Trials

STUDY PROTOCOL

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The effect of fear-avoidance intervention on kinesiophobia and self-efficacy in patients after percutaneous coronary intervention: study protocol for a clinical randomized controlled trial

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Abstract

Background Kinesiophobia after percutaneous coronary intervention (PCI) may lead to decreased compliance with rehabilitation exercises. Effective interventions are essential to overcome kinesiophobia after PCI. The aim of this trial is to investigate the clinical effects of an intervention based on the fear-avoidance model (FAM) on kinesiophobia in post-PCI patients.

Methods Eighty participants will be recruited in the Department of Cardiology in Hebei Provincial People's Hospital. And they will be randomly allocated to the test group and undergo a 5-day step-to-step intervention. The primary outcome will be the scores of a scale on kinesiophobia. Secondary outcome measures included self-efficacy for exercise, psychogenic anxiety, and the occurrence of cardiovascular adverse events. Primary and secondary outcome data will be collected at baseline (t_0), on the day of discharge (t_1), and one month after discharge (t_2).

Discussion The effectiveness of an intervention based on the FAM to increase exercise self-efficacy and decrease kinesiophobia in post-PCI patients will be demonstrated. The findings of this study will facilitate post-PCI patients to participate in cardiac rehabilitation.

Trial registration ChiCTR2200065649 Effect of an intervention based on the fear-avoidance model on exercise fear in patients after percutaneous coronary intervention. Registered on November 10, 2022.

Keywords Kinesophobia, Percutaneous coronary revascularization, Efficacy, Self, Coronary heart disease, Exercise

Background

Percutaneous coronary intervention (PCI) is one of the significant treatments for coronary heart disease (CHD) [1]. Nevertheless, it could not reverse the process of coronary atherosclerosis, which leads to re-stenosis or cardiovascular events. According to studies, the prevalence of re-stenosis after PCI is 5–20% [2–4]. In patients over 65, adverse cardiovascular events were fatal in roughly 22% of cases after PCI [5].

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For patients with CHD, cardiac exercise rehabilitation has emerged as a successful preventative strategy and therapeutic approach [6, 7]. It helps a lot as a preventative and therapeutic measure. Exercise rehabilitation can help patients improve their heart function and myocardial blood perfusion, in addition to their physical recoveries and pharmacological treatment [8]. Following PCI, patients are advised by numerous national and international clinical guidelines to engage in exercise rehabilitation [9–12]. However, clinical studies have found that patients who have undergone PCI exhibit a clear fear of exercise, which is harmful to postoperative compliance and long-term rehabilitation [13, 14].

Kinesiophobia, commonly called exercise fear [15], is the desire to avoid or experience excessive panic during physical exertion. After PCI, kinesiophobia develops because of the psychological dread of experiencing further chest discomfort and being readmitted to the hospital. Various reports on the prevalence of kinesiophobia in China and other countries have reported kinesiophobia in CHD patients. Liu Tingyang and other Chinese researchers conducted a comprehensive survey on kinesiophobia in patients with CHD after PCI. According to the findings, 20% of patients had a high level of kinesiophobia [16]. According to Back's assessment of 332 CHD patients in Sweden, 20% of those patients scored highly on the exercise fear scale [17]. A study in Poland in 2019 showed that kinesiophobia impacted more than 70% of patients with CHD [18]. Additionally, it is indicated that kinesiophobia may hinder CHD patients' participation in exercise rehabilitation and will reduce their compliance with cardiac rehabilitation. Interventions are needed to overcome kinesiophobia in patients with CHD after PCI. Current interventions for post-PCI kinesiophobia include graded exposure and cognitive therapy. Graded exposure refers to a gradual acceptance of exercise to gradually reduce fear, based on psychological desensitization therapy [19]. The BÄCK study showed that graded exposure had a beneficial effect in an exercise-based cardiac rehabilitation program for patients with myocardial infarction [20]. Another study by Farris, which used cognitive therapy to intervene in kinesiophobia in patients with cardiovascular disease, also showed significant results [21]. However, in the Chinese cultural context, the knowledge and skills of nurses are not sufficient to provide such professional psychological interventions, so a multidisciplinary team approach is preferred in clinical practice.

A persuasive clinical intervention is supposed to be theoretically grounded. Patients who had PCI avoid cardiac rehabilitation exercises for psychological and physiological reasons because they are concerned that activity would exacerbate their existing heart conditions. One of the theories for explaining cognitive behavior is the fear-avoidance model (FAM) [22]. In this model, it is vital to identify one's fear. Patients who perceive pain as a terrible stimulus and sense it growing worse adopt negative coping mechanisms, which results in avoidance of pain-producing actions. It shows up as kinesiophobia or exercise fear in cardiac rehabilitation. On the other hand, if patients actively engage in rehabilitation procedures and have a high level of exercise self-efficacy, they will adopt progressive behavior and deal with kinesiophobia head-on. A scoping review of elderly patients in the community showed that higher levels of kinesiophobia were found among frailer and older people. Kinesiophobia has been related to other constructs of the fear-avoidance model. Nevertheless, fewer studies aimed to construct interventions directly targeting kinesiophobia or fear avoidance [23]. Smith et al. [24] employed FAM as the theoretical framework. A prospective study was conducted in chronic pain patients to explore the relationship between kinesiophobia and fear-avoidance, which may serve as a guide for developing intervention strategies. FAM explained kinesiophobia proposed by Lethem et al. in 1983 [25]. It explains the fear avoidance behavior of exercise caused by painful stimulation. Later, physiological, psychological, and sociological factors have been combined to describe how individuals who are exposed to pain develop kinesiophobia, which leads to disability and abandonment [26]. According to this model, providing psychological support and activity-based intervention to patients with kinesiophobia may hopefully reduce negative strategies. In this trial, the FAM frames the design, implementation, and evaluation of the intervention are shown (Fig. 1). Physical elements, such as chest pain and unpleasant stimuli, psychological factors, such as self-efficacy and psychogenic anxiety, and sociological factors, such as social support, coping strategy, etc., all have an impact on kinesiophobia. Both positive and negative behavior to exercise is present in patients with kinesiophobia. Still, the former often have strong exercise self-efficacy, can combat anxiety, and actively participate in cardiac rehabilitation; the latter typically lack exercise willingness and exhibit resistance and avoidance. The research hypothesis of the current study is that the intervention based on the FAM may improve exercise self-efficacy and decrease kinesiophobia in inpatients after PCI.

Based on the previous literature review, this trial intends to address three research issues: (1) to test the clinical effect of a FAM-based intervention on kinesiophobia in patients after PCI; (2) to evaluate the clinical effect of the intervention on self-efficacy and psychogenic anxiety; and (3) estimating the occurrence of kinesiophobia within the sample size available for this study.

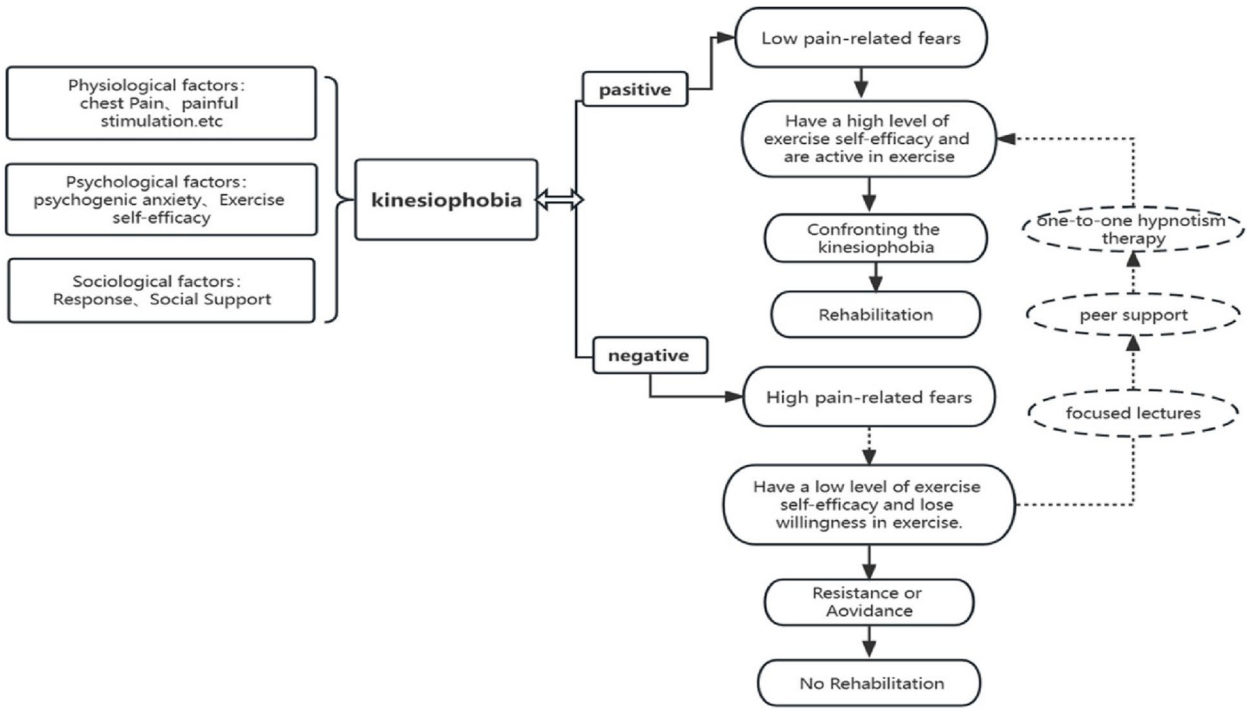

Fig. 1 Theoretical framework

Methods

Study design

The purpose of this single-center, parallel-group, randomized, two-arm superiority trial is to investigate the efficacy of a FAM-based intervention in patients with kinesiophobia after PCI. Participants are assigned 1:1 to either the intervention or control groups. The number of participants was quantified as the primary outcome measure, the total TSK-SV Heart score [27]. Participants enrolment started January 01, 2023, in the Department of Cardiology in Hebei Provincial People's Hospital. And it will be completed on June 31, 2023. Participants will be assigned either to the intervention or control groups randomly and the intervention group will receive the FAM-based intervention for 5 days. Data on observed indicators will be collected on the day of discharge, as well as 1 month later (Fig. 2).

Sample size

G*Power 3.1.9.4. is employed to calculate the sample size, with an estimated effect size (D) of 0.70 in the current study. Assuming an effective rate of 80% and a significance level of 5%, the sample size required is 67 cases. With a 20% loss rate, the final sample size is 80 cases in total.

Eligibility criteria

Inclusion criteria

The participants will be as follows: (1) aged from 18 to 75 years old [28, 29]; (2) undergo elective PCI following the Guidelines for Percutaneous Coronary Intervention [30]for the first time; (3) within Grade III (including Grade III) according to New York Cardiac Function Classification; Grade III (including Grade III) is defined as breathlessness with activities of daily living such as dressing, washing, or eating [31]; (4) with TSK-HV score ≥ 37; (5) communicable and memory unimpaired; (6) no infectious diseases; and (7) signed the informed consent after fully understanding the study and participating voluntarily.

Exclusion criteria

Those who (1) received emergency intervention; (2) suffered from malignant tumors, liver and kidney insufficiency, thrombotic diseases, and severe physical disorders; and (3) are in other research programs will be excluded.

Setting and recruitment

Over 100 PCI surgeries are guaranteed at Hebei Provincial People's Hospital each week, which is adequate

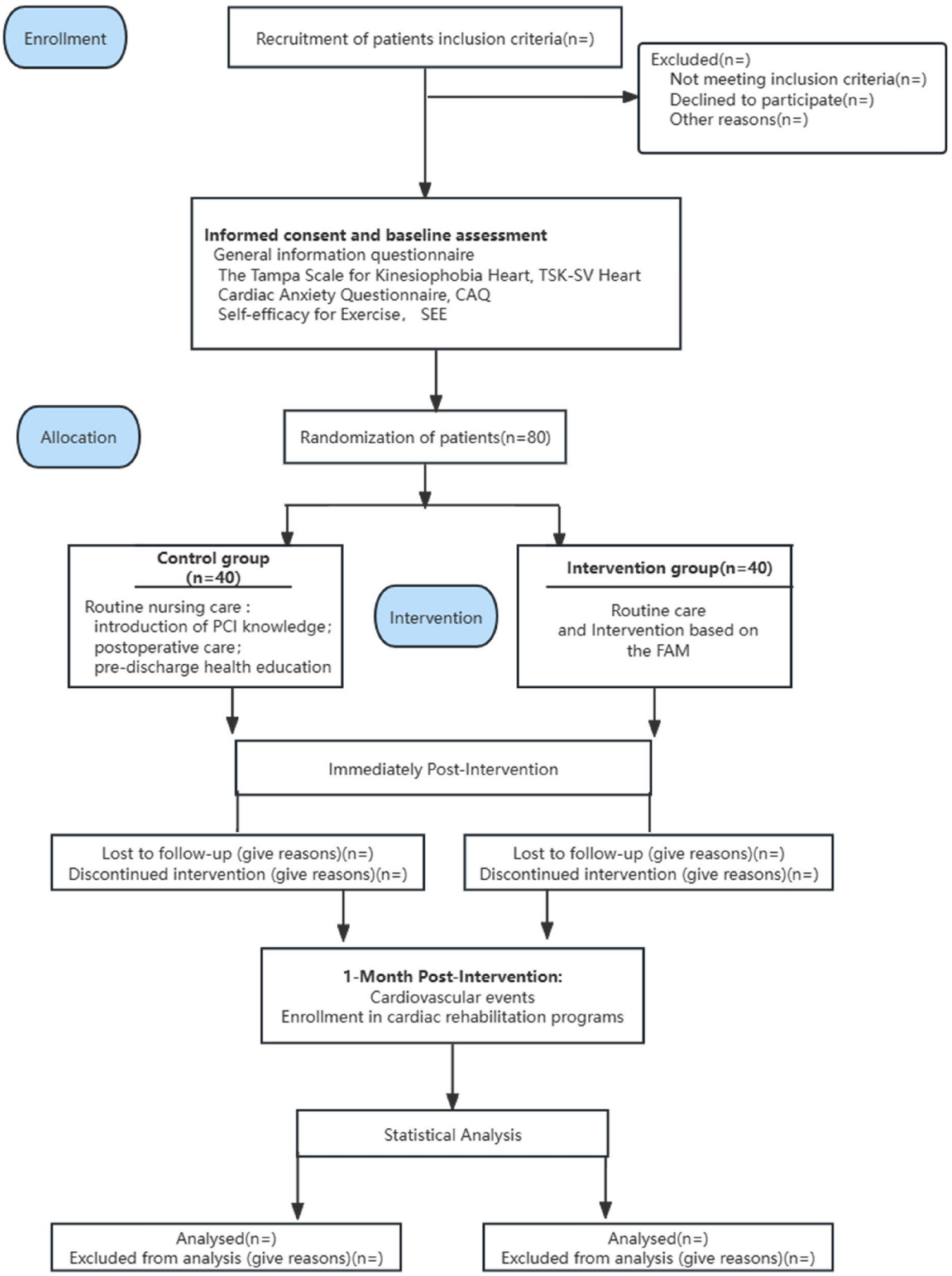

Fig. 2 The flowchart of the study process

for patient recruiting. Three nurses (who have been engaged in CHD nursing for at least 5 years), a researcher, and a psychotherapist make up the intervention team. They possess excellent coordination and communication abilities and receive training before the intervention process. The time schedule of the study is shown in Fig. 3.

Randomization, distribution, hiding, and blinding

The randomization and grouping will be managed by a specific team member who was not involved in the study's design or the intervention's planning. Random numbers generated by SPSS were placed in consecutively numbered, sealed, opaque cowhide envelopes. Upon admission to the hospital, a random number is extracted from an envelope and serves to identify the patient. Subsequently, the corresponding group is identified by consulting the table of random numbers. The participants will be blinded, while the researcher and psychotherapist are not. It is common in psychotherapy studies when the therapist needs to know the specific treatment process. Additionally, the clinical research assistant and data analyst must also be blinded. It is vital to ensure that data collection and analysis is unbiased and objective. Participant blinding was achieved by extending the time between participant enrolment to avoid information exchange.

Intervention

The subsequent procedures were used to design the intervention program. Literature review is the first step. We used the search terms "cardiac exercise rehabilitation," "kinesiophobia," "activity phobia," and "fear of exercise" to look for articles in the databases CNKI, Wanfang, China Biomedical Literature Database, Pub Med, and others. We also used the terms "coronary heart disease," "percutaneous coronary intervention," and "after PCI." Discussion and consultation in the second step. The development of the intervention program involved numerous rounds of talks and consultations with clinical professionals. The cardiology department's head nurses, psychologists, senior nurses, and doctors in charge of rehabilitation offered their professional opinions on the safety and clinical viability of the intervention. The third step is pre-laboratory. The pre-lab included ten hospitalized patients with TSK-SV Heart $\geq$ 37 following PCI. We communicated with participants to obtain their feelings and opinions and revised the procedure accordingly.

STUDY PERIOD	Enrolment	Allocation	Post-allocation	
TIMEPOINT**	$-t_1$	t_0	t_1	t_2
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Routine Nursing Care			X	
Intervention Program Based on the FAM			X	
ASSESSMENTS:				
Scores on kinesiophobia		X	X	X
Exercise self-efficacy		X	X	X
Psychogenic anxiety		X	X	X
Cardiovascular adverse events				X

Fig. 3 Standard protocol items: schedule of enrollment, interventions, and assessments (according to SPIRIT)

Both participants in the control group and intervention group will receive routine nursing care under the guidelines in local hospital, which include (1) introduction of PCI knowledge (coronary angiography, drug balloon dilatation, and stent implantation) prior to surgery, including disease etiology, primary nursing interventions, and pharmacological and dietary recommendations; (2) after the PCI, ECG monitor will be applied in both groups within 48 h [32, 33], and participants will be instructed on hemostasis approaches and on movement of the limbs; participants without heart failure will be encouraged to take in enough water to facilitate the excretion of contrast material; and (3) health education will be provided as usual prior to discharge. The content of health education encompasses various aspects, including the proper use of medication after surgery, reducing sodium intake, avoiding a sedentary lifestyle, quitting smoking, limiting alcohol consumption, and adhering to sports and exercise [34, 35].

The intervention group

Following the pretest, the research team developed a step-by-step intervention program based on the FAM with the goal of improving exercise self-efficacy and decreasing kinesiophobia. The average hospitalization days of PCI are 5–7 days according to Chinese guidelines [36]; the intervention program usually takes 4–5 days when the patients are in the ward. Knowledge of cardiac rehabilitation after PCI is emphasized based on the routine care of the control group. To make sure the participants understand the information fully, focused lectures will be held by the research nurse. Patients' past sports experiences and achievements also play as a positive support to overcome fear. On the social aspect, other patients' experiences and positive examples [37] will be provided according to Bandura's self-efficacy theory [38] through an incentive interview, oral persuasion, and group study. At the same time, the psychological counselor will provide hypnotism to break psychological fears from the subconscious level and to evoke emotion and passion [39]. Direct exercise stimulation exposure in cognitive behavioral theory [40] will be provided by visiting the aerobic training room. After visiting, participants will be guided to imagine physical exercise scenarios by free association and integrate themselves into the exercise.

The intervention program will start on the first day before and end on the fourth day after the PCI procedure in a step-by-step mode. For further details, please refer to Table 1. The focused lectures for participants will last around 30 min. The one-to-one hypnotism therapy will follow three steps (Fig. 4). The time of each meeting with the participant depends on the patient's condition. The place for intervention will be arranged in a quiet and isolated staff office.

Adherence

We will use the following strategies to encourage participants to participate and comply with our study: (1) a free book, *Life with a Stent*, compiled by a famous cardiovascular expert in China will be offered as a bonus for all participants; (2) a booklet of overcoming kinesiophobia

Table 1 This is the specific intervention steps based on the FAM

Time	Themes	Content
Preoperative Day 1	Understanding PCI procedure and perceiving the benefits of exercise	① The principle of PCI, precautions during surgery, and postoperative complications will be displayed in a video ② Explain the concept, content, and benefits of exercise rehabilitation, and help the patient to perceive the necessity of exercise rehabilitation after PCI
Postoperative Day 1	Sports scenes recall	① Encourage patients to recall past scenes of physical activities and experience the good feelings again through hypnosis ② Help the patients identify and analyze the possible difficulty to perform physical activities after PCI by face-to-face interview
Postoperative Day 2	The power of example	① Encourage patients who have undergone PCI in the same department to share their experiences of successful recovery, encourage patients to seek peer support ② Share the reading "Life with a Stent," to establish the concept and prospect of a healthy lifestyle after PCI
Postoperative Day 3	Emotion evoking	① Induce the participants' active expression about the disease and fears of exercise by hypnotherapy ② Understand their description of pain, fatigue, or anxiety and offer support
Postoperative Day 4	Free association	① Arrange visits to the aerobic training room and let them observe other post-PCI patients exercising ② Use free association in the third round of hypnotherapy, to guide the patient to imagine themselves exposed to the scenes of physical exercises

Notes: [14, 41–49]

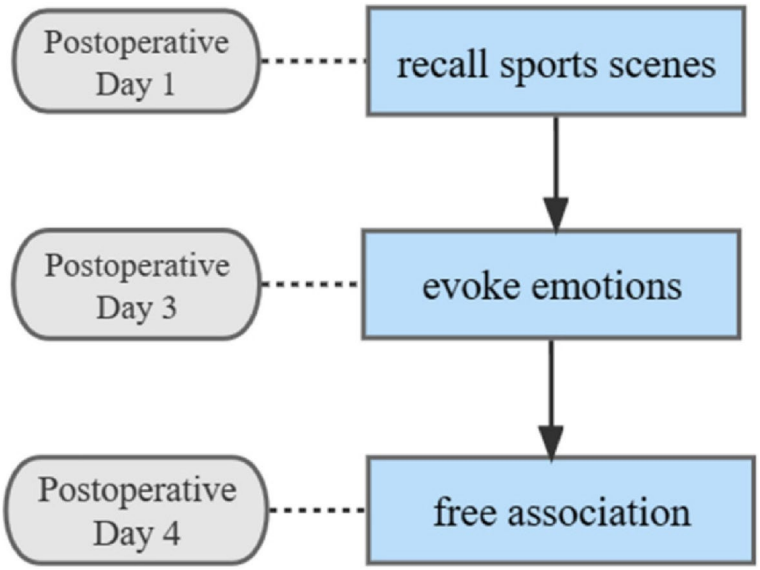

Fig. 4 The one-to-one hypnotism therapy

after PCI will be distributed to the control group before discharge with the hope to reduce exercise fear.

Outcome measures

Scores on kinesiophobia serve as the main outcome metric. Tampa Scale for Kinesiophobia Heart (TSK-SV Heart) [50] is a specialized scale to measure patients with CHD's fear of exercise and accurately reflects the severity of their kinesiophobia. The four aspects of motor perception, motor avoidance, exercise fear, and motor dysfunction will be assessed in patients. The items were rated on a 4-point Likert scale from 1 to 4, going from strongly disagree. Items 4, 8, 12, and 16 had reversed scores. An overall score of 37 and above is considered a high level of kinesiophobia. The incidence of cardiovascular adverse events, exercise self-efficacy, and psychogenic anxiety were considered secondary outcomes [51, 52]. The above measurements will be taken by the clinical research assistant at baseline, following the intervention, and one month after discharge. At baseline, we will gather both general demographic data and disease-specific data, such as gender, age, marital status, occupation, level of education, BMI, number of problems, and number of stents.

The Cardiac Anxiety Questionnaire (CAQ) [53] has 18 items and a maximum score of 72 points, which measures the patient's worry and anxiety, avoidance, and obsessive attention to their cardiac condition. A score greater than 30 indicates that the individual may be experiencing symptoms of psychogenic anxiety. The severity of the patients' psychogenic anxiety is correlated with the scores. The Cronbach's alpha coefficient for the scale in this study was 0.835.

The respondents' exercise self-efficacy will be evaluated using the self-efficacy for exercise (SEE) [54]. The exercise self-efficacy increases as the scores rise. A strong sense of self-efficacy was defined as having a SEE score of ≥ 50. The scale has a content validity of 0.90 and a Cronbach's α of 0.75.

Patient and public involvement

Given the importance of participants' sharing decision-making in clinical trials, we put patients' wishes, actual conditions, and needs first at the beginning of problems and the stages of formulating intervention plans. Therefore, we recruited ten patients in the pretest. At the end of the intervention program, their feelings and opinions were recorded and taken into account when revising the intervention. The trial process will be supervised and guided by research staff from the hospital and medical graduate school, which may increase patient participation.

Data collection and management

Eligible patients will be informed of the current trial. After they agree to participate and sign the informed consent form, the TSK-SV Heart scale will be delivered to screen those whose scores are 37 or above. Within 48 h of hospitalization, we will collect their general demographic information, exercise self-efficacy scores, and a psychogenic anxiety questionnaire. On the day of discharge, the kinesiophobia, exercise self-efficacy, and anxiety scores will be evaluated and documented. One month after discharge, the incidence of cardiovascular events (including non-fatal myocardial infarction, ischemic stroke,

readmission due to angina pectoris, heart failure, bleeding, and re-revascularization) will be collected through the data-filling platform of Hebei Chest Pain Center. We have devised a meticulous strategy for data collection. Our approach is centered on the anonymous collection of general demographic data from patients. In the process of data collection, we used the participant's ID number. This ID serves as their sole representation within our system, ensuring that their real-world identity remains undisclosed. This practice adheres strictly to ethical standards and privacy regulations, minimizing the risk of data misuse or unauthorized access. Furthermore, the information gathered from the participants is stored in a highly secure database. Strict access controls are implemented, limiting access to only the study leader and the statistical expert. By anonymizing the data, assigning unique identifiers, and storing it in a secure database, we ensure that the privacy and confidentiality of the participants are safeguarded at all times.

Data monitoring

DMC comprises instructors and statistical experts, and all raw data is submitted to the administration. There are no sponsors involved. This is a low-risk intervention, and thus, it does not include the various anticipated problems that are detrimental to participants.

Harm

Serious adverse events (SAEs) may not appear in low-risk studies. Adverse events (AEs) may include patient complaints, which are dealt with by specialized hospital organizations at any given time and place.

Auditing

The Ethics Committee meets regularly. Monthly inspections and briefings were conducted by the Project Management Group. The Trial Steering Group meets once a month to review the conduct of the trial. DMC is responsible for the checking of data, which takes place once every 3–6 months.

Statistical analysis

Data will be tested for normality first, those which are distributed normally will be described by mean ± standard deviation, and those skewed data will be described by the median and quartile interval. The categorical variables will be described as frequency and percentage. The equilibrium of the two sets of variables will be tested. The comparison between normal distribution and the variance homogeneity data of the two groups will adopt the independent sample *t*-test, and the comparison between the multi-groups will adopt the Analysis of Variance. The Wilcoxon test will be carried out on non-normally distributed data. Categorical variables will be tested by the χ^2 test or Kruskal-Walli's test. Kinesiophobia scores between the two groups before and after the intervention will be tested by two independent samples *t* tests or non-parametric Wilcoxon tests. The analysis of all results will be based on an intention-to-treat principle. All data will be analyzed by SPSS 26.0 statistical software, and statistical significance is defined as bilateral $P < 0.05$.

Discussion

Kinesiophobia may lead to an unwillingness to attend cardiac rehabilitation which may result in patients' physical function and cardiopulmonary endurance decline [55, 56]. This trial aims to explore the effect of intervention based on the FAM on the exercise fear of patients after PCI.

The intervention based on the FAM we developed is a multi-professional, step-by-step intervention program. Among the societal, psychological, and physical factors affecting kinesiophobia in FAM, health care professionals can influence social support through focus lectures, peer support, and one-on-one hypnosis therapy to encourage patients' exercise self-efficacy and relieve anxiety (see Fig. 3 for the specific intervention pathway). Within the psychological domain, the FAM identifies "Pain Experience" as a key element, which is shaped by "Low Self-Efficacy"—a belief in one's limited ability to manage pain—and "Negative Emotions" such as anxiety and depression that often accompany chronic pain. The model underscores the role of "Cognitive Factors" like "Pain Catastrophizing," a cognitive distortion where individuals perceive their pain as overwhelmingly negative and unmanageable. "Misconceptions and Wrong Cognitive Concepts" about pain can lead to ineffective coping strategies and increased suffering. The intervention-based FAM aims to modify cognitive and emotional responses. Environmental factors are also crucial in the model, with "Support from Outside"—including peer support and understanding from the community—identified as a significant buffer against the detrimental effects of pain. Conversely, a lack of support can exacerbate the pain experience. The model also highlights "Communication" and "Avoidance Psychology" as factors that can influence how individuals manage their pain. Effective communication can lead to better understanding and support, while avoidance can hinder the healing process and isolation. In summary, the intervention program presents a holistic view of pain management, emphasizing the complex interplay between internal psychological states, external environmental factors, and the role of social support. It advocates for a multidisciplinary approach to kinesiophobian management that addresses both the psychological and environmental aspects of

the pain experience. In contrast to the knowledge-based health education technique currently used in clinical practice, we choose the influential FAM components that may be adapted to improve efficacy, confront fears, and achieve goals in a number of ways.

The advantages of the current research are as follows. First, we will address the special clinical problem of kinesiophobia in patients after PCI using the intervention-based FAM, a specialized theory rather than a broadly applied one. Second, a key element of FAM is exercising self-efficacy, which is often achieved through nursing interventions in a variety of ways with a potential for a positive outcome [57]. Third, we will use a multidisciplinary approach that includes a nursing team as the intervention performer, a psychology team as one of the primary interferences, a rehabilitation team as a guide, and a clinical doctor as a safety supporter. This trial does, however, have definite limitations. Firstly, the limitation of our study is that the convenience sampling method was used and the sample was obtained from one hospital. If the results of this study are encouraging, another multi-center intervention trial might be performed consequently. In addition, it is likely that some participants will not understand professional hypnotherapy interventions and will not be able to adhere to the intervention plan entirely due to the popularity and acceptance of psychologists in Chinese culture. We are confident that the predicted sample size will be attained because our hospital guarantees a certain number of inpatients per month.

Kinesiophobia is frequent following PCI, and the intervention provided in this study is done through multidisciplinary collaboration, which may address the patient's physical and mental health. The ideal cardiac rehabilitation plan emphasizes multidisciplinary cooperation, which is an integrated intervention consisting of medical, rehabilitation, nursing, and psychology. Patients get more social support from nurses, psychotherapists, doctors, and rehabilitators, which will help to fight against kinesiophobia.

We will gather data in accordance with the calculated sample size up until the collector has finished their whole experimental observation. The results of this trial will be published in Chinese or English academic journals to disseminate the results widely.

Trials status

Study protocol ChiCTR2200065649. Recruitment started on 01 January 2023. The end date of the study is January 31, 2024.

Abbreviations

CHD	Coronary heart disease
PCI	Percutaneous coronary intervention
FAM	Fear-avoidance model
TSK-SV Heart	Tampa Scale for Kinesiophobia Heart
SEE	Self-efficacy for exercise
CAQ	Cardiac Anxiety Questionnaire

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08349-6.

Additional file 1. SPIRIT checklist.

Additional file 2. Ethics Review-original.

Additional file 3. Ethics Review-translation.

Acknowledgements
We would like to commend all volunteers for participation in this study.

Roles and responsibilities
There is a postgraduate supervisor who acts as a coordinator; the group meets once a month to discuss the conduct of the trial. The Head Nurse and the Heads of Discipline Teams maintain close contact with the postgraduate supervisor. The hospital's Trial Steering Committee (TSC) is responsible for overseeing the running of the trial, meeting irregularly and reviewing it once a month.

Authors' contributions
Qi Li and Lingjun Yan contributed equally to this work. Qi Li conceived of the presented hypothesis. Qi Li and Yanmei Gu designed the study. Qi Li and Lingjun Yan wrote the main manuscript text. Wenhui Xing, Ce Zhou, Yu Li, Boya Wan, and Jingjing Piao contributed to the data collection. Yanmei Gu 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. Yanmei Gu is the study guarantor.

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Availability of data and materials
Any data required to support the protocol can be supplied on request. The datasets analyzed during the current study and statistical code are available from the corresponding author on reasonable request, as is the full protocol. We will share the data through the China Clinical Trials Registry completed within 6 months after trial completion.

Declarations

Ethics approval and consent to participate
This project conforms to the Helsinki Declaration and various ethical guidelines for clinical trials. Ethical approval and informed consent have been approved by the Ethics Committee of Hebei College of Traditional Chinese Medicine (Approval No.: YXLL202211002). Before the beginning of the trial, the participants and their families will be introduced in detail about the research background, research purpose, potential benefits, and risks, and obtain informed consent. The participant information materials and informed consent form are available from the corresponding author on request.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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