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Mediating effect of kinesiophobia between self-efficacy and physical activity levels in post-CABG patients: protocol for a prospective, multicentre, cross-sectional study in China

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ABSTRACT

Introduction Physical activity (PA) can improve cardiac function, exercise capacity, and quality of life, in addition to reducing mortality by 20%–30% and preventing the recurrence of adverse cardiovascular events in patients following coronary artery bypass graft (CABG). However, PA levels are low in patients after CABG. This study intends to explore the mediating effect of kinesiophobia between self-efficacy and PA levels in patients following CABG.

Methods and analysis The proposed study constitutes a prospective, multicentre and cross-sectional study comprising 413 patients. Four teaching hospitals with good reputations in CABG will be included in the study. All of them are located in Beijing, China, and provide medical service to the whole country. This study will assess the following patient-reported outcome measures: demographic information, International Physical Activity Questionnaire-Long, Social Support Rating Scale, Cardiac Exercise Self-Efficacy Instrument, Multidimensional Fatigue Inventory, Hospital Anxiety and Depression Scale, and Tampa Scale for Kinesiophobia Heart.

Ethics and dissemination This study conforms to the principles of the Declaration of Helsinki and relevant ethical guidelines. Ethical approval has been obtained from the Ethics Committee of The Sixth Medical Centre of PLA General Hospital (approval number: HZKY-PJ-2022–2). All study participants will provide written informed consent. Findings from this study will be published in Chinese or English for widespread dissemination of the results.

Trial registration number Chinese Clinical Trial Register, ChiCTR2100054098.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Prospective data collection enables achieving data integrality.
⇒ The multicentre design may improve data representativeness.
⇒ The use of a self-reported questionnaire may lead to bias.
⇒ The study design will limit causal interpretation of relationships among variables.

INTRODUCTION

Coronary artery bypass grafting (CABG) remains an important management option for patients with complex multivessel coronary artery disease (CAD) or left main stem disease.[1–4] However, postsurgical patients still experience reduced cardiac function, reduced activity tolerance, and are at a risk of recurrent adverse ischaemic events and other cardiovascular outcomes (coronary revascularisation, stroke and cardiac death).[5 6] The beneficial effects of physical activity (PA) have been well demonstrated in improving cardiac function, exercise capacity and quality of life, in addition to reducing mortality by 20%–30% and preventing the recurrence of adverse cardiovascular events.[7–9] PA following CABG has a class IA recommendation in the guidelines;[10–12] nonetheless, postoperative patients generally display poor PA levels. Yan Xiuying and Li Ying demonstrated that 85%–88% of the patients present low to moderate levels of PA 1 month following CABG, measured by the International Physical Activity Questionnaire (IPAQ).[13 14] Several factors influence the individual PA level, such as cognition, experience, family, society and culture.[15 16] As a result, identification of the effective factors for participation in PA following CABG is necessary.

Pender's health promotion model (HPM) combines factors that may influence one's behaviour, such as cognition, experience and society factors.[17] It has been widely applied to different health promotion behaviours, and has achieved substantial results.[18 19] The model includes three basic components that influence health-promoting behaviours as follows: (1) Individual characteristics and experiences (prior related behaviours and personal factors); (2) Behaviour-specific

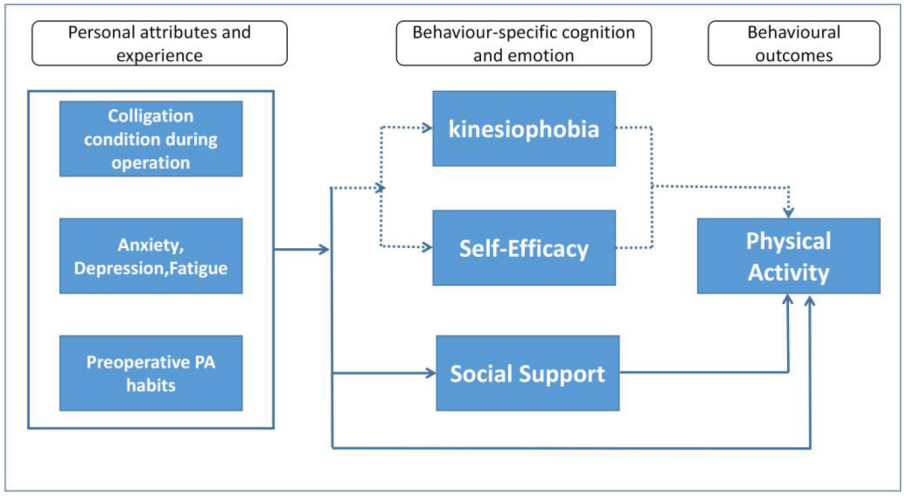

Figure 1 Theoretical framework of the study. PA, physical activity.

cognitions and affection (perceived benefits of action, perceived barriers of action, perceived self-efficacy, situational influences, interpersonal influences and activity-related affection); and (3) Desirable health-promoting behaviours. Individual characteristics and prior experiences assess previous relevant behaviours as well as the innate factors that influence health promotion behaviours. Behaviour-specific cognition and affects are the most central parts of the model. They are evaluated by perceived activity benefits and barriers, self-efficacy, and social support. Self-efficacy is a core construct that refers to the patient's confidence and belief in the ability to perform or adhere to exercise behaviours.[20] Social support is an important construct that examines the impact of social (family or friend support and interference) and environmental (family and neighbourhood) support on health behaviours. According to the HPM, desirable health-promoting behaviours, such as PA, are influenced by the above factors (figure 1).

Kinesiophobia demonstrates the perceived barriers and benefits of health-promoting behaviours among patients. The term refers to an excessive, irrational and debilitating fear of movement, stemmed from a feeling of vulnerability to painful injury or re-injury.[21] In the long term, kinesiophobia is associated with dysfunction and depression, as well as declines in quality of life and PA.[22 23] Researchers have observed kinesiophobia in various medical conditions, such as chronic lower back pain, fibromyalgia and osteoarthritis;[24–27] and also in patients with CAD.[28] However, there are limited studies on kinesiophobia in patients following CABG. CABG is considered to be a threatening stress for patients; therefore, this disorder presumably occurs in patients following CABG. Kinesiophobia may directly affect PA or have a mediating effect between self-efficacy and PA following CABG. We hypothesise that kinesiophobia exerts a mediating effect between self-efficacy and PA levels.

Based on the above literature, the proposed study intends to explore the factors influencing PA and kinesiophobia levels in patients following CABG. Moreover, this protocol aims to explore the mediating effect of kinesiophobia between self-efficacy and PA levels in these patients.

METHODS AND ANALYSIS

Study design and setting

The proposed protocol comprises a prospective, multicentre and cross-sectional study to investigate the mediating effect of kinesiophobia between self-efficacy and PA levels in patients following CABG based on the HPM.

Four teaching hospitals with good reputation in CABG will be included in the study. All of them are located in Beijing, China, and provide medical services to the entire country. The average number of annual CABG performed in each hospital is approximately over 500. The study will start from 1 July 2022 and is expected to be completed by 1 July 2023.

Participants

The inclusion criteria are as follows:

1. Three months following the successful completion of CABG;
2. Aged between 18 years and 75 years;
3. Conscious and able to complete the questionnaire in written or verbal form;
4. Have provided informed consent and are willing to participate; and
5. Have WeChat/QQ/email to maintain contact with the investigator in person/family.

The exclusion criteria are as follows:

1. Mobility impairment owing to other diseases;
2. Combined cardiovascular disease with contraindication to PA (eg, uncontrollable unstable angina or severe arrhythmias); and
3. Malignancy.

Sample size

This study will include 22 measured variables. Considering the suggestion of 15 participants per variable, the

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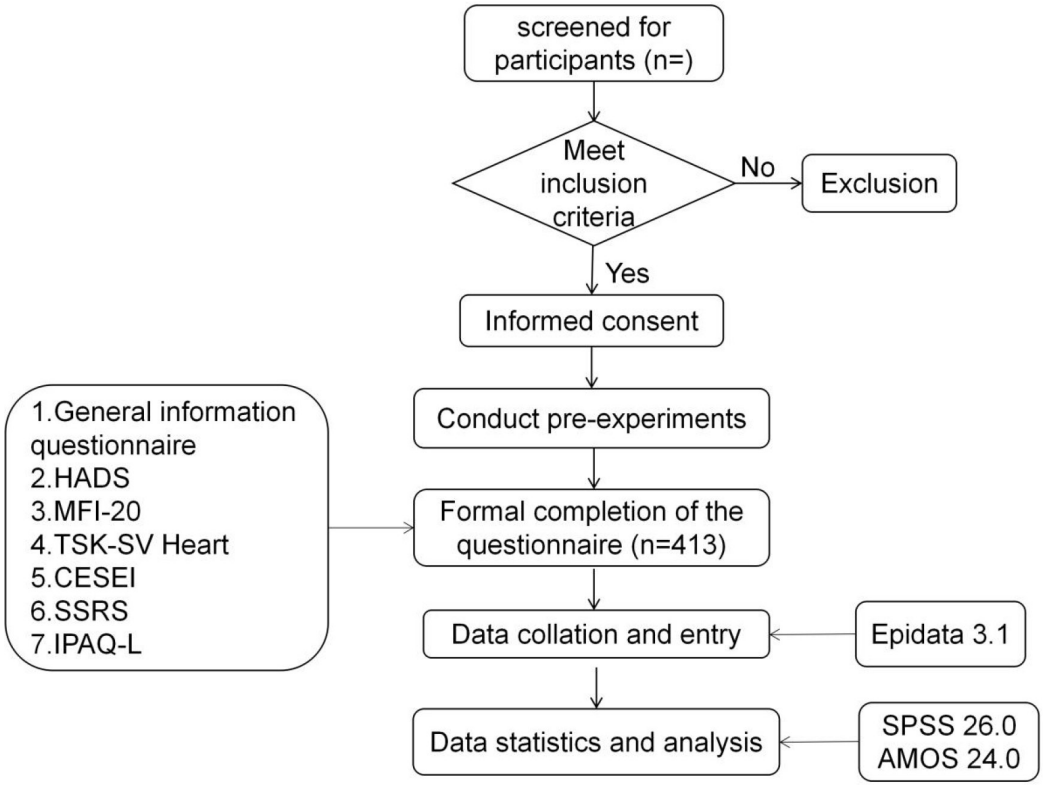

Figure 2 Study flow chart. CESEI, Cardiac Exercise Self-Efficacy Instrument; HADS, Hospital Anxiety and Depression Scale; IPAQ-L, International Physical Activity; MFI-20, Multidimensional Fatigue Inventory; SSRS, Social Support Rating Scale; TSK-SV Heart, Tampa Scale for KKinesiophobia Heart.

target sample size is set at 330.[29] The number of patients that will be enrolled increases to at least 413 considering bias, drop-off and invalid responses.

Data collection

The literature-based and paper-based questionnaire consists of a variety of validation tools. Initially, investigators will evaluate the questionnaire with patients of different ages following CABG in order to assess its readability, comprehensibility and the feasibility of the study's duration. The study nurse will send the questionnaire and informed consent form to each participant the day before (or on the day of) discharge and will add them to WeChat friends. Each questionnaire will be provided a unique ID code. All patients will be reminded by the study nurse via WeChat/QQ/email to complete the questionnaire on meeting the 3 months post-CABG mark. Once completed, the questionnaires will be returned via WeChat or to the study nurse at a later review. Figure 2 depicts the pathways for participant recruitment and data collection.

The proposed study will assess the following patient-reported outcome measures: demographic information, Hospital Anxiety and Depression Scale (HADS), Multidimensional Fatigue Inventory (MFI-20), Tampa Scale for Kinesiophobia Heart (TSK-SV Heart), Cardiac Exercise Self-Efficacy Instrument (CESEI), Social Support Rating Scale (SSRS), and International Physical Activity Questionnaire-Long (IPAQ-L). Results of the measurement diagram are depicted in table 1.

General information questionnaire

The investigator designed the general information questionnaire after reviewing substantial relevant literature and considering the purpose of the study. It was divided into three parts as follows: (1) Demographic and sociological information, including the age, gender, the type of occupation, marital status and medical payment method; (2) Disease-related information, including the mode of surgery (minimally invasive/open), extracorporeal circulation, cardiac function class and the number of bypass vessels; and (3) Patient perception of PA, preoperative knowledge of PA and preoperative exercise habits.

Hospital Anxiety and Depression Scale

The HADS is a 14-item scale consisting of two subscales, namely a single question for anxiety (represented by A) and a double question for depression (represented by D).[30] The items comprise four different answers ranging from 0 to 4, and are integrated by two subscales (anxiety and depression). The higher the HADS Score, the more severe the anxiety or depression. A HADS-A Score >7 indicates anxiety, whereas a score >11 indicates definite anxiety. By contrast, a HADS-D Score >7 indicates depression, whereas a score >11 indicates definite depression. The scale has been validated in several countries and clinical scenarios.[31 32]

Table 1 Summary of all constructs from the HPM assessed via self-reported questionnaires

Constructs	Content	Objectives	Instruments	Dimension	Cronbach's α
Personal attributes and experience	General information	To clarify prior related behaviours that influence physical activity	General information questionnaire	8	No
	Anxiety and Depression	To evaluate the patient's psychological status after surgery	HADS	2	0.92
	Fatigue	To evaluate the patient's postoperative fatigue level	MFI-20	5	0.882
Behaviour-specific cognition and emotion	Kinesiophobia	To evaluate barriers perceived as preventing patients from performing physical activity	TSK-SV Heart	4	0.859
	Self-efficacy	To evaluate the patient's self-reported self-confidence and capability in different situations	CESEI	1	0.941
	Social support	To evaluate the level of patient's social support	SSRS	3	0.92
Behavioural outcomes	Physical activity	To evaluate the patient's regular physical activities	IPAQ-L	4	0.674–0.934

CESEI, Cardiac Exercise Self-Efficacy Instrument; HADS, Hospital Anxiety and Depression Scale; HPM, health promotion model; IPAQ-L, International Physical Activity; MFI-20, Multidimensional Fatigue Inventory; SSRS, Social Support Rating Scale; TSK-SV Heart, Tampa Scale for Kinesiophobia Heart.

Multidimensional Fatigue Inventory

The MFI-20 is a universal fatigue assessment tool developed by Smets *et al* in 1995.[33] It consists of five dimensions, namely general fatigue, physical fatigue, reduced activity, reduced motivation and mental fatigue. The responses to each item are captured with a five-point Likert scale, ranging from 1 (yes, this is true) to 5 (no, this is not true). The Cronbach's coefficient for this scale was 0.882. It has been widely used in the assessment of patients' fatigue, and has good reliability.[34–36]

Tampa Scale for Kinesiophobia Heart

The TSK-SV Heart is the most widely used tool to assess the level of fear of exercise in cardiac patients.[37] It has been adapted from the TSK in patients with chronic back pain by Bäck *et al*[37] in Sweden, and includes four dimensions of risk perception, exercise avoidance, and the fear of exercise and dysfunction, with 17 entries. Each entry is scored on a four-point Likert scale, with a score of 1 to 4 indicating a range from strongly disagree to strongly agree. The total score ranges from 17 to 68, and a score >37 denotes a high level of motor fear. Meanwhile, the scale has been proven to have sound reliability and validity.[38]

Cardiac Exercise Self-Efficacy Instrument

The CESEI was developed by Hickey to measure exercise self-efficacy in patients undergoing cardiac rehabilitation.[39] In 2021, researchers developed a Chinese version of the CESEI by translation, back translation and cultural adjustment.[40] The Chinese version includes 16 items in one dimension, which is scored on a scale of 1 to 5. The total exercise self-efficacy score is calculated by adding the scores of each item and dividing them by the total number of items.The higher the score, the greater the self-efficacy in cardiac rehabilitation. The Cronbach's coefficient for the Chinese version of the CESEI was 0.941.

Social Support Rating Scale

The SSRS refers to a questionnaire that assesses social support levels of patients following CABG surgery.[41] The SSRS consists of 10 items divided into three dimensions, including objective support, subjective support and the use of social support. Total scores ranging from 0 to 22, 23 to 44, and 45 to 66 represent low, medium and high levels of social support, respectively. The Cronbach's α of the scale was 0.81.

International Physical Activity Questionnaire-Long

The IPAQ-L is the most widely used PA history questionnaire.[42] According to the scoring rules developed by the IPAQ International Expert Committee on Physical Activity, all PA levels in the questionnaire are converted into metabolic equivalents (METs), with weekly PA (MET-min/week)=MET value ×PA time (min) ×the number of activities per week.[43] The PA intensity will be divided into three intensity levels as follows: high, moderate and low (walking). Moreover, investigators will classify the total PA energy expenditure according to the IPAQ individual PA level grading scale as physically active (≥3000 MET-min/week), moderately physically active (≥600 MET-min/week) and physically inactive (<600 MET-min/week).

Statistical analysis

EpiData V.3.1 will be used for data entry, and the data will be statistically analysed by SPSS V.22.0 and Amos V.24.0.

1. Descriptive analysis: The numerical data will be tested for normality at the beginning of the data analysis. In the descriptive analysis, normally distributed numerical data will be described using the mean±SD. Skewed data will be described using the median (Ql, Q3), whereas categorical data will be described by frequencies and percentages.
2. One-way analysis of variance: In this study protocol, the dependent variables are IPAQ scores and are continuous variables. The Pearson correlation test (for normally distributed independent and dependent variables) or Spearman correlation test (at least one of the independent and dependent variables are non-normally distributed) will be performed when the independent variables are numerical variables. By contrast, the t-test or non-parametrical test will be performed when the independent variables are categorical variables. To avoid losing several variables included in the structural equation, $p<0.1$ will be used as the threshold for a statistically significant difference during the one-way analysis of variance.
3. Constructing structural equation models: Amos V.24.0 software will be used to construct a structural equation model, in addition to the bootstrapping approach of repeat sampling 5000 times to verify the statistical significance and calculate the CIs for the direct, indirect and total effects. The model fit will be evaluated using the relative χ^2 minimum discrepancy per degree of freedom, the root mean-square error of approximation, Comparative Fit Index, Goodness-Of-Fit Index and Adjusted Goodness-Of-Fit Index. Values of $p<0.05$ will indicate statistically significant differences.

Patient and public involvement

There is no patients or public involvement in the study.

Ethics and dissemination

This study conforms to the principles of the Declaration of Helsinki and relevant ethical guidelines. Ethical approval has been obtained from the Ethics Committee of The Sixth Medical Centre of PLA General Hospital (approval number: HZKY-PJ-2022–2). All study participants will provide written informed consent. Findings from this study will be published in Chinese or English for the widespread dissemination of the results.

DISCUSSION

According to numerous studies, high levels of PA are effective in improving the prognosis and recovery of patients with heart diseases.[15 44–46] However, PA levels in these patients are not promising. Multiple factors hinder these patients from engaging in PA. The HPM pays more attention to psychological factors, in addition to demographic information, such as the gender and age. In psychology, self-efficacy refers to the confidence and beliefs in one's ability to perform or adhere to an exercise.[20] Self-efficacy is a significant predictor of adherence,[47] and it primarily reflects the positive aspects. However, perceived activity barriers are expressed as a fear of exercise or even kinesiophobia in HPM. Kinesiophobia arises from negative emotions such as worry and anxiety, and may lead to overprotective avoidance of rehabilitation exercises.[48] Vigorous physical activities may lead to angina pectoris,[49] whereas patients are often forced to stop any movement during heart attack. In addition, incorrect perceptions or advice from healthcare professionals about PA may exert a negative impact on patients.[50] As a consequence of fear, patients with coronary heart disease (CHD) may consciously decide to reduce or avoid exercise.[50]

Self-efficacy influences PA in patients.[51] PA levels in patients with type 1 diabetes are significantly correlated with self-efficacy.[52] Moreover, those with chronic obstructive pulmonary disease and high self-efficacy scores demonstrate high PA levels.[53] By contrast, the kinesiophobia in older adults with chronic pain has been negatively correlated with PA levels. A previous longitudinal study by Bäck *et al* showed that 20% of patients with CAD had kinesiophobia at the 6 months follow-up after a coronary event.[54] Kinesiophobia has a detrimental impact on rehabilitation outcomes and prognosis, which leads to lower levels of PA and reduced involvement in exercise-based cardiac rehabilitation.[55] Furthermore, a comprehensive review of kinesiophobia in patients with chronic heart failure revealed a moderate correlation between kinesiophobia and fatigue.[56] Larsson mentioned that patients with low PA levels displayed higher levels of kinesiophobia.[57] Previous studies in patients with CHD have demonstrated that self-efficacy is one of the predictors of numerous health behaviours, such as smoking cessation and the reduction in sedentary behaviour.[58] CABG has developed from extracorporeal to minimally invasive procedures;[59] however, there are few studies on postoperative rehabilitation and even fewer on PA. The pathways by which exercise fear and self-efficacy affect PA in patients with CABG are unclear. The proposed study intends to explore the association among kinesiophobia, self-efficacy and PA, and to analyse the mediating effects of kinesiophobia, with the intention of exploring ways to alleviate exercise fear, enhance exercise self-efficacy and promote PA level in patients.

The proposed study protocol has several strengths. First, prospective data collection enables achieving data integrality. Second, the multicentre design may improve data representativeness. Third, this study will further analyse the mediating effect of kinesiophobia between self-efficacy and PA levels in patients following CABG.

The protocol has certain limitations that should be acknowledged. First, this study will use self-reported questionnaires, which may lead to biased results. Second, only quantitative methods will be used to explore the influencing factors, without collecting qualitative information from the participants.

At present, domestic and international studies on kinesiophobia in patients following CABG are at the initial stage. Moreover, researchers are yet to explore the

assessment, influencing factors, and intervention strategies of kinesiophobia. Future researchers can conduct studies in the following aspects: combining cross-sectional studies with longitudinal studies, quantitative studies with qualitative studies, and comprehensively exploring the influencing factors of PA in Chinese patients following CABG from multiple aspects and perspectives.

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