RESEARCH PROTOCOL

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Investigation of the Effect of Prehabilitation on Patient Outcomes in Frail Patients Planned for Elective Coronary Artery Bypass Graft

Protocol No. :230219

Research Type :

Research Center: University of Health Sciences Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital

Supporter (If Any): None

Application : ☐Individual Research ☒Thesis

We undertake that we have read the current versions of the Declaration of Helsinki, Good Clinical Practices (GCP) Guide and Good Laboratory Practices (GLP) Guide and that the study will be conducted in accordance with this Research Protocol, the Declaration of Helsinki, GCP/GLP. In addition, the researchers mentioned below have been informed in detail about the study by the Coordinator (multicenter) / Principal Investigator (single center) of this study.

Responsible Researcher: Specialist Nurse Gamze ATAMAN YILDIZ
History :
Signature :

Consultant Researcher: Prof. Dr. Fatma ETİ ASLAN
History :
Signature :

[1] In single-center studies, the coordinating investigator is the principal investigator. In multi-center studies, the principal investigator of the center where the study will be conducted is the Coordinating Investigator.

[2] You can duplicate the responsible and assistant worker fields.

CONTACT INFORMATION [3]

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[3] You can add according to the number of principal investigators and assistant investigators.

CONTENTS

1. SUMMARY

Title of the Study : Investigation of the Effect of Prehabilitation on Patient Outcomes in Frail Patients Planned for Elective Coronary Artery Bypass Graft

Rationale : To see the effect of preoperative routine and improved practices on the patient after surgery.

Purpose : The purpose of the research is, To determine the effect of prehabilitation care on patient outcomes.

Objective : To evaluate the effect of preoperative prehabilitation on patient outcomes and contribute to the literature.

Population : Frail patients scheduled for elective coronary artery bypass grafting at the University of Health Sciences, Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital.

Number of Volunteers : The sample calculation of the study was made using Power (G-power) analysis, and the minimum sample size was calculated as 30 patients for both groups, while the Type I error amount was 0.05 and the power of the test was 0.80 (α=0.05, 1-β=0.80).

Research Design : The study was planned as a randomized controlled trial.

Procedure : After obtaining institutional approval, the study will continue until the sample size is reached with patients who meet the criteria. Patients identified with the preoperative mini mental test and frailty scale will be administered a patient information form, mini nutritional test, Charlson Comorbidity Index, and Duke activity status index 3-4 weeks before surgery in the intervention group, and 1 day before surgery in the control group. Before postoperative discharge, the appropriate section of the patient information form and the Clavien Dindo classification will be administered and recorded. On the 30th

postoperative day, the mini nutritional test, Duke activity status index, activities of daily living scale, and postoperative recovery index will be administered and recorded.

Research Duration : After obtaining institutional permission, the study will continue until the sample size is reached on patients who meet the criteria.

2. ABBREVIATIONS

3. WORKING SCHEDULE AND DURATION

May 27, 2025	Obtaining ethics committee approval
May 28, 2025 - January 1, 2026	- Data collection - Literature review
January 1, 2026 – April 1,	- Writing phase of the research
April 2026	- Analysis
May 2026	- Analysis interpretation
May 2026	- Discussing analyses
May 2026	- Writing and presenting research results

4. RATIONALE / IMPORTANCE AND CONTRIBUTION OF THE RESEARCH

Frailty is multifactorial, making it difficult to estimate its prevalence; older age, female gender, unhealthy lifestyle, and low economic status have been identified as potential risk factors. Social factors such as marital status, smoking history, social isolation, and low education levels also place individuals at risk (Dent, E., et al. 2019; Dent, E., et al. 2019). Research suggests that frailty increases with the number of health deficits and the presence of multiple comorbidities. Higher rates of frailty have been documented in patients diagnosed with diabetes, respiratory disease, stroke, dementia, multiple sclerosis, connective tissue disease, osteoarthritis, and chronic fatigue syndrome (Liu, X., et al. 2019).

There is currently no recommendation to routinely screen for frailty. However, to optimize care and communicate appropriately with families, clinicians may need to identify at-risk patients and those who may already be frail (Hsieh, T.J., et al. 2019). Frailty is not defined by a single patient-reported symptom or physical examination finding, and no single laboratory test or imaging study can diagnose frailty. Instead, frailty is assessed through a comprehensive history and physical examination, focusing on several key elements (Arrieta, H., et al. 2019). A patient considered frail should be assessed using validated frailty assessment tools. A suggested approach to optimizing preoperative care is presented, which includes recommendations for identifying underlying physical disability, malnutrition, cognitive dysfunction, and mental health diagnoses following frailty assessment (Braun, T., et al. 2019).

The fundamental concept of prehabilitation is to increase an individual's functional capacity to withstand an anticipated injury. It embodies the idea of a proactive approach to rehabilitation, as opposed to the reactive approach commonly used in rehabilitation (Esser, T., Zimmer, P., Schier, R. 2022). While the initial prehabilitation model was limited to physical training, it has evolved into a multimodal entity that, in addition to exercise programs, includes nutritional optimization, psychosocial preparation, and smoking cessation. Over the past decade, there has been an increasing effort to coincide prehabilitation with surgery, as surgery is rightfully perceived as a stressor for human structural and physiological functions (McIsaac, DI., et al. 2022).

5. PURPOSES

The aim of the study is to determine the effect of prehabilitation care on patient outcomes.

6. EXPECTED BENEFITS FROM THE RESEARCH

Frailty is an increasingly recognized risk factor for surgery. The degree of frailty and how it may impact postoperative recovery profiles are unclear. Preoperative frailty may predispose patients to poorer outcomes in cardiac surgery; however, there are limited data on how preoperative frailty impacts patient outcomes through prehabilitation practices.

7. TYPE OF RESEARCH

☒**Prospective** ☐**Retrospective**
Descriptive studies
☐Descriptive
Analytical studies
☐Observational studies
☐Cross-sectional studies
☐Cohort studies (prospective, retrospective, bidirectional)
☐Case-control studies
☐Qualitative analyses
☐Survey studies
☐Case-control studies
☒Randomized
☐Non-Randomized
☐Self-Control (Paired Series)
☐Cross-Checked
☐Externally Controlled
☐Those Without a Control Group
☐Meta-Analyses
☐Methodological Research
☐Experimental Studies (No Direct Intervention, No Drug or Medical Device Studies)
In vitro studies
☐Studies to be conducted with blood, urine and pathology collection materials
☐Cell and tissue culture studies
☐Studies with genetic material that are for identification purposes and are not included in gene therapy clinical trials

8. POPULATION TO BE STUDIED

How was the sample size decided: It was decided by G-power analysis.
Number of volunteers planned to be included: 30+30
Volunteer Age Range: 60+
• Agreeing to participate in the research, • Undergoing elective open coronary artery bypass grafting • Being 60 years old or older, • Being in the frail patient status as a result of the FRIED Frailty Scale, • Being able to communicate in Turkish.
Exclusion Criteria: Patients whose surgery has been postponed and those whose mini mental test result is 23 or below will not be included.
Gender: Male and female
Are there any vulnerable groups/individuals (children, disabled people, unconscious individuals) planned to be included? ☐Yes ☒No

9. RESEARCH METHOD

Data for the study will be collected in two stages. In stage 1, patients will be visited before surgery (3-4 weeks before for the intervention group, 1 day before for the control group) and informed about the researchers and the study. Patients who agree to participate and meet the inclusion criteria will be included in the study. Patients will be interviewed face-to-face, and they will complete a patient information form prepared by the researchers based on literature, a mini nutritional test, a 6-minute walk test, and the Borg scale. The intervention group will receive prehabilitation, while the control group will receive routine procedures. Postoperatively, patients will complete a patient information form before discharge, and on the 30th day after surgery, a mini nutritional test, an activities of daily living scale, a postoperative recovery index, a 6-minute walk test, and the Borg scale.

10. RESEARCH PRODUCT / TREATMENT

No products or drugs will be used in the study.

11. RESEARCH DESIGN / METHOD

The study was planned as a randomized controlled trial.

12. PROCEDURE TO FOLLOW

The study was planned as a randomized controlled trial to be conducted at the cardiovascular surgery clinic of the Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital. Patients meeting the sample selection criteria will be included in two groups. Data will be collected using a patient information form, mini nutritional test, Borg scale, activities of daily living scale, and postoperative recovery index. A 6-minute walk test will be administered and recorded. All data will be collected by the researchers.

13. EVALUATION AND PARAMETERS TO BE RECORDED

Patients will be interviewed face-to-face and a "Patient Information Form," prepared by the researchers based on literature, will be completed. A mini mental test and frailty scale will be used to select patients. A preoperative mini nutritional test, comorbidity scale, 6-minute walk test, and Borg scale will be used for both groups. A patient information form and complication classification will be completed before discharge. On the 30th postoperative day, a mini nutritional test, activities of daily living scale, postoperative recovery index, 6-minute walk test, and Borg scale will be used.

14. RESEARCH CENTERS

Center: Republic of Turkey Ministry of Health, SBU. Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital

Researcher Name Surname: Gamze Ataman Yıldız

15. STATISTICS

The data obtained in the study will be analyzed using SPSS 25.0. Descriptive statistical methods such as number, percentage, mean, and standard deviation will be used in the data analysis. Based on the results, the data will be analyzed using relevant tests (t-test, chi-square, Man-Whitney U, Fisher's exact, and regression analysis).

H0: Prehabilitation does not affect patient outcomes in fragile cases undergoing elective coronary artery bypass grafting.

H1: Prehabilitation affects patient outcomes in fragile cases undergoing elective coronary artery bypass grafting.

16. SUB-STUDY

No.

17. INFORMED VOLUNTARY CONSENT

Before the surgery, the patient will be visited in the room, informed and consent will be obtained before data collection.

18. RESEARCH BUDGET

Budget
Coverage of research expenses & Sponsor declaration *(The costs of tests and laboratory examinations performed on volunteers for research purposes cannot be covered by public or private health insurance, nor can they be paid by the volunteers. The costs of all research-related procedures, such as printing survey/interview forms, fees for services such as consultancy, tests, and laboratory examinations received from within or outside the institution, reimbursement of volunteer expenses, telephone charges to reach volunteers, payments to researchers/interviewers, etc., must be planned and their source must be explained.)*
☒There are no anticipated expenses.
☐Research Funds (TÜBİTAK etc. Please write the name: .....
☐Other (Please Explain): .....

Research expense items *(Adjust the possible expense items below according to your research. You can add or remove items if necessary. If there are no projected expenses, leave them blank.)*	**AMOUNT**
☐Payments to researchers	
☐Payments to be made to the research institution	
☐Payments to be made to volunteers	
☐Service purchases from the research site	
☐Service purchases outside the research site	
☐Consumable purchases	
☐Stationery purchases	
☐Travel expenses	

19. LITERATURE

1. Chia-Hui Chen, C., Yang, YT, Lai, IR, Lin, BR, Yang, CY, Huang, J., Tien, YW, Chen, CN, Lin, MT, Liang, JT, Li, HC, Huang, GH, & Inouye, SK (2019). Three Nurse-administered Protocols Reduce Nutritional Decline and Frailty in Older Gastrointestinal Surgery Patients: A Cluster Randomized Trial. *Journal of the American Medical Directors Association* , *20* (5), 524–529.e3. https://doi.org/10.1016/j.jamda.2018.09.016
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