


BMJ Open Effects of different brisk walking intensities on adherence and cardiorespiratory endurance of cardiac rehabilitation among patients with CHD after PCI: protocol for a randomised controlled trial

Jing Jing Piao ,¹ Boya Wan,^{1,2} Haomei Zhao,¹ Zhiyang Shang,³ Lingjun Yan,^{1,4} Zhina Hao,⁵ Yonghong Wang,¹ Yanqing Zhang,¹ Yanmei Gu^{1,6}

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JJP and BW contributed equally.

JJP and BW are joint first authors.

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For numbered affiliations see end of article.

Correspondence to

Yanmei Gu;
guyanmei@hebcm.edu.cn

ABSTRACT

Introduction Cardiac rehabilitation (CR) is a critical treatment for patients with coronary heart disease after percutaneous coronary intervention. Unfortunately, participation and adherence of CR are unexpectedly poor. This study aims to test whether low-intensity or medium-intensity brisk walking is more helpful in improving early attendance, adherence and physical results.

Methods and analysis This randomised controlled study will compare the effects of low-intensity and medium-intensity brisk walking to improve adherence and cardiopulmonary endurance. Participants will be randomly allocated to low-intensity or medium-intensity groups and will be followed-up for 8 weeks. Primary and secondary outcome data will be collected at baseline and at 2, 4 and 8 weeks. Primary outcomes measure changes in oxygen consumption (VO_2) peak value (mL/kg/min), as well as adherence. Secondary outcomes include changes in body mass index, oxygen pulse, maximal metabolic equivalent, breathing reserve, vital capacity, ratio of forced expiratory volume in 1 s to forced vital capacity, Δ oxygen consumption/ Δ work rate ($\Delta\text{VO}_2/\Delta\text{WR}$), minute ventilation/carbon dioxide production and self-efficacy.

Ethics and dissemination Ethical approval and informed consent form have been obtained from the Ethics Committee of Hebei General Hospital (approval number: NA-2021-03). The study background and main objective, as well as potential benefits and risks, will be fully explained to the participants and their families. Findings from this study will be published on academic journals in Chinese or in English for widespread dissemination of the results

Trial registration number ChiCTR2100047568.

INTRODUCTION

Coronary heart disease (CHD) is one of the major non-communicable diseases that is threatening human being.¹ It is estimated that more than 11 million people in China suffer from CHD, and this number is expected to

Strengths and limitations of this study

- Brisk walking, as the most common and easy way of exercising, is hoping to receive a sufficient compliance.
- WeChat group offers social support and ensures participation.
- WeChat messages and videos provide direct guiding and professional supervising of the rehabilitation process.
- Brisk walking steps could not be separated from common steps in WeChat pedometer record, but could be estimated roughly by timing of brisk walking or using extra pedometer.
- Blinding of participants and clinical data collectors is unachievable in the current trial.

increase steadily in the coming decades.²⁻⁴ Percutaneous coronary intervention (PCI) is the main treatment strategy for CHD. In China, 560 000 patients with CHD have been treated by PCI with a promising success rate of 91%–97%.⁵ Nevertheless, successful PCI is not the end of treatment for CHD. Cardiac rehabilitation (CR) is an important part of continuous of care for patients with CHD after PCI.⁶ CR has been shown to improve the quality of life, hospital readmission, mortality and reduce the risk factors for CHD,⁷⁻⁹ and is recommended by guidelines all around the world. The American Heart Association/American College of Cardiology and the European Society of Cardiology guidelines provide a class IA recommendation.¹⁰⁻¹² However, participation and adherence rates for CR are unfortunately low.¹³⁻¹⁶ It is challenging for patients with CHD to adhere to recommended CR programmes.

The poor participation and adherence rates for CR are related to various factors. First, patients who have undergone PCI may have kinesiophobia due to concerns that the recommended intensity of exercise is too high and may increase the risk of restenosis.¹⁷ Second, at present, many CR programmes, often time and financial consuming, carry out mostly in CR centre, which is a big obstacle for patients.¹⁸ Third, PCI patients discharged from hospital often lack professional guidance and supervision, and doctors' advice has a crucial influence on patients' participation.¹⁹ Medical staffs' support plays an important role in patients' attendance and adhering to CR programmes. Therefore, it is a health priority to develop an effective intervention that is acceptable for most patients after PCI with improving compliance.

Brisk walking is an exercise option in many guidelines for several reasons. First of all, brisk walking an achievable common form of physical activity among patients with CHD.²⁰ Second, walking exercise can be carried out with little limitation of time and place, which can help patients overcome many obstacles.²¹ Third, the speed and duration of walking can be regulated timely by oneself, that is, to say, exercise intensity is under patients' control, which makes a feeling of safety.^{22,23} Finally, WeChat as the most common social media, not only provides rehabilitation guidance and supervision from medical staffs, but also acts as peer support for patients.²⁴ Therefore, this comparative trial is designed to test the effect, attendance and adherence rate of different intensity of brisk walking and WeChat group's role of support.

Given the previous review, this study aims to address three research questions. (1) Can brisk walking patients adapt to medium-intensity exercise and continue to adhere to it up until 8 weeks after PCI? (2) If patients cannot adapt to medium-intensity exercise, will low-intensity brisk walking help improve their exercise ability and confidence? (3) Do different intensities of brisk walking influence the cardiorespiratory endurance and rehabilitation self-efficacy of patients after PCI?

METHODS AND ANALYSIS

Study design

The current study will compare the effects of different intensity of brisk walking (low-intensity and medium-intensity) at the beginning period of CR. Participants will be allocated randomly to low-intensity group or medium-intensity group and will be followed-up for 8 weeks. Data will be collected at baseline, 2, 4 and 8 weeks. [Figure 1](#) shows the flowchart of study process, and the data collecting schedule is shown in [table 1](#). The current protocol follows the 2013 Standard Protocol Items: Recommendations for Intervention Trials guidelines.

Sample size

Sample size was calculated based on primary outcome, peak oxygen consumption (VO_2 peak). Sample size was calculated on the basis of the changes in the VO_2 peak

between groups with a significance level of 5% and a two-tailed critical region to ensure the same effect size with 80% power by SPSS V.26 software. The means and SD (mean \pm SD) of the VO_2 peak in the control and intervention group were (22.58 \pm 4.5, 25.9 \pm 5.5, respectively) at post-intervention according to the published literature.²⁵ The calculation result was 86, considering 20% loss, 108 enrolments is required in the current study with 54 to each group.

Participants

Inclusion criteria

1. Clear diagnosed CHD by clinical physician with criteria of Knuuti *et al*.²⁶
2. Low risk based on the standard risk stratification for CR; (No angina symptoms or ECG ischaemic changes during exercise or recovery; No complex arrhythmias caused by rest or exercise; Thrombolysis and recanalisation of Acute Myocardia Infarction (AMI) vessels; No psychological disorders (anxiety and depression, etc); Left ventricular ejection fraction $\geq 50\%$; Peak oxygen uptake ≥ 20 ; Estimated percentage of peak oxygen uptake ≥ 15 ; Cardiac troponin concentration was normal; Selective PCI to simple lesions.);
3. Age between 18 and 75;
4. Possess a smartphone with an active WeChat account;
5. Understand the instruction and voluntarily participate with written informed consent.

Exclusion criteria

1. AMI within 2 weeks;
2. Malignant tachyarrhythmia or severe valvular dysfunction;
3. Limited movement because of any medical reason;
4. Expressing or language obstacle on communication;
5. Being enrolled in any other research project;
6. Other situation that is contraindicated to exercise rehabilitation.

Setting and recruitment

Subjects will be recruited in the four wards of the Department of Cardiovascular Medicine in Hebei Provincial People's Hospital. The estimated average number of hospitalised patients annually was 2000, among whom 108 eligible participants are supposed to be recruited from June 2021 to the end of May 2022. Cardiopulmonary exercise test and subsequent evaluation will be conducted by rehabilitation therapists to confirm whether they fulfil the inclusion criteria.

Randomisation, allocation concealment and blinding

A random sequence of 108 numbers was created by IBM SPSS Statistics V.26.0, and information will be put into sealed, opaque envelopes by staffs who are not involved with the study. Participants will be allocated at a 1:1 ratio to low-intensity group or medium-intensity group. Outcome assessors, laboratory technicians, data managers and statisticians will be blinded to treatment allocation. Informed consent will be obtained from eligible participants prior

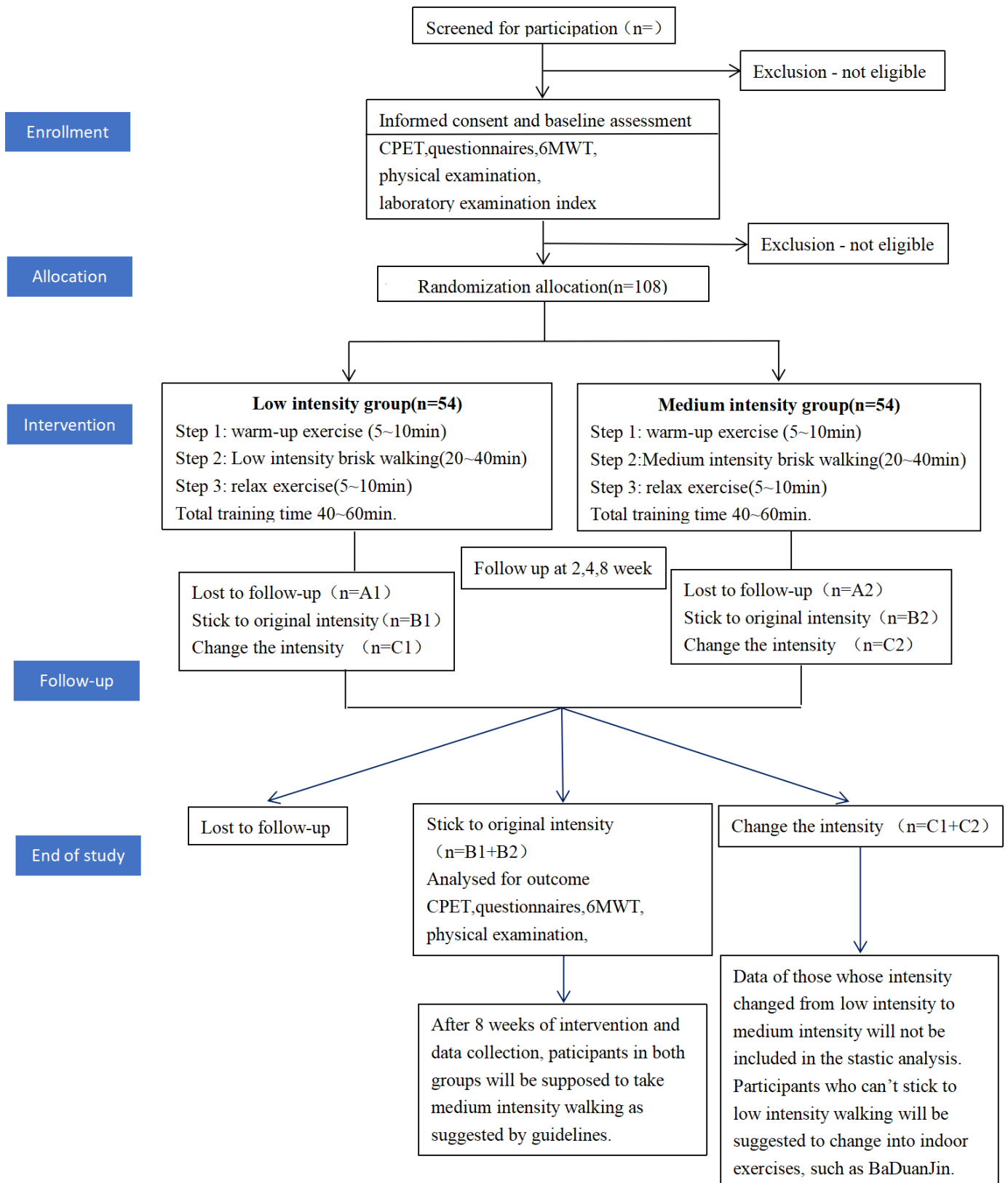


Figure 1 The flowchart of study process. CPET, cardiopulmonary exercise testing; 6MWT, 6-minute walk test distance.

to the baseline assessment. Benefit and responsibility of attending the trial and the way to monitor the exercise intensity will be informed by clinical physician. The use of WeChat group will be instructed by research nurse.

Interventions

After recruitment, researchers will collect baseline data and communicate with the subjects about the arrangement of the CR programme. The programme includes

Table 1 Time points for the outcome assessment

Outcome	Assessment	Baseline	2 weeks	4 weeks	8 weeks
Primary outcomes					
VO ₂ peak	CPET	✓	✓	✓	✓
Adherence					
Secondary outcomes					
MaxVO ₂	CPET	✓	✓	✓	✓
6MWT	Change in 6MWT distance	✓	✓	✓	✓
BMI		✓	✓	✓	✓
O ₂ /HR	CPET	✓	✓	✓	✓
AT/kg	CPET	✓	✓	✓	✓
MET _{max}	CPET	✓	✓	✓	✓
BR	CPET	✓	✓	✓	✓
VC	CPET	✓	✓	✓	✓
FEV ₁ /FVC	CPET	✓	✓	✓	✓
ΔVO ₂ /ΔWR	CPET	✓	✓	✓	✓
VE/VCO ₂	CPET	✓	✓	✓	✓
Self-efficacy	Secd-6 questionnaire	✓	✓	✓	✓

AT/kg, anaerobic threshold/kg; BMI, body mass index; BR, breathing reserve; CPET, cardiopulmonary exercise testing; FEV₁/FVC, forced expiratory volume in 1 s/forced vital capacity; MaxVO₂, maximal oxygen uptake; MET_{max}, metabolic equivalent max; 6MWT, 6-minute walk test distance; O₂/HR, oxygen pulse; VC, vital capacity; VE/VCO₂, ventilation/carbon dioxide production; VO₂ peak, peak oxygen uptake; ΔVO₂/ΔWR, Δoxygen consumption/Δwork rate.

health education on diet and nutrition, medication, smoking cessation and other health information for CR. An electronic tracker device will be employed to obtain quantitative data on heart rate and timely steps count. Low intensity will be acknowledged as 50%–59% of the patient's maximum heart rate (MHR) (MHR=220 – age in years) and medium intensity as 60%–70% of MHR.

Low-intensity group

Step 1: Warm-up exercise (5~10 min) which includes arm-swinging and gentle stretches of the neck, shoulders, spine, arms and legs.

Step 2: Low-intensity brisk walking (30~40 min) with targets 50% and 59% of the MHR.

Step 3: Cool-down exercise (5~10 min) which involves dynamic and static stretching.

Medium-intensity group

Step 1: Warm-up exercise (5~10 min) which includes arm swinging and gentle stretches of the neck, shoulders, spine, arms and legs.

Step 2: Medium-intensity brisk walking (30~40 min) with 30–40 min of walking that targets 60% and 75% of the MHR.

Step 3: Cool-down exercise (5~10 min) which involves dynamic and static stretching.

Participants are expected to submit statistic information on the monitor (detected MHR and step counts) to

research nurse in WeChat group. Clinical physicians in WeChat group will instruct and monitor the rehabilitation process and communicate timely with the patients.

Participants are allowed to adjust the intensity of brisk walking on their own will according to the perceived health condition. The reason, time and number of participants who adjust the exercise intensity will be recorded in detail, which will be shown as compliance in the results. The final analysis will include participants who change and did not change exercise intensity within 8 weeks.

All subjects are expected to complete 24 sessions of brisk walking (3 days a week for continuingly 8 weeks). After 8 weeks, all patients will be recommended to join medium-intensity brisk walking according to the Chinese guidelines. For those who failed to maintain the brisk walking but still in WeChat group to follow instructions, Chinese traditional practice of Baduanjin will be introduced as indoor exercises alternatively.

Adherence

Adherence will be recorded as the proportion of participants who stick to the designed walking intensity at 2, 4 and 8 weeks. Several strategies will be used to encourage the participants to adhere to the assigned exercise. (1) Instructions and guidance from the clinical physicians in WeChat group are free of charge for all participants. (2) The participants will receive prioritised outpatient

evaluation by clinical specialists. (3) A free cardiopulmonary exercise test will be awarded to participants who complete the trial. (4) Research nurses in master's programme will be in charge in the WeChat group to send reminders to patients.

Outcome measures

VO₂ peak value is the primary outcome, as well as the adherence rate. Secondary outcomes include body mass index, oxygen pulse (O₂/HR), maximal metabolic equivalent (MET_{max}), breathing reserve (BR), vital capacity (VC), ratio of forced expiratory volume in 1s to forced vital capacity (FEV₁/FVC), Δoxygen consumption/Δwork rate (ΔVO₂/ΔWR), minute ventilation/carbon dioxide production (VE/VCO₂), 6-minute walking test and self-efficacy. Clinical research assistants will perform the above measurements at baseline and at 2, 4 and 8 weeks. Demographic information, such as age, gender, race, marital status and education level will be collected at baseline.

Weight and height will be measured barefoot and in exercise clothing before the test using a MasterScreen CPX device (Jaeger, Germany) in the hospital. Cardiopulmonary exercise testing is an objective evaluation for the cardiac function. The participants will warm up for 3 min, and the exercise load will be increased over the test. A cycling rate of 60–70 rpm/min is instructed to maintain until the participant experiences exhaustion. The test will stop in case chest tightness, chest pain, asthma, dyspnoea or other uncomfortable symptoms occur. Five minutes of cooling down is needed before blood pressure and heart rate are measured. VO₂ peak value, O₂/HR, MET_{max}, BR, VC, FEV₁/FVC, ΔVO₂/ΔWR, VE/VCO₂ tests will be performed using the same equipment under close monitor. Patient's feelings are also recorded.

Exercise Self-Efficacy Scale will be employed to test participants' self-efficacy. Higher scores indicate higher levels of self-efficacy. The 6-minute walking test will be performed to measure cardiac function and exercise endurance. Any potential side effects or adverse events will be recorded as well.

Patient and public involvement

Given the importance of involving patients in the development and design of clinical trials, we aimed to develop exercise programmes that were aligned with the patients' priorities, values, level of preparation and willingness to participate in the intervention. Therefore, we created a discussion group in June 2021 using a representative sample of participants who were introduced to different exercise intensities and asked to evaluate whether these methods were appropriate or difficult to perform. The participants' opinions were recorded, and they were informed that the entire trial would be supervised and guided by professional rehabilitation experts to ensure that they were psychologically prepared for the intervention.

Data collection and management

Clinical research assistants will evaluate the completeness and integrity of the data before entering into EpiData Manager (free data management software). The project manager will then perform data cleaning, coding and conversion to ensure that the data are in the correct format for analysis. All data will be stored on a dedicated computer in a secure location. Data sorting and statistical analyses will be performed under the instruction of statistician at the Hebei University of Chinese Medicine. All researchers involved in the data management and analysis will be blinded to treatment allocation.

Statistical analysis

Continuous variables will be described as mean±SD for normal distributions or median for non-normal distributions; categorical variables will be described as frequency. Baseline data mainly describe the demographic features and clinical characteristic of the subjects. We will test the equalisation of the two groups of variables. Continuous variables will be tested with a two-sample Student's t-test for normal distributions or Wilcoxon test for non-normal distributions. Categorical or enumeration variables will be tested by the χ^2 test or Kruskal-Wallis test. The difference between low-intensity group and medium-intensity group at each time point (2, 4, 8 weeks after intervention) will be tested by repeated analysis of variance or generalised estimating equation (GEE model). The analysis of primary or secondary outcomes will be based on an intention-to-treat principle. Participants who either drop out from the study or fail to adhere to the protocol will have their last known data carried forward. The missing data will be input using a multiple imputation method. All data will be analysed with SPSS packages. Statistical significance is defined as a two-sided p value<0.05.

DISCUSSION

A recent national survey showed that only 30 in 124 investigated medical centres in China have operational CR programmes, which means approximately two programmes per 100 million inhabitants.²⁷ With the prevalence of cardiovascular diseases, and the social and economic burden of the disease, more CR centres are called in general hospitals to provide professional rehabilitation instruction in China and abroad. There is a long and complex way to go before we achieve the goal of providing CR for most patients.²⁸ Previous systematic review reported that the participation rates of CR programme globally is lower than 30% or even worse.^{16 29 30} Therefore, it is a health priority to explore a CR exercise programme that combined with more common daily activities. Many clinical trials devoted to improve participation and adherence rate have been introduced, such as telerehabilitation programmes with the help of social media.^{31–33} Social media, which include Twitter, Instagram, YouTube and WeChat, is well accepted in public. Hence, an activity with benefit to patients with



CHD health status supervised by professionals through social media would be promising.³⁴ However, the introducing of such a programme needs a period of adaptation to patients' daily life.

This trial will evaluate the participation and adherence rate of different brisk walking intensities among patients after PCI, which is performed at home as one of the daily activities. Rehabilitation activities are related to self-efficacy, the belief that a person can successfully complete a task or behaviour under certain circumstances.³⁵ Researches find that self-efficacy may predict activity level 6 months after cardiac surgery.³⁶ We pay special attention to developing an active daily activity and establishing a rehabilitative exercise habit. Several strengths of the current study protocol are worth mentioning there. First, the low-intensity and medium-intensity groups will be compared in terms of effect and self-efficacy, which will provide useful data for developing an easier way to start a CR programme that has good efficacy and compliance. Second, self-efficacy is a key factor that affects patient compliance, and this trial will consider self-efficacy as an outcome to determine whether a specific exercise intensity is linked to greater self-efficacy and a better rehabilitation effect. Third, we will use WeChat group to communicate with the patients, permitting professional supervision of the rehabilitation exercise, as well as guidance and social support. However, the trial also has one important limitation that should be acknowledged, as the nature of the exercise intervention (low-intensity or medium-intensity brisk walking) precludes the blinding of the participants. Nevertheless, every effort will be made to ensure that data managers and statisticians are blinded to the treatment allocations.

In conclusion, this trial aims to identify the optimal exercise style for early CR after PCI with the hope to achieve a balance between patient acceptance, compliance, safety and efficacy.

ETHICS AND DISSEMINATION

This study conforms to the principles of the Declaration of Helsinki and relevant ethical guidelines. Ethical approval and informed consent form have been obtained from the Ethics Committee of Hebei General Hospital (approval number: NA-2021-03). The study background and main objective, as well as potential benefits and risks, will be fully explained to the participants and their families. Findings from this study will be published on academic journals in Chinese or in English for widespread dissemination of the results.

Author affiliations

¹School of Nursing, Hebei University of Chinese Medicine, Shijiazhuang, China

²Hebei General Hospital, Shijiazhuang, China

³Affiliated Hospital of Hebei University, Baoding, Hebei, China

⁴The Third Hospital Of Shijiazhuang, Shijiazhuang, China

⁵Hospital of Stomatology Hebei Medical University, Shijiazhuang, China

⁶Key Laboratory for HealthCare with Chinese Medicine of Hebei Province, Shijiazhuang, China

Contributors YG and JJP designed the study. BW, ZH, LY, YW and YZ organise the WeChat group and collect clinical data. ZS and HZ are in charge of the data management and statistical analyse. JJP drafted the manuscript. YG contributed to the interpretation of the results and critical revision of the manuscript for important intellectual content and approved the final version of the manuscript. All authors have read and approved the final manuscript. YG is the study guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID ID

Jing Jing Piao <http://orcid.org/0000-0003-2022-5947>

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