise training sessions are defined as deaths or other medical occurrences resulting in hospitalisation during CR sessions or immediately after training sessions in an hour. Other adverse events are defined as medical occurrences resulting in hospitalisation, disability or deaths without connection to training sessions. We will report all these adverse events to the Ethics Committee as required.

Data collection, management and analysis

All patients' data will be recorded by trained clinical researchers using a standardised case report form (CRF). We will record raw data appropriately and accurately and will keep copies of the laboratory reports. We will also store the CRFs in areas with restricted access.

Statistical analysis

Test for significance

Categorical variables will be described as frequencies and percentages, and the difference between two groups will be compared using the χ^2 test or Fisher's exact test. Continuous variables will be reported as mean and SD, the t-test will be used if the data show a normal distribution, and

**Table 1** Completed Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram for the study

	Study period				
	Enrolment	Allocation	Postallocation		Close-out
Timepoint *	-t1	0	t1	t2	t3
Enrolment					
Eligibility screen	X				
Informed consent		X	X	X	
Randomisation		X	X	X	
Allocation		X	X	X	
Interventions					
Group 1*		<----->			
Group 2†		<----->			
Assessments					
Adherence			X	X	
VO _{2 peak}		X	X	X	
GAD-7		X	X	X	
PHQ-9		X	X	X	
SF-12		X	X	X	
GSES		X	X	X	
Life-related risk factors‡		X	X	X	
Adverse event reporting		<----->			
Satisfaction/usability tests§			X	X	

t1=6 weeks, t2=12 weeks, t3=12 weeks.

*IERMS in the first phase and usual care in the second phase.

†Usual care in the first phase and IERMS in the second phase.

‡Part of routine care and therefore assessed before informed consent.

§Satisfaction/usability test will only be performed after IERMS intervention in each group.

GAD-7, Generalised Anxiety Disorder Scale-7; GSES, General Self-Efficacy Scale; IERMS, Intelligent Exercise Rehabilitation Management System; PHQ-9, Patients' Health Questionnaire Depression Scale-9; SF-12, the 12-item Short Form Health Survey.

effects if the data do not show normal distribution. We will also compare the differences between patients who are adherent and those who are non-adherent to analyse the factors that influence adherence. Furthermore, the secondary comparison will be conducted according to the intent-to-treat comparison, which will include the full sample of randomised patients. All statistical analyses will be two-sided, and $p < 0.05$ will be considered statistically significant. SPSS V.20.0 will be used for data analysis.

Test for carryover effects

Carryover effects will also be analysed in this specific context. We will analyse the changes in the two groups at 12 weeks, in other words, the changes in the first stage plus the changes in the second stage. Continuous variables will be analysed using the t-test or rank test to compare the differences between the two groups. Categorical variables will be compared using the χ^2 test. No significant difference indicates no carryover effect.

Patient and public involvement

Patient and public involvement has played an important part in this research. During the IERMS development,

CHD patients were invited to participate in surveys and discussions to help the research team better design the function and interface of the IERMS according to patients' priorities and preferences. In the pilot study, we also invited patients to give constructive feedback, which allows us to better understand their needs and barriers in HBCR and valuable suggestions in IERMS. In addition, patients were also invited to give reasonable recommendations for study design, questionnaire selection and outcome measurements while considering the burden of intervention. The results of the study will be disseminated to participants who wish to be notified.

ETHICS AND DISSEMINATION

The Human Research Ethics Committee of the School of Nursing at Jilin University has approved for the study (HREC 2019120901). Research reports will be disseminated through scientific forums, including peer-reviewed publications and presentations at national and international conferences.

DISCUSSION

The IERMS-based HBCR programme developed in this study evaluates the role of HBCR by combining m-health interventions (monitoring devices, internet and mobile applications) with evidence-based CR guidance strategies, including exercise intensity monitoring, feedback on CR progress and self-management life-style risk factors. The purpose of this study is to investigate whether HBCR using IERMS could improve adherence of CR in patients with CHD and the maintenance of the intervention.

CR is a Class I recommendation for managing CHD patients.³³ However, despite increasing evidence that has proven its cost-effectiveness and efficacy in reducing cardiovascular morbidity and mortality, CR services remain limited in China.^{8 15} HBCR is a method to increase the CR participation rate in CHD patients.²¹ Setting the prescribed amount of exercise and monitoring its intensity are the key points of HBCR to ensure that the exercise is both appropriate and within safe limits.³⁴ The planter pressure sensors have been proven to be accurate in measuring the patient's exercise type and intensity.^{29 30} Combined with intelligent insoles and wearable HR monitors, our system can evaluate whether patients reach the required exercise intensity and are able to promptly alert patients should the intensity fall outside the preset range. Furthermore, before each CR session, the cardiologist will evaluate the suitability of the exercise programme according to the patients' health data patients synchronised by IERMS to ensure patient safety. IERMS also encourages patients to upload BP, HR, weight and physical activity to track their own progress and give objective feedback, which could motivate self-monitoring, thereby improving patients' adherence.

Another key point which has impact on HBCR is the maintenance of the rehabilitation. The effectiveness of rehabilitation programmes after stopping intervention has proven to be unsustainable in both CBCR and HBCR.³⁵ We will, therefore, also evaluate if there are any significant carryover effects in order to observe the maintenance of effects after the termination of the intervention.

An improvement in adherence may be associated with better physical and psychological states. We will also evaluate these in this study. CPET can be used to assess a patient's exercise performance and VO_{2peak} which has been shown to be the strongest predictor of mortality³⁶ and which we have, therefore, chosen as a secondary outcome. In addition, mental status, self-efficacy, quality of life and lifestyle risk factors are important for HBCR assessment; thus, our study will also evaluate them.

In China and other lower middle-income countries where access to CR is often limited, m-health interventions, such as IERMS used in our study, may effectively overcome barriers, such as inconvenience, geographical isolation and financial burden, and deliver the core components of HBCR to many patients with CHD.

Limitations

Our current study has several limitations. First, as the study is of relatively short duration, no data will be available beyond 12 months and longer-term effectiveness will not be able to be evaluated. Second, the study is limited to patients with smartphones and internet access which may cause selective bias. Third, we will not be able to allow participants to have a familiarisation period of several weeks before using IERMS.

CONCLUSION

In conclusion, our study will evaluate the role of the IERMS intervention on the delivery of HBCR as advocated in various guidelines. If this technology-based HBCR intervention is shown to be effective, it may be an alternative method to implement evidenced-based CR for patients with CHD.

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Contributors LX and FL conceived the original concept of the study and wrote the first draft of the protocol manuscript. WX, JL, HS, MS, XZ, YP, YN, WZ, YL, LG, SZ and LZ contributed to the design of the study. LX, FL, JL, MS and XZ revised the manuscript. All authors read and approved the final manuscript.

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Competing interests None declared.

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