

Effectiveness of Remotely Monitored Home-Based Baduanjin using Wearable Devices for Elder Patients after coronary revascularization: A Study Protocol for a Randomized Controlled Trial

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Abstract

Introduction:

Coronary artery disease(CAD) is a prevalent cardiovascular disorder, and coronary revascularization, including percutaneous coronary intervention(PCI) and coronary artery bypass grafting(CABG), is a common treatment. However, many patients still suffer from cardiopulmonary dysfunction after the surgery. Baduanjin, a traditional Chinese exercise, may have potential benefits for these patients, but evidence is limited. This trial aims to determine the effectiveness and safety of remotely monitored home-based Baduanjin for post-coronary revascularization patients with cardiopulmonary dysfunction.

Methods and analysis:

This is a multicenter, assessor-blinded, two-armed randomized controlled trial. Three hundred and ninety-eight patients will be recruited from China-Japan Friendship Hospital, Fuwai Hospital, Xuanwu Hospital, and Guang'anmen Hospital, and randomly assigned to two groups (group A or group B) in a 1:1 ratio. Patients in group A will receive remotely monitored home-based Baduanjin training combined with conventional secondary prevention education of CHD, while patients in group B will receive conventional secondary prevention education alone for 12 weeks. The primary outcome will be the peak oxygen uptake (VO_2 peak) obtained from cardiopulmonary exercise testing (CPET) at week 12 compared with baseline. Secondary outcomes will include 6-minute walk distance (6MWD), Seattle Angina Questionnaire (SAQ), health-related quality of life measured by EQ-5D-VAS and EQ-5D-5L, left ventricular ejection fraction (LVEF), anxiety and depression scales (GAD-7 and PHQ-9), Montreal Cognitive Assessment (MoCA), composite cardiovascular events (including re-revascularization, AMI, death, stroke, heart failure rehospitalization), and other relevant indicators at weeks 0, 4, 8, and 12. Safety indicators will be monitored throughout the trial.

Ethics and dissemination:

This study has been approved by the clinical research ethics committee of China-Japan Friendship Hospital (No.2024-KY-031), the results of this study will be disseminated via peer-reviewed publications or conference presentations.

Trial registration number:

Chinese Clinical Trial Registry (No. ChiCTR2400088668, <https://www.chictr.org.cn/showproj.html?proj=232409>) registered on 23 August 2024.

Introduction

Coronary artery disease is a major cause of morbidity and mortality worldwide^[1-4]. Coronary revascularization, including PCI and CABG, is a common treatment for CAD^[5-7]. Although these procedures can improve blood flow and relieve symptoms, many patients still experience cardiopulmonary dysfunction after surgery, which affects their quality of life and daily activities^[8]. Cardiac rehabilitation (CR), as a continuum of care for patients with CHD after initial treatment, has been approved to significantly promote wellness, improve exercise capacity, and preserve cardiac function^[9, 10]. However, CR participation rate is very low in China, and the main barriers include lack of center-based cardiac rehabilitation (CBCR) facilities and lack of patient awareness^[11, 12]. A recent survey indicates that China currently has approximately 500 Cardiac Rehabilitation(CR)centers, predominantly situated in major urban areas. However, the majority of patients who would benefit from these services reside in rural regions where access to hospital-based rehabilitation is limited^[13]. Recent evidence suggests that remotely monitored cardiac rehabilitation appears to be at least as effective as traditional center-based cardiac rehabilitation^[14]. Several studies have used wearable devices, such as heart rate and electrocardiogram (ECG) monitors, to remotely monitor the intensity and safety of exercise regimens in patients with cardiac disease^[14].

Baduanjin is a traditional Chinese exercise that combines slow movements, breathing regulation, and mental concentration^[15]. It has been widely practiced in China for centuries and is believed to have multiple health benefits, including improving cardiopulmonary function, enhancing physical fitness, and reducing stress^[16-18]. Several clinical trials have confirmed the effectiveness of Baduanjin for patients after cardiac revascularization^[17, 19]. This clinical trial is to further investigate the feasibility, effectiveness and safety of home-based Baduanjin exercise using wearable devices, with the aim of increasing participation in cardiac rehabilitation and improving the cardiovascular prognosis for more patients.

Methods

Study design

This is a multicenter, assessor-blinded, two-armed randomized controlled trial. The study will be conducted in accordance with the Declaration of Helsinki and the SPIRIT guidelines. The protocol has been registered on Chinese Clinical Trial Registry (No. ChiCTR2400088668). The flow diagram of the trial is shown in Fig. 1.

Study setting, recruitment, and ethics

The recruitment will be conducted at China-Japan Friendship Hospital, Fuwai Hospital, Xuanwu Hospital, and Guang'anmen Hospital. The study has been approved by the medical ethical review committee of China-Japan Friendship Hospital (No.2024-KY-031). Patients will be recruited from outpatient and

inpatient department, meanwhile, posters will be posted on the we-media and the outpatient hall. According to the principle of fair distribution of burden and benefit, relevant information will be released through subject recruitment announcement, interested subjects will read the study introduction, and qualified subjects will sign the written informed consent, then selected subjects will be randomly divided. Before signing the written informed consent, the researcher needs to explain the study in detail with potential patients, for example, the study purpose, procedures, as well as the potential risks and benefits associated with participation in the study. The confidentiality of patient records will be protected. Data will be processed in a "data anonymous" manner, omitting information that can identify individual subjects. If the results of the trial are published, the identity information of the subjects shall remain confidential.

Inclusion criteria

1. 1. Aged 60–80 years, male or female.
2. 2. Confirmed diagnosis of CAD by coronary angiography and undergone coronary revascularization (PCI or CABG) within the past 2–4 weeks.
3. 3. Presence of cardiopulmonary dysfunction with New York Heart Association (NYHA) functional class I-II.
4. 4. Ability to use wearable devices and sign the informed consent.

Exclusion criteria

1. 1. History of acute ST-segment elevation myocardial infarction in this episode.
2. 2. Left ventricular ejection fraction < 45%, or uncontrolled angina.
3. 3. Valvular heart disease, various cardiomyopathies, atrial fibrillation, severe arrhythmias (such as ventricular tachycardia, ventricular fibrillation), etc.
4. 4. Uncontrolled hypertension (systolic blood pressure > 180mmHg, diastolic blood pressure > 110 mmHg).
5. 5. Presence of other severe diseases, such as severe liver or kidney dysfunction (ALT > 1.5 times the normal value, Scr > 1.5 times the normal value), cachexia, or malignancy.
6. 6. Cognitive impairment or mental disorders.
7. 7. Presence of motor dysfunction.
8. 8. Participation in another clinical trial within the past month.
9. 9. Judged by the investigator as unsuitable for the study.

Randomization and allocation concealment

Eligible patients will be randomly assigned to group A (home-based Baduanjin exercise using wearable devices combined with conventional secondary prevention education) or group B (conventional secondary prevention education alone) in a 1:1 ratio using a web-based central randomization system.

The randomization sequence will be generated by an independent statistician and concealed in sequentially numbered, opaque, sealed envelopes.

Blinding

Due to the nature of the Baduanjin training, it is not possible to blind the patients and the trainers. However, the outcome assessors and statisticians will be blinded to the group assignments to ensure the reliability of the results.

Interventions

Patients in group A and group B will receive routine secondary prevention education according to the 2018 Chinese Guidelines for the diagnosis and treatment of stable CAD, including medication adherence education, lifestyle change education and risk factor control education, except for exercise style advice. Patients in group A will use wearable devices to perform home Baduanjin exercise on the basis of education. Patients in group B only receive routine secondary prevention education of CAD, without any additional CR-related interventions. For both of the two arms, the participants will not accept any in-hospital cardiac rehabilitation.

Patients in the group A will be managed with the continuous cardiac rehabilitation management model based on the "Internet Plus" remote mode for 3 months, the specific content is as follows:

The training of Baduanjin for patients in this group will be carried out by experienced coaches through offline collective teaching or online video. Patients were encouraged to practice Baduanjin at home for at least 30 minutes per day, 3–5 days per week. Wearable devices will be used to monitor continuous electrocardiograms, exercise intensity, breathing signals, and provide real-time feedback.

Researchers will provide the wearable device (DEG-A-P, developed by Chinese Academy of Science Institute of Healthcare Technologies) and electronic blood pressure tester (A223, developed by Bioland Medical Device Co., LTD) for patients, and help patients install remote monitoring software (provided by Chengdu Heart Medical Technology Co., LTD) on their smartphones. The monitoring data will be automatically transmitted to the Digital Management and Follow-up of cardiovascular Diseases platform (developed by Chinese Academy of Science Institute of healthcare technologies) through a connected smartphone. The medical staff monitored the patient's exercise frequency, amplitude, blood pressure and heart rate before and after exercise on the computer side of the monitoring equipment. Borg Rating of Perceived Exertion Scale^[20] will be used to investigate the fatigue degree of patients after exercise, and they were communicated with patients by SMS (Wechat and other applications) and telephone every week. The exercise status (including exercise frequency, exercise intensity, exercise time, blood pressure and heart rate response before and after exercise), completion of Baduanjin maneuver and exercise prescription were inquired. The frequency of feedback was generally once a week. Researchers checked

the information on the website every day commonly. If patients have questions, they would answer them in time. Feedback is based on cognitive and behavioral theories and is individualized.

Outcomes

Table 1 shows the treatment and outcome measurement schedules.

Primary outcome measurement

The primary outcome measure is the change in peak VO_2 obtained from Cardiopulmonary Exercise Testing (CPET)^[21] at Week 12 compared with baseline. peak VO_2 is a key indicator of cardiopulmonary function and reflects the maximum amount of oxygen an individual can uptake during exercise. During CPET, participants typically perform incremental exercise on a cycle ergometer or treadmill until they reach maximal effort or are unable to continue. Throughout the test, continuous monitoring of oxygen uptake (VO_2), carbon dioxide output (VCO_2), heart rate, and blood pressure is conducted to comprehensively reflect the functional capacity and impairment of the respiratory, cardiovascular, metabolic, and musculoskeletal systems.

Secondary outcome measurements

Secondary outcomes will include 6-minute walk distance (6MWD)^[22], Seattle Angina Questionnaire (SAQ)^[23], health-related quality of life measured by EQ-5D-VAS and EQ-5D-5L^[24], left ventricular ejection fraction (LVEF), Generalized Anxiety Disorder 7-item scale (GAD-7)^[25], Patient Health Questionnaire-9 (PHQ-9)^[26], Montreal Cognitive Assessment (MoCA)^[27], composite cardiovascular events (including revascularization, AMI, death, stroke, heart failure rehospitalization), the timing of measurement of the outcome measures is shown in Table 1.

Adverse events

Safety indicators, including routine tests of blood, urine, stool, and the function of the liver, kidney, and coagulation, will be performed at week 0 and week 12.

All adverse events will be monitored and recorded throughout the trial. Patients will be instructed to report any adverse events or discomfort during the study period. The severity, duration, and relationship to the intervention will be documented. Common potential adverse events related to exercise training, such as musculoskeletal injuries or cardiovascular symptoms, will be closely monitored.

Data collection, management and monitoring

The Case Report Form (CRF) will be completed in paper form by a data entry operator (DEO) and then entered into an Excel spreadsheet by an electronic data interchange (EDI) administrator independently to ensure the accuracy of the data. The researchers will keep all trial data, including signed informed

consent, CRF, operation procedure records, etc. The results of this study may be published in medical journal, but we will not disclose the privacy of patients. The research supervision department, the ethics committee of the hospital, and its relevant personnel can inspect the data.

Quality

Before the inclusion of patients, all the researchers will be trained on the implementation program, including scale evaluation, data measurement, and the CRF filling. Set up a special quality examiner to check the quality of the research regularly. The CRF should be strictly managed, and the researchers should truthfully, meticulously record as required to ensure the contents of the CRF are reliable and complete. Regular follow-up will be conducted to ensure the compliance of patients during the study, and the shedding rate of cases should be controlled within 20%.

Sample size

According to our previous research results of remote cardiopulmonary rehabilitation intervention in patients with coronary heart disease after revascularization, the peak oxygen intake of cardiopulmonary function was 31.2 ± 8.8 in the intervention group and 28.7 ± 6.9 in the control group. The test level $\alpha = 0.05$ was set, and the test efficacy was 0.8. The sample size of each group calculated by G-Power software^[28] was at least 318 cases. Consider a 20% shedding rate, 199 cases per group were needed. Therefore, the total sample size for this study was 398 cases.

Statistical analysis

Intention-to-treat (ITT) set and per-protocol (PP) set will be used for the analysis of all outcomes. The ITT set includes all randomized patients who receive at least one session treatment but excludes those without any follow-up observation data after inclusion. The PP set includes only those who complete at least three sessions and all planned follow-ups, and have no major protocol violations (taking other drugs during the trial, etc.). The ITT set will be mainly used, and the PP set will be used as an auxiliary.

SPSS 19.0 software will be used for statistical analysis. For all statistical tests, $P < 0.05$ will be considered to be statistically significant. Continuous data will be presented as mean $\pm$ standard deviation ($M \pm SD$), while enumeration data will be presented as a percentage. The independent sample t-test or χ^2 test will be used to compare demographic data and other baseline indicators to measure the equilibria between the two groups. A paired t-test will be used to compare intra-group differences before and after treatment.

Covariance analysis will be used for continuous data and logistic regression analysis will be used for dichotomous data, which will be adjusted according to baseline, temporary painkiller dosages, and presented as mean difference or odds ratio, providing a 95% confidence interval (CI). Intention to treat analysis (ITT) will be carried out for all the randomized patients. For the case data that failed to observe the whole process, the last observation carry forward (LOCF) method and the maximum likelihood regression analysis will be used to fill in the missing data. Finally, the sensitivity analysis will be carried out by using the PP set.

Discussion

Coronary revascularization, including percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), is a crucial treatment for patients with CAD^[6, 7]. However, postoperative rehabilitation is essential for improving patients' quality of life and reducing cardiovascular events^[29–31]. This study will focus on patients who have undergone coronary revascularization and explore whether the home-based remote Baduanjin exercise using wearable devices is a feasible, effective, and safe rehabilitation method. The mechanisms underlying the benefits of Baduanjin remain unclear, but several studies have shown that it may improve cardiopulmonary function^[32–34], psychological state^[16], and cognitive function^[35–37]. Additionally, Baduanjin may enhance myocardial blood perfusion and reduce ventricular remodeling^[19, 38], which could be beneficial for postoperative myocardial repair and functional recovery. Evidence also suggests that Baduanjin can optimize levels of cardiovascular-related biomarkers^[19].

This study will be conducted by experienced rehabilitation specialists following a standardized protocol. To ensure consistency and standardization, all remote Baduanjin interventions were guided by the same senior rehabilitation therapist through remote video recording or live streaming. Rigorous supervision and monitoring will be applied to maintain methodological rigor and implementation normativity. The remote intervention will be delivered through an internet platform, ensuring that patients receive regular guidance and supervision.

This study has several advantages. Firstly, it is a large-scale, multi-center research, which can make the results more accurate. Secondly, it uses wearable devices and conducts remote home-based rehabilitation under platform monitoring. The promotion of this model can make cardiac rehabilitation more convenient and safer.

This study has several limitations. First, due to the nature of Baduanjin intervention, patients and the therapist cannot be blinded during the intervention. This may introduce subjective bias and affect the objective assessment of the intervention's effectiveness. Second, the follow-up period in this study was relatively short. This limits the assessment of the long-term impact of Baduanjin intervention and may not fully capture its potential benefits for long-term recovery and cardiovascular events.

This study will contribute to a better understanding of the effectiveness and safety of home-based remote Baduanjin intervention using wearable devices. The results will be of great importance for developing clinical therapy guidelines and may benefit more patients undergoing coronary revascularization.

Trial status

This recruitment has begun in September 1, 2024. Trial recruitment is expected by the end of April 2026.

Abbreviations

CAD
coronary artery disease
AMI
acute myocardial infarction
PCI
percutaneous coronary intervention
CABG
coronary artery bypass grafting
BDJ
Baduanjin
SAQ
Seattle Angina Scale
CEPT
cardiopulmonary exercise test
6MWD
6-minute walking distance
LVEF
Left Ventricular Ejection Fraction
GAD-7
Generalized Anxiety Disorder-7
PHQ-9
Patient Health Questionnaire-9
MoCA
Montreal Cognitive Assessment
ITT
Intention-to-treat
PP
per-protocol
LOCF
Last Observation Carry Forward
CI
Confidence Interval
CRF
Case Report Form
DEO
Data Entry Operator
EDI
Electronic Data Interchange

Declarations

Ethics approval and consent to participate

The study has been approved by the medical ethical review committee of China-Japan Friendship Hospital (No.2024-KY-031). Written informed consent will be obtained from all patients before they enroll in the study.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

PY and LTL: conception, design of the study, and manuscript writing. HJ and XX: design of the study and manuscript writing. ZZL,XLL,MRL, TG, LZ: critical revision of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

Queries about the full protocol for the study can be consulted with the corresponding author. The results of the trial may be published in peer-reviewed journals, no matter positive or negative results. Personal information of patients will not be disclosed due to privacy protection.

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Tables

Table 1 is available in the Supplementary Files section.

Figures

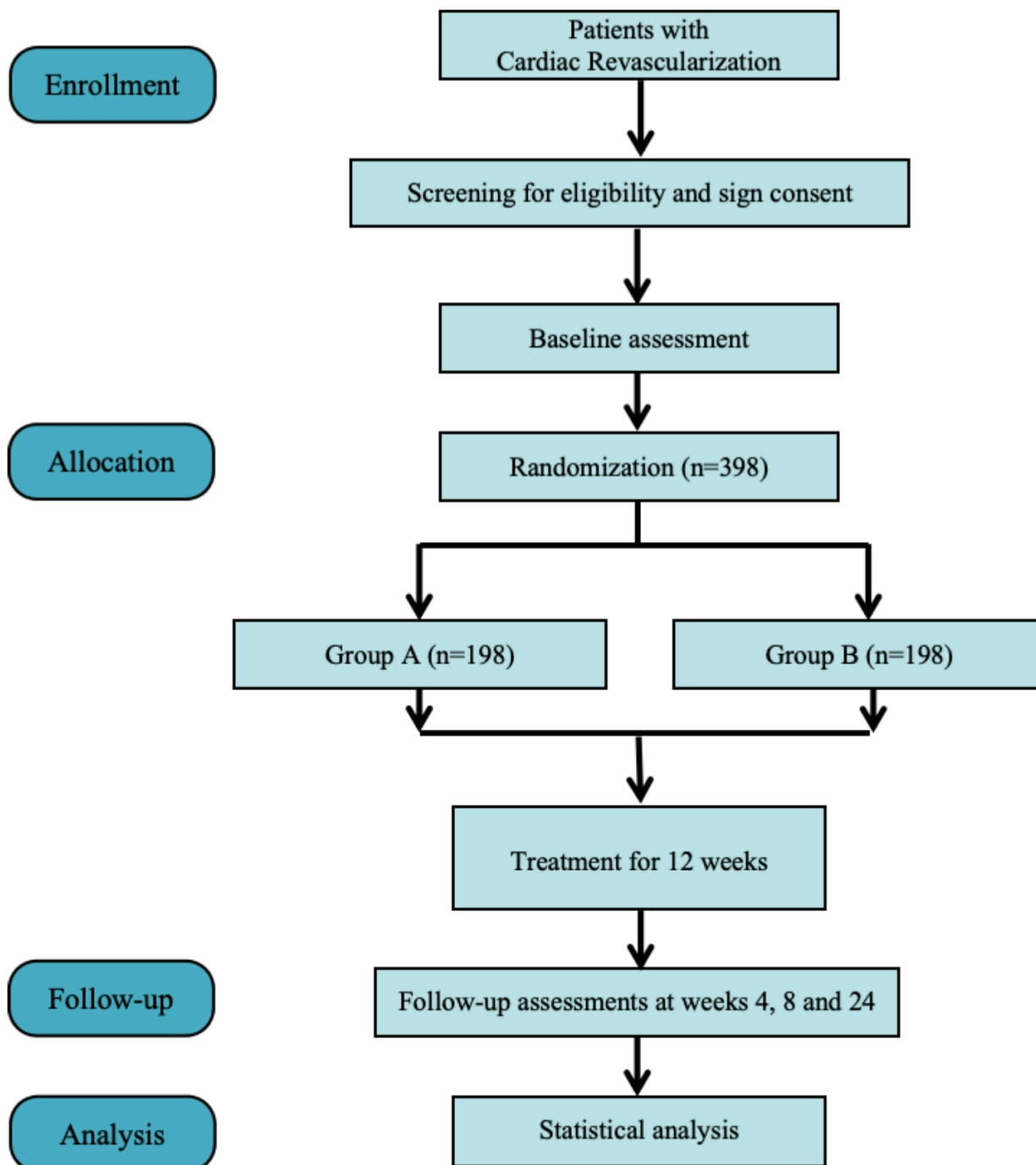


Figure 1

Flow diagram. Group A: home-based Baduanjin training using wearable devices combined with conventional secondary prevention education, Group B: conventional secondary prevention education alone

Supplementary Files

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- [Table1.docx](#)