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Effects of PreCABG program on discharge readiness and surgery outcomes for patients undergoing elective CABG surgery: A study protocol for a randomized control trial

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Abstract

Background: Cardiovascular diseases (CVD), a leading cause of death globally, impose significant health and economic burdens, particularly in countries like Iran. Coronary artery bypass grafting (CABG) is a common intervention for ischemic heart disease (IHD), yet it entails a long recovery process with potential complications and psychological impacts.

Objective: This study aims to evaluate the effectiveness of a prehabilitation program (PreCABG) on postoperative outcomes and discharge readiness in patients undergoing elective CABG.

Methods: This randomized controlled trial (RCT) involves 60 patients diagnosed with coronary artery disease at Imam Khomeini Hospital Complex, Tehran. Participants will be randomly assigned to either the intervention group, receiving the PreCABG program, or the control group, receiving standard care. The PreCABG program includes patient education, stress management techniques, respiratory muscle training, and nutritional guidance. Primary outcomes include discharge readiness, duration of intubation, ICU stay, occurrence of atelectasis, onset of mobility, hospital stay, and levels of anxiety and depression. Secondary outcomes include the rate of 30-day readmissions. Data collection will involve standardized scales and checklists administered at various stages pre- and post-operation.

Ethics and dissemination: The research study has received approval from the Research Ethics Committee at Tehran University of Medical Sciences' School of Nursing and Midwifery & Rehabilitation. All participants must provide written consent for their involvement in this study. The findings will be shared with appropriate groups and published in peer-reviewed journals.

Trial registration number: The study is registered with the Iranian Registry of Clinical Trials (IRCT) under the ID **IRCT20231019059768N1.**

Keywords: Cardiovascular diseases, Coronary artery bypass grafting, Prehabilitation, Randomized controlled trial, Discharge readiness, Postoperative outcomes.

Word Count: 3460

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Strenghts and Limitation

- This nurse-led, two-arm, randomized controlled trial evaluates the effectiveness of a comperhensive Prehabilitation program on surgery outcomes, discharge readiness, hospital anxiety and depression, and 30-days readmissions, for which experimental evaluations are lacking

- The prehabilitation program is well-defined, including specific components such as stress management techniques, nutritional guidance, respiratory exercises, and patient education. This comprehensive approach addresses multiple factors that can affect surgical outcomes and recovery.

- Emphasizing discharge readiness as a primary outcome is significant, as it is directly related to patient recovery, hospital resource utilization, and overall healthcare costs.

- While outcome assessors and statisticians are blinded, patients and interventionists are not, which could introduce bias in how interventions are administered and reported.

- Conducting the study at a single center (Imam Khomeini Hospital Complex) may limit the generalizability of the findings to other settings with different patient populations or healthcare practices.

- The protocol acknowledges the risk of attrition, especially given the remote aspects of follow-up. Strategies to minimize drop-out rates are mentioned, but attrition could still impact the study's power and validity.

- The sample size calculation is based on prior studies, but the relatively small number of participants (30 per group) might limit the detection of small but clinically significant differences between groups.

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Introduction

Cardiovascular diseases (CVD) are a leading cause of death and a significant global health issue. (1). It is predicted that in 2030, about 23 million deaths in the world will be due to CVD (2). CVD is one of the leading causes of a significant reduction in quality of life and life expectancy and also imposes enormous costs on health systems in different countries (1). Several risk factors have been identified, including physical inactivity, obesity, hypertension, hyperlipidemia, hyperglycemia, and stress. These factors also influence the recovery process from major cardiac events (3). Studies conducted in Iran also show that coronary artery disease is the leading cause of death in Iran, and Iran has the highest disease burden caused by this disease in the region (4). Based on the studies, cardiovascular diseases are the leading cause of 46% of deaths and about 20-23% of the total burden of disease in Iran, and it is one of the main problems of Iran's health system (5, 6). Current therapeutic interventions for IHD include drug therapy (antiplatelet drugs, beta-blockers, or statins) to stabilize the disease and reduce acute events (such as myocardial infarction or sudden death) or immediate restoration of blood flow through surgical revascularization treatment, such as coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (7, 8). The recovery process for these surgeries is long and involves caregiving challenges (9). Nevertheless, this method is a common choice for heart patients and surgeons. Complications of this surgery include increased hospitalization time, delirium, anxiety related to treatment and their ability to adhere to recommended physical activity, depression, stroke, bleeding and cardiac tamponade, myocardial dysfunction, sternal wound infection, and pulmonary complications (10-12).

Despite all the advantages, CABG is a stressful and traumatic event and usually has negative psychological consequences in the preoperative period that may persist after the surgery (13, 14). When a person is diagnosed with coronary artery disease, it causes high levels of anxiety, which is exceptionally high in the preoperative period and when the client is waiting for major surgery (13, 15). High anxiety reduces quality of life and worsens long-term psychological consequences (11). Persistent stress can negatively affect the prognosis and physiological parameters of patients (preoperatively and intraoperatively or during anesthesia), which may prolong recovery and length of stay and negatively impact quality of life (16, 17). Also, the relationship between depression and cardiovascular disease and its effect on the outcome of patients hospitalized for acute coronary artery disease, as well as before and after vascular surgery, is well known (18). The presence of depressive symptoms during or shortly after hospitalization increases the risk of death or non-fatal cardiac events by two to three times and significantly increases the morbidity and mortality of these clients (19, 20). Studies have shown a lower health-related functional status and quality of life, as well as a higher rate of readmission after discharge and increased mortality in these clients (21).

Surgeries that require a thoracotomy, such as coronary artery bypass surgery, carry a high risk of pulmonary complications (22). Patients undergoing cardiac surgery are more vulnerable to developing these pulmonary complications after surgery (23). Today, in most hospitals, chest physiotherapy is used to minimize postoperative pulmonary complications after CABG (24, 25). Various studies have reported that early rehabilitation significantly reduces long-term mortality in patients undergoing coronary artery bypass graft surgery (26-28). Despite the well-documented importance of postoperative rehabilitation, insufficient information on the value of preoperative interventions is available (23, 29).

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Prehabilitation is a method of preparing the patient for heart surgery (30). Patients admitted to the hospital for CABG surgery may have to wait up to a week for the procedure, which may lead to regression and physical weakness and negatively affect the outcome of the surgery. (31). To better use this waiting period, patients can participate in prehabilitation programs. These programs can include various aspects such as increasing physical fitness, increasing information about surgery, teaching strategies to deal with anxiety, and improving the patient's nutritional conditions (32). There has yet to be a theoretical consensus on prehabilitation methods and protocols.

As the person who has the most contact with patients, nurses are responsible for providing optimal care to their patients at all times (33). Nursing interventions for patients who will undergo coronary artery bypass surgery include preparing patients for surgery, providing care during and after surgery, and providing information and education to patients and family members about home care after discharge from the hospital (34). One of the essential goals of the educational program for patients is to improve self-care behavior (12). Improving self-care reduces the number of preventable complications, and hence, discharge preparation is an essential part of the care process Because it has the potential to promote self-care (35). Little is known about which protocol is most effective, and there needs to be more certainty about the effectiveness of different approaches. Facilitating people's readiness to leave the hospital environment following coronary artery bypass surgery is considered a critical factor in successful discharge and is a way to save scarce economic resources (36).

Therefore, we developed a randomized controlled trial (RCT) to evaluate the effectiveness of a rehabilitation program for patients undergoing CABG and investigate its effects on post-surgery outcomes and clients' discharge readiness.

Methods and Analysis

Study Design

This research utilizes a double-arm, parallel-group randomized controlled trial (RCT) approach. An overview of the study design is depicted in a flow chart in Figure 1. The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (37).

Study Setting

Participants will be recruited from the cardiac surgery clinic at Imam Khomeini Hospital Complex (IKHC), which is associated with Tehran University of Medical Sciences (TUMS) in Tehran, Iran. IKHC is a major government-owned hospital and referral center that offers specialized medical services.

Eligibility Criteria

Patients diagnosed with coronary artery disease who are referred to the cardiac surgery clinic at IKHC will be evaluated based on the following eligibility criteria:

Inclusion Criteria

The study inclusion criteria include 1- having an on-pump coronary bypass surgery; 2- being on the elective coronary artery bypass surgery list; 3- experiencing Heart surgery for the first time; 4- ability to speak and understand Persian; 5-not having diagnosed with anxiety or other

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psychological disorders (self-report); and 6- non-concurrency of CABG surgery with valve replacement or other surgeries.

Exclusion Criteria

Exclusion criteria for the study include 1- Lack of consent to continue participating in the study; 2- postoperative hemodynamic instability; 3- aortic dissection or aneurysm; 4- hemodynamic instability leading to surgical cancellation or need for emergency surgery; 5- previous COPD disease; 6- atrial fibrillation; 7- having a history of stroke; 8-previous heart surgery; 9- valve diseases; and 10- patients with cognitive disorders and Alzheimer's disease.

Intervention

This study involves a prehabilitation program led by a nurse. A cardiac surgeon and nurse interventionist will determine patients' eligibility during a face-to-face visit. Participants who meet the eligibility criteria and agree to participate will be randomly divided into intervention and control groups. The control group will receive standard care, while patients in the intervention group will receive the PreCABG intervention. This includes three visits from the nurse interventionist - the first during the surgery clinic meeting with the surgeon and the next two while in the hospital waiting for surgery. During the first session, patients in the intervention group will receive an educational booklet with four sections and an incentive spirometry.

The PreCABG intervention

This intervention program will encompass the following steps:

1. a meeting between the interventional nurse, the patient, and the surgeon during clinic visits.
2. Delivering a comprehensive explanation of the surgical procedure in a manner designed to minimize patient anxiety.
3. Encouraging patients to discuss anxiety triggers and rectifying any misconceptions with the intervention team's assistance.
4. Introducing stress management techniques, such as progressive muscle relaxation, deep breathing, guided imagery, and recommended practice repetition. Patients will choose their preferred stress management method, which will be taught and practiced.
5. Providing preoperative nutritional guidance, emphasizing reduced carbohydrate intake and increased protein, vitamins, and micronutrient consumption.
6. Advise patients to quit smoking if necessary and offer respiratory muscle strengthening exercises, such as the pursed lip breathing method, incentive spirometry before the operation, and diaphragmic breathing with hands-on practice until proficiency is achieved.

Participants will complete a demographic information questionnaire upon expressing interest and providing informed consent. For the intervention group, the intervention will commence approximately seven days before surgery, with the first session during the surgery clinic visit. The subsequent two sessions will occur during hospitalization in the cardiac surgery department two days before the operation, focusing on face-to-face training, continued prehabilitation activities, and answering questions.

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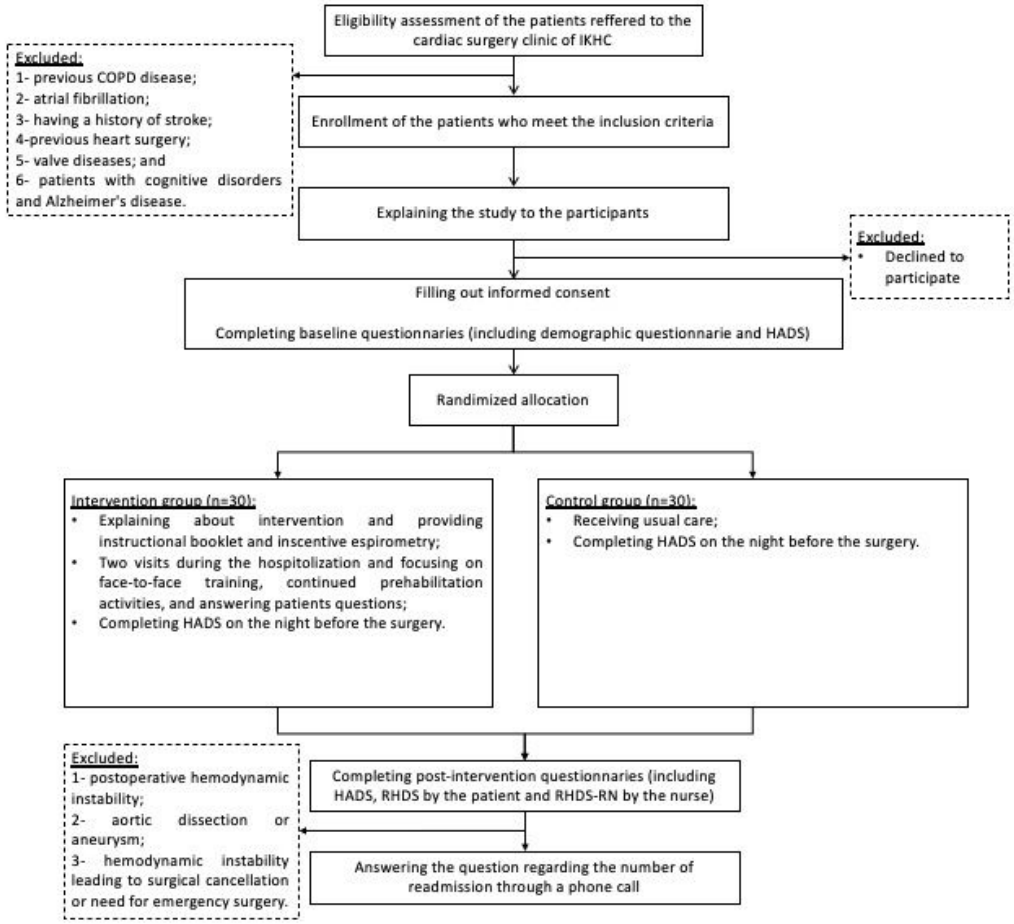

Figure 1 Flow Chart

The first session will involve the steps mentioned earlier. The second and third sessions will be held in the heart surgery ward during the patient's hospitalization. The researcher and the patient will review previous topics, address patient concerns, and reinforce stress management techniques and breathing exercises. Each session will last 45 to 60 minutes, catering to individual patient needs.

Both control and intervention groups will receive routine care, including drug therapy and hemodynamic monitoring. The hospital anxiety and depression scale (HADS) will be completed at the end of the third session. Additional assessments, such as intubation duration, intensive care unit stay, occurrence of atelectasis, overall hospital stay, and discharge readiness (assessed by adult form Readiness for hospital discharge scale patient version and nurse version), will be conducted before patient discharge. 30-day re-hospitalization checklist will be completed four weeks post-discharge for both control and intervention groups, ensuring a comprehensive evaluation of the intervention's impact.

Outcome measures

The study will evaluate the intervention's effectiveness based on the following primary and secondary outcomes:

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Primary outcomes

The primary outcomes (measured variables) of this study will include 1) Discharge readiness, 2) duration of intubation period, 3) duration of ICU stay, 4) occurrence of atelectasis, 5) first day of starting mobility, 6) duration of hospital stay, 7) anxiety and depression during the hospital stay.

Discharge readiness will be assessed using the short form of the Readiness for Hospital Discharge Scale (RHDS) for both patients and nurses. The RHDS evaluates a patient's preparedness to transition home from acute care, typically administered four hours before discharge. The RHDS includes eight items that cover four domains: Personal Status, Knowledge, Perceived Coping Ability, and Expected Support. Scores range from 0 to 10, representing the average of item scores. The Persian versions of RHDS for both patients and nurses have been validated for reliability and validity by Mehraeen et al. (38, 39).

Anxiety and depression during the hospital stay will be measured using the Hospital Anxiety and Depression Scale (HADS), a 14-item tool developed by Sigmon and Snaith in 1983. HADS assesses anxiety and depression symptoms, scored on a four-point scale (0-3), with a cutoff score of 11 indicating significant symptoms. The Persian version of HADS has been validated by Kaviani et al. (40, 41).

Other outcomes, including the duration of intubation, the occurrence of atelectasis (determined by chest X-ray and physician diagnosis), duration of ICU stay, length of hospitalization, and the initiation of mobility, will be measured using a researcher-made checklist.

Secondary outcomes

The secondary outcome is the number of hospital readmissions, defined as emergency and unexpected readmissions due to symptoms suggesting myocardial infarction, pneumonia, or atelectasis. Participants will report the number of readmissions within 30 days post-discharge, confirmed through the hospital information system or medical records from other health centers if applicable.

Data Collection

Data will be gathered using a demographic information questionnaire, HADS, RHDS-RN, RHDS-Pt, a researcher-made checklist, and a question on the number of readmissions. Demographic information will be collected through self-report and medical records at the study's onset. HADS will be completed at the study's start, on the night before the surgery, and on the day of discharge. The RHDS forms will be filled out approximately four hours before discharge. Thirty days post-discharge, the outcome assessor will inquire about emergency readmissions via phone. The data about the duration of intubation, the occurrence of atelectasis, duration of ICU stay, length of hospitalization, and the initiation of mobility will be extracted by the researcher by daily observation of patients progress and data on the patients documents.

Sample Size

Based on the primary outcomes and assuming a 5% type I error rate and 80% power, the sample size is calculated to be 26 patients per group, following the study by Nurhayati et al. Allowing for

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a 15% attrition rate, the estimated number of participants is 30 per group, totaling 60 participants.

Recruitment

Participants will be recruited at the IKHC cardiac surgery clinic. Eligible patients will be screened by a nurse interventionist and a cardiac surgeon, and those meeting the criteria will receive detailed information about the study. Patients will be randomly assigned to the control or intervention group by nurse interventionists after providing written informed consent. The intervention will be conducted in clusters of 6-8 participants, continuing until the sample size is reached.

Random allocation

Participants will be randomized into control or intervention groups using balanced block randomization with a block size of six, stratified by gender, artery blockage percentage, and symptom severity. An independent researcher will generate the allocation sequence, ensuring concealment with sealed opaque envelopes.

Blinding

In this research, one-way blinding will be used. Patients will be admitted to separate rooms to prevent interaction between control and intervention groups. The outcome assessor and the statistician will be kept uninformed and directed not to ask about the group allocations of the participants.

Data management

Data will be gathered through hard-copy questionnaires and lists, except for the 30-day follow-up, which will be conducted over the phone. Patients will be urged to complete the questionnaires to reduce missing data, and the person assessing the outcomes will receive training to ensure precise data collection. The data entered into SPSS software V.22 will undergo double verification to ensure accuracy. The data will be stored using anonymized ID codes to safeguard confidentiality, and the analysis will be carried out by a statistician specialized in epidemiology.

Statistical analysis

Frequency and percentage will describe qualitative data, while mean and standard deviation (or median and first-third quartile) will describe quantitative variables. The normality of the data will be checked using the Shapiro-Wilk test and the P-P Plot diagram, and the Levine test will check the homogeneity of the variance.

Independent t-tests will be used to compare means in two independent groups, and paired t-tests will be used in two dependent groups. A comparison of qualitative variables in two groups will be done using chi-square or Fisher's exact test. The correlation of two quantitative variables will be investigated using the Pearson or Spearman correlation coefficient. In this study, analysis of covariance or linear regression will be used to eliminate the effect of confounders in examining the impact of the intervention. If the normality of the data is not met, the non-parametric

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equivalent of statistical tests will be used. All analyses will be done in SPSS22 software at a significance level of 0.05.

Discussion

The proposed randomized control trial (RCT) investigates the PreCABG program's potential impact on discharge readiness and surgery outcomes for patients undergoing elective Coronary Artery Bypass Grafting (CABG). Coronary artery bypass graft surgery is a standard procedure for patients with severe coronary artery disease (7). However, the recovery process after CABG surgery can be challenging and may involve complications such as infections, prolonged hospital stays, and delayed discharge (10, 11). This study aims to evaluate the impact of a PreCABG program on improving discharge readiness and surgery outcomes in patients undergoing elective CABG surgery. The PreCABG program provides patient education, encourages respiratory muscle training, offers preoperative nutritional guidance, and introduces stress management techniques to optimize patient readiness for surgery and postoperative recovery. The PreCABG program prepares patients both physically and mentally for their CABG surgery. Previous studies support the inclusion of patient education in the PreCABG program (42-44). Prehabilitation before elective CABG, which includes patient education, exercise training, and social support, has improved patients' physical and psychological readiness for surgery and reduced postoperative complications (45-47). The importance of patient education in promoting positive outcomes for CABG surgery patients has been highlighted by various studies. Varaei et al. found that educational interventions effectively promote cardiac self-efficacy in patients undergoing CABG surgery (48). Additionally, Akbari and Çelik conducted a study that applied discharge training and counseling to patients undergoing CABG surgery, decreasing their problems (49). Rief et al. found that optimizing patients' expectations pre-surgery improved outcomes, particularly regarding disability and quality of life, six months after treatment (50).

Furthermore, the research article highlights the potential benefits of preoperative rehabilitation and prehabilitation. Patients who are waiting for CABG surgery often experience fear and anxiety, which can hinder their engagement in rehabilitation postoperatively (51). However, this waiting period offers an opportunity for preoperative rehabilitation or prehabilitation to improve the surgical intervention's safety and outcome and encourage ongoing postoperative engagement in rehabilitation (46). Prehabilitation has gained recognition in cardiac surgery, with the idea that interventions before surgery can enhance patients' physical and psychological well-being and improve surgical outcomes. Furthermore, the emphasis on preoperative preparation in the PreCABG program may lead to shorter hospital stays and earlier patient discharge. This can improve patient satisfaction and alleviate the burden on healthcare facilities by freeing up resources for other patients in need of care. In conclusion, implementing a PreCABG program shows promise in improving discharge readiness and surgery outcomes for patients undergoing elective CABG surgery. Assessing the impact of such a program through a randomized control trial will provide valuable insights into its effectiveness and potential for enhancing the overall care and recovery of patients undergoing this standard cardiac procedure.

Strengths and Limitations

As with any study, this research has its limitations. Despite efforts to address them, certain challenges may persist. For instance, accurately completing the RHDS-RN and RHDS-Pt

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questionnaires precisely four hours before discharge may be difficult due to paperwork complications and unpredictable discharge times, which can sometimes occur at inconvenient hours like midnight. To manage this issue, the questionnaires will be filled out as soon as the discharge decision is made. Additionally, the nature of the intervention prevents blinding for participants and interventionists, although outcome assessors and the statistician will remain blinded. Remote interventions also carry risks of attrition and inadequate adherence, but we plan to motivate participants through valuable information, proper guidance, and continuous follow-up.

We hypothesize that the comprehensive prehabilitation program will enhance discharge readiness, improve surgery outcomes, and reduce emergency readmissions. Positive results from this study could benefit patients undergoing elective CABG and be applicable in both Iran and other countries.

Patient and public involvement

There was no patient or public involvement in the development of this protocol.

Ethics and dissemination

The study received approval from the School of Nursing and Midwifery Research Ethics Committee on October 10, 2023, with the approval number IR.TUMS.IKHC.REC.1402.287. The study protocol has been registered with the ID IRCT20231019059768N1 in the Iranian Registry of Clinical Trials (IRCT). All participants must provide written consent and be fully informed of their rights to voluntary participation and withdrawal. Data will be confidentially and anonymously stored and handled. Participants will be given contact information so the nurse researcher can address any queries. The findings will be shared with representative groups and published in peer-reviewed journals.

Trial status

The recruitment for this study began in April 2024 and is estimated to end in August 2024.

Acknowledgments

This study protocol is a component of PD's Master of Science thesis in Medical-Surgical Nursing at TUMS. The achievement of this study has been facilitated by the invaluable assistance of the Education and Research Deputy and the Medical-Surgical Nursing Department at the School of Nursing and Midwifery, TUMS. We extend our deep appreciation for their endorsement of the thesis and their consistent support, which has played a crucial role in our research journey.

Conflicts of Interests

None declared.

Patient Consent for Publication

Not applicable.

Authors' Contributions

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PD leads the trial, and MZ supervises the project. The project was conceived by PD, ZA, MR, SMR, AK, and MZ. PD and MR will carry out the implementation. MR, who is a Cardiothoracic Surgeon at IKHC, will also assess the educational content and confirm patient eligibility. PD and MZ will work together to create the educational material. SMR will provide statistical expertise for the trial design and conduct the statistical analyses. All authors were involved in drafting this paper and have given approval for the final manuscript.

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Data availability statement

Since this is a study protocol, data is not currently accessible. However, we want to guarantee that once the study concludes, deidentified data can be obtained upon reasonable request. We have a rigorous process in place to ensure that only qualified researchers who are affiliated with academic or research institutions and who can demonstrate their qualifications and data protection measures are given access. This access is exclusively for research purposes, safeguarding the integrity and security of our data.

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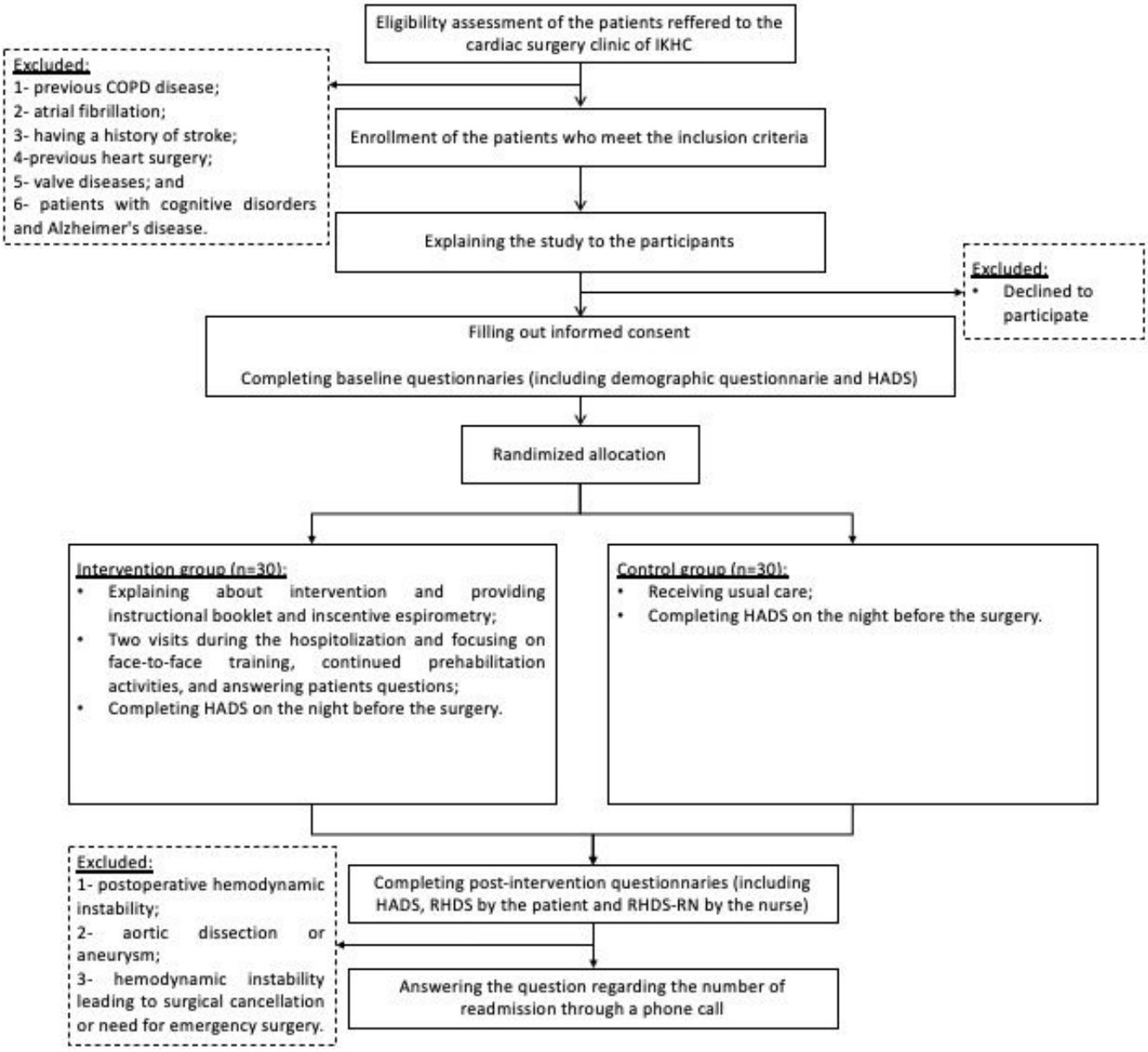

Figure 1 Flow Chart

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Effects of PreCABG program on discharge readiness and surgery outcomes for patients undergoing elective CABG surgery: A study protocol for a randomized control trial

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Effects of PreCABG program on discharge readiness and surgery outcomes for patients undergoing elective CABG surgery: A study protocol for a randomized control trial

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Abstract

Background: Cardiovascular diseases (CVD), a leading cause of death globally, impose significant health and economic burdens, particularly in countries like Iran. Coronary artery bypass grafting (CABG) is a common intervention for ischemic heart disease (IHD), yet it entails a long recovery process with potential complications and psychological impacts.

Objective: This study aims to evaluate the effectiveness of a prehabilitation program (PreCABG) on postoperative outcomes and discharge readiness in patients undergoing elective CABG.

Methods: This randomized controlled trial (RCT) involves 60 patients diagnosed with coronary artery disease at Imam Khomeini Hospital Complex, Tehran. Participants will be randomly assigned to either the intervention group, receiving the PreCABG program, or the control group, receiving standard care. The PreCABG program includes patient education, stress management techniques, respiratory muscle training, and nutritional guidance. Primary outcomes include discharge readiness, duration of intubation, ICU stay, occurrence of atelectasis, onset of mobility, hospital stay, and levels of anxiety and depression. Secondary outcomes include the rate of 30-day readmissions. Data collection will involve standardized scales and checklists administered at various stages pre- and post-operation.

Ethics and dissemination: The research study has received approval from the Research Ethics Committee at Tehran University of Medical Sciences' School of Nursing and Midwifery & Rehabilitation. All participants must provide written consent for their involvement in this study. The findings will be shared with appropriate groups and published in peer-reviewed journals.

Trial registration number: The study is registered with the Iranian Registry of Clinical Trials (IRCT) under the ID **IRCT20231019059768N1.**

Keywords: Cardiovascular diseases, Coronary artery bypass grafting, Prehabilitation, Randomized controlled trial, Discharge readiness, Postoperative outcomes.

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Strenghts and Limitation of this study

- This nurse-led, randomized controlled trial evaluates the effectiveness of a comperhensive Prehabilitation program filling an existing gap in evidence.
- The prehabilitation program is well-defined, including specific components such as stress management techniques, nutritional guidance, respiratory exercises, and patient education.
- Emphasizing discharge readiness as a primary outcome is significant, as it is directly related to patient recovery, hospital resource utilization, and overall healthcare costs.
- Single-center design may limit the generalizability of findings.
- Unblinded participants and interventionists may introduce bias.
- Relatively small sample size may limit detection of minor differences between groups.

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Introduction

Cardiovascular diseases (CVD) are a leading cause of death and a significant global health issue. [1]. It is predicted that in 2030, about 23 million deaths in the world will be due to CVD [2]. CVD is one of the leading causes of a significant reduction in quality of life and life expectancy and also imposes enormous costs on health systems in different countries [1]. Several risk factors have been identified, including physical inactivity, obesity, hypertension, hyperlipidemia, hyperglycemia, and stress. These factors also influence the recovery process from major cardiac events [3]. Studies conducted in Iran also show that coronary artery disease is the leading cause of death in Iran, and Iran has the highest disease burden caused by this disease in the region [4]. Based on the studies, cardiovascular diseases are the leading cause of 46% of deaths and about 20-23% of the total burden of disease in Iran, and it is one of the main problems of Iran's health system [5, 6]. Current therapeutic interventions for IHD include drug therapy (antiplatelet drugs, beta-blockers, or statins) to stabilize the disease and reduce acute events (such as myocardial infarction or sudden death) or immediate restoration of blood flow through surgical revascularization treatment, such as coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) [7, 8]. The recovery process for these surgeries is long and involves caregiving challenges [9]. Nevertheless, this method is a common choice for heart patients and surgeons. Complications of this surgery include increased hospitalization time, delirium, anxiety related to treatment and their ability to adhere to recommended physical activity, depression, stroke, bleeding and cardiac tamponade, myocardial dysfunction, sternal wound infection, and pulmonary complications [10-12].

Despite all the advantages, CABG is a stressful and traumatic event and usually has negative psychological consequences in the preoperative period that may persist after the surgery [13, 14]. When a person is diagnosed with coronary artery disease, it causes high levels of anxiety, which is exceptionally high in the preoperative period and when the client is waiting for major surgery [13, 15]. High anxiety reduces quality of life and worsens long-term psychological consequences [11]. Persistent stress can negatively affect the prognosis and physiological parameters of patients (preoperatively and intraoperatively or during anesthesia), which may prolong recovery and length of stay and negatively impact quality of life [16, 17]. Also, the relationship between depression and cardiovascular disease and its effect on the outcome of patients hospitalized for acute coronary artery disease, as well as before and after vascular surgery, is well known [18]. The presence of depressive symptoms during or shortly after hospitalization increases the risk of death or non-fatal cardiac events by two to three times and significantly increases the morbidity and mortality of these clients [19, 20]. Studies have shown a lower health-related functional status and quality of life, as well as a higher rate of readmission after discharge and increased mortality in these clients [21].

Surgeries that require a thoracotomy, such as coronary artery bypass surgery, carry a high risk of pulmonary complications [22]. Patients undergoing cardiac surgery are more vulnerable to developing these pulmonary complications after surgery [23]. Today, in most hospitals, chest physiotherapy is used to minimize postoperative pulmonary complications after CABG [24, 25]. Various studies have reported that early rehabilitation significantly reduces long-term mortality in patients undergoing coronary artery bypass graft surgery [26-28]. Despite the well-documented importance of postoperative rehabilitation, insufficient information on the value of preoperative interventions is available [23, 29].

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Prehabilitation is a method of preparing the patient for heart surgery [30]. Patients admitted to the hospital for CABG surgery may have to wait up to a week for the procedure, which may lead to regression and physical weakness and negatively affect the outcome of the surgery. [31]. To better use this waiting period, patients can participate in prehabilitation programs. These programs can include various aspects such as increasing physical fitness, increasing information about surgery, teaching strategies to deal with anxiety, and improving the patient's nutritional conditions [32]. There has yet to be a theoretical consensus on prehabilitation methods and protocols.

As the person who has the most contact with patients, nurses are responsible for providing optimal care to their patients at all times [33]. Nursing interventions for patients who will undergo coronary artery bypass surgery include preparing patients for surgery, providing care during and after surgery, and providing information and education to patients and family members about home care after discharge from the hospital [34]. One of the essential goals of the educational program for patients is to improve self-care behavior [12]. Improving self-care reduces the number of preventable complications, and hence, discharge preparation is an essential part of the care process Because it has the potential to promote self-care [35]. Little is known about which protocol is most effective, and there needs to be more certainty about the effectiveness of different approaches. Facilitating people's readiness to leave the hospital environment following coronary artery bypass surgery is considered a critical factor in successful discharge and is a way to save scarce economic resources [36].

Therefore, we developed a randomized controlled trial (RCT) to evaluate the effectiveness of a rehabilitation program for patients undergoing CABG and investigate its effects on post-surgery outcomes and clients' discharge readiness.

Methods and Analysis

Study Design

This research utilizes a double-arm, parallel-group randomized controlled trial approach. An overview of the study design is depicted in a flow chart in Figure 1. The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [37].

Study Setting

Participants will be recruited from the cardiac surgery clinic at Imam Khomeini Hospital Complex (IKHC), which is associated with Tehran University of Medical Sciences in Tehran, Iran. IKHC is a major government-owned hospital and referral center that offers specialized medical services.

Eligibility Criteria

Patients diagnosed with coronary artery disease who are referred to the cardiac surgery clinic at IKHC will be evaluated based on the following eligibility criteria:

Inclusion Criteria

The study inclusion criteria include 1- having an on-pump coronary bypass surgery; 2- being on the elective coronary artery bypass surgery list; 3- experiencing Heart surgery for the first time; 4- ability to speak and understand Persian; 5-not having diagnosed with anxiety or other

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psychological disorders (self-report); and 6- non-concurrency of CABG surgery with valve replacement or other surgeries.

Exclusion Criteria

Exclusion criteria for the study include 1- Lack of consent to continue participating in the study; 2- postoperative hemodynamic instability; 3- aortic dissection or aneurysm; 4- hemodynamic instability leading to surgical cancellation or need for emergency surgery; 5- previous COPD disease; 6- atrial fibrillation; 7- having a history of stroke; 8-previous heart surgery; 9- valve diseases; and 10- patients with cognitive disorders and Alzheimer's disease.

Intervention

This study involves a prehabilitation program led by a nurse. A cardiac surgeon and nurse interventionist will determine patients' eligibility during a face-to-face visit. Participants who meet the eligibility criteria and agree to participate will be randomly divided into intervention and control groups. The control group will receive standard care, while patients in the intervention group will receive the PreCABG intervention. This includes three visits from the nurse interventionist - the first during the surgery clinic meeting with the surgeon and the next two while in the hospital waiting for surgery. During the first session, patients in the intervention group will receive an educational booklet with four sections and an incentive spirometry.

The PreCABG intervention

This intervention program will encompass the following steps:

1. a meeting between the interventional nurse, the patient, and the surgeon during clinic visits.
2. Delivering a comprehensive explanation of the surgical procedure in a manner designed to minimize patient anxiety.
3. Encouraging patients to discuss anxiety triggers and rectifying any misconceptions with the intervention team's assistance.
4. Introducing stress management techniques, such as progressive muscle relaxation, deep breathing, guided imagery, and recommended practice repetition. Patients will choose their preferred stress management method, which will be taught and practiced.
5. Providing preoperative nutritional guidance, emphasizing reduced carbohydrate intake and increased protein, vitamins, and micronutrient consumption.
6. Advise patients to quit smoking if necessary and offer respiratory muscle strengthening exercises, such as the pursed lip breathing method, incentive spirometry before the operation, and diaphragmic breathing with hands-on practice until proficiency is achieved.

Participants will complete a demographic information questionnaire upon expressing interest and providing informed consent. For the intervention group, the intervention will commence approximately seven days before surgery, with the first session during the surgery clinic visit. The subsequent two sessions will occur during hospitalization in the cardiac surgery department two days before the operation, focusing on face-to-face training, continued prehabilitation activities, and answering questions.

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The first session will involve the steps mentioned earlier. The second and third sessions will be held in the heart surgery ward during the patient's hospitalization. The researcher and the patient will review previous topics, address patient concerns, and reinforce stress management techniques and breathing exercises. Each session will last 45 to 60 minutes, catering to individual patient needs.

Both control and intervention groups will receive routine care, including drug therapy and hemodynamic monitoring. The hospital anxiety and depression scale (HADS) will be completed at the end of the third session. Additional assessments, such as intubation duration, intensive care unit stay, occurrence of atelectasis, overall hospital stay, and discharge readiness (assessed by adult form Readiness for hospital discharge scale patient version and nurse version), will be conducted before patient discharge. 30-day re-hospitalization checklist will be completed four weeks post-discharge for both control and intervention groups, ensuring a comprehensive evaluation of the intervention's impact.

Outcome measures

The study will evaluate the intervention's effectiveness based on the following primary and secondary outcomes:

Primary outcomes

The primary outcome (measured variables) of this study will include Discharge readiness; Discharge readiness will be assessed using the short form of the Readiness for Hospital Discharge Scale (RHDS) for both patients and nurses. The RHDS evaluates a patient's preparedness to transition home from acute care, typically administered four hours before discharge. The RHDS includes eight items that cover four domains: Personal Status, Knowledge, Perceived Coping Ability, and Expected Support. Scores range from 0 to 10, representing the average of item scores. The Persian versions of RHDS for both patients and nurses have been validated for reliability and validity by Mehraeen et al. [38, 39].

[Insert Figure 1 about here]

Secondary outcomes

The secondary outcomes will include: 1- Number of hospital readmissions, 2- Duration of intubation, 3- Length of ICU stay, 4- Occurrence of atelectasis, 5- Timing of the first mobilization, 6- Total length of hospital stay, and 7- Levels of anxiety and depression during hospitalization.

The number of hospital readmissions is defined as emergency and unexpected readmissions due to symptoms suggesting myocardial infarction, pneumonia, or atelectasis. Participants will report the number of readmissions within 30 days post-discharge, confirmed through the hospital information system or medical records from other health centers if applicable.

Anxiety and depression during the hospital stay will be measured using the Hospital Anxiety and Depression Scale (HADS), a 14-item tool developed by Sigmon and Snaith in 1983. HADS assesses anxiety and depression symptoms, scored on a four-point scale (0-3), with a cutoff score of 11 indicating significant symptoms. The Persian version of HADS has been validated by Kaviani et al. [40, 41].

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Other outcomes, including the duration of intubation, the occurrence of atelectasis (determined by chest X-ray and physician diagnosis), duration of ICU stay, length of hospitalization, and the initiation of mobility, will be measured using a researcher-made checklist.

Data Collection

Data will be gathered using a demographic information questionnaire, HADS, RHDS-RN, RHDS-Pt, a researcher-made checklist, and a question on the number of readmissions. Demographic information will be collected through self-report and medical records at the study's onset. HADS will be completed at the study's start, on the night before the surgery, and on the day of discharge. The RHDS forms will be filled out approximately four hours before discharge. Thirty days post-discharge, the outcome assessor will inquire about emergency readmissions via phone. The data about the duration of intubation, the occurrence of atelectasis, duration of ICU stay, length of hospitalization, and the initiation of mobility will be extracted by the researcher by daily observation of patients progress and data on the patients documents.
Data displayed in Table 1 provides the present study's enrolment, interventions, and assessment schedule.

Sample Size

Based on the primary outcome and assuming a 5% type I error rate and 80% power, the sample size is calculated to be 26 patients per group, following the study by Nurhayati et al. Allowing for a 15% attrition rate, the estimated number of participants is 30 per group, totaling 60 participants [42]. The assumptions used for sample size calculation are:

Mean Readiness for Discharge Score: 7.11 ± 0.59
Effect Size (d): 0.71
Significance Level (α): 0.05
Power (1 − β): 80% (β = 0.2)
Attrition Rate: 15%
Allocation Ratio: 1

Recruitment

Participants will be recruited at the IKHC cardiac surgery clinic. Eligible patients will be screened by a nurse interventionist and a cardiac surgeon, and those meeting the criteria will receive detailed information about the study. Patients will be randomly assigned to the control or intervention group by nurse interventionists after providing written informed consent. The intervention will be conducted in clusters of 6-8 participants, continuing until the sample size is reached.

Random allocation

Participants will be randomized into control or intervention groups using balanced block randomization with a block size of six, stratified by gender, artery blockage percentage, and

Table 1 Schedule for enrolment, interventions and assessments

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symptom severity. An independent researcher will generate the allocation sequence, ensuring concealment with sealed opaque envelopes.

Blinding

In this research, one-way blinding will be used. Patients will be admitted to separate rooms to prevent interaction between control and intervention groups. Ideally, patients will be placed in private, single-occupancy rooms to minimize the risk of interaction between the intervention groups and other patients. However, this arrangement may be subject to changes based on hospital policies and the availability of beds within the ward. In cases where private rooms are not available, the researcher will make every effort to admit study participants into the same room, ensuring that intervention groups are housed separately. If this is not feasible, the researcher will document and acknowledge this limitation in the final study results. The outcome assessor and the statistician will be kept uninformed and directed not to ask about the group allocations of the participants.

Data management

Data will be gathered through hard-copy questionnaires and lists, except for the 30-day follow-up, which will be conducted over the phone. Patients will be urged to complete the questionnaires to reduce missing data, and the person assessing the outcomes will receive training to ensure precise data collection. The data entered into SPSS software V.22 will undergo double verification to ensure accuracy. The data will be stored using anonymized ID codes to safeguard confidentiality, and the analysis will be carried out by a statistician specialized in epidemiology.

Statistical analysis

Frequency and percentage will describe qualitative data, while mean and standard deviation (or median and first-third quartile) will describe quantitative variables. The normality of the data will be checked using the Shapiro-Wilk test and the P-P Plot diagram, and the Levine test will check the homogeneity of the variance.

Independent t-tests will be used to compare means in two independent groups, and paired t-tests will be used in two dependent groups. A comparison of qualitative variables in two groups will be done using chi-square or Fisher's exact test. The correlation of two quantitative variables will be investigated using the Pearson or Spearman correlation coefficient. In this study, analysis of covariance or linear regression will be used to eliminate the effect of confounders in examining the impact of the intervention. If the normality of the data is not met, the non-parametric equivalent of statistical tests will be used. All analyses will be done in SPSS22 software at a significance level of 0.05.

Progression Criteria and Evaluation

To ensure methodological rigor and consistency throughout the study, we have outlined specific progression criteria that will guide the execution of this research. These criteria will be evaluated at each stage of the study, from the initial planning phase to data analysis.

1. Clarity of Research Question: The research hypothesis, evaluating the effectiveness of a prehabilitation program for improving discharge readiness and surgery outcomes in CABG

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patients, will be refined as necessary throughout the study to maintain alignment with the evolving research context.

2. Methodological Rigor: The study design follows a RCT approach, adhering to the SPIRIT guidelines to ensure methodological consistency. Randomization procedures and blinding protocols will be closely monitored to minimize bias and maintain the integrity of the trial.
3. Intervention Delivery: The PreCABG intervention will be delivered as planned, with periodic monitoring to ensure that all elements of the program, such as stress management techniques, educational sessions, and preoperative health guidance, are consistently applied to all participants.
4. Outcome Measurement: Primary and secondary outcomes will be measured at predefined intervals using validated instruments such as the HADS and RHDS. Any missing data will be handled using appropriate methods, such as imputation or exclusion of incomplete cases, depending on the nature of the missing data.
5. Statistical Analysis: Statistical analyses will be conducted in SPSS software to assess the impact of the intervention on the primary and secondary outcomes. Specific attention will be paid to potential confounders, and appropriate statistical tests will be employed to account for these variables.
6. Discussion and Study Limitations: The findings of the study will be discussed in relation to existing literature, and limitations related to the study design, such as the inability to blind patients to the intervention, will be critically evaluated.

Discussion

The proposed RCT investigates the PreCABG program's potential impact on discharge readiness and surgery outcomes for patients undergoing elective CABG. Coronary artery bypass graft surgery is a standard procedure for patients with severe coronary artery disease [7]. However, the recovery process after CABG surgery can be challenging and may involve complications such as infections, prolonged hospital stays, and delayed discharge [10, 11]. This study aims to evaluate the impact of a PreCABG program on improving discharge readiness and surgery outcomes in patients undergoing elective CABG surgery. The PreCABG program provides patient education, encourages respiratory muscle training, offers preoperative nutritional guidance, and introduces stress management techniques to optimize patient readiness for surgery and postoperative recovery. The PreCABG program prepares patients both physically and mentally for their CABG surgery. Previous studies support the inclusion of patient education in the PreCABG program [43-45]. Prehabilitation before elective CABG, which includes patient education, exercise training, and social support, has improved patients' physical and psychological readiness for surgery and reduced postoperative complications [46-48]. The importance of patient education in promoting positive outcomes for CABG surgery patients has been highlighted by various studies. Varaei et al. found that educational interventions effectively promote cardiac self-efficacy in patients undergoing CABG surgery [49]. Additionally, Akbari and Çelik conducted a study that applied discharge training and counseling to patients undergoing CABG surgery, decreasing their problems [50]. Rief et al. found that optimizing patients' expectations pre-surgery improved outcomes, particularly regarding disability and quality of life, six months after treatment [51].

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Furthermore, the research article highlights the potential benefits of preoperative rehabilitation and prehabilitation. Patients who are waiting for CABG surgery often experience fear and anxiety, which can hinder their engagement in rehabilitation postoperatively [52]. However, this waiting period offers an opportunity for preoperative rehabilitation or prehabilitation to improve the surgical intervention's safety and outcome and encourage ongoing postoperative engagement in rehabilitation [47]. Prehabilitation has gained recognition in cardiac surgery, with the idea that interventions before surgery can enhance patients' physical and psychological well-being and improve surgical outcomes. Furthermore, the emphasis on preoperative preparation in the PreCABG program may lead to shorter hospital stays and earlier patient discharge. This can improve patient satisfaction and alleviate the burden on healthcare facilities by freeing up resources for other patients in need of care. In conclusion, implementing a PreCABG program shows promise in improving discharge readiness and surgery outcomes for patients undergoing elective CABG surgery. Assessing the impact of such a program through a randomized control trial will provide valuable insights into its effectiveness and potential for enhancing the overall care and recovery of patients undergoing this standard cardiac procedure.

Strengths and Limitations

As with any study, this research has its limitations. Despite efforts to address them, certain challenges may persist. For instance, accurately completing the RHDS-RN and RHDS-Pt questionnaires precisely four hours before discharge may be difficult due to paperwork complications and unpredictable discharge times, which can sometimes occur at inconvenient hours like midnight. To manage this issue, the questionnaires will be filled out as soon as the discharge decision is made. Additionally, the nature of the intervention prevents blinding for participants and interventionists, although outcome assessors and the statistician will remain blinded. Remote interventions also carry risks of attrition and inadequate adherence, but we plan to motivate participants through valuable information, proper guidance, and continuous follow-up.

We hypothesize that the comprehensive prehabilitation program will enhance discharge readiness, improve surgery outcomes, and reduce emergency readmissions. Positive results from this study could benefit patients undergoing elective CABG and be applicable in both Iran and other countries.

Patient and public involvement

There was no patient or public involvement in the development of this protocol.

Ethics and dissemination

The study received approval from the School of Nursing and Midwifery Research Ethics Committee on October 10, 2023, with the approval number IR.TUMS.IKHC.REC.1402.287. The study protocol has been registered with the ID IRCT20231019059768N1 in the Iranian Registry of Clinical Trials (IRCT). All participants must provide written consent and be fully informed of their rights to voluntary participation and withdrawal. Data will be confidentially and anonymously stored and handled. Participants will be given contact information so the nurse researcher can address any queries. The findings will be shared with representative groups and published in peer-reviewed journals.

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Trial status

The recruitment for this study began in April 2024 and is estimated to end in January 2025.

Acknowledgments

This study protocol is a component of PD's Master of Science thesis in Medical-Surgical Nursing at TUMS. The achievement of this study has been facilitated by the invaluable assistance of the Education and Research Deputy and the Medical-Surgical Nursing Department at the School of Nursing and Midwifery, TUMS. We extend our deep appreciation for their endorsement of the thesis and their consistent support, which has played a crucial role in our research journey.

Conflicts of Interests

None declared.

Patient Consent for Publication

Not applicable.

Authors' Contributions

PD leads the trial, and MZ supervises the project. The project was conceived by PD, ZA, MR, SMR, AK, and MZ. PD and MR will carry out the implementation. MR, who is a Cardiothoracic Surgeon at IKHC, will also assess the educational content and confirm patient eligibility. PD and MZ will work together to create the educational material. SMR will provide statistical expertise for the trial design and conduct the statistical analyses. All authors were involved in drafting this paper and have given approval for the final manuscript.

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Data availability statement

Since this is a study protocol, data is not currently accessible. However, we want to guarantee that once the study concludes, deidentified data can be obtained upon reasonable request. We have a rigorous process in place to ensure that only qualified researchers who are affiliated with academic or research institutions and who can demonstrate their qualifications and data protection measures are given access. This access is exclusively for research purposes, safeguarding the integrity and security of our data.

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Figure Legends:

Figure 1: Flowchart showing patient allocation to intervention and control groups.

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Table 2 Schedule for enrolment, interventions and assessments

	STUDY PERIOD				
	Enrolment	Allocation	Intervention	Follow up	
TIMEPOINT	Baseline	0	Clinic meeting to day of the surgery	Day of the surgery to day of discharge	4 weeks after discharge
ENROLMENT:					
Eligibility Screen	*				
Informed Consent	*				
Randomization		*			
INTERVENTION GROUP:					
The PreCABG program			*		
Usual Care			*	*	*
ASSESSMENTS:					
Demographic information	*				
Marital status	*				
Level of education	*				
Occupation status	*				
Income	*				
Medical history	*				
Smoking	*				
Alcohol	*				
PRIMARY OUTCOMES:					
Discharge Readiness				*	
SECONDARY OUTCOMES:					
Duration of intubation				*	
Duration of ICU stay				*	
Occurrence of atelectasis				*	
First day of starting mobility				*	
Duration of hospital stay				*	
Anxiety and depression during the hospital stay	*		*	*	*
Hospital readmissions					*

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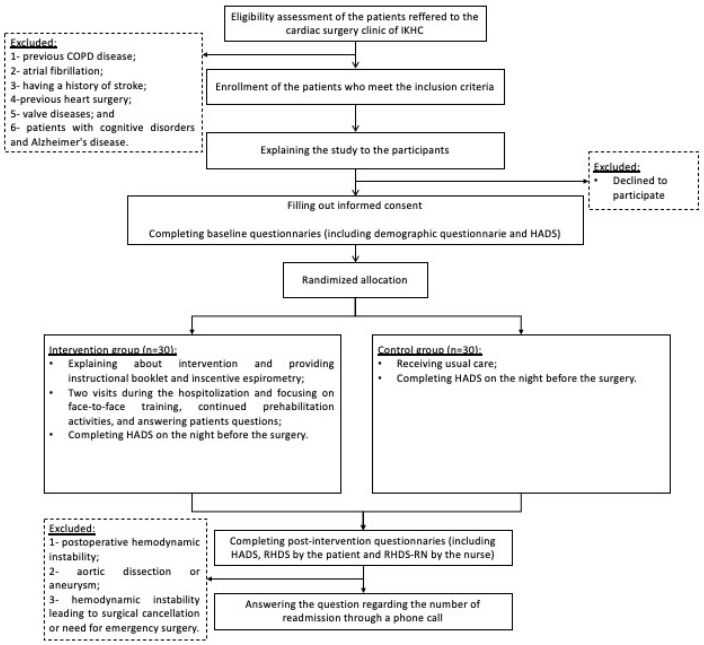

Flowchart showing patient allocation to intervention and control groups.

338x500mm (54 x 54 DPI)

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Effects of PreCABG program on discharge readiness and surgery outcomes for patients undergoing elective CABG surgery: A study protocol for a randomized control trial

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Secondary Subject Heading:	Cardiovascular medicine, Nursing
Keywords:	Randomized Controlled Trial, Cardiovascular Disease, Coronary intervention < CARDIOLOGY, Nursing Care

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Effects of PreCABG program on discharge readiness and surgery outcomes for patients undergoing elective CABG surgery: A study protocol for a randomized control trial

Pouya Dolat Abadi[1], Masoumeh Zakerimoghadam[2]*, Zahra Abbasi Dolat Abadi[3], Mehrzad Rahmanian[4], Seyed Mohammad Riahi[5], Ali Khanipour-Kencha[6]

Abstract

Intruduction: Cardiovascular diseases (CVD), a leading cause of death globally, impose significant health and economic burdens, particularly in countries like Iran. Coronary artery bypass grafting (CABG) is a common intervention for ischemic heart disease (IHD), yet it entails a long recovery process with potential complications and psychological impacts. This study aims to evaluate the effectiveness of a prehabilitation program (PreCABG) on postoperative outcomes and discharge readiness in patients undergoing elective CABG.

Methods and analysis: This randomized controlled trial (RCT) involves 60 patients diagnosed with coronary artery disease at Imam Khomeini Hospital Complex, Tehran. Participants will be randomly assigned to either the intervention group, receiving the PreCABG program, or the control group, receiving standard care. The PreCABG program includes patient education, stress management techniques, respiratory muscle training, and nutritional guidance. Primary outcomes include discharge readiness, duration of intubation, ICU stay, occurrence of atelectasis, onset of mobility, hospital stay, and levels of anxiety and depression. Secondary outcomes include the rate of 30-day readmissions. Data collection will involve standardized scales and checklists administered at various stages pre- and post-operation.

Ethics and dissemination: The research study has received approval from the Research Ethics Committee at Tehran University of Medical Sciences' School of Nursing and Midwifery & Rehabilitation. All participants must provide written consent for their involvement in this study. The findings will be shared with appropriate groups and published in peer-reviewed journals.

Trial registration number: The study is registered with the Iranian Registry of Clinical Trials (IRCT) under the ID **IRCT20231019059768N1.**

Keywords: Cardiovascular diseases, Coronary artery bypass grafting, Prehabilitation, Randomized controlled trial, Discharge readiness, Postoperative outcomes.

Word Count: 3474

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Strenghts and Limitation of this study

- The prehabilitation program is well-defined, including specific components such as stress management techniques, nutritional guidance, respiratory exercises, and patient education.
- Emphasizing discharge readiness as a primary outcome is significant, as it is directly related to patient recovery, hospital resource utilization, and overall healthcare costs.
- Single-center design may limit the generalizability of findings.
- Unblinded participants and interventionists may introduce bias.
- Relatively small sample size may limit detection of minor differences between groups.

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Introduction

Cardiovascular diseases (CVD) are a leading cause of death and a significant global health issue. [1]. It is predicted that in 2030, about 23 million deaths in the world will be due to CVD [2]. CVD is one of the leading causes of a significant reduction in quality of life and life expectancy and also imposes enormous costs on health systems in different countries [1]. Several risk factors have been identified, including physical inactivity, obesity, hypertension, hyperlipidemia, hyperglycemia, and stress. These factors also influence the recovery process from major cardiac events [3]. Studies conducted in Iran also show that coronary artery disease is the leading cause of death in Iran, and Iran has the highest disease burden caused by this disease in the region [4]. Based on the studies, cardiovascular diseases are the leading cause of 46% of deaths and about 20-23% of the total burden of disease in Iran, and it is one of the main problems of Iran's health system [5, 6]. Current therapeutic interventions for IHD include drug therapy (antiplatelet drugs, beta-blockers, or statins) to stabilize the disease and reduce acute events (such as myocardial infarction or sudden death) or immediate restoration of blood flow through surgical revascularization treatment, such as coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) [7, 8]. The recovery process for these surgeries is long and involves caregiving challenges [9]. Nevertheless, this method is a common choice for heart patients and surgeons. Complications of this surgery include increased hospitalization time, delirium, anxiety related to treatment and their ability to adhere to recommended physical activity, depression, stroke, bleeding and cardiac tamponade, myocardial dysfunction, sternal wound infection, and pulmonary complications [10-12].

Despite all the advantages, CABG is a stressful and traumatic event and usually has negative psychological consequences in the preoperative period that may persist after the surgery [13, 14]. When a person is diagnosed with coronary artery disease, it causes high levels of anxiety, which is exceptionally high in the preoperative period and when the client is waiting for major surgery [13, 15]. High anxiety reduces quality of life and worsens long-term psychological consequences [11]. Persistent stress can negatively affect the prognosis and physiological parameters of patients (preoperatively and intraoperatively or during anesthesia), which may prolong recovery and length of stay and negatively impact quality of life [16, 17]. Also, the relationship between depression and cardiovascular disease and its effect on the outcome of patients hospitalized for acute coronary artery disease, as well as before and after vascular surgery, is well known [18]. The presence of depressive symptoms during or shortly after hospitalization increases the risk of death or non-fatal cardiac events by two to three times and significantly increases the morbidity and mortality of these clients [19, 20]. Studies have shown a lower health-related functional status and quality of life, as well as a higher rate of readmission after discharge and increased mortality in these clients [21].

Surgeries that require a thoracotomy, such as coronary artery bypass surgery, carry a high risk of pulmonary complications [22]. Patients undergoing cardiac surgery are more vulnerable to developing these pulmonary complications after surgery [23]. Today, in most hospitals, chest physiotherapy is used to minimize postoperative pulmonary complications after CABG [24, 25]. Various studies have reported that early rehabilitation significantly reduces long-term mortality in patients undergoing coronary artery bypass graft surgery [26-28]. Despite the well-documented importance of postoperative rehabilitation, insufficient information on the value of preoperative interventions is available [23, 29].

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Prehabilitation is a method of preparing the patient for heart surgery [30]. Patients admitted to the hospital for CABG surgery may have to wait up to a week for the procedure, which may lead to regression and physical weakness and negatively affect the outcome of the surgery. [31]. To better use this waiting period, patients can participate in prehabilitation programs. These programs can include various aspects such as increasing physical fitness, increasing information about surgery, teaching strategies to deal with anxiety, and improving the patient's nutritional conditions [32]. There has yet to be a theoretical consensus on prehabilitation methods and protocols.

As the person who has the most contact with patients, nurses are responsible for providing optimal care to their patients at all times [33]. Nursing interventions for patients who will undergo coronary artery bypass surgery include preparing patients for surgery, providing care during and after surgery, and providing information and education to patients and family members about home care after discharge from the hospital [34]. One of the essential goals of the educational program for patients is to improve self-care behavior [12]. Improving self-care reduces the number of preventable complications, and hence, discharge preparation is an essential part of the care process Because it has the potential to promote self-care [35]. Little is known about which protocol is most effective, and there needs to be more certainty about the effectiveness of different approaches. Facilitating people's readiness to leave the hospital environment following coronary artery bypass surgery is considered a critical factor in successful discharge and is a way to save scarce economic resources [36].

Therefore, we developed a randomized controlled trial (RCT) to evaluate the effectiveness of a rehabilitation program for patients undergoing CABG and investigate its effects on post-surgery outcomes and clients' discharge readiness.

Methods and Analysis

Study Design

This research utilizes a double-arm, parallel-group randomized controlled trial approach. An overview of the study design is depicted in a flow chart in Figure 1. The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [37].

Study Setting

Participants will be recruited from the cardiac surgery clinic at Imam Khomeini Hospital Complex (IKHC), which is associated with Tehran University of Medical Sciences in Tehran, Iran. IKHC is a major government-owned hospital and referral center that offers specialized medical services.

Eligibility Criteria

Patients diagnosed with coronary artery disease who are referred to the cardiac surgery clinic at IKHC will be evaluated based on the following eligibility criteria:

Inclusion Criteria

The study inclusion criteria include 1- having an on-pump coronary bypass surgery; 2- being on the elective coronary artery bypass surgery list; 3- experiencing Heart surgery for the first time; 4- ability to speak and understand Persian; 5-not having diagnosed with anxiety or other

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psychological disorders (self-report); and 6- non-concurrency of CABG surgery with valve replacement or other surgeries.

Exclusion Criteria

Exclusion criteria for the study include 1- Lack of consent to continue participating in the study; 2- postoperative hemodynamic instability; 3- aortic dissection or aneurysm; 4- hemodynamic instability leading to surgical cancellation or need for emergency surgery; 5- previous COPD disease; 6- atrial fibrillation; 7- having a history of stroke; 8-previous heart surgery; 9- valve diseases; and 10- patients with cognitive disorders and Alzheimer's disease.

Intervention

This study involves a prehabilitation program led by a nurse. A cardiac surgeon and nurse interventionist will determine patients' eligibility during a face-to-face visit. Participants who meet the eligibility criteria and agree to participate will be randomly divided into intervention and control groups. The control group will receive standard care, while patients in the intervention group will receive the PreCABG intervention. This includes three visits from the nurse interventionist - the first during the surgery clinic meeting with the surgeon and the next two while in the hospital waiting for surgery. During the first session, patients in the intervention group will receive an educational booklet with four sections and an incentive spirometry.

The PreCABG intervention

This intervention program will encompass the following steps:

1. a meeting between the interventional nurse, the patient, and the surgeon during clinic visits.
2. Delivering a comprehensive explanation of the surgical procedure in a manner designed to minimize patient anxiety.
3. Encouraging patients to discuss anxiety triggers and rectifying any misconceptions with the intervention team's assistance.
4. Introducing stress management techniques, such as progressive muscle relaxation, deep breathing, guided imagery, and recommended practice repetition. Patients will choose their preferred stress management method, which will be taught and practiced.
5. Providing preoperative nutritional guidance, emphasizing reduced carbohydrate intake and increased protein, vitamins, and micronutrient consumption.
6. Advise patients to quit smoking if necessary and offer respiratory muscle strengthening exercises, such as the pursed lip breathing method, incentive spirometry before the operation, and diaphragmic breathing with hands-on practice until proficiency is achieved. The accuracy of the patient's technique will be assessed, and if necessary, additional teaching sessions will be provided until the patient is proficient.
7. Implementing a logbook in which patients will record the number of training sessions completed and the duration of each session. ven that patients with cardiovascular conditions often experience high levels of anxiety and fear of death, they tend to follow the instructions with great attention to detail.

Participants will complete a demographic information questionnaire upon expressing interest and providing informed consent. For the intervention group, the intervention will commence

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approximately seven days before surgery, with the first session during the surgery clinic visit. The subsequent two sessions will occur during hospitalization in the cardiac surgery department two days before the operation, focusing on face-to-face training, continued prehabilitation activities, and answering questions.

The first session will involve the steps mentioned earlier. The second and third sessions will be held in the heart surgery ward during the patient's hospitalization. The researcher and the patient will review previous topics, address patient concerns, and reinforce stress management techniques and breathing exercises. Each session will last 45 to 60 minutes, catering to individual patient needs.

Both control and intervention groups will receive routine care, including drug therapy and hemodynamic monitoring. The hospital anxiety and depression scale (HADS) will be completed at the end of the third session. Additional assessments, such as intubation duration, intensive care unit stay, occurrence of atelectasis, overall hospital stay, and discharge readiness (assessed by adult form Readiness for hospital discharge scale patient version and nurse version), will be conducted before patient discharge. 30-day re-hospitalization checklist will be completed four weeks post-discharge for both control and intervention groups, ensuring a comprehensive evaluation of the intervention's impact.

Outcome measures

The study will evaluate the intervention's effectiveness based on the following primary and secondary outcomes:

Primary outcomes

The primary outcome (measured variables) of this study will include Discharge readiness; Discharge readiness will be assessed using the short form of the Readiness for Hospital Discharge Scale (RHDS) for both patients and nurses. The RHDS evaluates a patient's preparedness to transition home from acute care, typically administered four hours before discharge. The RHDS includes eight items that cover four domains: Personal Status, Knowledge, Perceived Coping Ability, and Expected Support. Scores range from 0 to 10, representing the average of item scores. The Persian versions of RHDS for both patients and nurses have been validated for reliability and validity by Mehraeen et al. [38, 39].

[Insert Figure 1 about here]

Secondary outcomes

The secondary outcomes will include: 1- Number of hospital readmissions, 2- Duration of intubation, 3- Length of ICU stay, 4- Occurrence of atelectasis, 5- Timing of the first mobilization, 6- Total length of hospital stay, and 7- Levels of anxiety and depression during hospitalization.

The number of hospital readmissions is defined as emergency and unexpected readmissions due to symptoms suggesting myocardial infarction, pneumonia, or atelectasis. Participants will report the number of readmissions within 30 days post-discharge, confirmed through the hospital information system or medical records from other health centers if applicable.

Anxiety and depression during the hospital stay will be measured using the Hospital Anxiety and Depression Scale (HADS), a 14-item tool developed by Sigmon and Snaith in 1983. HADS

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assesses anxiety and depression symptoms, scored on a four-point scale (0-3), with a cutoff score of 11 indicating significant symptoms. The Persian version of HADS has been validated by Kaviani et al. [40, 41].

Other outcomes, including the duration of intubation, the occurrence of atelectasis (determined by chest X-ray and physician diagnosis), duration of ICU stay, length of hospitalization, and the initiation of mobility, will be measured using a researcher-made checklist.

Data Collection

Data will be gathered using a demographic information questionnaire, HADS, RHDS-RN, RHDS-Pt, a researcher-made checklist, and a question on the number of readmissions. Demographic information will be collected through self-report and medical records at the study's onset. HADS will be completed at the study's start, on the night before the surgery, and on the day of discharge. The RHDS forms will be filled out approximately four hours before discharge. Thirty days post-discharge, the outcome assessor will inquire about emergency readmissions via phone. The data about the duration of intubation, the occurrence of atelectasis, duration of ICU stay, length of hospitalization, and the initiation of mobility will be extracted by the researcher by daily observation of patients progress and data on the patients documents.

Data displayed in Table 1 provides the present study's enrolment, interventions, and assessment schedule.

	STUDY PERIOD				
	Enrolment	Allocation	Intervention	Follow up	
TIMEPOINT	Baseline	0	Clinic meeting to day of the surgery	Day of the surgery to day of discharge	4 weeks after discharge
ENROLMENT:					
Eligibility Screen	*				
Informed Consent	*				
Randomization		*			
INTERVENTION GROUP:					
The PreCABG program			*		
Usual Care			*	*	*
ASSESSMENTS:					
Demographic information	*				
Marital status	*				
Level of education	*				
Occupation status	*				
Income	*				
Medical history	*				
Smoking	*				
Alcohol	*				
PRIMARY OUTCOMES:					
Discharge Readiness				*	
SECONDARY OUTCOMES:					
Duration of intubation				*	
Duration of ICU stay				*	
Occurrence of atelectasis				*	

Table 1 Schedule for enrolment, interventions and assessments

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First day of starting mobility				*	
Duration of hospital stay				*	
Anxiety and depression during the hospital stay	*		*	*	*
Hospital readmissions					*

Sample Size

Based on the primary outcome and assuming a 5% type I error rate and 80% power, the sample size is calculated to be 26 patients per group, following the study by Nurhayati et al. Allowing for a 15% attrition rate, the estimated number of participants is 30 per group, totaling 60 participants [42]. The assumptions used for sample size calculation are:

Mean Readiness for Discharge Score: 7.11 ± 0.59
Effect Size (d): 0.71
Significance Level (α): 0.05
Power (1 − β): 80% (β = 0.2)
Attrition Rate: 15%
Allocation Ratio: 1

Recruitment

Participants will be recruited at the IKHC cardiac surgery clinic. Eligible patients will be screened by a nurse interventionist and a cardiac surgeon, and those meeting the criteria will receive detailed information about the study. Patients will be randomly assigned to the control or intervention group by nurse interventionists after providing written informed consent. The intervention will be conducted in clusters of 6-8 participants, continuing until the sample size is reached.

Random allocation

Participants will be randomized into control or intervention groups using balanced block randomization with a block size of six, stratified by gender, artery blockage percentage, and symptom severity. An independent researcher will generate the allocation sequence, ensuring concealment with sealed opaque envelopes.

Blinding

In this research, one-way blinding will be used. Patients will be admitted to separate rooms to prevent interaction between control and intervention groups. Ideally, patients will be placed in private, single-occupancy rooms to minimize the risk of interaction between the intervention groups and other patients. However, this arrangement may be subject to changes based on hospital policies and the availability of beds within the ward. In cases where private rooms are not available, the researcher will make every effort to admit study participants into the same room, ensuring that intervention groups are housed separately. If this is not feasible, the researcher will document and acknowledge this limitation in the final study results. The outcome assessor and the statistician will be kept uninformed and directed not to ask about the group allocations of the participants.

Data management

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Data will be gathered through hard-copy questionnaires and lists, except for the 30-day follow-up, which will be conducted over the phone. Patients will be urged to complete the questionnaires to reduce missing data, and the person assessing the outcomes will receive training to ensure precise data collection. The data entered into SPSS software V.22 will undergo double verification to ensure accuracy. The data will be stored using anonymized ID codes to safeguard confidentiality, and the analysis will be carried out by a statistician specialized in epidemiology.

Statistical analysis

Frequency and percentage will describe qualitative data, while mean and standard deviation (or median and first-third quartile) will describe quantitative variables. The normality of the data will be checked using the Shapiro-Wilk test and the P-P Plot diagram, and the Levine test will check the homogeneity of the variance.

Independent t-tests will be used to compare means in two independent groups, and paired t-tests will be used in two dependent groups. A comparison of qualitative variables in two groups will be done using chi-square or Fisher's exact test. The correlation of two quantitative variables will be investigated using the Pearson or Spearman correlation coefficient. In this study, analysis of covariance or linear regression will be used to eliminate the effect of confounders in examining the impact of the intervention. If the normality of the data is not met, the non-parametric equivalent of statistical tests will be used. All analyses will be done in SPSS22 software at a significance level of 0.05.

Progression Criteria and Evaluation

To ensure methodological rigor and consistency throughout the study, we have outlined specific progression criteria that will guide the execution of this research. These criteria will be evaluated at each stage of the study, from the initial planning phase to data analysis.

1. Clarity of Research Question: The research hypothesis, evaluating the effectiveness of a prehabilitation program for improving discharge readiness and surgery outcomes in CABG patients, will be refined as necessary throughout the study to maintain alignment with the evolving research context.
2. Methodological Rigor: The study design follows a RCT approach, adhering to the SPIRIT guidelines to ensure methodological consistency. Randomization procedures and blinding protocols will be closely monitored to minimize bias and maintain the integrity of the trial.
3. Intervention Delivery: The PreCABG intervention will be delivered as planned, with periodic monitoring to ensure that all elements of the program, such as stress management techniques, educational sessions, and preoperative health guidance, are consistently applied to all participants.
4. Outcome Measurement: Primary and secondary outcomes will be measured at predefined intervals using validated instruments such as the HADS and RHDS. Any missing data will be handled using appropriate methods, such as imputation or exclusion of incomplete cases, depending on the nature of the missing data.
5. Statistical Analysis: Statistical analyses will be conducted in SPSS software to assess the impact of the intervention on the primary and secondary outcomes. Specific attention will be paid to potential confounders, and appropriate statistical tests will be employed to account for these variables.

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6. Discussion and Study Limitations: The findings of the study will be discussed in relation to existing literature, and limitations related to the study design, such as the inability to blind patients to the intervention, will be critically evaluated.

Discussion

The proposed RCT investigates the PreCABG program's potential impact on discharge readiness and surgery outcomes for patients undergoing elective CABG. Coronary artery bypass graft surgery is a standard procedure for patients with severe coronary artery disease [7]. However, the recovery process after CABG surgery can be challenging and may involve complications such as infections, prolonged hospital stays, and delayed discharge [10, 11]. This study aims to evaluate the impact of a PreCABG program on improving discharge readiness and surgery outcomes in patients undergoing elective CABG surgery. The PreCABG program provides patient education, encourages respiratory muscle training, offers preoperative nutritional guidance, and introduces stress management techniques to optimize patient readiness for surgery and postoperative recovery. The PreCABG program prepares patients both physically and mentally for their CABG surgery. Previous studies support the inclusion of patient education in the PreCABG program [43-45]. Prehabilitation before elective CABG, which includes patient education, exercise training, and social support, has improved patients' physical and psychological readiness for surgery and reduced postoperative complications [46-48]. The importance of patient education in promoting positive outcomes for CABG surgery patients has been highlighted by various studies. Varaei et al. found that educational interventions effectively promote cardiac self-efficacy in patients undergoing CABG surgery [49]. Additionally, Akbari and Çelik conducted a study that applied discharge training and counseling to patients undergoing CABG surgery, decreasing their problems [50]. Rief et al. found that optimizing patients' expectations pre-surgery improved outcomes, particularly regarding disability and quality of life, six months after treatment [51].

Furthermore, the research article highlights the potential benefits of preoperative rehabilitation and prehabilitation. Patients who are waiting for CABG surgery often experience fear and anxiety, which can hinder their engagement in rehabilitation postoperatively [52]. However, this waiting period offers an opportunity for preoperative rehabilitation or prehabilitation to improve the surgical intervention's safety and outcome and encourage ongoing postoperative engagement in rehabilitation [47]. Prehabilitation has gained recognition in cardiac surgery, with the idea that interventions before surgery can enhance patients' physical and psychological well-being and improve surgical outcomes. Furthermore, the emphasis on preoperative preparation in the PreCABG program may lead to shorter hospital stays and earlier patient discharge. This can improve patient satisfaction and alleviate the burden on healthcare facilities by freeing up resources for other patients in need of care. In conclusion, implementing a PreCABG program shows promise in improving discharge readiness and surgery outcomes for patients undergoing elective CABG surgery. Assessing the impact of such a program through a randomized control trial will provide valuable insights into its effectiveness and potential for enhancing the overall care and recovery of patients undergoing this standard cardiac procedure.

Strengths and Limitations

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As with any study, this research has its limitations. Despite efforts to address them, certain challenges may persist. For instance, accurately completing the RHDS-RN and RHDS-Pt questionnaires precisely four hours before discharge may be difficult due to paperwork complications and unpredictable discharge times, which can sometimes occur at inconvenient hours like midnight. To manage this issue, the questionnaires will be filled out as soon as the discharge decision is made. Additionally, the nature of the intervention prevents blinding for participants and interventionists, although outcome assessors and the statistician will remain blinded. Remote interventions also carry risks of attrition and inadequate adherence, but we plan to motivate participants through valuable information, proper guidance, and continuous follow-up.

We hypothesize that the comprehensive prehabilitation program will enhance discharge readiness, improve surgery outcomes, and reduce emergency readmissions. Positive results from this study could benefit patients undergoing elective CABG and be applicable in both Iran and other countries.

Patient and public involvement

There was no patient or public involvement in the development of this protocol.

Ethics and dissemination

The study received approval from the School of Nursing and Midwifery Research Ethics Committee on October 10, 2023, with the approval number IR.TUMS.IKHC.REC.1402.287. The study protocol has been registered with the ID IRCT20231019059768N1 in the Iranian Registry of Clinical Trials (IRCT). All participants must provide written consent and be fully informed of their rights to voluntary participation and withdrawal. Data will be confidentially and anonymously stored and handled. Participants will be given contact information so the nurse researcher can address any queries. The findings will be shared with representative groups and published in peer-reviewed journals.

Trial status

The recruitment for this study began in April 2024 and is estimated to end in January 2025.

Acknowledgments

This study protocol is a component of PD's Master of Science thesis in Medical-Surgical Nursing at TUMS. The achievement of this study has been facilitated by the invaluable assistance of the Education and Research Deputy and the Medical-Surgical Nursing Department at the School of Nursing and Midwifery, TUMS. We extend our deep appreciation for their endorsement of the thesis and their consistent support, which has played a crucial role in our research journey.

Conflicts of Interests

None declared.

Patient Consent for Publication

Not applicable.

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Authors' Contributions

PD leads the trial, and MZ supervises the project. The project was conceived by PD, ZA, MR, SMR, AK, and MZ. PD and MR will carry out the implementation. MR, who is a Cardiothoracic Surgeon at IKHC, will also assess the educational content and confirm patient eligibility. PD and MZ will work together to create the educational material. SMR will provide statistical expertise for the trial design and conduct the statistical analyses. All authors were involved in drafting this paper and have given approval for the final manuscript. Pouya Dolat Abadi (PD) is responsible for the overall content as guarantor.

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Data availability statement

Since this is a study protocol, data is not currently accessible. However, we want to guarantee that once the study concludes, deidentified data can be obtained upon reasonable request. We have a rigorous process in place to ensure that only qualified researchers who are affiliated with academic or research institutions and who can demonstrate their qualifications and data protection measures are given access. This access is exclusively for research purposes, safeguarding the integrity and security of our data.

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Figure Legends:

Figure 1: Flowchart showing patient allocation to intervention and control groups.

Table 2 Schedule for enrolment, interventions and assessments

	STUDY PERIOD				
	Enrolment	Allocation	Intervention	Follow up	
TIMEPOINT	Baseline	0	Clinic meeting to day of the surgery	Day of the surgery to day of discharge	4 weeks after discharge
ENROLMENT:					
Eligibility Screen	*				
Informed Consent	*				
Randomization		*			
INTERVENTION GROUP:					
The PreCABG program			*		
Usual Care			*	*	*
ASSESSMENTS:					
Demographic information	*				
Marital status	*				
Level of education	*				
Occupation status	*				
Income	*				
Medical history	*				
Smoking	*				
Alcohol	*				
PRIMARY OUTCOMES:					
Discharge Readiness				*	
SECONDARY OUTCOMES:					
Duration of intubation				*	
Duration of ICU stay				*	
Occurrence of atelectasis				*	
First day of starting mobility				*	
Duration of hospital stay				*	
Anxiety and depression during the hospital stay	*		*	*	*
Hospital readmissions					*

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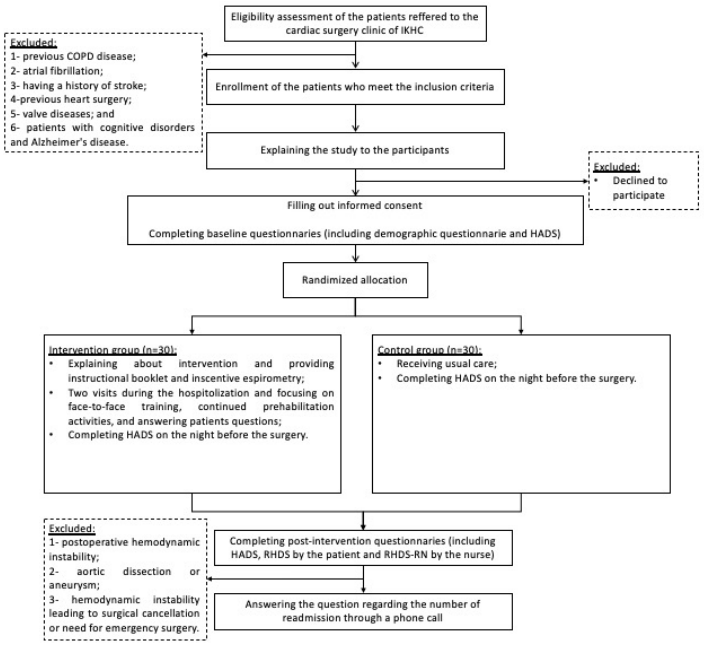

Flowchart showing patient allocation to intervention and control groups.

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