# INPLASY PROTOCOL

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Conflicts of interest: None declared.

## **INTRODUCTION**

**Review question / Objective:** The aim of this systematic review is to investigate the effectiveness of comprehensive CR

programs in improving outcomes for patients who had undergone CABG. The explicit statement of the research question considered for this systematic review is formulated by using (PICOS) criteria;

The Effect of Comprehensive Cardiac Rehabilitation Programs on Outcomes for Patients Undergoing Coronary Artery Bypass Graft, A Systematic Review of Contemporary Randomized Controlled Trials

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Review question / Objective: The aim of this systematic review is to investigate the effectiveness of comprehensive CR programs in improving outcomes for patients who had undergone CABG. The explicit statement of the research question considered for this systematic review is formulated by using (PICOS) criteria; Population (patients who had undergone CABG), Intervention (comprehensive CR programs), Comparator (control groups), Outcome (HRQoL, stress, anxiety, depression, readmission, and the occurrence of major adverse cardiac/ cerebrovascularevents MACCE)and Study (RCTs).

Condition being studied: The effectiveness of comprehensive cardiac rehabilitation programs in improving the outcomes for patients with coronary artery disease who had undergone coronary artery bypass graft surgery.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 January 2023 and was last updated on 11 January 2023 (registration number INPLASY202310027). Population (patients who had undergone CABG), Intervention (comprehensive CR programs), Comparator (control groups), Outcome (HRQoL, stress, anxiety, depression, readmission, and the occurrence of major adverse cardiac/ cerebrovascularevents MACCE)and Study (RCTs).

Rationale: A cardiac rehabilitation program can be offered to different types of patients with cardiac diseases like (PCI patients AMI and HF), but CABG generally is done for complicated cases or when the other means of treatment failed, these patients are vulnerable to a different type of physical and psychological complications and they may need special care that differs from other patients. So, it is imperative to focus on this type of patient exclusively. The RCT is the most rigorous and strong study method to verify if a cause-effect relation is presented between the intervention and the result. Trusted evidence can be inferred by conducting RCT when assessing the impact of an intervention(Bhide, Shah, & Acharya, 2018). To maximize benefits of the CR program and to involve all risk factors, the CR program must be comprehensive rather than a single component (van Halewijn et al., 2017). As stated by kabboul et al in his study in 2018. important recommendations for future work which inferred from this study. Which mixture of main components can maximize cost-effectiveness, and effect of these components on PRO such as QoL should be examined (Kabboul et al., 2018) .To the best of our knowledge, no recent systematic review of RCTs investigated the effectiveness of comprehensive CR programs on the outcomes of CABG; several systematic reviews were conducted to assess the effectiveness of CR, but they included studies either with non-comprehensive CR program (one component) or their participants (heterogeneous population) not limited to patients with CABG or they included RCTs and non-RCTs trials(Fredericks & You, 2017; Kabboul et al., 2018; Saeidifard et al., 2021). For instance, a previous systematic review conducted in 2017 to assess the effect of CR for patients after cardiac (Bhide et al., 2018) surgery compared with usual care, 18 **RCTs and 15 observational studies** evaluated 3654 patients were included, Bhide et al applied no restriction on the type of cardiac surgery, type of CR program and included studies with different design; RCTs, guasi-randomized and observational studies. Bhide et al could not reach any conclusion about the effectiveness of CR, they mentioned that due to insufficient data preplanned subgroup analyses could not be performed, sequence of CR programs (Blokzijl et al., 2018). What is new about this systematic review is that it aims to investigate the impact of a comprehensive (multi-component) CR program on the outcomes of patients with CABG, using only contemporary RCTs (2017-2022). having such information can help nurses and other healthcare providers in providing care and education for these patients.

Condition being studied: The effectiveness of comprehensive cardiac rehabilitation programs in improving the outcomes for patients with coronary artery disease who had undergone coronary artery bypass graft surgery.

## **METHODS**

Participant or population: Patients with coronary artery disease who had undergone coronary artery bypass graft surgery.

Intervention: Comprehensive cardiac rehabilitation program which include education ,excise and psychological support.

**Comparator:** The control group (patients with coronary artery disease who had undergone coronary artery bypass graft surgery and received the usual car)

Study designs to be included: Randomized Controlled Trials.

**Eligibility criteria:** The study was considered eligible if it met the following criteria, randomized control trials (RCT) that measure the effect of a comprehensive CR program on outcomes for patients who have undergone CABG, were published in English between 1st January 2017 and 31th December 2022, using a comprehensive CR program (exercise with education and psychosocial intervention), the participants were both male and female, aged≥18 years old.

Information sources: The databases that will be used to retrieve the relevant studies are Cumulative Index to Nursing And Allied Health Literature CINAHL, PUBMED, MEDLINE, EMBASE, EBSCO Scopus, Cochrane Central Register of Controlled Trials, and additionally the references of included studies.

Main outcome(s): The outcomes of interest are health related quality of life, stress, anxiety, depression, readmission, and the occurrence of major adverse cardiac/ cerebrovascular events MACCE.

Quality assessment / Risk of bias analysis:

The risk of bias in the included studies will be assessed using the Cochrane Risk of Bias tool. The Cochrane risk-of-bias tool for randomized trials (RoB 2) is recommended tool to evaluate the risk of bias in RCTs. RoB 2 is designed into a predetermined aroup of domains, focusing on different characteristics of the trials design, conduct, and reporting. for each domain, number of questions ('signaling questions') seek to extract information about characteristics of the trial's risk of bias. decision regarding the risk of bias coming up from each domain is made by an algorithm, based on answers to these questions. Judgment about risk of bias can be 'Low', 'High or can state 'Some concerns'. The included domains in this review were: 1- random sequence generation (selection bias),2- allocation concealment (selection bias), 3- blinding of participants and personnel (performance bias), 4-blinding of outcome assessment (detection bias), 5-incomplete outcome data (attrition bias), 6-selective reporting bias, 7- other bias 8- intention to treat analyses. Because of the nature of the rehabilitation trials, they cannot be completely blinded so all included studies

were graded high risk in domain number (3 blinding of participants and personnel (performance bias).

Strategy of data synthesis: The data synthesis will be conducted to inform about the efficacy (strength and limitation available) of Comprehensive Cardiac Rehabilitation Programs on Outcomes of (health related quality of life, stress, anxiety, depression, readmission, and the occurrence of major adverse cardiac/ cerebrovascular events MACCE). The data synthesis will be based on the included randomized control studies it will be structured around the intervention (programe), target population characteristics, and type of outcome.

Subgroup analysis: There is no subgroup analysis, because it is out of the scope of this systematic review.

Sensitivity analysis: Regarding the nature of this systematic review there is no Sensitivity analysis.

Language restriction: Regarding the nature of this systematic review there is no Sensitivity analysis.

Country(ies) involved: Malaysia.

Keywords: The keywords that will beused to retrieve the related studies are: "cardiac", "rehabilitation", "discharge plan", "coronary artery disease", "secondary prevention".

#### **Contributions of each author:**

Author 1 - Ali Harbi - The author have made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data and have been involved in drafting the manuscript and revising it critically for important intellectual content, and have given the final approval of the version to be published.

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