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Effects of Phase IV Pedometer Feedback Home-Based Cardiac Rehabilitation on Cardiovascular Functional Capacity in Patients With Myocardial Infarction: A Randomized Controlled Trial

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Abstract

Introduction: Pedometer feedback home-based cardiac rehabilitation (PFHCR) programs have been effective in augmenting exercise tolerance. Our aim was to investigate the effects of PFHCR on cardiovascular functional capacity in patients with myocardial infarction (MI).

Methods: Forty MI patients were divided into two intervention and two control groups (n=10) in a randomized controlled trial. The intervention group received a PFHCR program including routine medications along with continuous exercise program, whereas the control group received traditional care without PFHCR. Baseline evaluations and cardiovascular stresses were controlled during the 8-week follow-up rehabilitation program in all patients. Data analysis was conducted using one-way ANOVA and paired sample student's t-test ($P \leq 0.05$).

Results: At baseline, no significant differences were observed between the groups. After eight weeks of PFHCR, the intervention groups had significantly higher metabolic equivalent ($P=0.001$), VO2max ($P=0.001$), total exercise times ($P=0.001$), and total distance traveled ($P=0.003$) when compared with the control groups. However, no significant intragroup or intergroup differences in variables were observed between the men and women.

Conclusion: Our results showed that PFHCR exhibited significant optimal effects on the cardiovascular functional capacity in MI patients.

Keywords: Cardiac rehabilitation, Myocardial infarction, Functional capacity, Exercise test, Coronary heart disease

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Introduction

Cardiovascular diseases (CVDs) includes coronary heart disease (CHD), congestive heart failure, myocardial infarction (MI), peripheral artery disease, and carotid artery disease. Coronary artery disease (CAD), angina pectoris, and MI are among the main causes of death worldwide. According to the World Health Organization (WHO), mortalities due to CAD will increase from 7.1 million in 2002 to 11.1 million in 2020.[1,2] Evidence has shown that only one-third of all MI cases lead to serious heart diseases and death.[3] Hence, post-MI therapies have become the main focus of studies in medicine and sport science. Although the effect of regular aerobic exercises has been clarified on early prevention of cardiovascular diseases and risk of death caused by them,[4,5] supervised physical activity (PA) can prevent the relapse of cardiovascular events. Cardiac rehabilitation (CR) home-based programs are more effective than CR methods in hospitals and health centers due to needing less time and expense to perform,[6] reducing the likelihood of readmission[7] and risk of recurrent MI,[5] and upgrading physical performance.[3] However, some patients do not perform adequate levels of PA to experience its health benefits.[8]

Research evidence shows that walking

is a simple activity for cardiovascular patients and a flexible alternative for people who do not have access to hospital treatments. In addition, these types of therapeutic approaches play a major role in resuming everyday work and life in such patients.[9] Parmanto and Saptono[10] reported that 150 minutes of walking per week was enough to achieve health objectives, but Tudor-Locke et al stated that walking 100 steps per minute was an activity of moderate intensity and walking 3000 steps per week could have cardiovascular benefits.[11] Currently, it is not clear whether exercise approaches that include conventional programs (PA recommendations without a pedometer feedback) or pedometer-based programs will have benefits for MI patients.

Research findings indicate that only 10-20% of patients with acute MI participate in a secondary preventive program based on PA[3] and only 40% of patients taking part in the maintenance phase (Phase IV) of CR programs manage to achieve the recommended PA level.[12] CR programs are employed to recover health and prevent disease progression in people with heart diseases[3] and play a major role in secondary prevention (SP).[12] However, patients with MI do not usually perform adequate postoperative PA to prevent SP due to fear of movement and muscle weakness caused by immobility.

Hence, the present study investigated the assumption that use of a pedometer can increase daily home-based CR by creating self-motivation and thus is able to improve cardiovascular function and physical performance capacity in MI patients. Accordingly, the present study aimed to study the effects of pedometer-based feedback in an 8-week pedometer feedback home-based CR (PFHCR) program on cardiac functional parameters [i.e. metabolic equivalents (METs), VO2max, total exercise times following an aerobic exhaustive exercise on treadmill, distance traveled, and maximum heart rate during the Bruce test] in men and women with MI in comparison to those of a conventional treatment program.

Methods

Participants

The study population consisted of all MI patients hospitalized in the cardiac intensive care unit and cardiology ward of Shahid Madani hospital, Khoramabad, Iran from September to November 2017. Based on diagnosis made by specialists and the New York Heart Association (NYHA) classification,[13] all potential participants were diagnosed with heart failure and were classified as NYHA class II and III. They had left ventricular ejection fraction of 40-55% in electrocardiography, and took part in the outpatient program after discharge. Following MI, the patients had no persistent complications and were in phase IV CR. Ninety-five patients were initially enrolled (Figure 1), 55 of whom fulfilled the inclusion criteria. Finally, 44 male and female patients with MI aged 45-60 volunteered to participate in the study. They were randomly divided into four groups: 2 intervention groups (10 males and 10 females) and 2 control groups (12 men and 12 women). The intervention groups underwent CR walking program using waist-mounted pedometers (PA-S20, Switzerland) according to the manufacturer's instructions, and the number of steps taken, shown by the step counter, were recorded in a sport results notebook. The control groups performed the conventional CR program at 5:00 PM without pedometer feedback. Participants in the control group also received traditional care but were given no exercise education. The participants were asked to return after eight weeks for evaluations. After baseline evaluations, participants were randomly allocated to the intervention groups (with pedometer) or control groups (without pedometer).

Inclusion and Exclusion Criteria

The inclusion criteria were history of angioplasty, CAD and/or angiography of moderate CVD (e.g. mild CAD), lack of taking beta blockers (propranolol, methoral [metoprolol], verapamil, atenolol, and carvedilol) 24 hours before the exercise test, having physical ability to get the exercise test (e.g. lack of suffering from arthritis or amputation), lack of smoking, lack of drinking alcohol, and lack of taking antioxidant supplements, lack of having ECG abnormalities (e.g. signs of heart failure), and lack of suffering from infectious diseases or cold (because of the likelihood of abnormal ECG manifestations). The exclusion criteria were definite diagnosis of ischemia, lack of being permitted to get the exercise test, having ejection fraction of less than 40% and over 55%, and lack of history of using pacemaker (for CVD patients).

Interventional training

The PFHCR program in this study included walking at home for almost 45-60 minutes (7-minute warm-up, 40-minute walking, and 7-minute recovery and stretching exercises) and at 11-13 Borg score of perceived exertion. Five weekly exercise sessions were conducted in the afternoon for eight weeks with and without step counter feedback for both women and men in the intervention and control groups, respectively. The 8-week walking exercise was designed based on a protocol used in a previous study [14] yet with minor modifications. From the second week to the eighth week, the number of steps increased by 10% per week (by 100 steps/day to a total of 500 steps/week). In other words, 100 steps were added every day, as the extra load, to the number of steps taken. The participants were trained to add the extra load during the same 40 minutes of daily walking. A pilot study was conducted to evaluate the way according to which the progressive protocol was to be carried out by the participants and the number of steps to be taken at the start (3,500 steps/day). The control groups performed the same CR exercise program but did not use the step counter feedback.

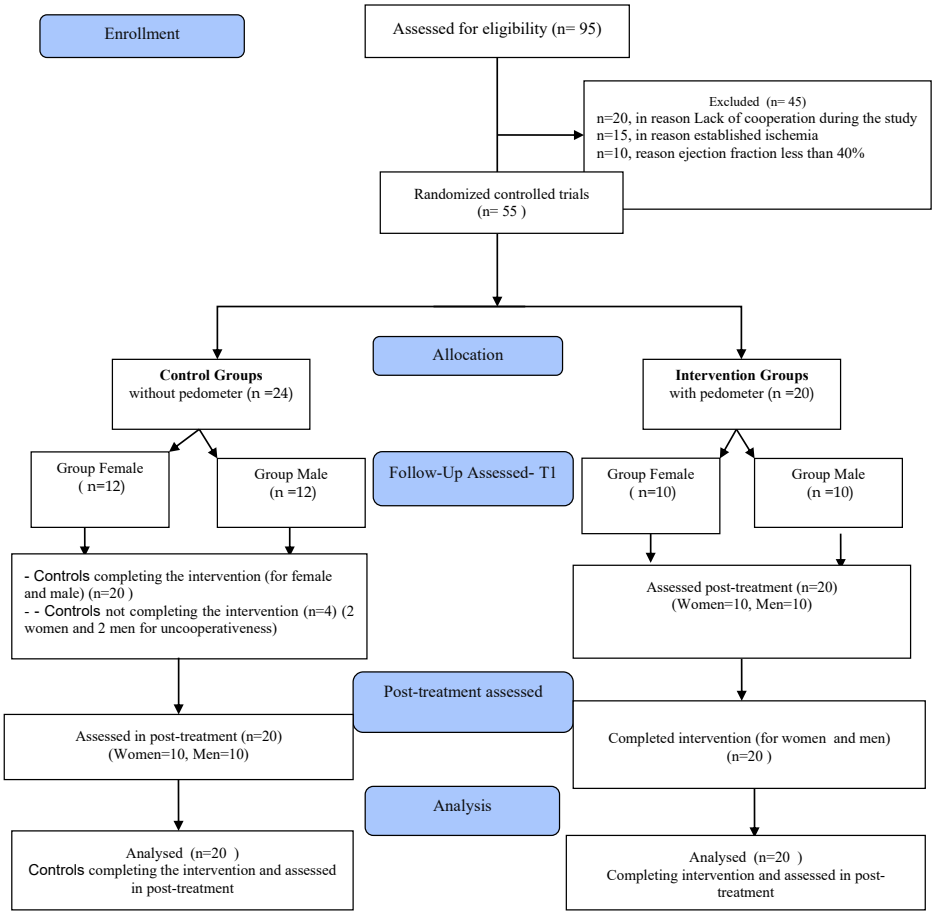

Figure 1. CONSORT Flowchart of the Trial.

The Bruce Protocol Stress Test and Assessment of Cardiovascular Functional Capacity Indicators and Termination Criteria

The protocol was implemented as a two-stage project (before and after the 8-week exercise-based CR). In both stages, the advanced treadmill test was performed using the modified Bruce Protocol (at 3 km/h rate with increases of 1.4 km/h after3 minutes, followed by a 3% increase in grade at a constant speed) to determine the cardiovascular and respiratory function indicators of aerobic exhaustive exercise .[15] Functional capacity including metabolic equivalent of task (MET), VO2max, total exercise times following an aerobic exhaustive exercise on the treadmill and the distance traveled on the treadmill during the activity were also measured and recorded. Before implementing the standardized Exercise Treadmill Test (ETT) using the Bruce Protocol to determine cardiac and respiratory function, the patients were examined by the physician in attendance, and were asked to wear light clothing and take off their shoes to measure their height and weight using standard methods. The exercise termination criteria, previously described,[16] were assessed during the last minute of each stage of the test.

Statistical Analysis

The SPSS version 22 (IBM Inc., New York, US) was used to perform statistical analysis. Normal distribution of data was investigated using the Shapiro-Wilk test. $P<0.05$ was considered significance level. Data was analyzed using one-way ANOVA and paired sample Student's t-test to investigate intragroup and intergroup differences in the studied variables.

Results

All demographic and clinical characteristics of the participants and clinical variables during hospitalization including age, gender, CHD classification, disease intensity, waist circumference, BMI, blood pressure, medications, and smoking were studied (Table 1). A total of 40 MI patients were evaluated during the 8 weeks. They were randomly divided into two intervention groups and two control groups (N=10). Table 1 presents baseline, demographic, and clinical characteristics of our patients. There was no significant difference in CHD classification, age, BMI, addiction, high blood pressure, family history of heart diseases or diabetes, coronary artery bypass grafting, ST-segment elevation myocardial infarction (STEMI), and non-STEMI between the groups.

Table 1. Baseline Characteristics of Participants

Variables	Male (n=20)			Female (n=20)		
	Intervention Group n=10	Control Group n=10	*P* value	Intervention Group n=10	Control Group n=10	*P* value
Age (y), mean±SD	51.4 ± 7.97	51.1 ± 7.86	0.559	51.5 ± 6.96	53 ± 7.33	0.331
BMI (kg/m^2), mean±SD	23.66±1.58	24.6±1.20	0.442	24.53±1.28	25.9±1.43	0.124
Smoking, No. (%)	2 (20)	2 (20)	0.653	-	-	0.411
Hypertension, No. (%)	3 (30)	3 (40)	0.371	3 (30)	2 (20)	0.204
Family history of heart disease, No. (%)	3 (30)	3 (30)	0.211	3 (30)	2 (20)	0.131
Diabetes mellitus, No. (%)	1 (10)	1 (10)	0.756	2 (20)	2 (20)	0.698
CABG, No. (%)	3 (30)	2 (20)	0.151	2 (20)	2 (20)	0.254
NSTEMI, No. (%)	1 (10)	2 (20)	0.134	2 (20)	2 (20)	0.372
STEMI, No. (%)	1 (10)	1 (10)	0.347	2 (20)	2 (20)	0.267

CABG: coronary artery bypass grafting; NSTEMI: non-ST segment elevation myocardial infarction; STEMI: ST-segment elevation myocardial infarction.
* Significant difference at $P \leq 0.05$.

Assessment of Functional Capacity in the Exercise Test

The effects of the exercise test on cardiovascular performance in participants are presented in Table 2. In the baseline evaluation, there were no statistically significant differences in any of the variables between the control groups. With regards to intragroup and intergroup effects after receiving the PFHCR, significant differences were observed in MET, VO2max, total exercise times and distance traveled during Bruce test between the female and male participants in the intervention group compared to the control group following the 8-week CR. However, no significant intragroup differences were observed between men and women in control groups.

Discussion

Recent studies on patients participating in CR have programs revealed that many of them do not meet the recommendations for physical activity.[17] This indicates the need for pedometer feedback during rehabilitation programs at home and in real life settings more than ever. Based on our information, few studies have so far evaluated the effects of PFHCR on VO2max based on estimated functional capacity, MET, total exercise time, and distance traveled in MI patients. Our results showed that PFHCR influenced these indicators in both female and male MI patients compared to the control groups.

MET that is a standardized measure of energy consumption is strongly associated with increased risk of CHD, adverse cardiovascular outcomes, and all-cause and cardiovascular mortality. In the Scandinavian Simuvastatin Survival Study[18] MET was commonly detected in patients with CHD. We in this study used MET to detect overall metabolic changes and to determine the impacts of our intervention. In our study, MET significantly improved in intervention group after 8-week follow-up. The modified Vo2max, total exercise times and distance traveled significantly improved in the intervention group. Therefore, the PFHCR was effective to improve cardiac function in MI patients.

CR should be considered as an integral component of any cardiology prevention-service continuum.[18] In patients with heart failure, VO2max is reduced because the respiratory restriction prevents the maximum capacity of the heart. Additionally, higher exercise intensity had greater impact on VO2max.[19,20] A significant difference was observed in VO2max compared to baseline between

Table 2. Comparison of Cardiac Functional Parameters Before and After Cardiac Rehabilitation Between Females and Males in the Control and Intervention Groups

Functional capacity parameter		Control Groups		Intervention Groups	
		Pre	Post	Pre	Post
Metabolic equivalent of task (MET) (O2)	Female	8.08±2.98	7.45±2.38	8.14±1.6	10.97±2.13***
	Male	10.08 ±3.1	9.77±3.26	8.23±2.49	11.29±2.21* **
VO2max (mL/kg/min)	Female	26.12±8.34	29.13±9.65	28.52±5.57	38.40±7.47***
	Male	34.48±8.99	33.40±9.55	28.83±8.72	39.52±7.74 ***
Total exercise times (min)	Female	5.46±2.78	5.32±2.41	5.33±1.94	8.01±2.40 ***
	Male	6.79±2.63	7.32±2.35	5.91±1.66	7.99±2.15 ***
Distance traveled (M)	Female	340±21	290.10±18	308.20±14	511.50±26***
	Male	447.90±24	480.70±24	365.10±13	557.80±20**

Values expressed as mean ±SD.
* Significant difference at $P \leq 0.05$. *$P < 0.05$, **$P < 0.01$, ***$P < 0.001$.

the studied groups in our study. However, PFHCR intervention significantly improved VO2max after 8 weeks compared to the traditional care.

Epidemiological studies indicate that even a slight increase in distance traveled per daily is effective to improve heart health. Based on these findings, general practitioners and health professionals play a key role in encouraging patients to increase distance traveled per day. As a preventive method, physical activity significantly reduces cardiovascular disease mortality by moderating risk factors such as increased blood flow in coronary artery branches and increased cardiac and muscle oxygen consumption.[21] It has been confirmed that VO2max is increases following regular physical exercises because of enhanced mitochondrial enzymes activity and increased myoglobin levels and skeletal muscles vasculature.[22] In the posttest of the present study, VO2max and METS values also significantly increased in men and women in the intervention group but decreased in men and women in the control group. The changes in the intervention group were also significant compared to the control group. Moreover, changes in VO2max and MET in both intervention groups and in both genders were in agreement with changes in the time to exhaustion during treadmill running and distance traveled shown by the pedometers. The present study showed that VO2max in PFHCR increased in men and women in intervention groups ($P<0.001$) after the 8-week CR program but no significant corresponding differences were observed in the control groups ($P\geq0.05$).

Aerobic exercise increases functional capacity, and 1 unit increase in functional capacity reduces the risk of cardiovascular events by 25%.[23,24] It has been confirmed that VO2max increases following regular physical exercises because of enhanced activity of mitochondrial enzymes, increased myoglobin levels, and augmented capillary surfaces in the skeletal muscles.[25] Our results showed significant increase in MET ($P<0.001$) in male and female MI patients after the 8-week PFHCR program. Besides, PFHCR results in a significant increase in aerobic capacity in individuals with sedentary lifestyle. The increase of functional capacity in male and female participants in intervention groups in the present research was accompanied by improved cardiac functional capacity in female and male participants in PFHCR groups compared to the control group ($P\leq0.05$). Sharma and McLeod noticed that CR significantly affected physical tolerance of patients.[26] In a study on 49 patients with MI after CABG procedure, Park et al observed that their functional capacity clearly improved after CR.[27] Given their findings, the increased walking stamina of women and men in PFHCR groups in the present study may also be due to improved function of the respiratory and cardiovascular systems that decreased the patients' locomotor disability. The small number of participants in the intervention groups was one of the limitations of our study. Future studies can obtain more reliable results if they are conducted with larger sample size and more careful control of patients' activities at home.

Conclusions

The present study showed improved cardiac functional parameters following the 8-week PFHCR program in MI patients. These changes including improved myocardial workload and oxygen consumption as well as improved indicators of cardiovascular function were gender independent and equal in men and women. Therefore, pedometers can be used for patients that do not have access to CR centers, cannot go to sports facilities for financial or otherwise reasons, or lack free time for walking.

Ethical Approval

All participants provided written informed consent to participate in the study and the study protocol conformed to the Declaration of Helsinki and was approved by the local ethics committee (Approval ID: IR.LUMS.REC.1397.105). All procedure of the study was registered in the Iranian Registry of Clinical Trials (identifier: IRCT20181122041725N1; https://www.irct.ir/trial/35414).

Competing interest

The authors declare no competing interests.

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