INPLASY PROTOCOL

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Corresponding author:
Dongmei Wei

21074295@qq.com

Author Affiliation:
Guangzhou University of Chinese Medicine First Affiliated Hospital.

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Conflicts of interest:
None declared.

Effects of Baduanjin exercise on cardiac rehabilitation after percutaneous coronary intervention: A protocol for systematic review and meta-analysis of randomized controlled trials

Wei, D[1]; Sun, Y[2]; He, H[3].

Review question / Objective: **Can Baduanjin exercise improve the cardiac rehabilitation of patients with coronary artery disease after percutaneous coronary artery surgery?**
Condition being studied: **Coronary heart disease (CHD), also known as coronary artery disease (CAD), is the single most common cause of death globally, with 7.4 million deaths in 2013, accounting for one-third of all deaths (WHO 2014). PCI has been shown to be effective in reducing mortality in patients with CHD. During follow-up, it has been shown that the benefits of PCI can be offset by the significant risks of coronary spasm, endothelial cell injury, recurrent ischemia, and even restenosis or thrombus. Numerous guidelines endorse the necessity for cardiac rehabilitation (CR), which is recommended for patients with chronic stable angina, acute coronary syndrome and for patients following PCI. Baduanjin have been widely practised in China for centuries, and as they are considered to be low risk interventions, their use for the prevention of cardiovascular disease is now becoming more widespread. The ability of Baduanjin to promote clinically meaningful influences in patients with CHD after PCI, however, still remains unclear.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2022 and was last updated on 14 April 2022 (registration number INPLASY202240080).

INTRODUCTION

Review question / Objective: **Can Baduanjin exercise improve the cardiac rehabilitation of patients with coronary artery disease after percutaneous coronary artery surgery?**

Rationale: **Coronary heart disease is a common chronic disease among middle-aged and elderly people, and the number of**

patients has been increasing rapidly in recent years. Percutaneous coronary intervention (PCI) is currently one of the main clinical methods for the treatment of coronary heart disease. It has the advantages of less complications and less trauma. But at the same time, patients after PCI still have the risk of recurring cardiac events. Therefore, long-term rehabilitation after surgery has important clinical significance for the outcome of the disease. This study uses the method of Meta analysis to systematically evaluate the effect of Baduanjin exercise in patients after coronary heart disease PCI, and hopes to provide evidence-based basis for the implementation of Baduanjin exercise for patients after coronary heart disease PCI.

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METHODS

Search strategy: ((Baduanjin) OR Baduanjin exercise) AND ((((((((((Coronary Heart Disease) OR Coronary Heart Diseases) OR CHD) OR Acute coronary syndrome) OR ACS) OR Acute myocardial infarction) OR AMI) OR Heart failure) OR HF) OR percutaneous coronary intervention) OR PCI).

Participant or population: Patients with coronary heart disease, who have received Baduanjin exercise interventions after PCI.

Intervention: Baduanjin exercise.

Comparator: Control group patients will be those receiving no treatment, or routine treatment.

Study designs to be included: RCT.

Eligibility criteria: We will include randomised controlled trials (RCTs) that compare the effects of baduanjin with a no exercise control on patients with CHD following PCI. The following study designs or publication types will be excluded: (1) non-clinical research literature, such as animal experiments, reviews or case reports; (2) duplicate publications; (3) literature with incomplete data, the study of chaos and (4) studies which lack primary outcome measures. If multiple intervention data can be obtained, the trails can be adopted. If data for comparison of multiple interventions cannot be directly obtained, we will try e-mailing the corresponding author to obtain the original data. If the data cannot be obtained, the trails will also be excluded.

Information sources: Seven databases in English and Chinese including PubMed, Web of Science, Cochrane Library, Embase, Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure, and Wanfang Database will be searched.

Main outcome(s): (1) All-cause mortality; (2) Revascularisation (CABG and PTCA); (3) Generic instrument of HRQL, such as SF-36 health survey scores; (4) The days of hospital readmission.

Additional outcome(s): (1) BNP; (2) Blood lipid indexes, such as TC, TG, LDL-C and

HDL-C; (3) Echocardiography; (4) Adverse events.

Data management: Two review authors independently screened the literature using the predetermined inclusion criteria and extracted data from the trials. We resolved any disagreements about the extracted data from the included studies by consensus and consulted a third review author if disagreements persisted.

Quality assessment / Risk of bias analysis: The methodological quality of included studies will be evaluated in terms of concealment allocation, randomisation, blinding and other biases, by two authors (Tian Zhang and Xiaoqi Zhou) according to the Cochrane revised tool for risk of bias. Particular attention will be paid to the adequacy of the random allocation concealment and blinding measures used, due to the potential for failure in studies in which these have been inadequately handled. IN addition, the sample size calculation method, the reporting of withdrawals and follow-ups, and other sources of bias will also be assessed, and another two authors (Xiaojiang Yu and Wei Wu) will assess the quality of the evidence using the GRADE framework, covering study limitations, inconsistencies, indirectness, imprecision and publication biases. The whole assessment procedure will therefore be undertaken as follows: (1) the presentation of direct and indirect effect estimates; (2) the assessment of the quality of the direct and indirect estimates; (3) a presentation of the results of the network meta-analysis; (4) an assessment of the quality of the network meta-analysis effect estimates.

Strategy of data synthesis: The Cochrane Collaboration's Review Manager 5.3 software was used to extract the relevant dichotomous or continuous data from the literature for analysis. Risk ratios (RRs) were calculated for dichotomous data, whereas the mean differences (MDs) and standard deviations (SDs) were calculated for continuous variables. The corresponding 95% confidence intervals (CI) and forest plots were used in both cases. In our meta-analysis, we used SD values when the data were in the same unit. When they were in different units, we performed a conversion. The chisquared and I^2 (inconsistency) tests were used to detect heterogeneity. A P value50% indicated that there was significant heterogeneity. The fixed-effect model was used when P>.10 and I^2<50%, and the random-effect model was used when P<.10 or I^2 ? 50%.

Subgroup analysis: Subgroup analysis will be carried out if significant levels of heterogeneity, or any incongruities, are detected within the network analysis. Inconsistent sources will be explored by performing a network meta-regression.

Sensitivity analysis: Sensitivity analysis will be conducted to exclude trials with small sample sizes (ie, arms of less than 10 patients) and remove trails that report the generation of non-random sequences. It is planned (if the number of trials is high enough) to perform sensitivity analysis with respect to age difference and geographical region.

Language: English and Chinese.

Country(ies) involved: China.

Other relevant information: None.

Keywords: baduanjin; cardiac rehabilitation; coronary heart disease, percutaneous coronary intervention.

Contributions of each author:

Author 1 - Dongmei Wei - Author 1 drafted the manuscript.
Email: 21074295@qq.com
Author 2 - Yang Sun - The author developed the search strategies and conducted data collection.
Email: 1662041182@qq.com
Author 3 - Hankang Hen - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Email: hehankang19650302@163.com