

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

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

Authors

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VERSION 1 - REVIEW

Reviewer	1
Name	Zhang, Dr Jufen
Affiliation	Anglia Ruskin University
Date	04-Oct-2024
COI	None

This's an interesting study but research methodology regarding sample size and outcome measures (primary and secondary) needs to be clear.

It looks that there were many variables that were considered as primary outcomes. A sample size calculation should have been done for all those outcomes and the main sample size analyses should have been described in the manuscript. All other outcomes should be interpreted as exploratory analyses and should be interpreted with care. However, it's not clear how the sample size of 52 (26 for each group) was calculated.

Primary and secondary objectives were not clear.

It seems that the progression criteria were not considered.

Suggest including the study period and the dates of the study. Please make it clear if the study is a planned or ongoing study.

P.6, lines 20-22. "The control group will receive standard care, while patients in the intervention group will receive the PreCABG intervention.". It's not clear if patients in PreCABG intervention will receive the standard care as well.

P.9, lines 25-27. "Patients will be admitted to separate rooms to prevent interaction between control and intervention groups.". Please indicate if patents in the same room will receive the same intervention or each room has one patient only.

Reviewer	2
Name	suzuki, ryoko
Affiliation	Bristol-Myers Squibb Co, Cardiovascular Medical
Date	06-Oct-2024
COI	None

This is a very important study in real clinical practice.

One of the challenges is the potential need to ensure the quality of prehabilitation programmes. When looking at the positive effects of a multi-component prehabilitation programme, the components of the programme need to be implemented properly. In terms of protocols, there may be a need to assess whether or not prehabilitation has been carried out by patients, and to use quality assurance measures to identify which elements have not been achieved. For example, if there is variation in the frequency and duration of respiratory training, or in the degree of detailed implementation of the nutrients to be ingested, it is difficult to evaluate the results, even if they are to be interpreted comprehensively.

VERSION 1 - AUTHOR RESPONSE

Dear Dr. Jufen Zhang,

Thank you for your valuable comments on our study. After reviewing the methodology and consulting with our epidemiologist, we have made the following changes to our objectives:

Primary Outcome:

The primary measured variable in this study is readiness for discharge.

Secondary Outcomes:

These include:

Number of hospital readmissions,

Duration of intubation,

Length of ICU stay,

Occurrence of atelectasis,
Timing of the first mobilization,
Total length of hospital stay,
Levels of anxiety and depression during hospitalization.

We acknowledge that, ideally, the sample size should be calculated based on all outcomes, selecting the one requiring the largest sample size to ensure adequate power for all analyses. However, due to constraints in patient availability and the limited time frame of this research (as it constitutes my master's thesis), we have opted to focus on readiness for discharge as the sole primary outcome.

The sample size calculation was based on a similar study (reference: [85]). Using the following assumptions and hypotheses, the sample size was determined to be 26 participants per group. Accounting for a 15% attrition rate, the final required sample size is 30 participants per group, for a total of 60 participants.

Mean Readiness for Discharge Score: 7.11 ± 0.59

Effect Size (d): 0.71

Significance Level (α): 0.05

Power ($1 - \beta$): 80% ($\beta = 0.2$)

Attrition Rate: 15%

Allocation Ratio: 1

We included the progression criteria. we did not mention it in the initial manuscript because we didn't see it included in other printed research in this journal.

In the "Trial status" subtitle we stated that "The recruitment for this study began in April 2024 and is estimated to end in December 2024."

In p.6, lines 4-5 we stated that " Both control and intervention groups will receive routine care, including drug therapy and hemodynamic monitoring."

The following statement is added to the manuscript in the blinding section "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." we did not add this initially because we were pessimistic about our ability to admit the patients in the private room.

Dear Dr. Ryoko Suzuki,

Thank you for your kind words and valuable feedback on our study. We have implemented a logbook in which patients will record the number of training sessions completed and the duration of each session. During the initial session, the interventionist will provide instruction on using the spirometer and other techniques. The accuracy of the patient's technique will be assessed, and if necessary, additional teaching sessions will be provided until the patient is proficient. Given 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.

VERSION 2 - REVIEW

Reviewer	1
Name	Zhang, Dr Jufen
Affiliation	Anglia Ruskin University
Date	06-Jan-2025
COI	

The authors have responded well to my previous comments.