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## Role of the Intelligent Exercise Rehabilitation Management System on adherence of cardiac rehabilitation in patients with coronary heart disease: a randomized controlled crossover study protocol

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## Title Page

### Title of the article:

Role of the Intelligent Exercise Rehabilitation Management System on adherence of cardiac rehabilitation in patients with coronary heart disease: a randomized 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 sub-optimal 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 essential to maintain an exercise intensity that is both effective and within safe limits. 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 Exercise 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, randomized control crossover study of 54 patients with coronary heart disease (CHD). Participants will be randomly assigned in a 1:1 ratio to one of two groups. Patients in Group 1 will receive the IERMS intervention together with usual care for the first six weeks and usual care for the last six weeks, while patients assigned to Group 2 will receive usual care for the first six weeks and will use IERMS in the last six weeks. The primary outcome is adherence to the program and secondary outcomes include

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4 exercise capacity, psychological well-being, quality of life, self-efficacy  
5  
6 and lifestyle-related risk factors. All secondary outcomes will be measured  
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8 at baseline, six weeks and 12 weeks.  
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10

11  
12 **Ethics and dissemination:** This study has been approved by the Human  
13  
14 Research Ethics Committee of the School of Nursing, Jilin University  
15  
16 (HREC 2019120901). The results will be published in peer-reviewed  
17  
18 journals and at conferences.  
19  
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22  
23 **Trial registration number:** ChiCTR1900028182; Pre-results.  
24  
25

26  
27 **Key words:** Cardiac rehabilitation, adherence, coronary heart disease  
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### 32 33 **Strength and Limitations of this study** 34 35

- 36  
37 1. Our home-based cardiac rehabilitation program (HBCR) is technology-  
38  
39 based and may improve adherence of CR in patients with coronary heart  
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41 disease (CHD).  
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- 44  
45 2. The measurements of plantar pressure and heart rate (HR) used in this  
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47 study are accurate in evaluating exercise type and intensity. This is  
48  
49 essential for reminding patients to exercise appropriately within safe  
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51 limits during CR sessions at home.  
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- 54  
55 3. The crossover study design allows us to observe the maintenance of  
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57 effects after the three-week IERMS intervention.  
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- 4 4. The study is of relatively short duration and long-term effectiveness will
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- 6 not be observed after 12 months.
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- 9
- 10 5. The study is limited to patients with smartphones and internet access.
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## 16 **1. Background**

17  
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20 Coronary heart disease (CHD) is the leading cause of mortality in  
21  
22 China and has increased by 20.6% from 1990 to 2017<sup>[1]</sup>. Studies over the  
23  
24 past few decades have shown an increased prevalence and incidence of  
25  
26 CHD and it was estimated that about 11 million patients suffered from it in  
27  
28 2017<sup>[2]</sup>. Patients with CHD have severe physical and often psychological  
29  
30 problems and show reduced health-related quality of life (HRQoL) scores,  
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32 which is associated with high mortality and additional cardiac events <sup>[3-4]</sup>.  
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39 Cardiac rehabilitation (CR), an integral component of the continuum  
40  
41 of care for patients with CHD<sup>[5]</sup>, has been demonstrated to reduce mortality  
42  
43 by up to 37% <sup>[6-7]</sup> to improve both physical functioning and quality of life<sup>[8-</sup>  
44  
45 <sup>10]</sup>, and is recommended by the American Heart Association (AHA)/  
46  
47 American College of Cardiology (ACC) and the European Society of  
48  
49 Cardiology (ESC) guidelines for patients with CHD<sup>[11-12]</sup>.  
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55 Despite proven benefits, the use of and adherence to CR remains sub-  
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57 optimal, with participation rates of between 10.3% and 16.3% <sup>[13]</sup> and  
58  
59 dropout rates of between 40% and 55% <sup>[14-15]</sup>. In China, access to CR  
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4 services remains very low, with the estimated availability of CR programs  
5  
6 about two programs per 100 million inhabitants<sup>[16]</sup>. This may due to poor  
7  
8 availability and problems with supplying CR in China, including a lack of  
9  
10 facilities, funding, staff training, and reimbursements for participating  
11  
12 patients <sup>[17-18]</sup>. Drop-out or non-adherence may lead to negative outcomes  
13  
14 in CHD <sup>[19]</sup>. Therefore, innovation is needed to improve the implementation  
15  
16 of CR in China.  
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22  
23 Besides center-based CR, home-based CR (HBCR) is an alternative  
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25 method recommended by AHA and ACC. HBCR may be more effective  
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27 in the provision of CR to many patients in China<sup>[20]</sup> and has proved to be  
28  
29 effective in improving adherence <sup>[21]</sup>. However, while effective  
30  
31 performance of the prescribed exercises is essential, difficulties, such as  
32  
33 managing the exercise type, intensity and duration appropriately at home,  
34  
35 occur with HBCR <sup>[22]</sup>. With the development of science and technology,  
36  
37 mobile health (m-health) interventions have emerged and have the  
38  
39 potential to deliver HBCR safely and effectively <sup>[23-25]</sup>. The m-health  
40  
41 interventions could help patients monitor exercise intensity, provide  
42  
43 objective feedback data and encourage patients to track their own progress,  
44  
45 which could help them self-manage their CR and may be useful in  
46  
47 improving their adherence. In addition, patients with CHD have shown  
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49 great interest in using m-health at home, providing clear signs of  
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51 developing such interventions <sup>[26]</sup>.  
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4 The Intelligent Exercise Rehabilitation Management system (IERMS)  
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6 has been designed to meet these requirements. It introduces a closed-loop  
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8 rehabilitation management system that supports the home-based  
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10 management of prescribed CR and lifestyle-related risk factors for patients  
11  
12 with CHD. The purpose of this study is to evaluate whether IERMS-based  
13  
14 HBCR could improve adherence to CR and to assess its effects on exercise  
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16 capacity, mental health, self-efficacy, quality of life and lifestyle-related  
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18 risk factors. The results of the trial are expected to facilitate the  
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20 development of effective m-health interventions for HBCR.  
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## 28 **2. Methods**

### 29 **2.1 Study Design**

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32 A single-blinded, two-arm, randomized control crossover study will  
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34 be conducted to evaluate the role of IERMS-based HBCR on adherence,  
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36 exercise capacity, mental health, self-efficacy, quality of life and lifestyle-  
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38 related risk factors. All participants will be recruited from the CR  
39  
40 outpatient setting of a medical center in Changchun, China. A total of 54  
41  
42 participants will be randomly assigned to one of two groups. Patients in  
43  
44 Group 1 will use IERMS in the first stage and receive usual care in the last  
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46 stage, while patients in Group 2 will receive usual care in the first stage  
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48 and IERMS-based HBCR in the last stage. Each stage of the study will last  
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50 for six weeks. As one of our main objectives is to assess whether there is  
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4 an interaction at the end of the intervention and to observe the maintenance  
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6 of the effects after the intervention, this study does not allow a wash-out  
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8 period. The profile of the study design is displayed in Figure 1. The trial  
9  
10 conforms to the SPIRIT reporting guidelines [27] and is registered at  
11  
12 Clinical Trials.gov: ChiCTR1900028182.  
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## 16 17 18 **2.2 Eligibility and Recruitment**

19  
20 Patients will be eligible to participate if they have: (1) a documented  
21  
22 diagnosis of CHD and having had a hospitalization incident within six  
23  
24 months prior to randomization; (2) been assessed as suitable by a  
25  
26 cardiologist and a physical therapist to participate in their CR; (3) no  
27  
28 contraindications to undergo a cardiopulmonary exercise test; (4) if they  
29  
30 are willing and able to participate in the study and to provide written  
31  
32 informed consent.  
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40 Exclusion criteria include: (1) severe heart failure (NYHA class IV);  
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42 (2) unstable angina; (3) unstable clinical status; (4) coronary artery bypass  
43  
44 grafting within the last three months; (5) patients are unable to use the  
45  
46 IERMS-enabled devices after instruction; (6) lack of internet access at  
47  
48 home; (7) requiring a walking aid for mobility; (8) participation in another  
49  
50 clinical trial.  
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55 We will recruit participants at a medical center in Changchun, China.  
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57 Patients admitted with CHD and eligible for CR will be screened and those  
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meeting the inclusion criteria will be invited to participate. We 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.

### 2.3 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 ~68% and ~94% for technology-based HBCR [28]. We will use two

sample rate calculation formula: 
$$N = \left[ \frac{z_{\alpha} \sqrt{\pi_c (1 - \pi_c) (Q_1^{-1} + Q_2^{-1})}}{\pi_1 - \pi_2} + \frac{z_{\beta} \sqrt{\pi_1 (1 - \pi_1) / Q_1 + \pi_2 (1 - \pi_2) / Q_2}}{\pi_1 - \pi_2} \right]$$
 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.

### 2.4 Randomization, Blinding and Concealed Allocation

After signing an informed consent, patients will complete baseline measurement. They will then be randomized in a 1:1 ratio to either Group 1 or the Group 2 by a computer-generated randomization list, using block randomization 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

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4 minimize selection bias, independent designated members of the School of  
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6 Nursing, Jilin University will assign random numbers based on local  
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8 researcher requirements.  
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## 11 12 **2.5 Usual care**

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15 Regardless of the IERMS intervention, all patients will receive usual  
16  
17 care. Patients will receive health education about CR provided by a  
18  
19 cardiologist and a physical therapist will give them personalized exercise  
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21 prescriptions according to the results of their cardiopulmonary exercise test  
22  
23 (CPET). Patients will be free to participate in any type of exercise classes,  
24  
25 Tai Chi programs, group dancing and available CR programs after  
26  
27 discharge from rehabilitation facilities. All patients are required to record  
28  
29 exercise logs, including exercise type, intensity and duration at home and  
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31 will receive follow-up calls at six weeks and 12 weeks.  
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## 40 41 **2.6 Key components of IERMS**

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43 The IERMS is a closed-loop rehabilitation management system which  
44  
45 can facilitate management of exercise prescription and lifestyle-related risk  
46  
47 factors and consists of three main components: Professional System,  
48  
49 Patient Station and the Cloud (Figure 2). This system has been authorized  
50  
51 as a China Invention Patent (Publication Patent Number (PPNO):  
52  
53 201810114305.3).  
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## 60 **Patient Station**

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4 The Patient Station consists of one mobile application and two  
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6 monitoring devices which including a pair of smart insoles and a heart rate  
7  
8 (HR) monitor.  
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11  
12 Smart insoles have been independently developed in this study and  
13  
14 are able to measure gait parameters using inserted plantar pressure sensors  
15  
16 and accelerometers during CR sessions. This has been shown to be accurate  
17  
18 in identifying the type of exercise and in calculating energy expenditure [29-  
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20 30]. The data collected by the smart insoles will be uploaded to the cloud  
21  
22 which will analyze the metabolic equivalent (METs) and then present the  
23  
24 results on the app. The HR monitor used in this study is tied around the  
25  
26 chest and can monitor HR in real-time.  
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34 The mobile application and these monitoring devices are connected  
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36 by Bluetooth. The mobile application is thus able to synchronize the data  
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38 collected by the sensors and provide real-time motivational feedback  
39  
40 automatically generated from actual exercise performances. Furthermore,  
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42 the mobile application can present educational materials and exercise  
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44 prescriptions prescribed by professionals and upload patients' data to the  
45  
46 professional system.  
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## 52 **The cloud**

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56 The cloud is the core part of the data processing, which stores and  
57  
58 analyzes the data transmitted by the monitoring devices and then  
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4 distributes the results to the patient station and professional system. The  
5  
6 cloud will use deep neural network models to train and evaluate the data  
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8 and generate feedback on the patient's exercise and send them to the mobile  
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10 application on the patient station. The cloud will also send a report of the  
11  
12 exercise performance of patients in CR sessions to the professionals  
13  
14 allowing them to update the exercise prescription for reference.  
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### 20 **Professional System**

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23 The Professional System is a web-based tool for medical  
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25 professionals, which can manage patients' CR exercise at home. Patient  
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27 files are stored in the system, including the patient's medical history, past  
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29 exercise prescriptions and lifestyle-related risk factors. The system can also  
30  
31 synchronize the patient's exercise progress, weight, HR and BP, etc. The  
32  
33 professionals can thus monitor the patient's health situations remotely  
34  
35 through the system and perform continuity of care for patients.  
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### 42 **2.7 Description of the IERMS intervention**

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45 Eligible and consenting participants will be enrolled prior to discharge  
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47 from an outpatient ambulatory CR program and will learn and practice all  
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49 features of the system in the hospital. Participants will be given a pair of  
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51 smart insoles, an HR monitor and a mobile application will be installed on  
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53 their smartphones.  
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### 59 **Tele-monitoring CR sessions**

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4 In order to ensure the patients' safety, a series of confirmations will  
5  
6 be performed before CR sessions including BP, HR and the presence or  
7  
8 absence of cardiac symptoms, such as dyspnea and chest distress. Patients  
9  
10 will receive immediate feedback on whether they are safe to exercise at  
11  
12 that time, and if not, the exercise time will be changed.  
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17  
18 During the exercise sessions, patients will be asked to wear a pair of  
19  
20 smart insoles and an HR monitor, which can monitor the intensity and type  
21  
22 of exercise to ensure both safety and effectiveness. Endurance and  
23  
24 resistance training are both included in CR sessions. The goal of the  
25  
26 endurance training is to reach the individual, pre-defined target zone<sup>[31]</sup>,  
27  
28 which will make sure the patient is safe while also allowing effective  
29  
30 exercise. When the exercise intensity is not enough, the mobile application  
31  
32 will automatically encourage the patients to speed up, and if the exercise  
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34 intensity is excessive or the exercise type is not appropriate, the mobile  
35  
36 application will remind the patients to slow down or change the type of  
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38 training.  
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### 46 **Encouraging self-management**

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50 The IERMS will provide an individualized exercise target according  
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52 to the prescribed exercise program developed by the physical therapists,  
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54 and which will be progressively updated weekly. The medical staff will be  
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56 able to monitor the exercise frequency, intensity and type of participants  
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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 through 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 behaviors, 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.

## 2.8 Outcome Measures and data collection

Outcome measures will be analyzed by researchers blinded to the group allocation. All assessments will be performed at baseline, six weeks, and 12 weeks (Figure 3). The profile of the outcome measures for the study is outlined in Table 1.

Table 1 Completed SPIRIT diagram for the study

	STUDY PERIOD			
	Enrollmen	Allocation	Post- Allocation	Close-out



	t				
<b>TIMEPOINT*</b>	<b>-t1</b>	<b>0</b>	<b>t1</b>	<b>t2</b>	<b>t3</b>
<b>ENROLLMENT:</b>					
Eligibility screen	X				
Informed consent		X	X	X	
Randomization		X	X	X	
Allocation		X	X	X	
<b>INTERVENTIONS:</b>					
Group 1*		←————→			
Group 2**		←————→			
<b>ASSESSMENTS:</b>					
Adherence			X	X	
VO <sub>2</sub> 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			X	X	

Tests					

t1 = six weeks, t2 = 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, Generalized Anxiety Disorder Scale-7; PHQ-9 Patients' Health Questionnaire Depression Scale-9; SF-12, the 12-item Short Form Health Survey; GSES, General Self-Efficacy Scale.

### Primary outcome

The primary outcome will be adherence for CR. Adherence is defined as attendance for four weeks (eight or more sessions) for usual care or uploading of four weeks' data for IERMS-based HBCR, and attending six-week assessments (both groups), as described in a similar study by Dalal et al. (2007)<sup>[32]</sup>. The participation information in IERMS-based HBCR phase will be collected by the IERMS, while the adherence in the usual care phase will be analyzed 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, six weeks and 12 weeks. Secondary outcomes include VO<sub>2</sub>peak, the Generalized Anxiety Disorder Scale-7 (GAD-7); Patients' Health Questionnaire Depression Scale-9 (PHQ-9); the 12-item Short Form

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4 Health Survey (SF-12); General Self-Efficacy Scale (GSES) and lifestyle-  
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6 related risk factors which include weight, smoking situation and physical  
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8 activity. Satisfaction/usability tests will be measured at the end of the  
9  
10 IERMS intervention in each group.  
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## 15 **2.9 Adverse events monitoring**

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18 We will report all adverse events that occurred during the 12 weeks  
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20 study period in the final paper. Adverse events during exercise training  
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22 sessions are defined as deaths or other medical occurrences resulting in  
23  
24 hospitalization during CR sessions or immediately after training sessions  
25  
26 in an hour. Other adverse events are defined as medical occurrences  
27  
28 resulting in hospitalization, disability or deaths without connection to  
29  
30 training sessions. We will report all these adverse events to the Ethics  
31  
32 Committee as required.  
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## 40 **3.0 Data collection, management and analysis**

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43 All patients' data will be recorded by trained clinical researchers using  
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45 a standardized case report form (CRF). We will record raw data  
46  
47 appropriately and accurately and will keep copies of the laboratory reports.  
48  
49 We will also store the CRFs in areas with restricted access.  
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## 54 **3.2 Statistical analysis**

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### 57 **Test for Significance**

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Categorical variables will be described as frequencies and percentages, and the difference between two groups will be compared using the  $\chi^2$  test or Fisher's exact test. Continuous variables will be reported as mean and standard deviation, the t-test will be used if the data shows a normal distribution, and effects if the data does not show normal distribution. We will also compare the differences between patients who are adherent and those who are non-adherent to analyze 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 randomized patients. All statistical analyses will be two-sided, and  $P < 0.05$  will be considered statistically significant. SPSS 20.0 will be used for data analysis.

### **Test for Carryover Effects**

Carryover effects will also be analyzed in this specific context. We will analyze 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 analyzed using the t-test or rank test to compare the differences between the two groups. Categorical variables will be compared using the  $\chi^2$  test. No significant difference indicates no carryover effect.

### **3. Ethics and dissemination**

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4 The Human Research Ethics Committee of the School of Nursing at  
5  
6 Jilin University has approved for the study (HREC 2019120901). Research  
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8 reports will be disseminated through scientific forums, including peer-  
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10 reviewed publications and presentations at national and international  
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12 conferences.  
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#### 17 **4. Discussion**

20  
21 The IERMS-based HBCR program developed in this study evaluates  
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23 the role of HBCR by combining mobile health interventions (monitoring  
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25 devices, internet and mobile applications) with evidence-based CR  
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27 guidance strategies, including exercise intensity monitoring, feedback on  
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29 CR progress and self-management life-style risk factors. The purpose of  
30  
31 this study is to investigate whether HBCR using IERMS could improve  
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33 adherence of CR in patients with CHD and the maintenance of the  
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35 intervention.  
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42 CR is a Class I recommendation for managing CHD patients [33].  
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44 However, despite increasing evidence that has proven its cost-effectiveness  
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46 and efficacy in reducing cardiovascular morbidity and mortality, CR  
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48 services remain limited in China [8, 15]. HBCR is a method to increase the  
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50 CR participation rate in CHD patients [21]. Setting the prescribed amount of  
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52 exercise and monitoring its intensity are the key points of HBCR to ensure  
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54 that the exercise is both appropriate and within safe limits [34]. The planter  
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4 pressure sensors have been proven to be accurate in measuring the patient's  
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6 exercise type and intensity [29-30]. Combined with intelligent insoles and  
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8 wearable HR monitors, our system can evaluate whether patients reach the  
9  
10 required exercise intensity and are able to promptly alert patients should  
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12 the intensity fall outside the preset range. Furthermore, before each CR  
13  
14 session, the cardiologist will evaluate the suitability of the exercise  
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16 program according to the patients' health data patients synchronized by  
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18 IERMS to ensure patient safety. IERMS also encourages patients to upload  
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20 BP, HR, weight and physical activity to track their own progress and give  
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22 objective feedback, which could motivate self-monitoring, thereby  
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24 improving patients' adherence.  
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33 Another key point which has impact on HBCR is the maintenance of  
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35 the rehabilitation. The effectiveness of rehabilitation programs after  
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37 stopping intervention has proven to be unsustainable in both CBCR and  
38  
39 HBCR [35]. We will, therefore, also evaluate if there are any significant  
40  
41 carryover effects in order to observe the maintenance of effects after the  
42  
43 termination of the intervention.  
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49 An improvement in adherence may be associated with better physical  
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51 and psychological states. We will also evaluate these in this study. CPET  
52  
53 can be used to assess a patient's exercise performance and peak  $VO_2$  which  
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55 has been shown to be the strongest predictor of mortality [36] and which we  
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57 have, therefore, chosen as a secondary outcome. In addition, mental status,  
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4 self-efficacy, quality of life and lifestyle risk factors are important for  
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6 HBCR assessment, thus our study will also evaluate them.  
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10 In China and other lower middle-income countries (LMICs) where  
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12 access to CR is often limited, mobile health interventions, such as IERMS  
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14 used in our study, may effectively overcome barriers, such as  
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16 inconvenience, geographical isolation and financial burden, and deliver the  
17  
18 core components of HBCR to many patients with CHD.  
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### 23 **Limitations**

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26 Our current study has several limitations. Firstly, as the study is of  
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28 relatively short duration, no data will be available beyond 12 months and  
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30 longer-term effectiveness will not be able to be evaluated. Secondly, the  
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32 study is limited to patients with smartphones and internet access which  
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34 may cause selective bias. Thirdly, we will not be able to allow participants  
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36 to have a familiarization period of several weeks before using IERMS.  
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### 43 **4. Conclusion**

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46 In conclusion, our study will evaluate the role of the IERMS  
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48 intervention on the delivery of HBCR as advocated in various guidelines.  
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50 If this technology-based HBCR intervention is shown to be effective, it  
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52 may be an alternative method to implement evidenced-based CR for  
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54 patients with CHD.  
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5  
6 contribution made by the patients and public representatives during the  
7  
8 study design and intervention development.  
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11  
12 **Contributors** Linqi Xu and Feng Li: conceived the original concept of the  
13  
14 study and wrote the first draft of the protocol manuscript. Wenji Xiong,  
15  
16 Jinwei Li, Hongyu Shi, Meidi Shen, Xin Zhang, Yue Pang, Yuanyuan Ni,  
17  
18 Wei Zhang, Yuewei Li, Lirong Guo, Shuang Zhang, Lijing Zhao:  
19  
20 contributed to the design of the study. All authors read and approved the  
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22 final manuscript.  
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36  
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39 the draft report.  
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45 **Competing interests** None declared.  
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48 **Provenance and peer review** Not commissioned; externally peer  
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50 reviewed.  
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54 **Data sharing statement** For patient confidentiality concerns and the  
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56 access possibilities of the data source, the clinical data collected will not  
57  
58 be shared with the public. However, non-clinical data, such as educational  
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materials, will be shared with the public and other researchers.

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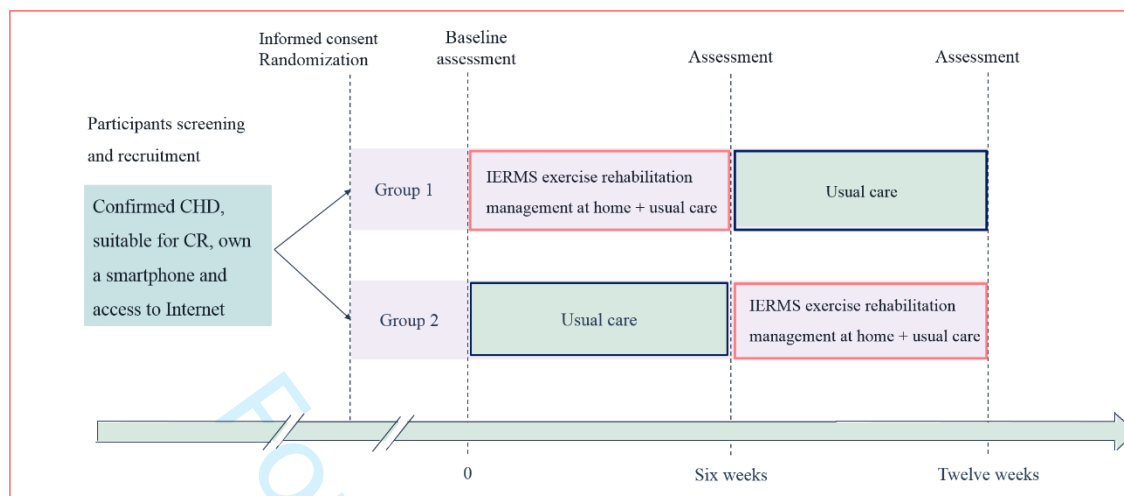
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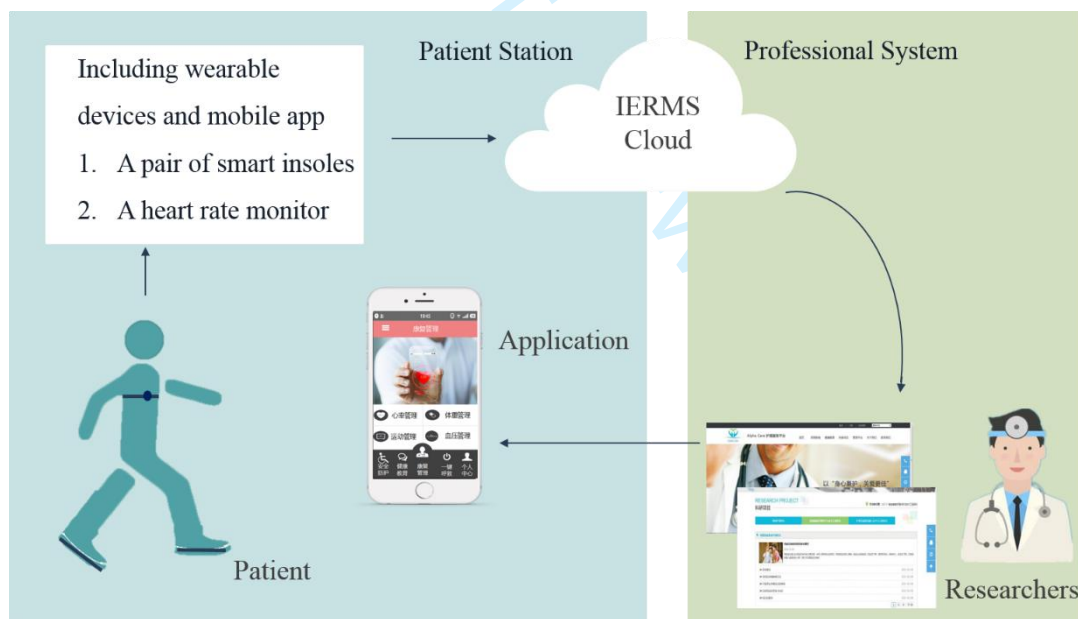
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Figure 1 Profile of the randomized controlled crossover study design.



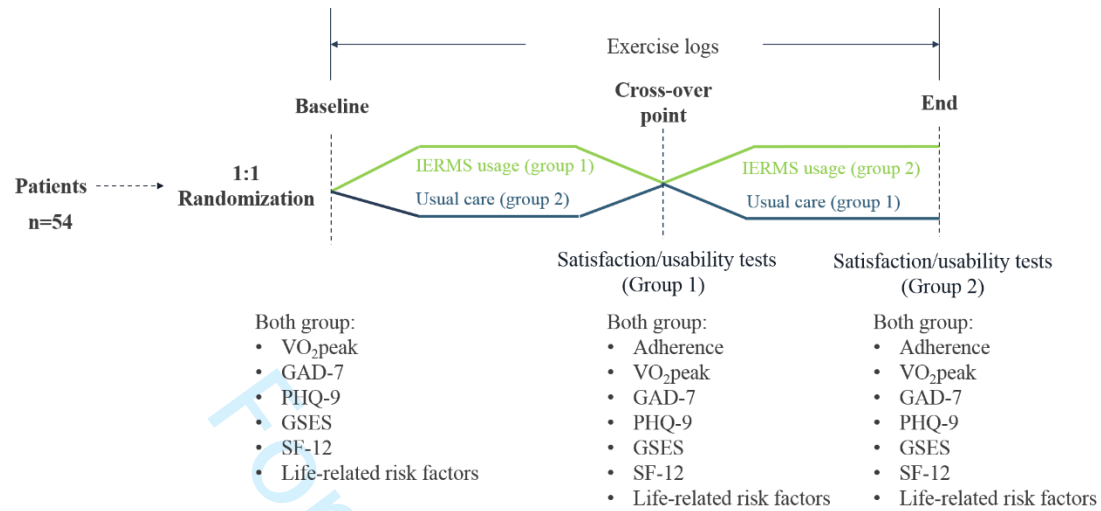
CHD, Coronary heart disease; IERMS, Intelligent Exercise Rehabilitation Management System.

Figure 2 Components of the IERMS.



IERMS, Intelligent Exercise Rehabilitation Management System.

Figure 3 Assessment time points for primary and secondary outcomes.




VO<sub>2</sub>peak, peak oxygen uptake; GAD-7, the Generalized Anxiety Disorder Scale-7; PHQ-9, Patients' Health Questionnaire Depression Scale-9; SF-12, the 12-item Short Form Health Survey; GSES, General Self-Efficacy Scale.

吉林大学护理学院  
涉及人的科研项目伦理审查表

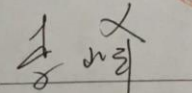
审查编号: 2019120901

申报项目名称 (需与申请书完全一致)	智慧运动康复管理系统对冠心病患者居家心脏康复依从性的影响研究		
项目负责人及职称	李峰/教授	拟申报项目类别及资助金额 (或在研项目资金来源及金额)	无
研究目的	<p>基于前期研发的智慧运动康复管理系统 (IERMS), 研究 IERMS 对冠心病 (CHD) 患者居家运动康复的参与率、依从性及完成率, 从身体功能、运动能力及心理状态等多维度探讨 CHD 患者居家心脏康复运动依从性的影响因素; 并通过设计交叉试验, 探索干预效果的维持效应。</p>		
立项依据 (简述)	<p>目前已有大量临床研究证据证实: 心脏康复 (CR) 能够使 CHD 患者的预后得到充分的改善, 使他们的生活质量有效提高, 减少再次发病的可能, 使患者患病后通过心脏康复重新恢复。虽然 CR 的益处已被证实, 但并未能在实践中被大规模采用或在社区中成功实施, 存在 CR 认知度和参与度低、依从性差等问题。随着移动医疗的快速发展以及智能电子设备的普及, 基于移动医疗的 CR (eHealth CR) 是指通过信息和通信技术 (ICT) 交付 CR, 它已发展成为提高 CR 可用性和可访问性的替代方式。国外研究表明, 基于移动技术的心脏康复提高了心肌梗死后患者心脏康复的参与度和依从性, 而我国针对移动医疗在心脏康复中的研究较少。本项目基于前期研发的智慧运动康复管理系统 (IERMS), 可实时监测患者的运动康复过程。本项目通过设计随机对照试验, 研究患者居家运动康复的参与率、依从性及完成率; 从身体功能、运动能力及心理状态等多维度探讨 CHD 患者居家心脏康复运动依从性的影响因素; 并通过设计交叉试验, 探索干预效果的维持效应。</p>		
受试者类别 (医院患者/社区居民/健康志愿者等)	医院患者	受试者例数	54
受试者选择 (入选标准及排除标准)	<p>纳入标准: ①年龄 18-70 周岁; ②诊断为冠状动脉粥样硬化性心脏病, (包括急性心肌梗死, 不稳定心绞痛), 并在入院期间接受 PCI 治疗; ③经吉大一院心内科医生和理疗师评估为适合参加 CR; ④愿意提供书面知情同意; ⑤拥有智能手机; ⑥精通中文。</p> <p>排除标准: ①运动康复的禁忌症 (例如, 未经治疗的室性心动过速, 严重的心力衰竭, 无法控制的高血压或低血压, 明显的运动限制); ②指导后无法</p>		



	使用 IERMS 的设备; ③居住地没有互联网连接; ④需要助行器才能行动; ⑤参加其他临床试验。
是否有书面知情同意及履行保密原则	均提供知情同意书, 尊重患者的履行保密原则
研究需要收集的具体材料【受试者信息, 血液体液(ml、次数)、组织或病理标本等】	仅收集受试者一般资料、心肺功能测试以及问卷, 无血液体液、组织或病理标本等。
所收集的受试者材料的检测实验室名称及地点(需具体说明)	所有资料、问卷的填写以及测试均在吉林大学第一医院心血管内科心脏康复中心进行, 地点: 吉林省长春市新民大街 71 号 7 号楼 4 层。
获取材料的方法、地点(手术切除标本、静脉穿刺、腹腔穿刺、住院病史摘录等)	心肺功能测试, 问卷调查法, 在吉大一院心血管内科心脏康复中心获得。
研究项目起止时间	2020.1~2021.12
审查结果	<p>伦理委员会审批意见:</p> <p>同意</p> <p>  </p> <p>伦理委员会主任委员签字(盖章)</p>

项目负责人(签名):



联系人及联系方式:

17790089009

申请日期:

2019.12.9

## 知情同意书·知情告知页

亲爱的患者：

医生已经确诊您为 冠状动脉粥样硬化性心脏病。我们将邀请您参加一项研究，本研究为 2018 年吉林大学白求恩计划 项目，课题编号：2018A04。本研究方案已经得到 吉林大学护理学院 伦理委员会审核，同意进行临床研究。

在您决定是否参加这项研究之前，请尽可能仔细阅读以下内容。它可以帮助您了解该项研究以及为何要进行这项研究，研究的程序和期限，参加研究后可能给您带来的益处、风险和不适。如果您愿意，您也可以和您的亲属、朋友一起讨论，或者请医生给予解释，帮助您做出决定。

### 一、研究背景和研究目的

#### 1.1 疾病负担和治疗现状

冠心病（Coronary heart disease, CHD）是由冠状动脉内的斑块积聚，导致动脉狭窄并减少富氧血液流入心脏引起的。WHO 统计数据表明，全球有 740 万人死于冠心病，并预测到 2020 年冠心病将成为致残的主要原因。心脏康复（Cardiac rehabilitation, CR）是 CHD 处理中不可缺少的组成部分，被定义为涉及医学评价、药物处方、运动处方、营养处方、教育、咨询及行为干预的综合长期康复计划，且已经被美国心脏协会（AHA）和心脏病学会（ACC）、欧洲心脏病学会（ESC）列为 CHD 治疗的 I 类推荐。目前已有大量临床研究证据证实：CR 能够使 CHD 患者的预后得到充分的改善，使他们的生活质量有效提高，减少再次发病的可能，使患者患病后通过心脏康复重新恢复。虽然 CR 的益处已被证实，但并未能在实践中被大规模采用或在社区中成功实施，存在 CR 认知度和参与度低、依从性差等问题。因此，如何促进心脏康复的实施，改善心脏康复质量也成为医疗服务体系的巨大挑战。

#### 1.2 本研究目的

本项目基于前期研发的智慧运动康复管理系统（IERMS），可实时监测患者的运动康复过程。通过设计随机对照试验，研究 IERMS 系统对患者居家运动康复的参与率、依从性及完成率的影响；从身体功能、运动能力及心理状态等多维度探讨 CHD 患者居家心脏康复运动依从性的影响因素；并通过设计交叉试验，探索干预效果的维持效应。

#### 1.3 研究参加单位和预计纳入参试者例数

吉林大学护理学院、吉林大学第一医院，参试者 54 人。

### 二、哪些人不宜参加研究

①运动康复的禁忌症（例如，未经治疗的室性心动过速，严重的心力衰竭，无法控制的高血压或低血压，明显的运动限制）；②指导后无法使用 IERMS 的设备；③居住地没有互联网连接；④需要助行器才能行动；⑤参加其他临床试验。

### 三、如果参加研究将需要做什么？

1. 在您入选研究前，医生将询问、记录您的病史，并进行 问卷调查。

您是合格的纳入者，您可自愿参加研究，签署知情同意书。

如您不愿参加研究，我们将按您的意愿施治。

2. 若您自愿参加研究，将按以下步骤进行：

您在出院前，需要填写一部分问卷，出院以后，按照医生给您制定的运动处方，以及医生给与您的 ECG 监护仪、智能鞋垫，下载 APP。回家进行居家心脏运动康复。出院后 6 周、12 周需要回院进行复查。



### 3. 需要您配合的其他事项

您必须按医生和您约定的随访时间带着 病历、运动日志 来医院就诊（随访阶段，医生可能通过电话、登门的方式了解您的情况）。您的随访非常重要，因为医生将判断您接受的治疗是否真正起作用，并及时指导您。

您必须按医生指导用药，并请您及时、客观地填写您的服药记录。您在每次随访时都必须归还未用完的药物及其包装，并将正在服用的其它药物带来，包括您有其它合并疾病须继续服用的药物。

## 四、参加研究可能的受益

尽管已经有证据提示 移动健康技术对居家运动康复依从性 有满意的疗效，但这并不能保证对您肯定有效。本研究所采用的 智慧运动康复管理系统 也不是管理心脏康复运动的唯一的方法。如 智慧运动康复管理系统 对您的康复无效，您可以向医生询问有可能获得的替代管理方法。

## 五、参加研究可能的不良反应、风险和不适、不方便

如果在研究期间您出现任何不适，或病情发生新的变化，或任何意外情况，不管是否与研究有关，均应及时通知您的医生，他/她将对此作出判断并给与适当的医疗处理。

您在研究期间需要按时到医院随访，做一些检查，这些占用您的一些时间，也可能给您造成麻烦或带来不方便。

## 六、有关费用

本研究中智能鞋垫、ECG 监护仪的费用可免，回院复查时进行心肺运动试验（CPET）的费用需自己承担。

医生将尽全力预防和治疗由于本研究可能带来的伤害。如果在临床试验中出现不良事件，医学专家委员会将会鉴定其是否与本干预有关。申办者将按照我国规定对与试验相关的损害提供治疗的费用及相应的经济补偿。

对于您同时合并的其他疾病所需的治疗和检查，将不在免费的范围之内。

## 七、个人信息的保密

您的医疗记录（研究病历/CRF、化验单等）将完整地保存在您所就诊的医院。医生会将化验和其它检查结果记录在您的病历上。研究者、伦理委员会和药品监督管理部门将被允许查阅您的医疗记录。任何有关本项研究结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您个人医疗资料的隐私。

按照医学研究伦理，除了个人隐私信息外，试验数据将可供公众查询和共享，查询和共享将只限于基于网络的电子数据库，保证不会泄漏任何个人隐私信息。

## 八、怎样获得更多的信息？

您可以在任何时间提出有关本项研究的任何问题，并得到相应的解答。

如果在研究过程中有任何重要的新信息，可能影响您继续参加研究的意愿时，您的医生将会及时通知您。

## 九、可以自愿选择参加研究和中途退出研究

是否参加研究完全取决于您的意愿。您可以拒绝参加此项研究，或在研究过程中的

任何时间退出本研究，这都不会影响您和医生间的关系，都不会影响对您的医疗或有其他方面利益的损失。

出于对您的最大利益考虑，医生或研究者可能会在研究过程中随时中止您继续参加本项研究。

如果您因为任何原因从研究中退出，您可能被询问有关您使用试验药物的情况。如果医生认为需要，您也可能被要求进行实验室检查和体格检查。

## 十、现在该做什么？

是否参加本项研究由您自己（和您的家人）决定。

在您做出参加研究的决定前，请尽可能向您的医生询问有关问题。

感谢您阅读以上材料。如果您决定参加本项研究，请告诉您的医生，他/她会为您安排一切有关研究的事务。请您保留这份资料。

## 知情同意书. 同意签字页

临床研究项目名称：基于 IERMS 的多维尺度心脏康复体系构建及实施科学研究

课题承担单位：吉林大学护理学院

课题协作单位：吉林大学第一医院

课题任务书编号：2018A04

### 同意声明

我已经阅读了上述有关本研究的介绍，而且有机会就此项研究与医生讨论并提出问题。我提出的所有问题都得到了满意的答复。

我知道参加本研究可能产生的风险和受益。我知晓参加研究是自愿的，我确认已有充足时间对此进行考虑，而且明白：

- 我可以随时向医生咨询更多的信息。
- 我可以随时退出本研究，而不会受到歧视或报复，医疗待遇与权益不会受到影响。

我同样清楚，如果我中途退出研究，特别是由于药物的原因使我退出研究时，我若将我的病情变化告诉医生，完成相应的体格检查和理化检查，这将对整个研究十分有利。

如果因病情变化我需要采取任何其他的药物治疗，我会在事先征求医生的意见，或在事后如实告诉医生。

我同意药品监督管理部门伦理委员会或申办者代表查阅我的研究资料。

我将获得一份经过签名并注明日期的知情同意书副本。

最后，我决定同意参加本项研究，并保证尽量遵从医嘱。

患者签名：\_\_\_\_\_ 年 \_\_\_ 月 \_\_\_ 日

联系电话：\_\_\_\_\_

我确认已向患者解释了本试验的详细情况，包括其权力以及可能的受益和风险，并给其一份签署过的知情同意书副本。

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医生签名: \_\_\_\_\_ 年 月 日

医生的工作电话: \_\_\_\_\_

For peer review only

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	P7
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	P7
Protocol version	<a href="#">#3</a>	Date and version identifier	n/a
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	P21
Roles and responsibilities:	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	P21

contributorship

Roles and responsibilities: sponsor contact information [#5b](#) Name and contact information for the trial sponsor P21

Roles and responsibilities: sponsor and funder [#5c](#) Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities P21

Roles and responsibilities: committees [#5d](#) Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) n/a, did not establish the committee

## Introduction

Background and rationale [#6a](#) Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention P4-6

Background and rationale: choice of comparators [#6b](#) Explanation for choice of comparators P4-6

Objectives [#7](#) Specific objectives or hypotheses P6

Trial design [#8](#) Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory) P6-7

## Methods: Participants, interventions, and outcomes

1	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P6
2				
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8	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P7
9				
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15	Interventions: description	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P9-13
16				
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20	Interventions: modifications	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a, intervention did not involve harms or others
21				
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27	Interventions: adherence	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	P9-13
28				
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32	Interventions: concomitant care	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P9
33				
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36	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P13-15
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49	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
50				
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56	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions	P8
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supporting any sample size calculations

1  
2 Recruitment [#15](#) Strategies for achieving adequate participant P7-8  
3 enrolment to reach target sample size  
4  
5

6 **Methods:**

7 **Assignment of**  
8 **interventions (for**  
9 **controlled trials)**  
10  
11

12  
13 Allocation: sequence [#16a](#) Method of generating the allocation sequence (eg, P8-9  
14 generation computer-generated random numbers), and list of  
15 of any factors for stratification. To reduce predictability  
16 of a random sequence, details of any planned  
17 restriction (eg, blocking) should be provided in a  
18 separate document that is unavailable to those who  
19 enrol participants or assign interventions  
20  
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22  
23  
24 Allocation [#16b](#) Mechanism of implementing the allocation P8-9  
25 concealment sequence (eg, central telephone; sequentially  
26 mechanism numbered, opaque, sealed envelopes), describing  
27 any steps to conceal the sequence until  
28 interventions are assigned  
29  
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32  
33 Allocation: [#16c](#) Who will generate the allocation sequence, who will P8-9  
34 implementation enrol participants, and who will assign participants  
35 to interventions  
36  
37

38 Blinding (masking) [#17a](#) Who will be blinded after assignment to P8-9  
39 interventions (eg, trial participants, care providers,  
40 outcome assessors, data analysts), and how  
41  
42

43 Blinding (masking): [#17b](#) If blinded, circumstances under which unblinding is n/a, not blind to  
44 emergency permissible, and procedure for revealing a participants or  
45 unblinding participant's allocated intervention during the trial researchers  
46  
47

48 **Methods: Data**  
49 **collection,**  
50 **management, and**  
51 **analysis**  
52  
53

54  
55 Data collection plan [#18a](#) Plans for assessment and collection of outcome, P15-16  
56 baseline, and other trial data, including any related  
57 processes to promote data quality (eg, duplicate  
58  
59

1 measurements, training of assessors) and a  
 2 description of study instruments (eg, questionnaires,  
 3 laboratory tests) along with their reliability and  
 4 validity, if known. Reference to where data  
 5 collection forms can be found, if not in the protocol  
 6  
 7

8	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete	P9
9	retention		follow-up, including list of any outcome data to be	
10			collected for participants who discontinue or deviate	
11			from intervention protocols	
12				
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15	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage,	P16
16			including any related processes to promote data	
17			quality (eg, double data entry; range checks for data	
18			values). Reference to where details of data	
19			management procedures can be found, if not in the	
20			protocol	
21				
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25	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and	P16-17
26			secondary outcomes. Reference to where other	
27			details of the statistical analysis plan can be found,	
28			if not in the protocol	
29				
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31				
32	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup	P16-17
33	analyses		and adjusted analyses)	
34				
35				
36	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol	P17
37	population and		non-adherence (eg, as randomised analysis), and	
38	missing data		any statistical methods to handle missing data (eg,	
39			multiple imputation)	
40				
41				
42	<b>Methods:</b>			
43	<b>Monitoring</b>			
44				
45				
46	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	n/a, less safe
47	formal committee		summary of its role and reporting structure;	risks in this
48			statement of whether it is independent from the	study
49			sponsor and competing interests; and reference to	
50			where further details about its charter can be found,	
51			if not in the protocol. Alternatively, an explanation of	
52			why a DMC is not needed	
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58	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	n/a, not apply
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1	interim analysis		guidelines, including who will have access to these interim results and make the final decision to terminate the trial	DMC in this trial
2				
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5	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P16
6				
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12	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
13				
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17	<b>Ethics and dissemination</b>			
18				
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21	Research ethics approval	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P17-18
22				
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24				
25	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
26				
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33	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P8
34				
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39	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a, not needed in this study
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44	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P16
45				
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51	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	P21
52				
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55	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a, not needed in this study
56				
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1	Ancillary and post	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care,	n/a, not needed
2	trial care		and for compensation to those who suffer harm from	in this study
3			trial participation	
4				
5				
6	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate	P17
7	trial results		trial results to participants, healthcare professionals,	
8			the public, and other relevant groups (eg, via	
9			publication, reporting in results databases, or other	
10			data sharing arrangements), including any	
11			publication restrictions	
12				
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16	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended	P16-17
17	authorship		use of professional writers	
18				
19				
20	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	P16-17
21	reproducible		protocol, participant-level dataset, and statistical	
22	research		code	
23				
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25	<b>Appendices</b>			
26				
27				
28	Informed consent	<a href="#">#32</a>	Model consent form and other related	n/a, not needed
29	materials		documentation given to participants and authorised	in this study
30			surrogates	
31				
32				
33	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and	n/a, not needed
34			storage of biological specimens for genetic or	in this study
35			molecular analysis in the current trial and for future	
36			use in ancillary studies, if applicable	
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40 None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution  
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 42 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

## Role of the Intelligent Exercise Rehabilitation Management System on adherence of cardiac rehabilitation in patients with coronary heart disease: a randomized controlled crossover study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-036720.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Apr-2020
Complete List of Authors:	Xu, Linqi; Jilin University, School of Nursing Xiong, Wenji; Jilin University, The First Hospital Li, Jinwei; Jilin University, School of Nursing Shi, Hongyu; Jilin University, School of Nursing Shen, Meidi; Jilin University, School of Nursing Zhang, Xin; Jilin University, School of Nursing Pang, Yue; Jilin University, School of Nursing Ni, Yuanyuan; Jilin University, School of Nursing Zhang, Wei; Jilin University, School of Nursing Li, Yuewei; Jilin University, School of Nursing Guo, Lirong; Jilin University, School of Nursing Zhang, Shuang; Jilin University, School of Nursing Zhao, Lijing; Jilin University, School of Nursing Li, Feng; Jilin University, School of Nursing
<b>Primary Subject Heading</b>:	Cardiovascular medicine
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine
Keywords:	Coronary heart disease < CARDIOLOGY, Rehabilitation medicine < INTERNAL MEDICINE, Information technology < BIOTECHNOLOGY & BIOINFORMATICS

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**Title Page****Title of the article:**

Role of the Intelligent Exercise Rehabilitation Management System on adherence of cardiac rehabilitation in patients with coronary heart disease: a randomized 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 sub-optimal 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 Exercise 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, randomized control crossover study of 70 patients with coronary heart disease (CHD). Participants will be randomly assigned in a 1:1 ratio to one of two groups. Patients in Group 1 will receive the IERMS intervention together with usual care for the first six weeks and usual care for the last six weeks, while patients assigned to Group 2 will receive usual care for the first six weeks and will use IERMS in the last six weeks. The primary outcome is adherence to the program 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, six 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-

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4 reviewed journals and at conferences.  
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7 **Trial registration number:** ChiCTR1900028182; Pre-results.  
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10 **Key words:** Cardiac rehabilitation, adherence, coronary heart disease  
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### 17 **Strength and Limitations of this study**

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20 1. Our home-based cardiac rehabilitation program (HBCR) is technology-based and may improve  
21 adherence of CR in patients with coronary heart disease (CHD).  
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26 2. The measurements of plantar pressure and heart rate (HR) used in this study are accurate in  
27 evaluating exercise type and intensity. This is essential for reminding patients to exercise  
28 appropriately within safe limits during CR sessions at home.  
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34 3. The crossover study design allows us to observe the maintenance of effects after the six-week  
35 IERMS intervention.  
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41 4. The study is of relatively short duration and long-term effectiveness will not be observed after 12  
42 months.  
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48 5. The study is limited to patients with smartphones and internet access.  
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### 52 **1. Background**

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56 Coronary heart disease (CHD) is the leading cause of mortality in China and has increased by 20.6%  
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58 from 1990 to 2017<sup>[1]</sup>. Studies over the past few decades have shown an increased prevalence and  
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4 incidence of CHD and it was estimated that about 11 million patients suffered from it in 2017<sup>[2]</sup>. Patients  
5  
6 with CHD have severe physical and often psychological problems and show reduced health-related  
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8 quality of life (HRQoL) scores, which is associated with high mortality and additional cardiac events <sup>[3-</sup>  
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12 4].

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15 Cardiac rehabilitation (CR), an integral component of the continuum of care for patients with CHD<sup>[5]</sup>,  
16  
17 has been demonstrated to reduce mortality by up to 37% <sup>[6-7]</sup> to improve both physical functioning and  
18  
19 quality of life<sup>[8-10]</sup>, and is recommended by the American Heart Association (AHA)/ American College  
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21 of Cardiology (ACC) and the European Society of Cardiology (ESC) guidelines for patients with CHD<sup>[11-</sup>  
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25 12].

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29 Despite proven benefits, the use of and adherence to CR remains sub-optimal, with participation  
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31 rates of between 10.3% and 16.3% <sup>[13]</sup> and dropout rates of between 40% and 55% <sup>[14-15]</sup>. In China, access  
32  
33 to CR services remains very low, with the estimated availability of CR programs about two programs  
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35 per 100 million inhabitants<sup>[16]</sup>. This may be due to poor availability and problems with supplying CR in  
36  
37 China, including a lack of facilities, funding, staff training, and reimbursements for participating patients  
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39 <sup>[17-18]</sup>. Drop-out or non-adherence may lead to undesirable outcomes in CHD <sup>[19]</sup>. Therefore, innovation  
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44 is needed to improve the implementation of CR in China.

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48 Besides center-based CR, home-based CR (HBCR) is an alternative method recommended by AHA  
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50 and ACC. HBCR may be more effective in the provision of CR to many patients in China<sup>[20]</sup> and has  
51  
52 proved to be effective in improving adherence <sup>[21]</sup>. However, while effective performance of the  
53  
54 prescribed exercises is essential, difficulties, such as managing the exercise type, intensity and duration  
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56 appropriately at home, occur with HBCR <sup>[22]</sup>. With the development of new digital technologies, mobile  
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4 health (m-health) interventions have emerged and have shown the potential to deliver HBCR safely and  
5  
6 effectively [23-25]. The m-health interventions could help patients monitor exercise intensity, provide  
7  
8 objective feedback data and encourage patients to track their own progress, which could help them self-  
9  
10 manage their CR and may be useful in improving their adherence. In addition, patients with CHD have  
11  
12 shown great interest in using m-health at home, providing clear potential for developing such  
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14 interventions [26].  
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20 In HBCR, m-health that could accurately monitor the intensity and type of exercise is required to  
21  
22 ensure both safety and effectiveness. The Intelligent Exercise Rehabilitation Management system  
23  
24 (IERMS) has been designed to meet these requirements. It introduces a closed-loop rehabilitation  
25  
26 management system that supports the home-based management of prescribed CR and lifestyle-related  
27  
28 risk factors for patients with CHD. The purpose of this study is to evaluate whether IERMS-based HBCR  
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30 could improve adherence to CR and to assess its effects on exercise capacity, mental health, self-efficacy,  
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32 quality of life, and lifestyle-related risk factors. The results of the trial are expected to facilitate the  
33  
34 development of effective m-health interventions for HBCR.  
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## 41 **2. Methods**

### 42 **2.1 Study Design**

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45 A single-blinded, two-arm, randomized control crossover study will be conducted to evaluate the  
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47 role of IERMS-based HBCR on adherence, exercise capacity, mental health, self-efficacy, quality of life  
48  
49 and lifestyle-related risk factors. All participants will be recruited from the CR outpatient setting of a  
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51 medical center in Changchun, China. A total of 70 participants will be randomly assigned to one of two  
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53 groups. Patients in Group 1 will use IERMS in the first stage and receive usual care in the last stage,  
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4 while patients in Group 2 will receive usual care in the first stage and IERMS-based HBCR in the last  
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6 stage. Each stage of the study will last for six weeks. As one of our main objectives is to assess whether  
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8 there is an interaction at the end of the intervention and to observe the maintenance of the effects after  
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10 the intervention, this study does not allow a wash-out period. An illustration of the study design is  
11  
12 displayed in Figure 1. The trial conforms to the SPIRIT reporting guidelines <sup>[27]</sup> and is registered at  
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14 Clinical Trials.gov: ChiCTR1900028182.  
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## 20 **2.2 Eligibility and Recruitment**

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23 Patients will be eligible to participate if they have: (1) a documented diagnosis of CHD and having  
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25 had a hospitalization incident within six months prior to randomization; (2) been assessed as suitable by  
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27 a cardiologist and a physical therapist to participate in their CR; (3) no contraindications to undergo a  
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29 cardiopulmonary exercise test; (4) should own a smartphone and be willing and able to upload data and  
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31 that they should have access to internet at home; (5) if they are willing and able to participate in the study  
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33 and to provide written informed consent.  
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40 Exclusion criteria include: (1) severe heart failure (NYHA class IV); (2) unstable angina; (3)  
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42 unstable clinical status; (4) coronary artery bypass grafting within the last three months; (5) patients are  
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44 unable to use the IERMS-enabled devices after instruction; (6) requiring a walking aid for mobility; (7)  
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46 participation in another clinical trial.  
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51 Our research group has formed a team with experienced clinical nurses and rehabilitation therapists  
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53 in the cardiovascular department at a medical center in Changchun, China. Experienced clinical nurses  
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55 and researchers in our team will be responsible for recruiting participants. Patients admitted with CHD  
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57 and eligible for CR will be screened and those meeting the inclusion criteria will be invited to participate.  
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4 Rehabilitation therapists will inform them of the study details, and if they agree to participate in the  
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6 study, they will be asked to sign the consent form. If complex clinical problems are encountered, our  
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8 researchers, nursing experts, and rehabilitation therapists will work together to develop a solution.  
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### 11 12 **2.3 Sample Size Calculation**

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15 This study selects the main outcome indicators of HBCR adherence as the calculation standard. A  
16  
17 previous study has shown CR adherence rates of ~94% for technology-based HBCR and ~68% for  
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19 traditional CR [28]. We will use two sample rate calculation formula:  $N = \left[ \frac{z_{\alpha} \sqrt{\pi_c (1 - \pi_c) (Q_1^{-1} + Q_2^{-1})}}{\pi_1 - \pi_2} + \frac{z_{\beta} \sqrt{\pi_1 (1 - \pi_1) / Q_1 + \pi_2 (1 - \pi_2) / Q_2}}{\pi_1 - \pi_2} \right]$  with 90% power (type I error = 5%) to calculate the sample size, and  
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25 a total sample size of 54 across both arms will be used in this study. Allowing for an estimated 20% loss  
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27 to follow-up, a total of 70 participants will be recruited.  
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### 32 **2.4 Randomization, Blinding and Concealed Allocation**

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35 After signing an informed consent, patients will complete a baseline assessment. They will then be  
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37 randomized in a 1:1 ratio to either Group 1 or the Group 2 by a computer-generated randomization list,  
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39 using block randomization and randomly selected block sizes of 4, 6, or 8. This assignment will be done  
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41 by independent individuals who will not participate in the recruitment process. Given the characteristics  
42  
43 of the intervention, the participants or researchers implementing the intervention cannot be blinded.  
44  
45 However, researchers evaluating the results will be unaware of patient assignments. To ensure hidden  
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47 assignments and minimize selection bias, independent designated members of the School of Nursing,  
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49 Jilin University will assign random numbers based on local researcher requirements.  
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### 56 **2.5 Usual care**

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60 Regardless of the IERMS intervention, all patients will receive usual care. Patients will receive

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4 health education about CR provided by a cardiologist and a physical therapist will give them personalized  
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6 exercise prescriptions according to the results of their cardiopulmonary exercise test (CPET). Patients  
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8 will be free to participate in any type of exercise classes, Tai Chi programs, group dancing and available  
9  
10 CR programs after discharge from rehabilitation facilities. All patients will be required to upload exercise  
11  
12 logs weekly at home, including exercise type, intensity and duration. Patients using IERMS will have  
13  
14 exercise logs automatically recorded by the system and are required to upload them to the research team.  
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16 Patients under usual care will record exercise logs in any form they like in the memorandum, and we will  
17  
18 remind them to send them to us weekly through WeChat which is a popular social media site in China.  
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20 In addition, all patients will receive follow-up calls at six weeks and 12 weeks.  
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## 28 **2.6 Key components of IERMS**

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31 The IERMS is a closed-loop rehabilitation management system which can facilitate management  
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33 of exercise prescription and lifestyle-related risk factors and consists of three main components:  
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35 Professional System, Patient Station and the Cloud (Figure 2). This system has been authorized as a  
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37 China Invention Patent (Publication Patent Number (PPNO): 201810114305.3).  
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### 42 **Patient Station**

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45 The Patient Station consists of one mobile application and two monitoring devices which include  
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47 a pair of smart insoles and a heart rate (HR) monitor.  
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51 Smart insoles have been independently developed in this study and are able to measure gait  
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53 parameters using inserted plantar pressure sensors and accelerometers during CR sessions. This has been  
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55 shown to be accurate in identifying the type of exercise and in calculating energy expenditure <sup>[29-30]</sup>. The  
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57 data collected by the smart insoles will be uploaded to the cloud, and the cloud will analyze the metabolic  
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4 equivalent (METs) through an algorithm which has been developed specifically for this study, and then  
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6 present the results on the mobile application. The HR monitor used in this study is attached around the  
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8 chest and can monitor HR in real-time.  
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12 The mobile application and these monitoring devices are connected by Bluetooth. The mobile  
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14 application is thus able to synchronize the data collected by the sensors and provide real-time  
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16 motivational feedback automatically generated from actual exercise performances. Furthermore, the  
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18 mobile application can present educational materials and exercise prescriptions prescribed by  
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20 professionals and upload patients' data to the professional system.  
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### 26 **The cloud**

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29 The cloud is the core part of the data processing, which stores and analyzes the data transmitted by  
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31 the monitoring devices and then distributes the results to the patient station and professional system. The  
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33 cloud will use deep neural network models to train and evaluate the data and generate feedback on the  
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35 patient's exercise and send them to the mobile application on the patient station. The cloud will also send  
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37 a report of the exercise performance of patients in CR sessions to the professionals allowing them to  
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39 update the exercise prescription for reference.  
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### 45 **Professional System**

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48 The Professional System is a web-based tool for medical professionals, which can manage patients'  
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50 CR exercise at home. Patient files are stored in the system, including the patient's medical history, past  
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52 exercise prescriptions and lifestyle-related risk factors. The system can also synchronize the patient's  
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54 exercise progress, weight, HR and BP, etc. The professionals can thus monitor the patient's health  
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56 situations remotely through the system and perform continuity of care for patients.  
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## 2.7 Description of the IERMS intervention

Eligible and consenting participants will be enrolled prior to discharge from an outpatient ambulatory CR program 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 dyspnea 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, pre-defined target zone<sup>[31]</sup>, which will make sure 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 individualized exercise target according to the prescribed exercise program developed by the physical therapists, and which will be progressively updated weekly. The

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4 medical staff will be able to monitor the exercise frequency, intensity, and type of exercise through the  
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6 information collected by the monitoring devices and give feedback on the completion of the rehabilitation  
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8 exercise and set goals, which can encourage patients to track their exercise progress. In addition, patients  
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10 can communicate with the professionals via short message service (SMS) built into the mobile  
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12 application and receive feedback within 24 hours.  
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17 The IERMS encourages patients to upload BP, HR, weight, smoking situation, and physical  
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19 activity to the mobile application. This enables them to track their own progress to motivate them to quit  
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21 smoking, lose weight, improve physical activity and reduce sedentary behaviors, which can, in turn,  
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23 improve their self-monitoring, thereby increasing patients' adherence. Participants will also be  
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25 encouraged to participate in other different types of physical activities, such as jogging, Tai Chi and  
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27 group dancing.  
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### 33 34 **2.8 Outcome Measures and data collection**

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36 Outcome measures will be analyzed by researchers blinded to the group allocation. All  
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38 assessments will be performed at baseline, six weeks, and 12 weeks (Figure 3). A summary of the  
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40 outcome measures for the study is outlined in Table 1.  
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45  
46 Table 1 Completed SPIRIT diagram for the study  
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	STUDY PERIOD				
	Enrollment	Allocation	Post- Allocation		Close-out
TIMEPOINT*	-t1	0	t1	t2	t3
<b>ENROLLMENT:</b>					
Eligibility screen	X				

Informed consent		X	X	X	
Randomization		X	X	X	
Allocation		X	X	X	
<b>INTERVENTIONS:</b>					
Group 1*		←————→			
Group 2**		←————→			
<b>ASSESSMENTS:</b>					
Adherence			X	X	
VO <sub>2</sub> 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 = six weeks, t2 = 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, Generalized Anxiety Disorder Scale-7; PHQ-9 Patients' Health Questionnaire Depression

Scale-9; SF-12, the 12-item Short Form Health Survey; GSES, General Self -Efficacy Scale.

### Primary outcome

The primary outcome will be adherence for CR. Adherence is defined as attendance for four weeks



(eight or more sessions) for usual care or uploading of four weeks' data for IERMS-based HBCR, and attending six-week assessments (both groups), as described in a similar study by Dalal et al. (2007)<sup>[32]</sup>.

The participation information in IERMS-based HBCR phase will be collected by the IERMS, while the adherence in the usual care phase will be analyzed 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, six weeks and 12 weeks. Secondary outcomes include VO<sub>2</sub>peak, the Generalized 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.

### **2.9 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 hospitalization during CR sessions or immediately after training sessions in an hour. Other adverse events are defined as medical occurrences resulting in hospitalization, disability or deaths without connection to training sessions. We will report all these adverse events to the Ethics Committee as required.

### **2.10 Data collection, management and analysis**

All patients' data will be recorded by trained clinical researchers using a standardized case report

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4 form (CRF). We will record raw data appropriately and accurately and will keep copies of the laboratory  
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6 reports. We will also store the CRFs in areas with restricted access.  
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## 9 10 **2.11 Statistical analysis**

### 11 12 13 **Test for Significance**

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16 Categorical variables will be described as frequencies and percentages, and the difference between  
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18 two groups will be compared using the  $\chi^2$  test or Fisher's exact test. Continuous variables will be reported  
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20 as mean and standard deviation, the t-test will be used if the data shows a normal distribution, and effects  
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22 if the data does not show normal distribution. We will also compare the differences between patients  
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24 who are adherent and those who are non-adherent to analyze the factors that influence adherence.  
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26 Furthermore, the secondary comparison will be conducted according to the intent-to-treat comparison,  
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28 which will include the full sample of randomized patients. All statistical analyses will be two-sided, and  
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30  $P < 0.05$  will be considered statistically significant. SPSS 20.0 will be used for data analysis.  
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### 38 **Test for Carryover Effects**

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41 Carryover effects will also be analyzed in this specific context. We will analyze the changes in the  
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43 two groups at 12 weeks, in other words, the changes in the first stage plus the changes in the second  
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45 stage. Continuous variables will be analyzed using the t-test or rank test to compare the differences  
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47 between the two groups. Categorical variables will be compared using the  $\chi^2$  test. No significant  
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49 difference indicates no carryover effect.  
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## 54 55 **2.12 Patient and Public Involvement**

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58 Patient and Public Involvement (PPI) has played an important part in this research. During the  
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4 IERMS development, CHD patients were invited to participate in surveys and discussions to help the  
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6 research team better design the function and interface of the IERMS according to patients' priorities and  
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8 preferences. In the pilot study, we also invited patients to give constructive feedback which allows us to  
9  
10 better understand of their needs and barriers in HBCR and valuable suggestions in IERMS. In addition,  
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12 patients were also invited to give reasonable recommendations for study design, questionnaire selection,  
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14 and outcome measurements while considering the burden of intervention. The results of the study will  
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16 be disseminated to participants who wish to be notified.  
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### 23 **3. Ethics and dissemination**

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

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37 The IERMS-based HBCR program developed in this study evaluates the role of HBCR by  
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39 combining mobile health interventions (monitoring devices, internet and mobile applications) with  
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41 evidence-based CR guidance strategies, including exercise intensity monitoring, feedback on CR  
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43 progress and self-management life-style risk factors. The purpose of this study is to investigate whether  
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45 HBCR using IERMS could improve adherence of CR in patients with CHD and the maintenance of the  
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47 intervention.  
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54 CR is a Class I recommendation for managing CHD patients [33]. However, despite increasing  
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56 evidence that has proven its cost-effectiveness and efficacy in reducing cardiovascular morbidity and  
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58 mortality, CR services remain limited in China [8, 15]. HBCR is a method to increase the CR participation  
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4 rate in CHD patients [21]. Setting the prescribed amount of exercise and monitoring its intensity are the  
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6 key points of HBCR to ensure that the exercise is both appropriate and within safe limits [34]. The planter  
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8 pressure sensors have been proven to be accurate in measuring the patient's exercise type and intensity  
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10 [29-30]. Combined with intelligent insoles and wearable HR monitors, our system can evaluate whether  
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12 patients reach the required exercise intensity and are able to promptly alert patients should the intensity  
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14 fall outside the preset range. Furthermore, before each CR session, the cardiologist will evaluate the  
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16 suitability of the exercise program according to the patients' health data patients synchronized by IERMS  
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18 to ensure patient safety. IERMS also encourages patients to upload BP, HR, weight and physical activity  
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20 to track their own progress and give objective feedback, which could motivate self-monitoring, thereby  
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22 improving patients' adherence.  
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30 Another key point which has impact on HBCR is the maintenance of the rehabilitation. The  
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32 effectiveness of rehabilitation programs after stopping intervention has proven to be unsustainable in  
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34 both CBCR and HBCR [35]. We will, therefore, also evaluate if there are any significant carryover effects  
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36 in order to observe the maintenance of effects after the termination of the intervention.  
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41 An improvement in adherence may be associated with better physical and psychological states.  
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43 We will also evaluate these in this study. CPET can be used to assess a patient's exercise performance  
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45 and peak  $VO_2$  which has been shown to be the strongest predictor of mortality [36] and which we have,  
46  
47 therefore, chosen as a secondary outcome. In addition, mental status, self-efficacy, quality of life and  
48  
49 lifestyle risk factors are important for HBCR assessment, thus our study will also evaluate them.  
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54 In China and other lower middle-income countries (LMICs) where access to CR is often limited,  
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56 mobile health interventions, such as IERMS used in our study, may effectively overcome barriers, such  
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4 as inconvenience, geographical isolation and financial burden, and deliver the core components of HBCR  
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6 to many patients with CHD.  
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### 9 10 **Limitations**

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13 Our current study has several limitations. Firstly, as the study is of relatively short duration, no data  
14  
15 will be available beyond 12 months and longer-term effectiveness will not be able to be evaluated.  
16  
17 Secondly, the study is limited to patients with smartphones and internet access which may cause selective  
18  
19 bias. Thirdly, we will not be able to allow participants to have a familiarization period of several weeks  
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21 before using IERMS.  
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### 26 27 **5. Conclusion**

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30 In conclusion, our study will evaluate the role of the IERMS intervention on the delivery of HBCR  
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32 as advocated in various guidelines. If this technology-based HBCR intervention is shown to be effective,  
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34 it may be an alternative method to implement evidenced-based CR for patients with CHD.  
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41

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43  
44 public representatives during the study design and intervention development.  
45  
46

47 **Contributors** LX and FL conceived the original concept of the study and wrote the first draft of the  
48  
49 protocol manuscript. WX, JL, HS, MS, XZ, YP, YN, WZ, YL, LG, SZ, LZ contributed to the design of  
50  
51 the study. LX, FL, JL, MS, XZ revised the manuscript. All authors read and approved the final manuscript.  
52  
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55  
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57  
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59  
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5  
6 comment on planned methods, protocol, data analysis or the draft report.  
7  
8

9  
10 **Competing interests** None declared.  
11

12  
13 **Provenance and peer review** Not commissioned; externally peer reviewed.  
14

15  
16 **Data sharing statement** For patient confidentiality concerns and the access possibilities of the data  
17  
18 source, the clinical data collected will not be shared with the public. However, non-clinical data, such as  
19  
20 educational materials, will be shared with the public and other researchers.  
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3 Figure Legends  
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6 Figure 1 Illustration of the randomized controlled crossover study design.  
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9 CHD, Coronary heart disease; IERMS, Intelligent Exercise Rehabilitation Management System.  
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12 Figure 2 Components of the IERMS.  
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15 IERMS, Intelligent Exercise Rehabilitation Management System.  
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18 Figure 3 Assessment time points for primary and secondary outcomes.  
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21  
22 VO<sub>2</sub>peak, peak oxygen uptake; GAD-7, the Generalized Anxiety Disorder Scale-7; PHQ-9, Patients'  
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25 Health Questionnaire Depression Scale-9; SF-12, the 12-item Short Form Health Survey; GSES, General  
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28 Self-Efficacy Scale.  
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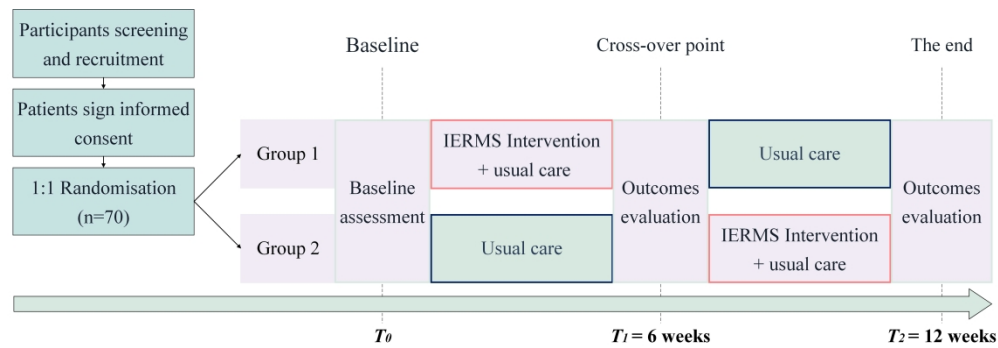


Figure 1 Illustration of the randomized controlled crossover study design.  
CHD, Coronary heart disease; IERMS, Intelligent Exercise Rehabilitation Management System.

661x228mm (300 x 300 DPI)

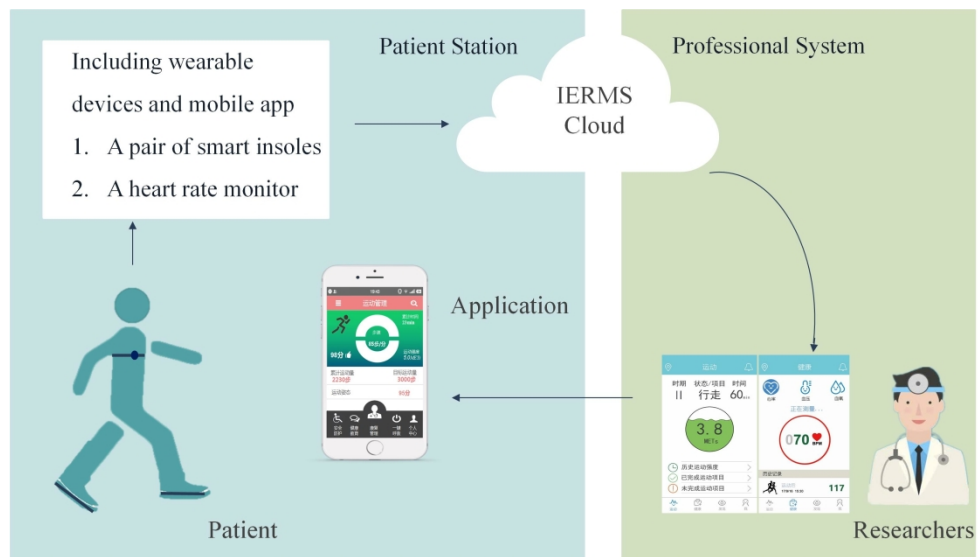


Figure 2 Components of the IERMS.  
IERMS, Intelligent Exercise Rehabilitation Management System.

268x147mm (300 x 300 DPI)

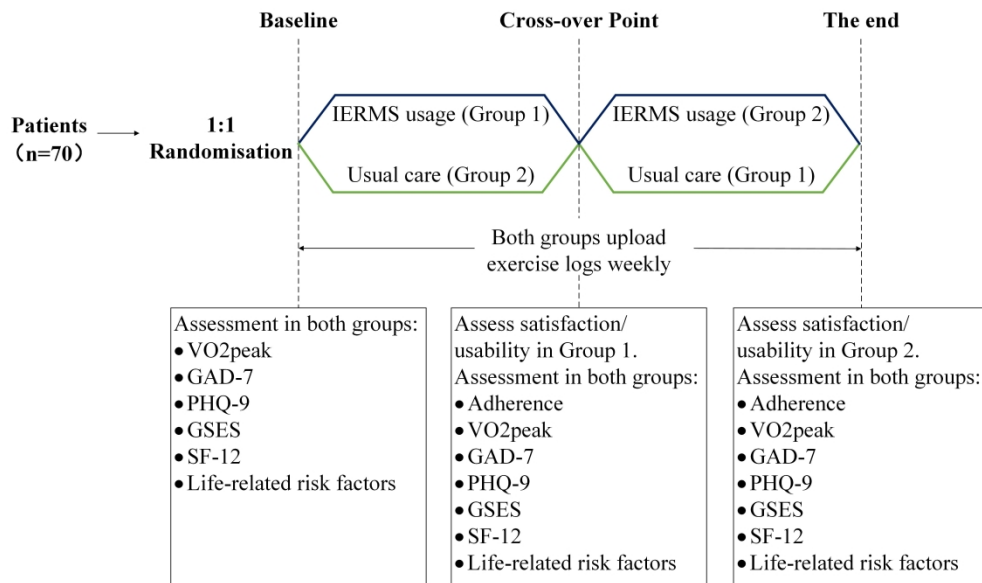


Figure 3 Assessment time points for primary and secondary outcomes. VO2peak, peak oxygen uptake; GAD-7, the Generalized Anxiety Disorder Scale-7; PHQ-9, Patients' Health Questionnaire Depression Scale-9; SF-12, the 12-item Short Form Health Survey; GSES, General Self-Efficacy Scale.

477x279mm (300 x 300 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
<b>Administrative information</b>		
Title	<a href="#">#1</a> Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	<a href="#">#2a</a> Trial identifier and registry name. If not yet registered, name of intended registry	P6
Trial registration: data set	<a href="#">#2b</a> All items from the World Health Organization Trial Registration Data Set	P6
Protocol version	<a href="#">#3</a> Date and version identifier	n/a
Funding	<a href="#">#4</a> Sources and types of financial, material, and other support	P17-18
Roles and responsibilities: contributorship	<a href="#">#5a</a> Names, affiliations, and roles of protocol contributors	P17
Roles and responsibilities: sponsor contact information	<a href="#">#5b</a> Name and contact information for the trial sponsor	P18

1	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design; collection,	P18
2	responsibilities: sponsor		management, analysis, and interpretation of data; writing of the report; and the	
3	and funder		decision to submit the report for publication, including whether they will have	
4			ultimate authority over any of these activities	
5				
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7				
8	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating centre, steering	n/a, did not
9	responsibilities:		committee, endpoint adjudication committee, data management team, and other	establish the
10	committees		individuals or groups overseeing the trial, if applicable (see Item 21a for data	committee
11			monitoring committee)	
12				
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14				
15	<b>Introduction</b>			
16				
17	Background and	<a href="#">#6a</a>	Description of research question and justification for undertaking the trial,	P3-5
18	rationale		including summary of relevant studies (published and unpublished) examining	
19			benefits and harms for each intervention	
20				
21				
22				
23	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	P3-5
24	rationale: choice of			
25	comparators			
26				
27				
28	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	P5
29				
30	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel group, crossover,	P5
31			factorial, single group), allocation ratio, and framework (eg, superiority,	
32			equivalence, non-inferiority, exploratory)	
33				
34				
35				
36	<b>Methods: Participants,</b>			
37	<b>interventions, and</b>			
38	<b>outcomes</b>			
39				
40				
41	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic hospital) and list of	P5-6
42			countries where data will be collected. Reference to where list of study sites can be	
43			obtained	
44				
45				
46				
47	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria	P6
48			for study centres and individuals who will perform the interventions (eg, surgeons,	
49			psychotherapists)	
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52	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including	P8-11
53	description		how and when they will be administered	
54				
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56	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial	n/a, intervention
57	modifications		participant (eg, drug dose change in response to harms, participant request, or	did not involve
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60				



		improving / worsening disease)	harms or others
1			
2	Interventions:	<a href="#">#11c</a> Strategies to improve adherence to intervention protocols, and any procedures for	P8-11
3	adherence	monitoring adherence (eg, drug tablet return; laboratory tests)	
4			
5	Interventions:	<a href="#">#11d</a> Relevant concomitant care and interventions that are permitted or prohibited	P8
6	concomitant care	during the trial	
7			
8	Outcomes	<a href="#">#12</a> Primary, secondary, and other outcomes, including the specific measurement	P11-13
9		variable (eg, systolic blood pressure), analysis metric (eg, change from baseline,	
10		final value, time to event), method of aggregation (eg, median, proportion), and	
11		time point for each outcome. Explanation of the clinical relevance of chosen	
12		efficacy and harm outcomes is strongly recommended	
13			
14	Participant timeline	<a href="#">#13</a> Time schedule of enrolment, interventions (including any run-ins and washouts),	Figure 1
15		assessments, and visits for participants. A schematic diagram is highly	
16		recommended (see Figure)	
17			
18	Sample size	<a href="#">#14</a> Estimated number of participants needed to achieve study objectives and how it	P7
19		was determined, including clinical and statistical assumptions supporting any	
20		sample size calculations	
21			
22	Recruitment	<a href="#">#15</a> Strategies for achieving adequate participant enrolment to reach target sample size	P6-7
23			
24	<b>Methods: Assignment</b>		
25	<b>of interventions (for</b>		
26	<b>controlled trials)</b>		
27	Allocation: sequence	<a href="#">#16a</a> Method of generating the allocation sequence (eg, computer-generated random	P7
28	generation	numbers), and list of any factors for stratification. To reduce predictability of a	
29		random sequence, details of any planned restriction (eg, blocking) should be	
30		provided in a separate document that is unavailable to those who enrol participants	
31		or assign interventions	
32	Allocation concealment	<a href="#">#16b</a> Mechanism of implementing the allocation sequence (eg, central telephone;	P7
33	mechanism	sequentially numbered, opaque, sealed envelopes), describing any steps to conceal	
34		the sequence until interventions are assigned	
35	Allocation:	<a href="#">#16c</a> Who will generate the allocation sequence, who will enrol participants, and who	P7
36	implementation	will assign participants to interventions	
37			
38	Blinding (masking)	<a href="#">#17a</a> Who will be blinded after assignment to interventions (eg, trial participants, care	P7
39		providers, outcome assessors, data analysts), and how	
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1	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for	n/a, not blind to
2	emergency unblinding		revealing a participant's allocated intervention during the trial	participants or
3				researchers
4				
5				
6	<b>Methods: Data</b>			
7	<b>collection,</b>			
8	<b>management, and</b>			
9	<b>analysis</b>			
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13	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline, and other trial data,	P11-13
14			including any related processes to promote data quality (eg, duplicate	
15			measurements, training of assessors) and a description of study instruments (eg,	
16			questionnaires, laboratory tests) along with their reliability and validity, if known.	
17			Reference to where data collection forms can be found, if not in the protocol	
18				
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22	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of	P11-13
23	retention		any outcome data to be collected for participants who discontinue or deviate from	
24			intervention protocols	
25				
26				
27	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes	P13-14
28			to promote data quality (eg, double data entry; range checks for data values).	
29			Reference to where details of data management procedures can be found, if not in	
30			the protocol	
31				
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33				
34	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to	P14
35			where other details of the statistical analysis plan can be found, if not in the	
36			protocol	
37				
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39				
40	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P14
41	analyses			
42				
43				
44	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-adherence (eg, as	P14
45	population and missing		randomised analysis), and any statistical methods to handle missing data (eg,	
46	data		multiple imputation)	
47				
48				
49	<b>Methods: Monitoring</b>			
50				
51	Data monitoring: formal	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary of its role and	n/a, less safe risks
52	committee		reporting structure; statement of whether it is independent from the sponsor and	in this study
53			competing interests; and reference to where further details about its charter can be	
54			found, if not in the protocol. Alternatively, an explanation of why a DMC is not	
55			needed	
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1	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines, including who will	n/a, not apply
2	interim analysis		have access to these interim results and make the final decision to terminate the	DMC in this trial
3			trial	
4				
5				
6	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited and	P15
7			spontaneously reported adverse events and other unintended effects of trial	
8			interventions or trial conduct	
9				
10				
11	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and whether the	n/a
12			process will be independent from investigators and the sponsor	
13				
14				
15	<b>Ethics and</b>			
16	<b>dissemination</b>			
17				
18				
19	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review board (REC /	P15
20	approval		IRB) approval	
21				
22				
23	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to	n/a
24			eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC /	
25			IRBs, trial participants, trial registries, journals, regulators)	
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29	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or	P8
30			authorised surrogates, and how (see Item 32)	
31				
32				
33	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and	n/a, not needed in
34	ancillary studies		biological specimens in ancillary studies, if applicable	this study
35				
36				
37	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be	P13-14
38			collected, shared, and maintained in order to protect confidentiality before, during,	
39			and after the trial	
40				
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42	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall	P18
43			trial and each study site	
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45				
46	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of	n/a, not needed in
47			contractual agreements that limit such access for investigators	this study
48				
49				
50	Ancillary and post trial	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those	n/a, not needed in
51	care		who suffer harm from trial participation	this study
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53				
54	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results to participants,	P15
55	trial results		healthcare professionals, the public, and other relevant groups (eg, via publication,	
56			reporting in results databases, or other data sharing arrangements), including any	
57			publication restrictions	
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1	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of professional writers	P15
2	authorship			
3				
4	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol, participant-level	P14-15
5	reproducible research		dataset, and statistical code	
6				
7				
8	<b>Appendices</b>			
9				
10				
11	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation given to participants and	n/a, not needed in
12	materials		authorised surrogates	this study
13				
14				
15	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of biological specimens for	n/a, not needed in
16			genetic or molecular analysis in the current trial and for future use in ancillary	this study
17			studies, if applicable	
18				
19				

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 21 can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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