Ministry of Health and Medical Education

Iran Cohort Consortium

Cohort Title:	Five-Year Cohort Study on Cardiovascular Events in Patients Referred to the Cardiac Rehabilitation Center at the Isfahan Cardiovascular Research Institute: (ISF-CRC)
University: **Research Center:**	Isfahan University of Medical Sciences. Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran.
Approval Date: **Starting Date:**	24/09/1399 (15/12/2020) 01/02/1400 (20/04/2021)
Goals:	Overall Objective: Investigating the relationship between demographic, clinical, paraclinical factors, and 5-year cardiovascular events: The Isfahan Cardiac Rehabilitation Cohort (CRC) Study. Applied Objective: Examining the current status of rehabilitation services, evaluating the effectiveness of the program in preventing and treating cardiovascular events, mortality reduction, and related complications. Specific Objectives: 1. Determining demographic characteristics (e.g., age, gender, marital status, etc.) of patients referred for cardiovascular rehabilitation. 2. Assessing the referral status of patients for cardiovascular rehabilitation. 3. Determining the level of patient participation during admission and completion of the rehabilitation program. 4. Evaluating the medical history and major risk factors (smoking duration, diabetes, hypertension, etc.) of patients seeking cardiovascular rehabilitation. 5. Assessing the echocardiography status of patients under study at admission and upon completion of the rehabilitation program. 6. Evaluating the physical activity status of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 7. Assessing the nutritional status of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 8. Determining medication adherence of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 9. Assessing tobacco consumption status of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 10. Determining the quality of life of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up.

	11. Assessing the anxiety status of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 12. Evaluating the depression status of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 13. Assessing blood pressure (systolic and diastolic) status of patients under study at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 14. Determining the lipid profile of patients registered at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 15. Assessing anthropometric indices of patients registered at admission, program completion, 6 months, 1 year, and 5 years of follow-up. 16. Determining the mortality and cardiovascular events in patients under study over 5 years. 17. Identifying determinants of mortality in patients under study over 5 years.
Study Population:	All patients diagnosed with ischemic heart disease who attended the Isfahan Cardiovascular Research Institute's cardiac rehabilitation center for cardiac rehabilitation between 1397 and 1401 are included in this study. Data on these patients, including both manual and electronic records, are examined. Patients who attended rehabilitation but completed less than half of their prescribed sessions are considered as the control group (approximately 1271 individuals).
Sampling Method and Sample Size:	The study utilizes a census method. Initially, demographic characteristics and initial information of all patients who visited the rehabilitation center between 1397 and 1401 (1271 patients during this period) are reviewed. These patients undergo a physical examination, standard electrocardiography, and exercise testing at the beginning of the study, conducted by the project executor. Subsequently, the recorded files of all participating patients in the cardiac rehabilitation program (before rehabilitation and after completing the rehabilitation period) are examined manually and electronically. The information collected from these patients, including demographic features, medical history, symptoms, laboratory tests, electrocardiograms, and questionnaires, will be reviewed annually and throughout the 5-year cohort study.

Data Collection:	- Phase One: Examination of manual and electronic records of patients referred to the cardiac rehabilitation center. Demographic information and initial data of these patients are collected by the project executor. Laboratory factors are assessed at the beginning and end of the rehabilitation period. All these data are collected before rehabilitation, after rehabilitation, and at 6-month intervals for each patient. - Phase Two: Information on all patients participating in the cardiac rehabilitation program, including demographic features, pre-event status, medical history, symptoms, patient interventions, and self-assessment questionnaires, will be registered. This information will be collected before rehabilitation, after completing the rehabilitation period, and annually for 5 years for cohort study participants. - Phase Three: Analysis of collected data in separate sections, examining the program's feasibility and effectiveness. Descriptive statistical methods (frequency, percentage of rehabilitated patients monthly, mean, standard deviation, and variance) and inferential statistical methods using SPSS_20 software will be employed. Repeated measures analysis of variance (ANOVA) will be used to examine the effect of the cardiac rehabilitation program on biological, psychological, and behavioral indices. Covariates such as age, gender, education, etc., will be included. Precondition for these tests includes normality and homogeneity of variances, which will be verified using Smirnov-Kolmogorov and Mauchly's sphericity tests, respectively.
Follow-up Methods:	Patients will be interviewed annually for 5 years by a trained specialist regarding cardiovascular events. The questionnaire includes inquiries about heart events, rehospitalization, health status, physical activity, psychological status, return to work, smoking habits, adherence to dietary regimens, medication compliance, and the number of sublingual tablets used. In the case of death, patient files will be reviewed by a specialized team, including a cardiologist, rehabilitation unit medical team, and project specialist. If the exact cause of cardiac or non-cardiac death is unclear, a Verbal Autopsy will be conducted by the project specialist in consultation with the patient's relatives.
Main Exposure:	Cardiac rehabilitation interventions.
Outcome:	The baseline data elements in this study encompass demographic characteristics (number of patients, gender distribution, age distribution, existing risk factors), anthropometric measurements, pre-event patient status, medical history, symptoms and laboratory factors, echocardiography, invasive therapeutic interventions, International Physical Activity Questionnaire (IPAQ), MACNEW standard quality of life questionnaire, Spielberger Anxiety Questionnaire, Beck Depression Questionnaire, and FFQ nutrition questionnaire. Patients are assessed annually for rehospitalization, mortality, and the need for intervention.
Related Link for study design:	https://crrc.mui.ac.ir/fa/crrc_cohort

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