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Protocol Article

Early remote rehabilitation to improve health of the elderly after cardiac surgery – study protocol for a randomised trial

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ABSTRACT

INTRODUCTION. Early rehabilitation is recommended after cardiac surgery to enhance recovery. However, due to precautions of sternum healing, the initiation of cardiac rehabilitation is often postponed for 6-8 weeks after surgery, leaving patients to face physical and emotional barriers on their own. This study aims to investigate whether early remote cardiac rehabilitation can enhance physical function and reduce the emotional challenges that older patients face after discharge.

METHODS. In this bi-entre, randomised controlled trial, 120 patients older than 65 years of age undergoing open heart surgery are assigned to individualised exercise training and step counting supported by a mobile health app and weekly calls with a physiotherapist as an adjunct to standard care (intervention group), or standard care alone (control group) for six weeks after discharge. Outcomes are assessed at baseline, a six-week follow-up and a six-month follow-up. The primary outcome is change in the 30-second Chair Stand Test. Secondary outcomes include health-related quality of life, cost-effectiveness and prevalence of sarcopenia.

CONCLUSIONS. This trial will determine if early remote rehabilitation after cardiac surgery can accelerate recovery and alleviate emotional distress, advocating for early post-discharge interventions through digitally delivered care.

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TRIAL REGISTRATION. ClinicalTrials.gov NCT06370611.

A growing number of older patients undergo heart surgery [1]. This patient group often suffers from multiple chronic diseases and may experience prolonged recovery with decreased physical functioning, alongside feelings of frustration and fear, and may never return to normality [2, 3]. Sarcopenia, the age-related loss of muscle mass and strength, is expected to be prevalent in this vulnerable population. Older patients who suffer from sarcopenia after heart valve surgery have shown significantly decreased long-term survival and are more likely to suffer from adverse cardiac and cerebrovascular events than older patients without sarcopenia [4].

Immediate comprehensive cardiac rehabilitation (CR) is recommended after cardiac surgery to enhance recovery and improve overall outcomes [5]. CR has shown the potential to positively affect overall mortality, myocardial infarction and all-cause hospitalisation. CR also affects health-related quality of life and is cost-effective in terms of gain in quality-adjusted life years after heart valve and bypass surgery [6].

However, initiation of CR is often postponed for six to eight weeks after surgery as upper body training may affect sternal healing [7]. In this critical period, patients are left to overcome physical and emotional barriers on their own. Research suggests that starting rehabilitation within the first few weeks after surgery is as safe and effective as postponing it for six weeks [8, 9]. Advancements in digital healthcare offer a promising opportunity to investigate the potential of remote rehabilitation in supporting early recovery and improving outcomes in older cardiac surgery patients.

Delays in rehabilitation may lead to muscle loss and slow recovery in older patients undergoing cardiac surgery. We hypothesise that remote rehabilitation in the early post-operative phase will enhance their physical and psychological outcomes.

This study aims to investigate whether early individualised remote CR can enhance physical function and reduce the emotional challenges faced by older cardiac surgery patients after discharge. In addition, we examine whether the intervention is safe and feasible, enhances quality of life, prevents sarcopenia and demonstrates cost-effectiveness.

Methods

Study design

Design

This study is an investigator-initiated, bi-centre, prospective, randomised controlled, parallel-arm, open-label, blinded endpoint trial with a superiority design. The trial is conducted at the cardiac surgery departments of two Danish university hospitals. The study population comprises 120 older patients scheduled for open heart surgery. The inclusion and exclusion criteria are presented in **Table 1**.

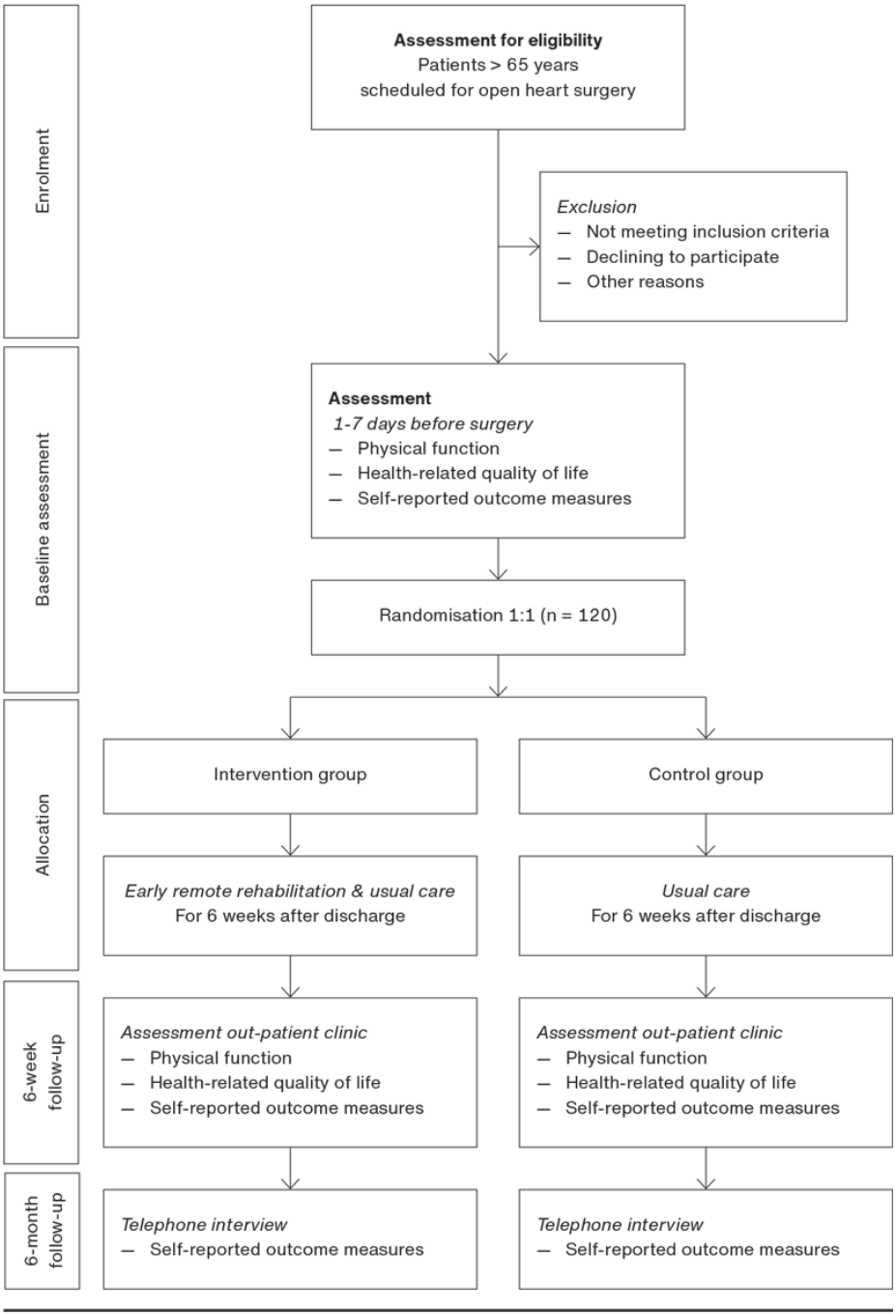
TABLE 1 Inclusion- and exclusion criteria.

Type	Description
Inclusion criteria	*To be eligible to participate, patients must meet all the following criteria*
	Scheduled for 1st-time heart surgery through median sternotomy
	≥ 65 yrs of age
	Provision of signed informed consent form
Exclusion criteria	*Patients who meet any of the following criteria will be excluded from participation in this study*
	Medical conditions requiring referral to specialized rehabilitation, e.g., severe heart- or lung failure, need for blood pressure monitoring during exercise
	Emergent procedures: within 24 h
	Anticipated inability to adhere to intervention, study assessment procedure, or follow-up
	Participation in any other interventional clinical study that may confound the outcome measures

Participants are randomly allocated (1:1) to receive exercise training supported by a mobile health application and weekly calls from a physiotherapist as an adjunct to standard care (intervention group), or standard care alone (control group) for six weeks after discharge. Outcomes are measured at baseline (within 1-7 days before surgery), at the end of the intervention (six-week outpatient follow-up) and at six months (six-month phone-

based follow-up). The patients' pathway through the study is shown in **Figure 1.**

FIGURE 1 Trial flow chart.



Enrolment procedure

All patients scheduled for elective cardiac surgery are screened for eligibility through electronic patient records. Eligible patients receive written and oral information about the study before their inclusion, along with a link to a short online video explaining the study in layman's terms [10].

Randomisation and blinding

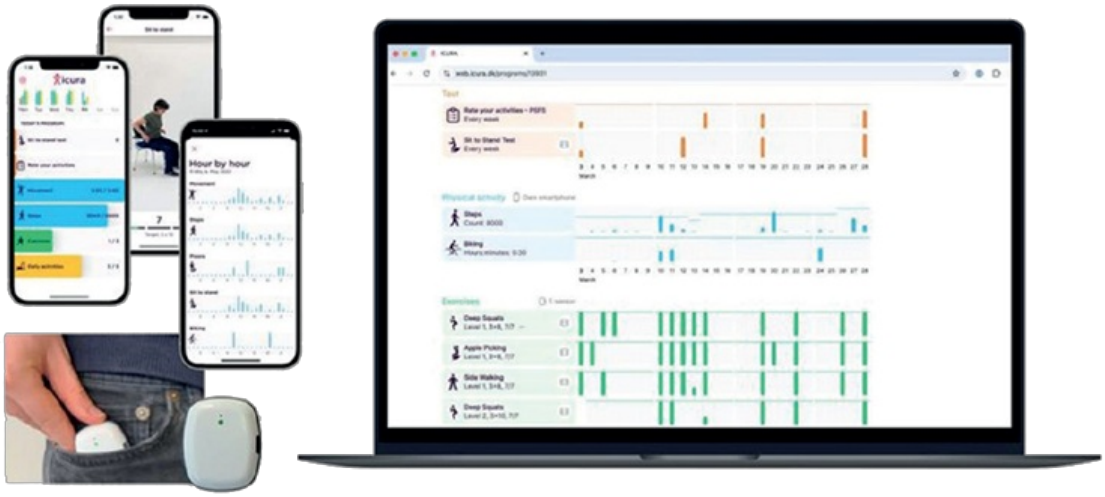
Before randomisation, blinded study personnel conduct baseline data assessment during the patients'

preoperative preparation visit. Patients are allocated to the intervention or control group in a 1:1 ratio using block randomisation. We stratify allocation by gender to account for the fact that fewer women undergo open heart surgery. The allocation sequence is generated using the secure web-based data management tool Research Electronic Data Capture (REDCap) hosted by Aarhus University [11, 12]. A blinded assessor collects follow-up data to minimise bias, after which blinding is lifted for structured interviews with the intervention group to assess feasibility.

Study intervention

Patients in the intervention group engage in home-based supervised exercise training for six weeks after discharge using the ICURA application and sensor-based technology (ICURA ApS, Copenhagen, Denmark). Patients are introduced to the application at baseline and receive a brief follow-up on using the equipment from the departmental physiotherapist before discharge. The intervention includes daily step count, a customised exercise programme and visualisation of exercises with videos, **Figure 2**. The initial training programme consists of three exercises: sit-to-stand, shoulder flexion and gluteal extension. These exercises have been selected to ensure minimal strain on the sternum. During the intervention, patients are contacted weekly by phone by a physiotherapist to discuss training progress, adjust the exercise programme, provide support and offer general post-operative advice. Compliance is assessed using sensor live feedback from the sensor system. Both the intervention and the control group receive standard care during hospitalisation consisting of physiotherapy education on mobilisation, respiratory care and sternal precautions. They are encouraged to walk daily, resume daily activities and engage in moderate physical activity (Borg scale 12–14). In line with Danish healthcare regulations, all patients are referred for CR in their local municipalities.

FIGURE 2 Mobile health application for remote cardiac rehabilitation. The mobile health application, accessible on the patient's smartphone, features integrated sensor technology to monitor daily step counts and deliver a personalised exercise programme. The equipment is provided in a compact carrying case. Patient progress is monitored by the physiotherapist through a secure web-based platform.



Outcome measures

All outcome measures are outlined in **Table 2**.

TABLE 2 Outcome measures.

Outcome variable	Instrument	Assessment time point
Physical function		
Physical function	Δ 30-Second Chair Stand Test[a, b]	Baseline, 6-wk FU
Gait speed	Δ 10-Metre Walk Test[a]	Baseline, 6-wk FU
Functional physical capacity	6-Minute Walk Test[a]	6-wk FU
Patient-reported outcome measures		
Health-related Quality of Life	Δ EuroQol-5-Dimension-5-Level Questionnaire[a]	Baseline, 6-wk FU, 6-mo. FU
Self-reported well-being, depression and anxiety	Δ 5-Item World Health Organization Well-being Index[a] Δ Major Depression Inventory-2[a] Δ Anxiety Symptom Scale-2[a]	Baseline, 6-wk FU, 6-mo. FU
Self-reported Physical Activity	Δ questionnaire assessing self-reported physical activity	Baseline, 6-wk FU, 6-mo. FU
Evaluation of feasibility	Semi-structured interviews	6-wk FU, 6-mo. FU
Substudy 1: Assessment of sarcopenia		
Skeletal muscle mass	Δ CT scan	Baseline, 6-wk FU
Muscle quality	Immunohistochemical assessment of pectoralis major muscle	On the day of the surgery
Markers of musculoskeletal health, inflammation, nutrition, liver function, kidney function, and hormone levels	Δ blood sampling	Baseline, 6-wk FU
Substudy 2: Economic evaluation		
Cost-effectiveness analysis	Questionnaire assessing the cost-effectiveness of the intervention in comparison to usual care	Baseline, 6-wk FU, 6-mo. FU

FU = follow-up.
a) Danish validated version.
b) Primary outcome.

Primary outcome

The primary outcome measure is change in the 30-second Chair Stand Test (30CST) as a measure of physical function between baseline and six-week follow-up [13]. Results can be categorised on age-specific reference ranges. Comparing changes in 30CST score between the groups will allow for direct assessment of treatment effect and optimal accounting for individual baseline variations.

Secondary outcomes

Physical function is further assessed through the measurement of gait speed, using the ten-meter walking test [14]. A six-minute walk test is used at the six-week follow-up to measure functional physical capacity [15]. The assessment of the six-minute walk test is not conducted at baseline as we expect the patients' performance to be primarily affected by their underlying heart disease rather than their baseline physical capacity.

Health-related quality of life is assessed with the standardised EuroQol-5-Dimension-5-Level Questionnaire (EQ-5D-5L) [16]. Well-being, depression and anxiety are measured with the five-item World Health Organization Well-being Index, the Major Depression Inventory-2 and the Anxiety Symptom Scale-2, respectively [17].

Furthermore, we employ seven selected questions sourced from the Danish National Health Profile to assess self-reported physical activity [18].

Sub-study 1: Sarcopenia assessment

We investigate sarcopenia prevalence and muscle health status to understand how heart surgery and early rehabilitation influence skeletal muscle.

All patients are examined with low-study cardiac computed tomography (CCT) images without contrast at baseline and at the six-week follow-up. The CCT images are analysed with artificial-intelligence-assisted medical image analysis (DAFS, Veronoi Health Analytics, Vancouver, Canada) to assess the quantity and quality of skeletal muscle.

Muscle health is assessed through immunohistochemistry analysis of small (0.5 × 2 cm) pectoralis major muscle biopsies, which are readily exposed during median sternotomy and collected at the beginning of surgery, before administration of heparin.

Biochemical markers of musculoskeletal health, inflammation, nutrition, liver function, kidney function and hormone levels are analysed.

Sub-study 2: Economic evaluation

We evaluate the cost-effectiveness of the intervention. Resource use and costs are assessed using a questionnaire with patient registrations and recordings of hospital visits in the administrative system. The difference in costs between groups will be analysed in conjunction with change in 30CST and EQ-5D-5L scores at the six-week and six-month follow-ups. The cost-effectiveness analysis will calculate the incremental cost-effectiveness ratio, expressing the cost per effect unit gained.

Pilot study

Prior to this study, we evaluated the mobile health application in the target population [19]. Our findings indicated that the intervention after cardiac surgery effectively supported recovery and encouraged physical activity in older patients. However, the pilot highlighted a need for further individualisation to address the users' diverse needs and experiences. Several key adjustments in organisational and communication aspects were implemented. Importantly, the application's built-in chat function proved insufficient for feedback. Therefore, regular phone calls were introduced. We also ensured interdisciplinary collaboration to address issues related to anxiety, depression and any post-operative complications.

Statistical considerations

Sample size calculation

The primary outcome measure is the difference in 30CST as a measure of physical function at the six-week follow-up. We defined the minimal clinically important difference as two repetitions, consistent with prior research on pulmonary rehabilitation [20]. Based on this, a population standard deviation of three, a significance level of 0.05 and a statistical power of 95%, an estimated 60 patients were needed in each group.

Statistical analysis

The primary analysis will adopt an intention-to-treat approach. Variables will be displayed as mean ± standard deviation for normal distributions assessed by quantile-quantile plots, or otherwise as median (IQR). Group comparisons will use statistical tests, such as the unpaired t-test or the Mann-Whitney U test, as applicable. Changes over time will be analysed using paired t-test or Wilcoxon signed-rank test for two time points (baseline and six-week follow-up), and repeated measures ANOVA or the Friedman test for three time points (baseline, six-week and six-month follow-ups). A p value < 0.05 is considered significant.

Organisation and ethics

The study protocol has been approved by the Danish National Medical Research Ethics Committee (31 January 2024, no: 2314027) and the Internal Registry of Research Projects in the Central Denmark Region (30 January 2024, no: 1-16-02-33-24).

Trial registration: ClinicalTrials.gov (NCT06370611).

Data sharing statement

In pursuance of the International Committee of Medical Journal Editors Data Sharing Statement, data sharing does not apply to this article as no new data were created or analysed. The full protocol, statistical analysis plan

and informed consent form are available upon reasonable request. The trial is conducted in accordance with the Helsinki Declaration, with all patients providing written informed consent before participation. The study is internally monitored following good clinical practice guidelines. Trial enrollment was initiated in May 2024 at the sponsor institution and in August 2024 at the second site, with completion expected by the end of 2025. As of 20 May 2025, 80 patients have been enrolled, 62 have completed the intervention and 34 have reached the six-month follow-up.

Conclusions

This trial will determine whether early remote rehabilitation after cardiac surgery can accelerate recovery and alleviate emotional distress. By delivering rehabilitation remotely, the study explores a practical solution for patients who face logistical or physical challenges accessing in-person sessions, aiming to provide vital support during the critical early recovery period. The study, conducted at two sites, also evaluates safety, feasibility, and cost-effectiveness, providing valuable insights for future CR guidelines.

Disclosure

This trial is part of a broader project focused on integrated CR pathways supported by public funds: the Novo Nordisk Foundation, the Health Foundation and the Eva & Henry Frænkels Memorial Fund.

Use of artificial intelligence

The authors' language editing was assisted by AI (ChatGPT).

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References can be found with the article at ugeskriftet.dk/dmj

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