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Protocol

Effect of modified and standard cardiac rehabilitation program on bio-psycho-physiological parameters among acute coronary syndrome patients at a tertiary care institute: a randomized controlled trial protocol

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ABSTRACT

Background: Coronary artery disease (CAD) is a significant cause of mortality globally, with acute coronary syndrome (ACS) being a critical manifestation. Cardiac rehabilitation (CR) programs improve quality of life, reduce mortality, and enhance recovery post-acute events. This study aims to evaluate the effects of a modified CR program compared to the standard CR program on bio-psycho-physiological parameters in ACS patients including exploring the barriers to adherence to MCR.
Methods: A randomized controlled trial will be conducted with 154 ACS patients at tertiary care institute. Participants will be allocated into experimental (modified CRP) and control (standard CRP) groups. The primary outcomes will include 6 min walk test (6MWT) and biological (lipid profile, HbA1c), physiological (BP, HR), and psychological (anxiety, depression, quality of life) parameters will be the secondary outcomes. Descriptive and inferential statistics will be employed to analyses the results, including an intention-to-treat (ITT) analysis to account for all participants as originally allocated. Qualitative data will be analyzed using thematic analysis with NVivo, identifying key barriers to modified cardiac rehabilitation through coding and theme development. Rigor will be maintained via member checking, peer debriefing, and audit trails to ensure credibility and trustworthiness.
Conclusion: The findings aim to inform the development of evidence-based, culturally appropriate CR programs in India.
Trial registration: CTRI/2024/12/078832

Keywords: Coronary artery disease, Acute coronary syndrome, Cardiac rehabilitation, Quality of life, Depression

INTRODUCTION

Coronary heart disease is a leading cause of death globally, with significant socio-economic impacts. In India, the burden is increasing, particularly in younger populations. CR programs provide a multidisciplinary approach for secondary prevention, improving physical, psychological, and social recovery.[1] Despite demonstrated benefits, CR remains underutilized in India due to limited infrastructure and awareness. Coronary heart disease (CHD), including acute coronary syndrome (ACS), continues to be a leading cause of morbidity and mortality worldwide, contributing to a substantial health and economic burden.[2] According to the World Health

Organization (WHO), cardiovascular diseases account for an estimated 17.9 million deaths each year, representing 32% of global deaths. Among these, a significant proportion are attributable to ischemic heart diseases such as ACS.[3]

In India, the prevalence of CHD has been rising at an alarming rate, particularly affecting individuals at a younger age compared to Western populations. Rapid urbanization, sedentary lifestyles, dietary changes, increasing prevalence of hypertension, diabetes, smoking, and psychosocial stress have been key contributors to this epidemic.[4]

The socio-economic impact is considerable, affecting the productive age group and placing a long-term burden on families and the healthcare system. Cardiac rehabilitation (CR) has emerged as a comprehensive, multidisciplinary intervention designed to support patients in achieving optimal recovery following a cardiac event.[5]

CR encompasses structured exercise training, patient education, nutritional counseling, psychological support, and risk factor modification. Studies have consistently demonstrated that CR programs reduce all-cause and cardiovascular mortality, decrease hospital readmissions, and improve quality of life, functional capacity, and psychological well-being. Despite strong evidence supporting its effectiveness, CR remains grossly underutilized in India.[6]

Barriers include limited availability of CR centers, lack of trained personnel, low physician referral rates, poor patient awareness, financial constraints, and sociocultural factors.[4]

Furthermore, standardized CR protocols tailored to the Indian context are lacking, which hampers the delivery and acceptance of these programs. To address these gaps, it is crucial to evaluate the comparative effectiveness of modified CR programs that are culturally relevant, resource-sensitive, and accessible, against standard protocols. Assessing their impact on bio-psycho-physiological parameters among ACS patients may inform clinical practice, improve patient outcomes, and support the integration of CR into routine cardiac care in tertiary settings. CR in India is fragmented, with few studies exploring its structured implementation. The absence of standardized protocols limits accessibility and effectiveness.

Therefore, the present study aims to develop and evaluate a modified cardiac rehabilitation (MCR) program tailored to the Indian healthcare context. It will assess and compare the six-minute walk test and selected bio-psycho-physiological parameters before and after the implementation of the MCR program. Additionally, the study will qualitatively explore the barriers to participation in the modified cardiac rehabilitation program.

METHODS

Study design and setting

This study is a randomized controlled parallel-group trial conducted at the All-India Institute of Medical Sciences (AIIMS), Rishikesh, a tertiary care institute equipped with specialized departments in cardiology and cardiothoracic surgery.

Study participants

The study will include adult male or female patients aged 18 to 70 years who have been diagnosed with acute coronary syndrome (ACS), specifically non-ST segment elevation myocardial infarction (non-STEMI) or unstable angina. Eligible participants must be clinically stable following a cardiac intervention such as percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG), and physically and mentally capable of participating in a cardiac rehabilitation (CR) program.

Exclusion criteria include patients with ST-segment elevation myocardial infarction (STEMI), those with diagnosed mental illnesses, pregnant women, individuals with severe physical disabilities, and those who have previously participated in any form of CR program.

Sample size

To determine the appropriate sample size, we used G power software (Version 3.1 9.7) for a two-group comparison based on the primary outcome, the 6-minute walk test. A study by Kumar et al reported a mean difference of 33.2 meters between experimental and control groups, with standard deviations of 65.3 and 49.9, respectively.[7,8]

With a significance level of 5% (alpha=0.05) and a power of 90% (beta=0.10), the minimum required sample size was calculated as 128 participants (64 per group). Accounting for a 20% attrition rate, the total sample size was increased to 154 participants (77 per group). This ensures adequate power to detect clinically meaningful differences between the interventions.

Recruitment

Participants will be recruited from the inpatient departments of cardiology and cardiothoracic surgery at AIIMS Rishikesh. A general survey of admitted ACS patients will ensure a consistent pool of eligible participants.

The recruitment process will include: Initial screening of medical records to identify patients meeting inclusion criteria, discussion with treating physicians to confirm stability and eligibility, face-to-face interactions with potential participants to explain the study's objectives, procedures, and benefits and obtaining informed consent

before enrolment, ensuring participants understand their rights and the voluntary nature of the study.

Recruitment and data collection began on July 2024 and it is expected to end on June 2025. There will be follow up according to the flow chart based on CONSORT (Consolidated Standards of Reporting Trials) (Figure 1).[9]

Randomization and allocation

To minimize selection bias and ensure equal distribution of participants between the experimental and control groups, a computer-generated randomization sequence will be employed, assigning participants in a 1:1 ratio.[10] Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes, each containing the group assignment. These envelopes will be opened only after the participant has been formally enrolled in the study. An independent researcher, not involved in the recruitment or intervention delivery, will oversee the randomization process to ensure blinding and methodological rigor. Table 1 shows study timeline based on SPIRIT guideline.[11] Allocation secrecy should be broken only in case of discontinuity of more than two consecutive sessions due to adverse events.

Interventions

Experimental group (modified cardiac rehabilitation program)

Participants will receive standard CR components, including structured physical exercises, lifestyle counselling, and psycho-education sessions focusing on healthy nutrition, medication adherence, stress management, and risk factor reduction. The modified program will incorporate yoga and breathing exercises tailored for relaxation and enhancing pulmonary function.[12,13] Initial in-person sessions at discharge to ensure participants understand the regimen. There will be weekly telephonic follow-ups to reinforce adherence, address concerns, and provide motivation. Participants will maintain a daily logbook documenting adherence to prescribed exercises and lifestyle changes. MCR Interventions will be delivered at after surgery, 4-6 weeks, and 10-12 weeks post-discharge. Modified cardiac rehabilitation program will be delivered in three phases such as

Phase I

Inpatient MCR

Early mobilization begins within 24–48 hours post-event, incorporating low-intensity, monitored exercises such as bed mobility (rolling in bed), neck stretches, shoulder shrugs and circles, bilateral upper extremity exercises, trunk rotation, leg stretching, ankle pumping and rotation, and short walks.[14]

Additionally, three types of breathing exercises—pursed-lip breathing, diaphragmatic breathing, and coughing exercises—are included. Patients also receive comprehensive education on dietary modifications, smoking and alcohol cessation, weight management, diabetes control, stress reduction, blood pressure regulation, and medication adherence to support overall recovery.

Phase II

Outpatient MCR

This phase begins at 4-6 weeks, focuses on structured exercise and rehabilitation, incorporating aerobic training (40–60 minutes, 5 times per week) and strength training (3 times per week).[2,15,16] Strength exercises include biceps curls, arm raises, sit-to-stand movements, calf exercises, triceps presses, step-ups, sit-ups, and seated deep breathing exercises.[17] The goal is to enhance cardiovascular endurance, muscle strength, and overall functional capacity for improved recovery and long-term health.

Phase III MCR

This phase begins 8–10 weeks and focuses on a more structured and intensive exercises to enhance cardiovascular fitness, strength, and overall functional capacity. This phase builds upon the foundation set in Phase I and Phase II, incorporating their key components while progressively increasing intensity and duration. It includes aerobic training: moderate-to-vigorous intensity exercises such as walking, cycling, swimming, workouts (40–60 minutes, 3–5 times per week) to improve cardiovascular endurance. Resistance exercises targeting major muscle groups (2–3 times per week), including biceps curls, arm raises, sit-to-stand movements, calf exercises, triceps presses, step-ups, and core-strengthening activities like sit-ups and continued practice of pursed-lip breathing, diaphragmatic breathing, and coughing exercises to improve lung function and oxygenation.

Control group (standard cardiac rehabilitation program)

The control group will receive standard post-surgical usual instructions from the cardiovascular nurse and cardiac/CTVS surgeon, covering medication adherence, follow-up schedules, and dietary modifications. These instructions will be provided after surgery and reinforced during each follow-up visit at 4–6 weeks and 8–10 weeks.

Outcome measures

The primary outcome will be the 6-minute walk test (6MWT), expressed as mean and standard deviation to evaluate functional exercise capacity. Secondary outcomes will include biological parameters such as lipid

profile, glycated hemoglobin (HbA1c), and random blood sugar (RBS); physiological parameters including weight, BMI, blood pressure, and heart rate; and psychological parameters assessing anxiety, depression, and heart-related quality of life (HRQOL). All outcome variables will be assessed at baseline, 4–6 weeks, and 8–10 weeks of follow-up.

Methods: data collection, management, monitoring and analysis

Measurement, instrument and monitoring

After consulting with treating cardiologist and surgeon and considering inclusion exclusion criteria the researcher will collect the baseline data. Following randomization into the experimental and control groups, the intervention group will undergo the modified cardiac rehabilitation program.

Strategies to ensure the adherence of patients will include sharing an audio-visual video and the distribution of booklet including all the instructions regarding modified cardiac rehabilitation program. The monitoring of the collected data will be done by researcher.

6 min walk test

The study participants from both experimental and control group will be asked to walk under supervision of researcher at two turnaround points of 30 meters in a straight corridor back and forth between these points for six minutes, and the total distance covered will be recorded. 6 MWT will be assesses at baseline and each 4-6 and 8-10 weeks of follow up.

Weight and body mass index

Weight will be measured using a calibrated digital weighing scale, the measurement will be recorded in kilograms (kg). Body mass index (BMI) will be calculated using the formula: BMI=Weight (kg)/Height (m2). Height will be measured using a stadiometer, with participants standing upright, barefoot, and with their heels, back, and head aligned to the wall.

The measurement will be recorded in meters (m). Both weight and BMI will be assessed at baseline, 4–6 weeks, and 8–10 weeks to monitor changes in body composition during the study.[18]

Biological parameters

Lipid profile

Lipid profile will be assessed through fasting blood samples collected from participants. The analysis will include the parameters like total cholesterol (TC), low-density lipoprotein (LDL-C), high-density lipoprotein (HDL-C), Triglycerides (TG). Lipid profile will be assessed at baseline and each 4-6 and 8-10 weeks of follow up.

Glycated haemoglobin

HbA1c will be measured to assess long-term glycemic control, reflecting the average blood glucose levels over the past 2–3 months. A venous blood sample will be collected and analyzed using high-performance liquid chromatography (HPLC) or an immunoassay-based method. Results will be expressed as a percentage (%). HbA1c will be assesses at baseline and each 4-6 and 8-10 weeks of follow up.

Random Blood Sugar (RBS): RBS will be measured to assess current blood glucose levels regardless of fasting status. A blood sample will be taken via fingerstick or venous blood draw, analyzed using a glucometer or laboratory-based enzymatic method. RBS will be assesses at baseline and each 4-6 and 8-10 weeks of follow up.

Blood pressure and hear rate

Blood pressure and heart rate will be measured using a validated digital sphygmomanometer in a standardized setting. Blood pressure will be recorded in millimeters of mercury (mmHg), including both systolic (SBP) and diastolic (DBP) values.

Heart rate will be measured in beats per minute (bpm) manually via radial pulse palpation for 60 seconds. Measurements will be conducted at baseline, 4–6 weeks, and 8–10 weeks as part of follow-up.

Psychological variables

The hospital anxiety and depression scale

In present study HADS will be used for assessing anxiety and depression among study participants. It consists of 14 items, divided into two subscales: anxiety (HADS-A) and depression (HADS-D), with 7 items each. Each item is scored on a 4-point Likert scale (0–3), resulting in a total score ranging from 0 to 21 for each subscale. Scores are interpreted as follows: 0–7 (normal), 8–10 (borderline), and 11–21 (clinical anxiety or depression).

This self-reported questionnaire is simple, reliable, and sensitive for detecting psychological distress in cardiac patients, making it an appropriate tool for assessing mental health outcomes in present study. HADS available in both English and Hindi for standardized assessment for research purpose.[19] A prior approval has been obtained from the author for its use in the present study.

Heart-related quality of life

HRQOL will be assessed using the MacNew Heart Disease Health-Related Quality of Life Questionnaire, a validated tool specifically designed for individuals with

cardiovascular conditions. This self-reported questionnaire evaluates three key domains: physical functioning, emotional well-being and social functioning.

Each item is rated on a 7-point Likert scale, with higher scores indicating better quality of life. The total and domain-specific scores will be analysed at baseline, 4–6 weeks, and 8–10 weeks to assess improvements following intervention.

Also, The MacNew HRQOL questionnaire is a paid tool available in both English and Hindi for standardized assessment for research purpose.[20] Proper authorization has been obtained from the author by paying the designated amount for its use in the present study.

Barriers to modified cardiac rehabilitation program

To explore the barriers to modified cardiac rehabilitation (MCR), a qualitative research approach will be employed using semi-structured questionnaires.

This method enables an in-depth understanding of patients' experiences, perceptions, and the multifaceted challenges they encounter in adhering to MCR programs, at last follow-up. Through semi structured questionnaires and guided discussions, the study aims to capture nuanced insights into individual, social, and systemic barriers of MCR.

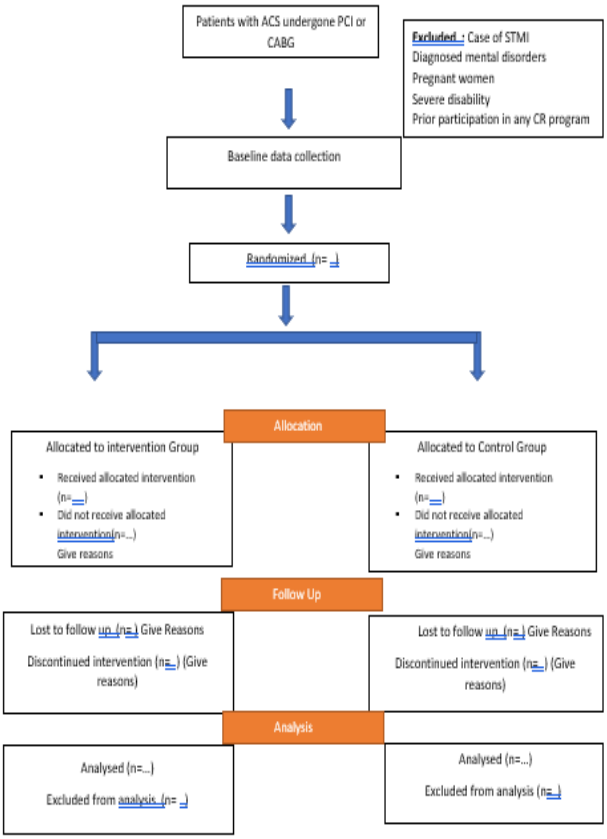

Figure 1: CONSORT diagram of the study protocol.

The qualitative data will be analyzed using thematic analysis with the assistance of qualitative data analysis software such as NVivo.[21] Data from semi-structured interviews will be transcribed verbatim and cross-checked for accuracy. Researchers will thoroughly review the transcripts to familiarize themselves with the content, followed by systematic coding using NVivo to identify key patterns and insights. Codes will be organized into sub-themes and broader themes representing barriers to modified cardiac rehabilitation (MCR), such as psychological, logistical, financial, and healthcare system-related factors.

Themes will be refined and interpreted in alignment with the study objectives, supported by direct participant quotes. Rigor and trustworthiness will be ensured through member checking, peer debriefing, audit trails, and detailed documentation.

Ethical and dissemination

Present study was approved by the institute research ethics committee wide letter no AIIMS/IEC/21/584 and study will be conducted in accordance with ethical principles outlined in the Declaration of Helsinki. Informed consent will be obtained from all participants, ensuring their voluntary participation and the confidentiality of their data.

The findings of this randomized controlled trial will be disseminated through peer-reviewed journals, conference presentations, and academic forums to contribute to evidence-based clinical practice in cardiac rehabilitation. Additionally, key insights will be shared with healthcare professionals and policymakers to optimize rehabilitation strategies for acute coronary syndrome patients in tertiary care settings.

Statistical analysis

Data will be analysed using SPSS (version 22.0) appropriate statistical methods to compare the effect of the modified and standard cardiac rehabilitation programs on bio-psycho-physiological parameters among acute coronary syndrome patients.[22] Shapiro-wilk test will be used to check normality of data. Descriptive statistics, including mean, standard deviation, and frequency distribution, will be used to summarize baseline characteristics.

Inferential statistics such as the independent t-test and chi-square test will be employed to assess differences between groups at baseline. Repeated measures ANOVA will conduct to evaluate within-group and between-group differences in physiological (e.g., heart rate, blood pressure, lipid profile), psychological (e.g., anxiety, depression and HRQOL). A p value of <0.05 will be considered statistically significant. An intention-to-treat (ITT) analysis will be used to account for all participants as originally allocated.

Table 1. SPIRIT Schedule of enrolment, intervention and assessment of outcome of 6 MWT, Bio-physiological, HADS & Macnew HRQOL.

	Study period					
	Enrollment	**Allocation/Baseline**	**Post-allocation**		**Reassessment**	
Time point	-1	0	1-2 weeks	2-4 weeks	4-6 Weeks	8-10 Weeks
Enrolment						
Eligibility screen	×					
Informed consent	×					
Allocation		×				
Intervention						
Modified cardiac rehabilitation program						
Assessments						
6 Min-walk test		×			×	×
Weight		×			×	×
BMI		×			×	×
Lipid profile		×			×	×
HbA1c		×			×	×
RBS		×			×	×
Blood pressure		×			×	×
Heart rate		×			×	×
HADS		×			×	×
HRQOL		×			×	×

6MWT;6 min walk test*HADS;Hospital anxiety and depression scale, *MacNew HRQOL;MacNew heart disease health related quality of life

DISCUSSION

Cardiac rehabilitation (CR) is a well-established, evidence-based program designed to improve cardiovascular health outcomes in patients recovering from acute coronary syndrome (ACS). It encompasses structured exercise training, risk factor modification, psychological support, and patient education to enhance recovery and reduce the risk of future cardiac events. However, despite its proven benefits, there remains a significant gap in standardized guidelines, particularly for post-surgery patients.

Various cardiovascular organizations, including the American heart association (AHA) and the European society of cardiology (ESC), provide general recommendations for CR but do not offer comprehensive, uniform protocols specifically tailored for patients who have undergone surgical interventions such as coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI). The lack of consensus on optimal rehabilitation strategies for post-surgical patients can lead to variability in care, potentially affecting patient adherence, recovery trajectories, and long-term outcomes.

Addressing this gap is crucial to developing a more inclusive and effective CR program that meets the specific needs of post-surgery ACS patients, ensuring a holistic approach to their physical, psychological, and physiological well-being. Thus, present study will analyze and interpret the findings of the study, comparing the effects of modified and standard cardiac rehabilitation programs on bio-psycho-physiological parameters among acute coronary syndrome (ACS) patients. The results will be evaluated in the context of existing literature to determine whether the modified program provides superior benefits in terms of physiological recovery, psychological well-being, and overall quality of life.

In the present study, the 6-minute walk test (6MWT) is the primary outcome variable to assess physical endurance. The previous researches have demonstrated significant improvements in functional capacity, as measured by 6MWT, following participation in structured cardiac rehabilitation programs.[3,23,24]

In addition, biological parameters such as lipid profile and random blood sugar levels are secondary outcome variables and earlier studies have reported favourable changes in lipid metabolism and glycaemic control after cardiac rehabilitation.[5,25,28] These improvements are crucial, as they contribute to the reduction of cardiovascular risk factors and overall disease progression. Also, in present study psychological outcomes are heart-related quality of life, anxiety, and depression scores and previous literature has indicated that cardiac rehabilitation not only addresses physical health but also promotes psychological well-being among coronary artery disease patients.[26-28]

Furthermore, the qualitative component of this study explored barriers to adherence to cardiac rehabilitation programs using semi-structured interviews and various previous studies have documented barriers to CR as financial constraints, physical limitations, lack of social

support, and transportation issues. These findings underscore the importance of addressing these multidimensional barriers to improve patient participation and adherence to cardiac rehabilitation programs.[29-31]

Potential mechanisms underlying the observed outcomes will be explored, along with implications for clinical practice in tertiary care settings. Additionally, limitations such as sample size, adherence rates, and potential biases will be acknowledged, and recommendations for future research will be suggested to optimize cardiac rehabilitation strategies for ACS patients.

CONCLUSION

The findings of this study are expected to generate evidence to support the effectiveness of a modified, potentially more feasible cardiac rehabilitation approach and to inform strategies that may enhance adherence among cardiac patients. Ultimately, this research may contribute to the development of more accessible, patient-centered rehabilitation programs, thereby improving recovery outcomes and quality of life for individuals with acute coronary syndrome.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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