

# Efficacy of Early Respiratory Physiotherapy and Mobilization After on-pump Cardiac Surgery: a Prospective Randomized Controlled Trial

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## Research article

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# Abstract

**Objective:** This randomized controlled trial aimed to investigate the influence of physical activity and respiratory physiotherapy on zero postoperative day on clinical, hemodynamic and respiratory parameters of patients undergoing cardiac surgeries under extracorporeal circulation.

**Methods:** 78 patients undergoing coronary artery bypass graft (CABG) or/and valvular heart disease surgeries were randomly assigned into active physiotherapy group (APG; n=39) and conventional physiotherapy group (CPG; n=39). Treatment protocol for APG included  $\leq 3$  Mets of physical activity and respiratory physiotherapy on zero post-operative day and an extra physiotherapy session during the first three post-operative days, whereas CPG was treated with usual physiotherapy care after the first post-operative day. The length of hospital and intensive care unit (ICU) stay were set as the primary study outcomes, while pre- and post-intervention measurements were also performed to assess the oxymetric and hemodynamic influence of early mobilization and physiotherapy.

**Results:** Participants' mean age was  $51.86 \pm 13.76$  years. Of them 48 (61.5%) underwent CABG. Baseline and peri-procedural characteristics did not differ between the 2 groups. The total duration of hospital and ICU stay were significantly higher in the CPG compared to the APG ( $8.1 \pm 0.4$  versus  $10.2 \pm 0.6$  days and  $32.1 \pm 1.7$  versus  $23.2 \pm 0.6$  hours,  $p < 0.001$ , respectively). Statistically significant differences in pre-intervention oxygen saturation, and post-intervention PO<sub>2</sub> and lactate levels were also observed between the 2 groups ( $p = 0.022$ ,  $0.027$  and  $0.001$ , respectively).

**Conclusion:** In on-pump cardiac surgery, early and active post-procedural physical activity ( $\leq 3$  METS) can prevent prolonged ICU stay and decrease the duration of hospitalization whilst ameliorating post-operative hemodynamic and oxymetric parameters.

## Introduction

Millions of patients benefit annually from open heart surgery, while the actual number of such operations in western countries remains stable over the last decade, despite the current advancements in cardiovascular medicine, offering pharmacological or minimally invasive alternatives[1, 2]. However, open heart surgeries are still associated with increased risk for cardiovascular morbidity, respiratory complications and prolonged length of intensive care unit (ICU) stay and hospitalization, which increases the financial healthcare burden[3]. Concurrently, physiotherapy and early physical activity have been considered as crucial factors with a seemingly positive impact on post-procedural functional capacity, muscle weakness, prevention or mitigation of post-operative complications succeeding heart surgery, and thereby leading to quality of life amelioration[4].

Nevertheless, despite the apparent sequelae of reduced mobility and subsequent muscle weakness in patients undergoing open heart surgery, the effect of the extent and timing of early respiratory physiotherapy and mobilization on the length of ICU stay in cardiothoracic patients, has not been thoroughly investigated[5]. Furthermore, significant variability exists in physiotherapy strategies and early

mobilization practices[6]. Several studies have attempted to examine whether physiotherapy and rehabilitation might be an effective non-pharmacological tool to improve post-operative outcomes and reduce hospitalization stay[7–11]. Nonetheless, none of them investigated the influence of intensified/intensive post-operative physiotherapy and rapid mobilization.

On the basis of the above, we conducted a randomized-controlled trial to investigate the influence of enhanced post-operative physiotherapy and mobilization on patients undergoing open heart surgery. In particular, we aimed to inquire into the potential impact of early mobilization and physical activity combined with extra sessions of active post-operative physiotherapy, on the duration of ICU stay and hospitalization, as well as on clinical and laboratory parameters following open heart surgery.

## **Methods**

### **Study Design and Sample Size Calculation**

A double-blinded randomized clinical trial was designed to investigate the effect of respiratory physiotherapy and early mobilization and exercise on patients undergoing cardiac surgery [coronary artery bypass grafting (CABG) or valvular surgery] under extracorporeal circulation. The protocol of the study and all trial procedures conformed to the CONSORT Statement recommendations for reporting randomized trials[12].

Based on a minimum effect size of interest approach to calculate the sample size required to detect a statistically significant difference between the intervention group and the control group in terms of the primary outcome, 80 study participants (40 in each group) were required to have a 90% power to detect the effect at a significance level of 0.05.

### **Study Participants and Eligibility Criteria**

Patients admitted to the University Cardiothoracic Surgical Departments of the University Hospitals of Thessaly and Thessaloniki between February 2019 and December 2020 to undergo elective CABG or valvular surgery with cardiopulmonary bypass were randomly allocated to control group (CPG) or active physiotherapy group (APG) to be included in this trial.

Patients of both genders were invited to participate in this study without any race limitation. The inclusion criteria consisted of: i. a written informed consent to participate in the study, ii. a Glasgow Coma Scale score=15, as well as iii. musculoskeletal, and cardiopulmonary conditions suitable for the accomplishment of the proposed activities. On the contrary, patients were excluded from the study if they met one or more of the following criteria: i. emergency, non-elective cardiac surgery ii. hemodynamic instability preventing protocol performance, iii. breathing discomfort or invasive ventilator support or oxygen saturation below 90%, iv. severe neurological sequelae or neurodegenerative disorders, and v. any mobile disability that did not permit to perform exercise according to our protocol.

### **Random Allocation and Blinding**

Patients were randomly assigned to an APG (n=39) or to a CPG (n=39). Eligible participants were allocated in each group in turn, according to the date of hospital admission. The anaesthesia, peri- and post-surgical management procedures were standardised for all patients (*ECMO: Medtronic Performer CPB, Oxygenation System: Medtronic Affinity NT, Autotransfusion System: Medtronic Autolog IQ, Heater-Cooler System: Stockert Basic Heater-Cooler Unit, Online Monitoring System: Spectrum Medical System M, Intra-Aortic Balloon Pump: Maquet Datascope GS300, Blood Flow Meter: Medistim MiraQ™ system, post-extubation: Venturi mask 50% oxygen flow rate*) and were performed by the same team of Cardiothoracic surgeons and Emergency and Critical Care technicians in the cardiothoracic surgery department of general university hospital of Larissa

The study was a double-blinded trial so that the participants were unaware of the existence of the other group. The blinded researcher was also not aware of the group of patients; whether they were in the CPG or in the APG. After collecting the data, the blinded researcher measured the defined outcomes of interest.

## Intervention

Usual physiotherapy care was applied to participants of the CPG twice a day commencing on the first post-operative day until their discharge. This routine physiotherapy care included deep breathing exercises, coughing, limb mobility exercises on bed, incentive spirometer, chest percussion, and 10 to 50 steps of walk, twice a day. On the contrary, patients, allocated to the APG group, were provided with an extra physiotherapy session during first three post-operative days or until ICU discharge.

Except for the aforementioned enhanced physiotherapy strategy, patients of the APG also received an early physiotherapy session performed during zero post-operative day in the ICU. This early and active physiotherapy strategy involved early mobilization and physical activity along with chest physiotherapy on zero postoperative day, as described below:

1. Respiratory physiotherapy included guided deep breathing techniques, utilization of the TriFlo Inspiratory Exerciser, incentive spirometer exercises, chest splinting by cushion, chest binder or using passive assistance of physical therapist, and patients were instructed to cough out, accompanied by moderate intensity chest percussion as per requirement.
2. Physical activity consisted of supported sitting over the edge of bed at bed side, performed on the first hours after extubation, assisted by the Subsequently, patients were mobilized out of bed standing for 1-2 minutes and 10 steps of static walk, along with deep breathing exercises, followed by sitting on the chair beside bed for half an hour, thereby achieving an estimated energy expenditure of no more than 3 metabolic equivalents of physical activity.

Briefly, the APG intervention comprised of an early mobilization and physiotherapy strategy during zero post-operative day, and an extra physiotherapy session taking place in the afternoon of the first three post-operative days or until ICU discharge. All physiotherapy interventions were undertaken by trained physiotherapists who were unaware of the existence of 2 study groups and were also assisted by nurses and doctors of the ICU.

# Ethical Considerations

The study protocol has been approved by the Institutional Review Board of Aristotle University of Thessaloniki, and the trial was conducted in compliance with the principles stated by the Declaration of Helsinki.

## Recorded variables and measurements performed

The measurements detailed in this section were taken before and after completion of the APG physiotherapy protocols on zero post-operative day. Despite no physiotherapy session was performed in the CPG on zero post-operative day, the following hemodynamic and laboratory measurements, as well as clinical and demographic parameters were also recorded for the CPG, aiming to perform inter-group comparison analyses. After admission to the ICU, arterial and central venous, and mixed venous blood samples were taken to accomplish these hemodynamic and laboratory measurements.

The demographics included data on: gender, age, body mass index (BMI) and cardiac surgery performed. Hemodynamic measurements included monitoring of body temperature, heart rate, respiratory rate, blood pressure, and oxygen saturation. Laboratory measurements consisted of serum electrolytes ( $\text{Ca}^{2+}$ ,  $\text{Na}^+$ ,  $\text{K}^+$ ), glucose and hemoglobin values as well as arterial blood gas analyses (pH,  $\text{SvO}_2$ ,  $\text{PO}_2$ ,  $\text{PCO}_2$ ,  $\text{HCO}_3$  and lactate). Echocardiographic and electrocardiographic assessment has been also performed in every participant to record baseline left ventricular ejection fraction (LVEF) values via the Modified Simpson method (biplane method of disks) and to document the occurrence of any cardiac arrhythmia, respectively.

Further procedure-related data have been recorded to perform relevant inter-group comparisons. In particular, we documented: length of hospital stay (in days), length of ICU stay (in hours), duration of extracorporeal membrane oxygenation (ECMO) and aortic cross-clamp time (in minutes), number of coronary artery grafts as well as units of red blood cells (RBC) and fresh frozen plasma (FFP) transfused.

## Definition of study outcomes

The primary outcome of this study was to identify any existing difference in the length of hospital and ICU stay between participants of the APG and those of the CPG. Secondary outcomes of interest were the comparisons of hemodynamic and laboratory measurements between the 2 study groups to detect any difference according to the physiotherapy protocol applied.

## Statistical analysis

Categorical variables are presented as frequencies with percentages, and continuous ones as means with standard deviations. Comparison among categorical variables was performed via the Pearson chi-square or Fisher's exact test, whereas the Wilcoxon rank-sum or Student's t-test were used to compare continuous variables, depending on the normality of data distributions. All analyses were conducted with the SPSS Statistics for Windows, Version 24.0 (Armonk, NY: IBM Corp) and a two-sided p value of less than 0.05 was considered as statistically significant.

## Results

After applying the inclusion and exclusion criteria, 78 patients (65 men, 13 women; mean age: 64.3±8.9 years old) were finally included in this study among the 90 patients initially assessed for eligibility. Four patients died during surgery, three surgeries were cancelled and three surgeries were performed without the use of extracorporeal circulation and two patients refused to participate in the study. Figure 1 describes the flowchart of patient participation; 39 patients were randomly allocated to the APG and 39 others to the CPG.

The baseline, pre- and post-operative data are summarized in Table 1 and show that after randomization, the two groups had similar characteristics regarding gender, age, and BMI. Surgical procedure data were also comparable between groups, demonstrated by similar ECMO time, aortic cross clamp time, type of surgery performed, number of coronary artery grafts and units of RBC and FFP transfused (all p-values>0.05).

Table 1  
Baseline demographic and clinical characteristics of study participants

Variable	APG (n=39)	CPG (n=39)	p-value
Age (years)	63.5 ± 8.9	65.1 ± 8.9	0.424
Male gender, n (%)	34 (87.2%)	31 (79.5%)	0.362
Body mass index (kg/m <sup>2</sup> )	26.8 ± 4.2	27.9 ± 4.2	0.234
Left Ventricular Ejection Fraction (%)	50±6	49.7±6.5	0.856
Type of surgery:			
Coronary artery bypass graft, n (%)	25 (64.1%)	23 (59%)	0.119
Aortic valve replacement, n (%)	9 (23.1%)	15 (38.5%)	
Mitral valve replacement, n (%)	5 (12.8%)	1 (2.5%)	
Coronary artery grafts (number)	3.1±0.8	3±0.8	0.593
Red blood cells transfused (units)	0.9±0.9	0.5±0.7	0.063
Fresh frozen plasma transfused (units)	1.9±1.1	1.9±1.2	0.772
Cardiopulmonary bypass time (CBT) (minutes)	100.1±21.3	99±27.7	0.848
Aortic cross-clamp time (minutes)	68.5±19.1	69.7±19.5	0.770

With regard to the primary outcome of this study (Table 2; Figure 2), patients of the APG had to stay in hospital for significantly less days than patients of the CPG (8.1±0.4 versus 10.2±0.6, p<0.001) after their surgery. The total duration of ICU stay was also significantly higher in the CPG compared to the APG

(32.1±1.7 hours versus 23.2±0.6 hours, p<0.001). Sub-analysis on the length of hospital and ICU stay according to the type of surgery performed did not demonstrate any significant difference (ANOVA: p=0.590 and 0.327, respectively).

Table 2  
Comparison of primary outcome parameters

Variable	APG(n=39)	CPG (n=39)	P value
Length of hospital stay after surgery (days)	8.1±0.4	10.2±0.6	<0.001
Length of stay in the intensive care unit (hours)	23.2±0.6	32.1±1.7	<0.001

The comparison of pre- and post-intervention laboratory, oxymetric and hemodynamic measurements between the 2 study groups is presented in Table 3 and yielded that most of the measurements did not differ significantly. In particular, pre- and post-intervention sodium, potassium, calcium, glucose, hemoglobin values were almost similar among the 2 groups (p-values>0.05) with an existing non-significant trend towards higher glucose levels in the CPG than those of the APG (pre-intervention: 153.5±39.1 mg/dl versus 140.6±25 mg/dl, p=0.087; and post-intervention: 156.8±33.5 mg/dl versus 146±24.1 mg/dl, p=0.105). Analyses on the observed respiratory rates, blood pressure levels, body temperatures, venous oxygen saturation, arterial blood pH and PCO2 levels did not yield any significant differentiation (p-values>0.05). However, mean arterial oxygen saturation was significantly higher in the CPG prior to the intervention (99% versus 98.1%, p=0.022) but non-significantly lower than that of the APG after the intervention (99% versus 99.4%, p=0.128). Finally, mean PO2 levels were significantly higher in the APG than in the CPG after the intervention (192.5±70.8 mmHg versus 159±60.2, p=0.027), whereas mean post-intervention lactate levels were significantly higher in the CPG when compared to those in the APG (1.5±0.7 mmol/L versus 1.1±0.2 mmol/L, p=0.001).

Table 3  
Comparison of pre- and post-intervention laboratory, oximetric and hemodynamic measurements

Variable	APC (n=39)	CPG (n=39)	p-value
Na <sup>+</sup> (mEq/L):			
Pre-intervention	137.3±2.6	139.1±6.6	0.105
Post-intervention	137.6±3	137.6±2.8	0.995
K <sup>+</sup> (mmol/L):			
Pre-intervention	4.0±0.4	4.0±0.7	0.729
Post-intervention	4.1±0.3	4.1±0.3	0.968
Ca <sup>2+</sup> (mg/dl):			
Pre-intervention	0.9±0.3	0.9±0.1	0.293
Post-intervention	0.9±0.2	0.9±0.1	0.488
Glucose (mg/dl):			
Pre-intervention	140.6±25	153.5±39.1	<i>0.087</i>
Post-intervention	146±24.1	156.8±33.5	<i>0.105</i>
Hemoglobin (g/dl):			
Pre-intervention	9.6±0.98	9.6±0.9	<i>0.813</i>
Post-intervention	9.8±1	9.8±0.9	<i>0.972</i>
Respiratory rate (breaths per minute):			
Pre-intervention	23.4±2.7	24.3±2.9	<i>0.183</i>
Post-intervention	24.3±2.8	24.9±1.7	<i>0.263</i>
Systolic arterial pressure (mmHg):			
Pre-intervention	130.4±14.2	127.1±16	<i>0.329</i>
Post-intervention	130.6±15.2	130.3±15.7	<i>0.942</i>
Diastolic arterial pressure (mmHg):			
Pre-intervention	59.1±8.5	63.9±19.8	<i>0.167</i>
Post-intervention	59.8±8	59.3±9.9	<i>0.803</i>

<b>Variable</b>	<b>APC (n=39)</b>	<b>CPG (n=39)</b>	<b>p-value</b>
Body temperature (°C):			
Pre-intervention	36.4±2.3	36.8±0.4	0.216
Post-intervention	37±0.4	36.9±0.3	0.424
Arterial oxygen saturation (%):			
Pre-intervention	98.1±1.9	99±1.2	0.022
Post-intervention	99.4±1	99±1.2	0.128
Venous oxygen saturation (%):			
Pre-intervention	61.8±6.8	58.4±9	0.187
Post-intervention	65.2±6.9	61.1±9.4	0.141
Arterial blood pH (pH):			
Pre-intervention	7.4±0.03	7.4±0.04	0.954
Post-intervention	7.4±0.04	7.4±0.04	0.951
PCO2 (mmHg):			
Pre-intervention	40.9±4.3	40±4	0.347
Post-intervention	40.6±4.9	40.9±4.3	0.787
PO2 (mmHg):			
Pre-intervention	137.5±63.8	149.4±68.3	0.430
Post-intervention	192.5±70.8	159±60.2	0.027
Lactate (mmol/L):			
Pre-intervention	1.5±0.6	1.6±0.7	0.694
Post-intervention	1.1±0.2	1.5±0.7	0.001

## Discussion

In this randomized-controlled trial enrolling patients undergoing selective open heart surgery, application of early and enhanced physiotherapy conferred an advantage in the length of hospital and ICU stay over a conventional physiotherapy strategy. In addition, our study indicated a statistically significant difference in mean post-intervention PO<sub>2</sub> between APG and CPG, in favour of active and enhanced physiotherapy. Our study adds to the existing literature as most of the studies dealt with enhanced sessions of physiotherapy after the first post-operative day or ICU discharge, or with enhanced pre-

operative physical activity. To our knowledge, this is the first study to compare, in terms of hospitalization length, a conventional physiotherapy strategy with an active physiotherapy, which included enhanced post-operative physical activity along with early mobilization. Of note, no adverse outcomes, such as oxygen desaturation, hypotension, acute coronary events, and arrhythmias were observed during protocols application.

Our results are consistent with those of other studies[8, 9, 13, 14] indicating that early mobilization can decrease hospitalization length. Furthermore, a meta-analysis conducted by Y. Kanejima et al suggested that early mobilization after cardiac surgery might improve physical function at discharge and subsequently prevent prolonged hospital stays[11]. For a patient undergoing open heart surgery, days spent in the ICU, as well as the next three ones, constitute the most critical time of their post-operative phase[15]. Multiple organs, with lungs being of outmost importance, are prone to dysfunction during this period[16].

After open heart surgery, deterioration of functional capacity can be triggered by muscle weakness and proteolysis, induced by reduced mobility. Prolonged inactivity and muscle atrophy are responsible for atelectasis, sensation of fatigue and aspiration pneumonia, which render rehabilitation a 'highly recommended' healthcare strategy in post-operative period of invasive cardiac procedures[17–19]. Therefore, the presence of a multi-professional team including physiotherapists in the ICU is proven by several studies to contribute to early patient recovery, reduced mechanical ventilation support need, and ultimately less number hospitalization days, by preventing respiratory complications[20].

On the other hand, some studies on post-operative ICU patients have questioned these outcomes and highlighted the absence of apparent differences between early mobilization and usual care[21, 22] regarding the length of hospitalization. Furthermore, no study has indicated survival benefits for APG patients, and thus a decreased hospitalization length does not seem to be translated into lower rates of all-cause mortality or/and cardiovascular mortality[22]. This is also supported by the fact that the effects of early and active physiotherapy are not reflected on changes in hemodynamic and laboratory indicators[7]. This is in harmony with our results, which only yielded a significant difference in post-operative PO<sub>2</sub> and lactate levels between APG and CPG.

Despite not having a clinically significant effect, in terms of hard clinical outcomes and laboratory parameters, active and early physiotherapy could still play a crucial role in reducing healthcare costs and decongesting ICUs. Indeed, another study, with original data deriving from a large registry, also showed that early cardiac rehabilitation was associated with a lower length of ICU and hospital stay, and by such means significantly reduced costs[13].

Our study should be interpreted in the context of its limitations. First of all, our randomized-controlled trial is single centred with a relatively limited number of included patients. Further, we were not capable of thoroughly elucidating our results in a pathophysiological basis, as well as providing clinical explanations about the fact that decreased hospitalization and ICU stay was not translated to altered hemodynamic and laboratory parameters. Moreover, we did not incorporate and analyze any techniques

of pre-operative physiotherapy. Finally, our results demonstrated the effect of a combined intervention, which included both early mobilization and enhanced physiotherapy sessions. However, we were not able to separately assess the clinical weight and significance of each intervention on our outcomes. Future clinical studies could test different combinations of physiotherapy and mobilization activities to form the most cost-effective physiotherapy strategy after open heart surgery, which could optimally be based on the clinical parameters of each patient, thereby providing a personalized approach in cardiovascular physiotherapy.

## Conclusion

In patients undergoing open heart surgery, early mobilization and physical activity along with enhanced respiratory physiotherapy significantly decreased both ICU and hospitalization stay. However, these outcomes were not reflected on significant differences in post-intervention hemodynamic and laboratory parameters, except for increased PO<sub>2</sub> and decreased lactate levels. Larger randomized-controlled trials are warranted to establish certain physiotherapy strategies and a structured physiotherapy program, which might lead to better clinical outcomes and faster postoperative recovery, decreasing the length of hospitalization and the subsequent financial healthcare burden.

## Declarations

-Ethics approval and consent to participate: The study protocol has been approved by the Institutional Review Board of Aristotle University of Thessaloniki, and the trial was conducted in compliance with the principles stated by the Declaration of Helsinki.

-Consent for publication: Obtained from every patient; available at request

-Availability of data and materials: The datasets during and/or analysed during the current study available from the corresponding author on reasonable request.

-Competing interests: The authors declare that they have no competing interests

-Funding: None

-Authors' contributions: GA and KA conceived the project, performed the trial and were the principal investigators, DVM, ASD and CT collected the data and wrote the manuscript, AL and IAA analyzed and interpreted the patient data and reviewed the manuscript, CF and GTK supervised the trial.

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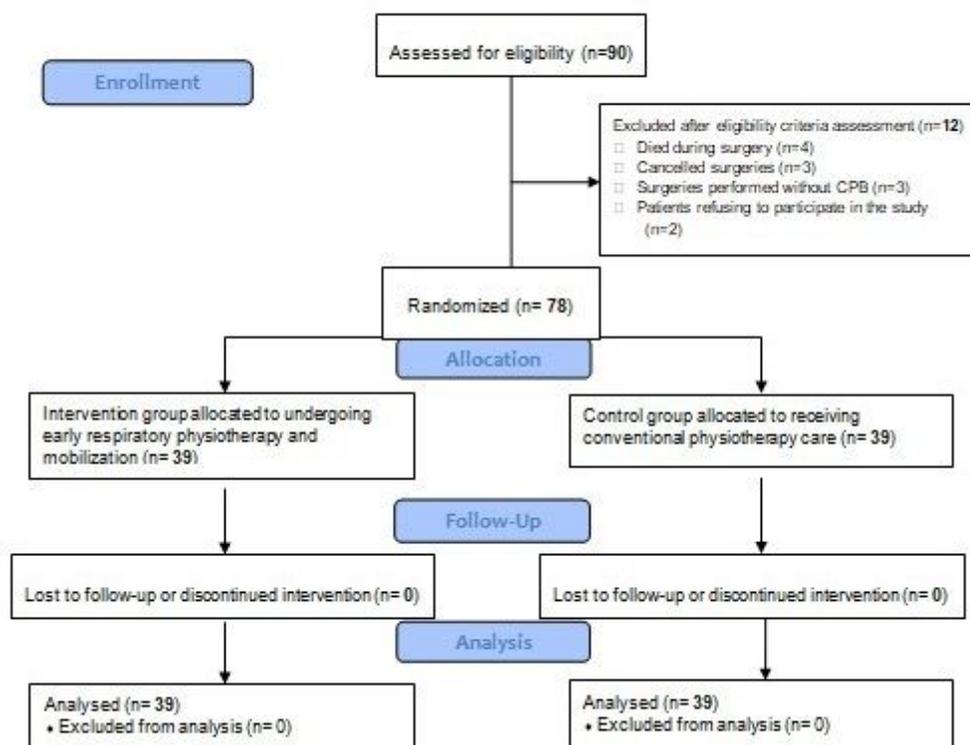
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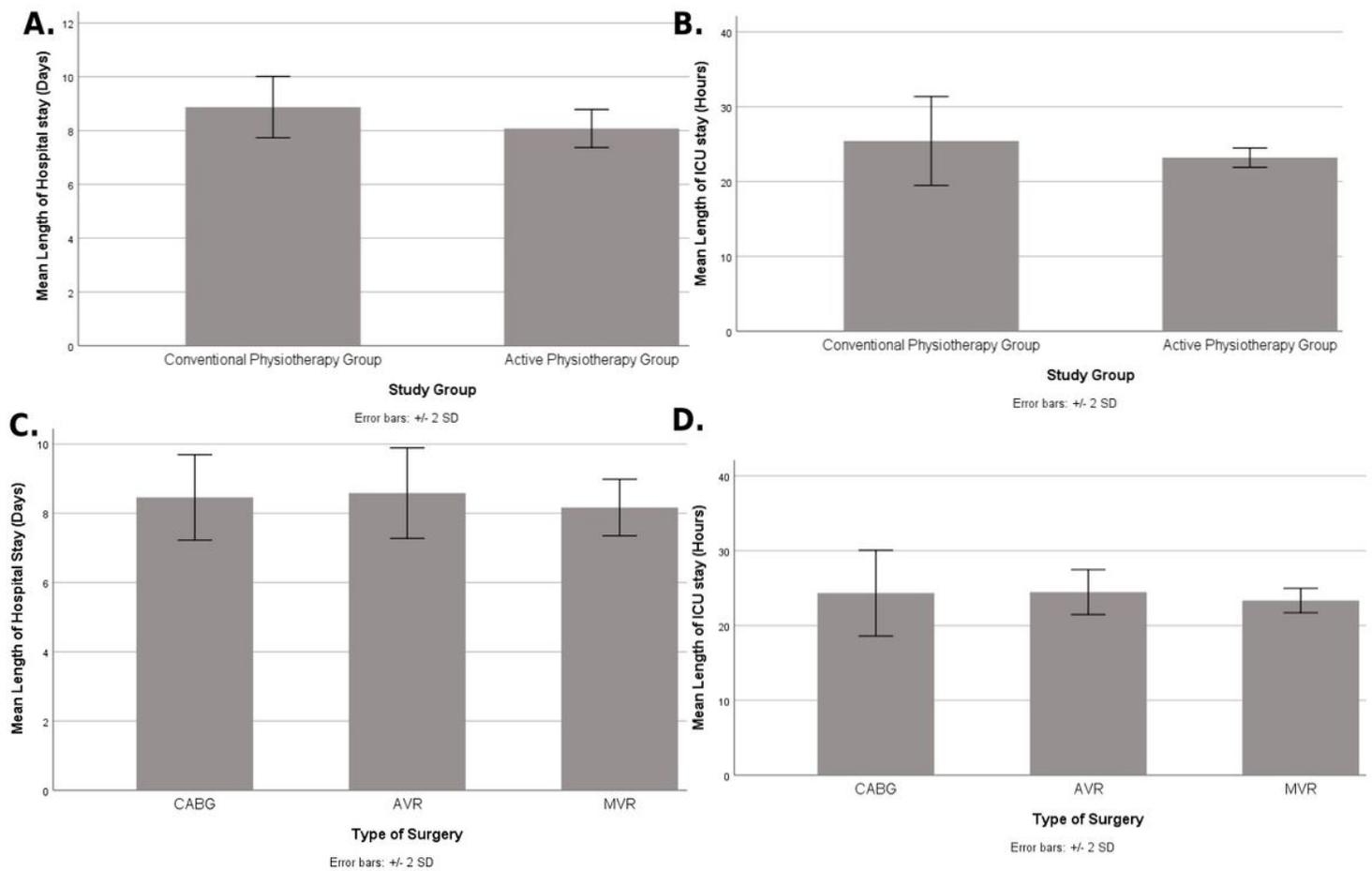
## Figures

CONSORT 2010 Flow Diagram



**Figure 1**

Flowchart of patient participation in this randomized controlled trial according to the CONSORT 2010 statement guidelines



**Figure 2**

Bar plots presenting: The mean length of hospital stay (in days) and the mean length of ICU stay (in hours) by: the 2 study groups (2A and 2B) and the type of surgery performed (2C and 2D).

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [PhysiotherapyOpenheartsurgery.png](#)