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DOI: 10.4103/jehp.jehp_1441_25

The effect of the 5A self-management model on treatment adherence and self-care in patients undergoing coronary artery bypass graft surgery: A RCT study protocol

Fatemeh Tajizadegan, Leila Mardanian Dehkordi, Sayed M. Hosseini¹, Mohsen Shahriari

Abstract:

BACKGROUND: Coronary artery bypass grafting (CABG) is one of the most effective treatments for coronary artery disease (CAD). However, its long-term success largely depends on patients' adherence to treatment and engagement in self-care behaviors. Patient-centered self-management programs can enhance health behaviors and improve these outcomes. This study aims to evaluate the effectiveness of the 5A self-management model on treatment adherence and self-care among patients undergoing CABG.

MATERIALS AND METHODS: This randomized clinical trial will be conducted on 60 patients undergoing CABG at a specialized cardiac hospital in Isfahan, Iran. Eligible participants will be randomly assigned to two intervention ($n = 30$) and control ($n = 30$) groups. The intervention group will receive a self-management program based on the 5A model, which includes the stages of assess, advise, agree, assist, and arrange. The control group will receive routine care. Data will be collected at three stages before, immediately, and 2 months after the intervention using the Modanloo treatment adherence questionnaire and self-care questionnaire for patients undergoing CABG. Data analysis will be performed with SPSS version 26, using descriptive statistics, Chi-square test, independent and paired t-tests, and repeated-measures ANOVA.

DISCUSSION: This study will examine the effect of the 5A self-management model on treatment adherence and self-care in CABG patients. The main strength of the study lies in its use of an evidence-based framework. However, its short-term follow-up, single-center design, and reliance on self-reported data represent key limitations. Findings may contribute to the development of policies aimed at improving cardiac patient care, strengthening self-management programs within healthcare systems, and providing an evidence-based framework for designing similar interventions in other patient populations.

Keywords:

Coronary artery bypass, educational, models, self-care, self-management, treatment adherence and compliance

Introduction

In recent decades, the rapid rise of noncommunicable diseases (NCDs) has emerged as a significant public health challenge, threatening both population health

and socioeconomic development.^[1] Among the most critical NCDs are cardiovascular diseases (CVDs), which remain the leading cause of mortality worldwide.^[2] According to the World Health Organization (WHO), an estimated 19.8 million people died from CVDs in 2022, representing approximately

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How to cite this article: Tajizadegan F, Mardanian Dehkordi L, Hosseini SM, Shahriari M. The effect of the 5A self-management model on treatment adherence and self-care in patients undergoing coronary artery bypass graft surgery: A RCT study protocol. J Edu Health Promot 2026;15:274.

Department of
Medical-Surgical Nursing,
School of Nursing and
Midwifery, Isfahan
University of Medical
Sciences, Isfahan,
Iran, ¹Department of
Epidemiology and
Biostatistics, School of
Health, Isfahan University
of Medical Sciences,
Isfahan, Iran

Address for correspondence:

Prof. Mohsen Shahriari,
Department of
Medical-Surgical Nursing,
School of Nursing and
Midwifery, Isfahan
University of Medical
Sciences, Isfahan, Iran.
Postal Code: 8174673461
E-mail: shahriari@
nm.mui.ac.ir

Received: 28-07-2025

Accepted: 25-10-2025

Published: 30-06-2026

32% of all global deaths.^[3] Furthermore, projections indicate that by 2030, CVDs will contribute to over 23 million deaths annually worldwide.^[4]

Coronary artery disease (CAD) is among the most critical and concerning forms of cardiovascular disease, and it has become the leading cause of mortality worldwide.^[5] In Iran, CAD accounts for nearly 50% of all annual deaths.^[6] Various therapeutic approaches are available for managing CAD, including thrombolytic therapy, balloon angioplasty, laser therapy, and atherectomy. However, coronary artery bypass grafting (CABG) remains the gold standard and most effective treatment for this condition.^[5] Globally, approximately 800,000 CABG procedures are performed each year.^[7] This procedure constitutes about 1.4% of all surgical operations performed worldwide,^[6] and an estimated 35,000 to 50,000 CABG surgeries are conducted annually in Iran.^[8]

Although CABG is effective in improving cardiac function and alleviating symptoms, patients frequently encounter postoperative challenges, including pain, insomnia, appetite changes, chest pain, respiratory difficulties, arrhythmias, palpitations, and inflammation at the chest and leg incision sites.^[9,10] Despite the availability of rehabilitation services, more than 16% of patients undergoing CABG are readmitted within the first month after surgery due to postoperative complications.^[11] The most common causes of readmission include postoperative infections (26%), pericardial effusion (19%), dysrhythmias (16%), and heart failure (11%).^[12] This high readmission rate is associated with significant implications for healthcare resource utilization, quality of care, and the exacerbation of underlying cardiovascular conditions.^[13]

A substantial portion of the long-term success of surgical interventions depends on treatment adherence, to the extent that even the most effective treatment regimens may become ineffective if patients fail to follow medical recommendations.^[14] According to the WHO, treatment adherence is defined as the extent to which a patient's behavior, encompassing medication use, adherence to a prescribed diet, and lifestyle modifications, aligns with the recommendations provided by healthcare professionals.^[15]

It seems that many patients do not sufficiently recognize the importance of acquiring the necessary skills, adopting behavioral changes, and implementing lifestyle modifications to prevent the recurrence of disease symptoms.^[14] In the initial months after surgery, patients often fail to adhere to the recommended treatment regimen due to factors such as depression, inability to resume presurgery activities, and imposed

limitations. Some patients mistakenly believe that surgery alone fully restores their health.^[16] Consequently, consistent adherence to therapeutic guidelines is critical for disease management, as nonadherence increases the likelihood of complications, disease progression, and recurrence.^[6]

The success of CABG surgery depends not only on treatment adherence but also on the extent of patient engagement in the care process and strict compliance with self-care principles.^[10] Furthermore, self-care is crucial for patients who have undergone cardiac surgery to prevent the recurrence of myocardial infarction, additional surgery, and premature death.^[17] A significant challenge for these patients is a lack of awareness regarding self-care behaviors. This issue persists postdischarge, as patients often face confusion and unanswered questions about self-care practices, medication regimens, dietary requirements, and disease-related complications when managing their condition at home.^[10] Multiple studies have indicated that self-care levels among CABG patients are suboptimal.^[5,10] This deficiency can lead to serious consequences, including an increased risk of complications, reduced quality of life, and elevated healthcare costs.^[18]

The healthcare system is shifting from a traditional disease-centered model toward a patient-centered model, leading to increased patient participation in treatment decisions. In this context, self-management is emerging as a critical skill for patients.^[19] The objective of implementing self-management programs is to actively engage patients, thereby transferring disease management responsibilities from healthcare providers to patients as much as possible. In this approach, patients play an active role, with all care and treatment activities centered on them. The primary goals are to achieve maximum independence, enhance self-determination, promote health based on individual capabilities and lifestyle, and improve quality of life.^[20]

Self-management can play a pivotal role in improving treatment outcomes and enhancing overall health in patients with cardiovascular diseases, particularly those undergoing CABG surgery.^[21] Research has shown that patient participation in self-management, based educational programs not only improves treatment adherence and increases engagement in physical activity^[22,23] but also facilitates faster recovery by reducing postoperative infections and preventing hospital readmissions.^[21]

One approach to implementing a self-management program is following a structured model. Among the models applied in self-management, the 5A self-management model, also known as the behavior

change model, has been widely used. It is evidence-based and designed to facilitate desirable behaviors and improve various health outcomes.^[24] As illustrated in Figure 1, this model emphasizes individualized self-management and comprises five stages: assess, advise, agree, assist, and arrange.^[25] In the first two stages, patients' problems are identified and appropriate guidance is provided. In the third stage (agree), the educator and participant reach a consensus on behavioral goals and practical plans to achieve them. In the fourth stage (assist), tailored education or counseling is delivered to the patient. Finally, in the fifth stage (arrange), progress toward behavioral goals and practical plans is monitored, reinforced, and encouragement is provided to continue the recommended actions.^[26]

The 5A model offers significant advantages over other self-management models, making it an effective approach for the sustainable management of chronic diseases. Grounded in scientific evidence and behavior change theories, this structured five-step model systematically targets health-related behaviors.^[27] Its adaptability to diverse patient needs and conditions, flexibility in implementation, and consideration of psychological and social barriers further enhance its strengths. In addition, the continuous follow-up stage plays a critical role in sustaining behavioral changes,^[28] a feature often underexplored in other similar models.^[13,14] Moreover, the model's simplicity, cost-effectiveness, and minimal reliance on advanced resources make it feasible for implementation across various clinical and community settings. Nurses can readily apply the 5A model during patient discharge processes and follow-up

visits, which makes it a practical and effective option for clinical settings in Iran.^[26-28]

Despite the high prevalence of coronary artery bypass grafting and the numerous challenges patients face in managing symptoms and their condition postoperatively, evidence on the application of the 5A self-management model in this population remains limited. The effectiveness of the 5A model in improving treatment adherence and self-care following CABG has not been sufficiently investigated in previous research. Therefore, this study aims to address this gap by developing and implementing a structured intervention based on the 5A self-management model to evaluate its impact on treatment adherence and self-care among patients undergoing CABG.

Materials and Methods

Study design and setting

This study proposes a protocol to enhance self-management and evaluate its impact on treatment adherence and self-care among patients undergoing coronary artery bypass graft surgery. This study is a two-group randomized clinical trial.

Study participants and sampling

The study population consists of patients undergoing CABG surgery at a specialized teaching heart hospital in Isfahan, Iran. Participants will be selected using a consecutive sampling method from among patients meeting the inclusion criteria. After explaining the study objectives and obtaining written informed

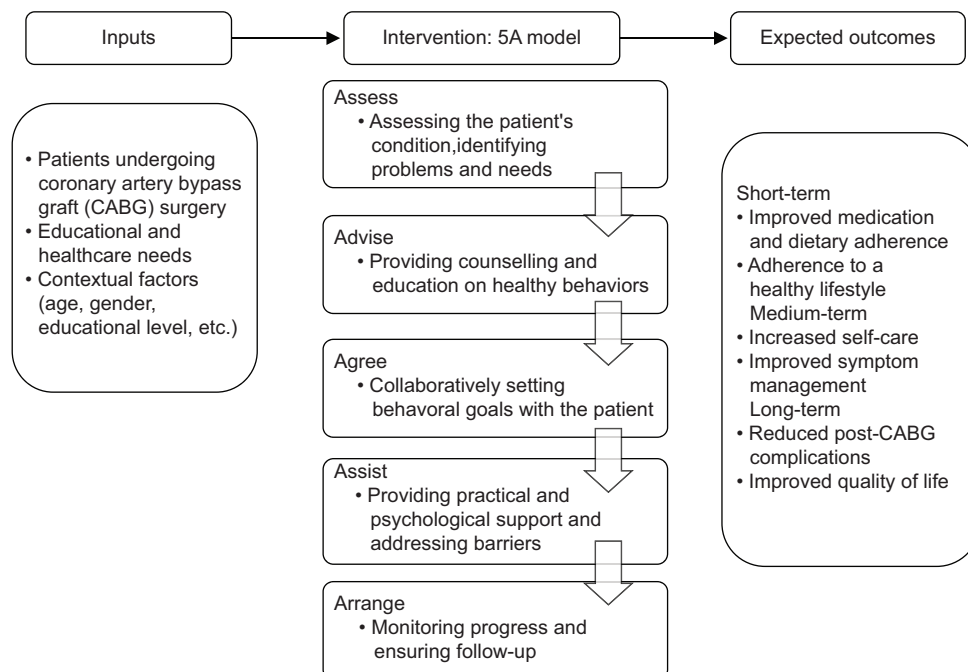


Figure 1: Conceptual framework of the 5A self-management model

consent, participants will be randomly assigned to either the intervention or control group. To ensure randomization, the researcher will use a random number table, assigning odd numbers to the intervention group and even numbers to the control group. To maintain randomization integrity and ensure systematic organization, a random starting point in the table will be selected, and progression through the table will follow a predetermined sequence until the required sample size of odd and even numbers is achieved. Subsequently, all numbers will be placed in separate sealed envelopes, and on each participant's entry, an envelope will be opened to determine their group assignment. This process ensures allocation concealment before study enrollment, thereby reducing the risk of bias in group assignment. It should be noted that this will be an unblinded study, and both participants and the researcher will be aware of group allocations. To prevent the exchange of information among participants and reduce the risk of contamination between groups, patients will be advised not to discuss the information they receive with other participants. Inclusion criteria are as follows: Iranian nationality; undergoing CABG surgery for the first time; ability to read and write; age between 30 and 75 years; no prior participation in similar educational programs; clinically stable with no acute medical conditions; no documented cognitive, visual, or sensorimotor impairments according to medical records; no physical disabilities or limb deficiencies; and no history of significant stressful life events in the past six months. Exclusion criteria include: unwillingness to continue participation in the study; missing more than one educational session; failure to respond to more than two follow-up phone calls; and development of acute physical or psychological problems during the sessions. The minimum sample size will be calculated according to the following formula: $n = ((Z(1-\alpha/2) + Z(1-\beta))^2 (S1^2 + S2^2))/d^2$. In this formula, $Z(1-\alpha/2)$ is the standard normal deviate for a 95% confidence level (1.96), and $Z(1-\beta)$ is the standard normal deviate for 80% statistical power (0.84). S denotes the estimated average standard deviation of the variables in both groups, and d , the study precision, is set at 4 based on previous studies.^[29] Considering a 20% dropout rate, the final sample size will be 30 participants per group.

Data collection tool and technique

In this study, data collection will be conducted as follows: after selecting the study participants and obtaining informed consent, the demographic questionnaire, the Modanloo treatment adherence questionnaire, and the self-care questionnaire for patients undergoing CABG surgery will be completed by the participants at three time points: before the study, immediately after the intervention, and two months following the study's onset. In addition, the checklist for assessing educational needs of patients undergoing CABG

surgery will be used during the assessment phase. This checklist will be completed by the researcher through interviews with participants in the intervention group. The demographic questionnaire includes items related to patients' personal characteristics, such as age, gender, education level, marital status, employment status, income level, cardiovascular risk factors, history of hospitalizations, and use of cardiac and noncardiac medications. The Modanloo Treatment Adherence Questionnaire was developed and psychometrically validated by Modanloo in 2013 to assess treatment adherence among patients with chronic conditions. The questionnaire consists of 40 items and seven subscales: treatment persistence, willingness to participate in treatment, adaptability, incorporation of treatment into daily life, adherence to treatments, commitment to treatment, and doubt in treatment implementation. Responses are rated on a 6-point Likert scale ranging from "completely" (score of 5) to "not at all" (score of 0). Some items are reverse-scored. The total score ranges from 0 to 200. A higher score indicates a greater adherence to treatments, while a lower score indicates little adherence to treatments. The content validity of the questionnaire has been reported with a content validity ratio of 0.914. Its reliability has been confirmed with a Cronbach's alpha coefficient of 0.921 and a correlation coefficient of 0.875.^[30] In the present study, the reliability of this instrument will also be assessed by calculating Cronbach's alpha in the study population. The self-care questionnaire for patients undergoing CABG Surgery was developed and psychometrically validated by Pooladi *et al.*^[31] in 2016. The questionnaire includes 41 items distributed across three subscales: knowledge (14 items), attitude (7 items), and practice (20 items). The knowledge subscale is rated on a three-point Likert scale (Yes = 2, No = 0, I don't know = 1). The attitude subscale is rated on a five-point Likert scale (strongly agree = 5, agree = 4, neutral = 3, disagree = 2, strongly disagree = 1), with item 7 scored in reverse. The practice subscale is rated on a five-point Likert scale (always = 5, often = 4, sometimes = 3, rarely = 2, never = 1). The total score ranges from 27 to 163, with higher scores indicating better self-care and lower scores indicating poorer self-care. The content validity ratio of the questionnaire were reported as 0.96. The overall Cronbach's alpha coefficient was 0.70, indicating acceptable reliability. In this study, the reliability of the instrument will also be assessed by calculating Cronbach's alpha within the study population. The educational needs assessment checklist, developed by Shirani in 2010, addresses demographic information, disease-related information, and the educational needs of patients undergoing CABG surgery.^[32] It should be noted that the data collected from this tool will not be analyzed and will solely be used to identify the educational needs of patients in the intervention group during the assessment phase.

Procedure

Eligible patients who meet the inclusion criteria will be enrolled in the study after providing informed consent. Participants will then be randomly assigned to either the intervention or control group. The intervention group will receive education based on the 5A self-management model, which consists of five stages. Stages 1 through 4 will be implemented from the time of admission to the cardiac surgery ward until discharge, while Stage 5 will continue for up to two months postdischarge. The 2-month follow-up period was selected based on existing evidence and clinical considerations, as previous studies have shown that the greatest effect of follow-up on consolidating new behaviors occurs within the first two months after cardiac surgery discharge.^[33,34] This period not only provides sufficient time to observe initial behavioral changes but is also operationally feasible and cost-effective for both patients and the research team. Patients in the control group will not receive any intervention from the researcher and will only receive routine care and educational materials typically provided by the center. In accordance with ethical guidelines, upon completion of data collection, the educational content delivered to the intervention group will also be made available to the control group, and a training session will be conducted for them. Participants' fidelity to the intervention will be assessed through attendance records at educational sessions, standardized forms for evaluating the implementation of intervention stages by the researcher, and follow-up phone calls [Table 1].

Ethical consideration

This study has been registered with the Ethics Committee of Isfahan University of Medical Sciences under the scientific code 3403679 and ethics approval number IR.MUI.NUREMA.REC.1403.181, and it has received the clinical trial registration code IRCT20250311065028N1. All administrative procedures, including obtaining necessary approvals, will be completed, and the study protocol will be fully explained to all participants. Informed consent will be obtained from participants before their enrollment in the study. Participants' personal information will be securely stored and analyzed confidentially. Participants will be assured that participation in this study will incur no additional costs or unexpected adverse effects, and they will not be deprived of standard treatment protocols. Withdrawal from the study will not affect participants' access to routine care, and any necessary services will be provided as needed. Throughout the study, any potential discomfort or adverse effects will be monitored through direct inquiry and standardized symptom reporting forms. In the event of any issues, the intervention will be halted, and the affected participant will be referred to the relevant physician or healthcare team. All reported adverse events will be recorded and followed up confidentially,

Table 1: Stages of the 5A self-management model

Stage	Actions
Assess	In this stage, the educational needs of each participant will be evaluated individually through face-to-face interviews using a question-and-answer approach. Participants will be assessed regarding their medication and dietary regimens, postoperative wound care, pain management, use of compression stockings, physical activity and rest, employment status after CABG surgery, sexual activity, and follow-up visits. The questions are based on the educational needs assessment checklist for patients undergoing CABG surgery.
Advise	Based on the results of the assessment stage, an in-person educational session of approximately two hours will be conducted for each participant. The sessions will use clear, culturally and socially tailored teaching methods to explain the advantages and disadvantages of each participant's specific behaviors related to their treatment and recovery.
Agree	During the agreement stage, educational objectives and priorities will be determined collaboratively with the participants. Consensus will be reached on the most important educational needs and their prioritization. The content of the educational sessions will then be developed in consultation with academic supervisors and advisors and approved by specialists in cardiology, cardiovascular surgery, and CABG procedures.
Assist	In this stage, the necessary training will be provided in at least two sessions lasting 1–2 hours each, with the maximum number of sessions determined based on the needs assessment. Sessions will be conducted in small groups of 4–7 participants who are homogeneous in terms of age, cultural background, and educational needs. The educational content will be designed based on a thorough needs assessment, using credible scientific resources and approved by experienced instructors. Educational booklets will also be provided to reinforce learning.
Arrange	The follow-up stage aims to ensure proper implementation of the educational program and the desired behavioral changes. Participants will be contacted regularly for two months postdischarge, daily during the first week and then weekly thereafter. These follow-ups will monitor participants' progress in implementing treatment adherence behaviors, achieving behavioral goals related to self-care, and identifying any potential need for specialized services. If adjustments to the practical program are required, changes will be made in coordination with the participant.

and participants retain the right to withdraw from the study at any time.

Statistical analysis method

Data will be analyzed using SPSS version 26. The 5A model will be considered the independent variable, and its effects on treatment adherence and patient self-care scores will be examined as the dependent variables, along with demographic characteristics as covariates. The normality of data distribution will be assessed using the Kolmogorov–Smirnov test, and descriptive statistics will include means, standard deviations, frequencies, and percentages. If less than 5% of data

are missing, a Complete Case Analysis approach will be applied. For missing data exceeding 5%, appropriate imputation methods, such as Multiple Imputation or Last Observation Carried Forward (LOCF), will be used depending on the type of variable and the pattern of missingness. All analyses will follow the intention-to-treat principle to minimize bias resulting from participant dropout. To evaluate within-group and between-group changes across three time points (pretest, posttest, and two-month follow-up), Repeated Measures ANOVA will be performed. Effect sizes will be reported using Partial Eta Squared (η^2), interpreted as small (0.01), medium (0.06), and large (0.14). Pairwise *post hoc* comparisons will be conducted using Cohen's *d*, and 95% confidence intervals will be provided for greater precision. A significance level of $P < 0.05$ will be considered statistically significant.

Discussion

This study was designed to evaluate the effectiveness of the 5A self-management model in enhancing treatment adherence and promoting self-care behaviors among patients undergoing CABG surgery. The staged and interactive implementation of this model facilitates active patient participation in their care process and enables effective education, which is expected to encourage treatment adherence and foster a sense of responsibility for personal health management. This is significant not only for individual patients and their families but also for enhancing the efficiency and effectiveness of the healthcare system. Therefore, a primary strength of this study lies in its use of an evidence-based framework and the meticulous execution of intervention stages, which enables a robust evaluation of the self-management model's effects. Given the staged structure and self-management principles of the model, it is anticipated that this framework could be adapted for other chronic conditions, such as diabetes, hypertension, and chronic respiratory diseases, although further research is needed to confirm its applicability. However, the study is not without limitations, which should be considered when interpreting the findings. Self-reported adherence and self-care behaviors by participants may be subject to recall bias or social desirability bias, potentially leading to an overestimation of actual adherence and the intervention's impact. In addition, the short-term follow-up period may not fully capture sustained behavioral changes, and the single-center design limits the generalizability of the results to other centers or patient populations. Furthermore, despite precautionary measures, the possibility of contamination between groups remains, which could influence the outcomes. Considering the study's strengths and limitations, its findings could contribute to the development of policies aimed at improving cardiac patient care and enhancing

self-management programs within the healthcare system. Moreover, it provides an evidence-based framework for designing similar interventions for other patient populations.

Acknowledgments

This protocol is based on a research project approved by Isfahan University of Medical Sciences under project number 3403679. We express our gratitude for the scientific and financial support provided by the university. In addition, we sincerely appreciate the participation of patients throughout the various stages of this study.

Abbreviations

CABG: Coronary artery bypass grafting; CAD: Coronary artery disease; RCT: Randomized controlled trial; SPSS: Statistical package for the social sciences.

Ethical considerations

This study has been registered with the Ethics Committee of Isfahan University of Medical Sciences under the code IR.MUI.NUREMA.REC.1403.181 and the scientific code 3403679. In addition, it has obtained the clinical trial registration number IRCT20250311065028N1. All administrative procedures and the issuance of introduction letters will be completed. The study objectives will be clearly explained to all participants, and informed consent will be obtained before enrollment. The participants' personal information will be kept confidential and analyzed anonymously. It will be assured that participation in this study entails no financial cost or adverse effects, and that participants will not be deprived of standard treatment methods. Furthermore, withdrawal from the study will not affect their access to routine care, and necessary services will be provided if needed.

Financial support and sponsorship

This study is financially supported by Isfahan University of Medical Sciences.

Conflicting interest

There is no conflict of interest.

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