

The Effects of Comprehensive Home-Based Cardiac Rehabilitation versus Usual Care in Patients with Ischemic Heart Disease in Iran: Study Protocol for a Multicenter Randomized Controlled Trial

Abstract

Background: Cardiovascular diseases are the leading causes of mortality all around the world. Patients with Ischemic heart disease (IHD) are at an increased risk of ischemic events; therefore, secondary prevention measures should continue for these patients. Although Cardiac rehabilitation (CR) is one of the secondary prevention measures for IHD patients which has favorable clinical outcomes, only 50% of patients are referred and among them, a small percentage attends CR. Therefore, other strategies should be considered, one of which is home-based cardiac rehabilitation. **Methods:** A multicenter, parallel-group randomized controlled trial has been conducting in three hospitals in Isfahan and patients have been assigned into a 1:1 ratio for the evaluation of the effectiveness of home-based cardiac rehabilitation versus usual care. Psycho-educational consultation based on the Health Action Process Approach including heart-healthy diet, stress management, lifestyle changes, smoking cessation, and physical activity has been performed. Primary outcomes, including the quality of life, psychological and smoking status, body mass index, blood pressure, blood cholesterol level, and physical activity level have been measured at 6 months after the randomization and intervention. One year after the intervention, primary and secondary outcomes, including cardiovascular events, the frequency of hospital admissions, and the death rates due to cardiovascular reasons will be assessed. **Conclusion:** HBCR program can increase patient accessibility to CR services its implantation can be reduce burden IHD.

Keywords: Cardiac rehabilitation, coronary disease, exercise, home-based

Introduction

Cardiovascular diseases are the leading cause of mortality globally; it accounts for one-third of all deaths—about 422 million deaths in 2015. While the rate of ischemic heart disease (IHD) in developing countries is increasing due to population aging, cardiovascular risk factors and the more survival rate of patients after cardiovascular events, the secondary prevention measures have reduced the death rate from IHD.^[1-3] After an acute coronary syndrome, especially in the 1-2 years, patients are at an increased risk of ischemic events such as myocardial infarction, stroke, and death. Therefore, secondary prevention measures should be continued for high-risk patients.^[4,5] Cardiac Rehabilitation (CR) is one of the secondary prevention measures which has favorable clinical outcomes such as reduce mortality, decrease hospitalization, increase muscle strength, improve exercise

capacity and oxygen consumption as well as health-related quality of life and also being cost-effective for IHD patients.^[6-8] CR is a comprehensive program that encompasses a wide range of measures such as patients risk assessment, nutrition counseling, weight, blood pressure, lipid, diabetes and psychosocial management, and smoking cessation.^[9,10] Despite the proven benefits of CR, patient referral to this valuable program is low and only 50% of patients are referred and among them, a small percentage attends CR. Several factors are influential in attending CR, some of which are related to patient characteristics, and others are related to access to cardiac rehabilitation services.^[11-14] Therefore, other strategies to increase participation in the CR program for More than 80% of eligible patients who do not participate in a center-based rehabilitation program should be considered, one of which is home-based

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cardiac rehabilitation (HBCR).^[15] Studies have shown that both center-based cardiac rehabilitation and HBCR have had similar outcomes, yet patients have been more satisfied with HBCR than with center-based CR. In addition, HBCR is more cost-effective than center-based CR.^[16-19] To the best of our knowledge, few studies have examined the efficacy of HBCR in Iran and no study has compared it with usual care. That is why we have designed this randomized controlled trial to evaluate the effectiveness of HBCR in IRAN/Isfahan, in the central region of Iran.

Methods

This study is a multicenter, parallel-group randomized controlled trial in which patients were allocated at a 1:1 ratio.

Eligibility and recruitment

This randomized clinical trial has been carried out on a sample of 240 patients with IHD in three hospitals in Isfahan named Alzahra, Chamran, and Noor hospitals. Using a convenient sampling method, Patients who had been reluctant to participate in a hospital-based rehabilitation program and simultaneously had been eligible for inclusion in the study have been selected during hospital discharge at the hospitals affiliated with Isfahan University of Medical Sciences. Participants have been selected among patients with documented IHD such as Myocardial Infarction (MI), Percutaneous Trans Luminal Coronary Angioplasty (PTCA), Coronary Artery Bypass Graft (CABG), and unstable angina. Patients with dementia, and uncontrolled cardiac arrhythmias as well as who were unable to do exercise were excluded from the study. All patients have been using secondary prevention drugs.

Sample size calculation

In order to detect a 2.7 point increase in peak oxygen consumption (VO₂ peak, ml/min/kg) during the exercise test as a primary outcome 6 months after the intervention with 80% power and an overall type I error rate of 5%, we required 220 participants. Taking into account the 10% drop in the samples, finally, 242 patients entered the study.

Randomization and blinding

Following baseline data collection, the 242 eligible and consented participants were stratified into 6 groups. Patients in each subgroup were allocated randomly into the intervention or control group through a generated randomization list using random permuted blocks.

A random sequence of the intervention and control group was provided for randomization.

In to either the intervention group or the control group with a random allocation method. The randomization sequence was generated by permuted block randomization. Firstly, all 242 patients were classified into a total of six groups based on three age groups and two sexes. Patients in each subgroup were assigned randomly into the two treatments groups (A: an intervention group and B: a control group) using the permutation block randomization method, a random sequence of A and B. Initially, patients were assessed by an exercise and sports medicine physician who is the cardiac rehabilitation specialist. Then, they were referred to a nurse who had a series of pockets for each of the 6 subgroups with unknown special code belonged to one of the study groups. Each patient was asked to open one of the pockets by which his/her study group had been determined. One group has received HBCR intervention which was included 4 sessions of supervised CR and 8 weeks rehabilitation at home, while the second group just has received the usual care, which including general recommendations about a healthy lifestyle, doing aerobic exercises, and nutritional instructions.

Project statistician and outcome assessors were blinded to the intervention.

Intervention group

Patients in the intervention group have received a physical activity program based on the initial exercise test (Modified Bruce) three times a week in four supervised programs, including warm-up containing stretchings for upper and lower extremities, main aerobic exercise based on physical ability at a moderate level of intensity with gradual increase in timing, and cool-down; this program has continued at home. Phone tracking has been used for everyone to check following the exercise program and their possible problems. In this study, educational contents had been designed on various aspects of rehabilitation based on health behavior change models. These contents had been prepared by specialists in the fields of health education and promotion, cardiology, and sports medicine in collaboration with other partners on the basis of their experience and expertise and in accordance with the Health Action Process Approach (HAPA). Indeed, an educational package has been a combination of motivational factors including outcome expectancy, self-efficacy, and risk perception as well as volitional factors including action and coping planning. This program has been offered in different methods of educations at the individual and interpersonal levels by the relevant experts and it contained a heart-healthy diet, stress management, lifestyle changes, smoking cessation, and an individualized exercise program.

Additionally, a nutritionist and a psychologist have been held nutritional and psychological counseling sessions and also, patients have been visited by a cardiologist and a sports medicine specialist at the baseline, six months, and are going to be visited 12 months later. People who could not attend hospital visits, have undergone home visits by trained nurses. Participants have had a telephone number to share their potential problems with related specialists. These patients have received routine education too.

Control group

The control group has received the usual care which is the same hospital routine program general recommendations. Patients with IHD have also received a series of training courses on needed care after discharge during hospitalization and have undergone clinical assessment in hospitals affiliated with Isfahan University of Medical Sciences, which includes a healthy lifestyle, doing aerobic exercise, and nutritional instructions. Additionally, some educational materials have been available to be used at home. Furthermore, cardiologists offer routine recommendations in the following visits at six months, and 12 months after discharge. An echocardiogram will be performed 12 months after being discharged from the hospital and outcome assessments will be done.

Outcome assessment

Primary outcomes including quality of life, psychological and smoking status, body mass index (BMI), blood pressure, blood cholesterol, and the physical activity level have been measured at six months after the randomization and intervention. A year after the intervention, secondary outcomes containing cardiovascular events, the frequency of hospital admissions, and the death rates due to cardiovascular reasons will be assessed.

The Iranian version of the short form SF-36 has been used to assess the health-related quality of life of participants.^[20] This questionnaire had been used in the previous studies in IHD patients in Iran.^[21,22] The modified version of the Godin Leisure-Time Exercise Questionnaire has estimated the physical activity levels of participants, and physical activity data has been converted into a metabolic equivalent (MET) - minutes.^[23]

Dietary intake has been recording with 24-hour dietary recalls over two days (one weekday and one weekend) apart.^[24] The Persian version of the Beck depression inventory-II (BDI-II) has been used as an assessment tool to determine the intensity of depression in the participants.^[25] Weight and height variables have been measured with a calibrated scale to the nearest 0.1 kg and a wall-mounted stadiometer to the nearest 0.1 cm, respectively. BMI has been calculated with weight in kilograms (kg) divided by height in meters squared.^[26]

Systolic and diastolic blood pressure has been measured with a mercury random zero sphygmomanometer after a

10-minute break after the participant locating in a sitting position, from right arm twice with at least one-minute interval.^[27] Maximal oxygen uptake has been measured based on the Modified Bruce treadmill exercise test that has been performed in all participants.^[28] To evaluation of the serum total cholesterol (TC), triglyceride (TG), low-density lipoprotein (LDL-C), and high-density lipoprotein (HDL-C) a five-milliliter sample of fasting blood has been taken from each patient and has been analyzed using an auto-analyzer and the Pars Azmoon standard kit. These tests will be all repeated at the end of the program.

Statistical considerations and data management

To analyze the data, appropriate parametric or non-parametric statistical tests will be used in accordance with the nature of the data. Repeated measures ANOVA for comparing the two groups as well as measured times (at the baseline, 6 months later and, 24 months later) and interaction between them will be employed for the quantitative outcome variables. Generally, this has performed the data analysis with 0.05 significant levels. The differences of quantitative outcome variables between the baseline and a year after will be compared between the two groups by controlling confounder variables through analysis of covariance. On the other hand, as there are several outcomes, Bonferroni confidence intervals will help to keep the significant level of all comparisons at 0.05. Furthermore, as it has been anticipated that some of the outcome variables will be significantly correlated, the differences between the values of quantitative outcome variables at baseline and after a year will be calculated. Then, these entire different variables will be regressed based on some important outcomes such as the frequency, severity of angina and also shortness of breath.

Ethics and dissemination

Before the entry into this trial, the patients had received a study information sheet; and a signed informed consent form obtained from each participant. Ethics Committee on Research of National Institute of Medical Research Development (NIMAD) of Iran has approved the Informed Consent (Code of Ethics:IR.NIMAD.REC.1394.019 Date of approval of the code of ethics: 2016 March 5) and the study has been conducted in accordance with the Helsinki Declaration.

Iranian Registry of Clinical Trials (IRCT) has approved the study protocol (approval number: IRCT2016022926820N1) according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).^[29] Participants has been assured of anonymity. No potentially serious risk to patients during HBCR has been identified.

Research findings will be published in relevant peer-reviewed journals; additionally, results will be reported to the local authorities. Depending on the comprehensiveness of the outcome measures and the extent

of the interventions, the results will be published in more than one journal.

Discussion

To the best of our knowledge, this trial is the first one that has been conducted in Iran and will consider all aspects of HBCR and compare the results of usual care with the HBCR program. The results of this trial could provide evidence for health care workers and local authorities for the impact of HBCR on patients who do not participate in a hospital-based rehabilitation program. If positive outcomes occur, patients will benefit from it, and local authorities can design better planning for the more patients benefit from cardiac rehabilitation programs.

Some subjects had not been interested in attending the study. However, investigators have tried to gain their cooperation by motivating and encouraging patients via a clear explanation about study objectives. One of the limitations of this study is that the control group had to receive health-related instructions that were somewhat similar to the intervention group as it is unethical to deprive them of these beneficial instructions. The major difference between these two groups has been the individually tailored exercise program. A meta-analysis that has compared HBCR with center-based CR has concluded similar benefits of them regarding the quality of life, clinical outcome and being cost-benefit.^[16] These results have been confirmed in other studies. Kraal study has published HBCR associated with better participation satisfaction and more cost-benefit than center-based programs.^[19] Rathore study in a review article has shown that HBCR can be a reasonable option in IHD patients in low to middle-income countries. Simple strategies such as HBCR are urgently needed to increase adherence in eligible patients.^[30] These studies have compared HBCR to center-based but few studies have compared HBCR to usual care. A study that was published in the Journal of Cardiopulmonary Rehabilitation and Prevention, has compared usual care with HBCR plus usual care; greater reductions in IHD major risk factors and an improvement in the quality of life have been demonstrated in participants who had received HBCR.^[31]

Authors' contribution

HO contributed in drafting the work and revising it, approval of the final version of the manuscript, and agreed to all aspects of the work.

AA contributed in drafting the work and revising it, approval of the final version of the manuscript, and agreed to all aspects of the work.

HR contributed in the conception of the work, Definition of intellectual content, approval of the final version of the manuscript, and agreed to all aspects of the work.

MM contributed in analyzing and interpreting of data and Statistical analysis, approval of the final version of the manuscript, and agreed for all aspects of the work.

LV contributed in conducting the study, Clinical studies and Literature search, approval of the final version of the manuscript, and agreed for all aspects of the work.

MA in conducting the study, approval of the final version of the manuscript, and agreed to all aspects of the work.

HH contributed in conducting the study, data acquisition, approval of the final version of the manuscript, and agreed to all aspects of the work.

GM in conducting the study, approval of the final version of the manuscript, and agreed to all aspects of the work.

SY contributed in conducting the study, data acquisition, approval of the final version of the manuscript, and agreed to all aspects of the work.

MS contributed in Manuscript Preparation, Manuscript editing, Manuscript review of the work, approval of the final version of the manuscript, and agreed to all aspects of the work.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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