Original Article

The Effects of an Exercise Empowerment Programme for Older Patients with Heart Failure: A Randomized Controlled Trial

Emine Karaman, PhD, RN
Assistant Professor, Medical Nursing Department, Ege University Faculty of Nursing, Izmir, Turkey

Cicek Fadiloglu, PhD, RN
Retired Professor, Medical Nursing Department, Ege University Faculty of Nursing, Izmir, Turkey

Yasemin Yildirim, PhD, RN
Professor, Medical Nursing Department, Ege University Faculty of Nursing, Izmir, Turkey

Mehdi Zoghi, MD
Professor, MD. Ege University, Faculty of Medicine, Cardiology Department, Izmir, Turkey

Yasar Guneri Sahin
Professor, Izmir Economics University, Faculty of Engineering and Computer Science, Software Engineering Department, Izmir, Turkey

Fisun Senuzun Aykar, PhD, RN
Professor, Medical Nursing Department, Ege University Faculty of Nursing, Izmir, Turkey

Correspondence: Emine Karaman, PhD.RN.Ege University Faculty of Nursing, Department of Internal Medicine Nursing, Bornova, Izmir, Turkey E-mail: emine.karaman@ege.edu.tr

Abstract

Introduction: Patients with heart failure have decreased exercise tolerance, balance problems, and fall risks.
Aim: The purpose of this research was to investigate the effect of an exercise program based on the Empowerment Model for participants with heart failure.
Method: This randomized, controlled study including pre-test/post-test and the measurements were performed between January-November 2014 at a university hospital in Izmir, Turkey. Intervention group (n = 11) and control group (n = 10) participated in the research. The intervention group received 45-60 minute individual training and 12 weeks of individual follow-up. The weekly motivational phone calls structured according to the empowerment model and home visits when necessary were repeated. Patients in the control group did not receive any intervention except for their routine treatment. Data were collected before the education of exercise and after 12 weeks; sociodemographic data questionnaire, pedometer, accelerometer, Berg Balance Scale, HF Empowerment Scale, estimated weekly exercise monitoring form and exercise booklet had been utilised. The SPSS statistical package program was used to analyze the data.
Results: After the exercise program, a significant increase was seen in comparison with the control group in the mean scores of the intervention group on the Heart Failure Empowerment Scale, on the Berg Balance Scale. But, at the end of the exercise program, no significant increment was seen in comparison with the control group in the mean scores of the intervention group on the activity level (X, Y and Z axis).
Conclusion: The results of this study were evidence that showed the effects of Empowerment Model-based exercise program conducted by nurses and multidisciplinary team.

Keywords: Aging, randomized controlled trials (RCT), nursing, physical activity

Introduction

Heart failure (HF) is a global pandemic disease affecting at least 26 million people worldwide and will increase with an ageing population (Gianluigi and Lund, 2017). Patients with heart failure have reported symptoms of decreased exercise tolerance, reduced cognitive impairments, and postural hypotension which are associated with falls (Mozaffarian et al., 2015; Murad and Kitzman, 2012). Some studies reported that patients with HF had alterations in sites of the brain associated with motor regulation which may affect gait and balance (Kumar et al., 2011; Woo et al., 2015). There is important evidence that chronic/acute disease, cerebral infarction, and physiological illness are associated with falls (Lee et al., 2016). It is also known that the cardiac drugs used by HF patients also increase the risk of falls (De jonk et al., 2013). Therefore patients with heart failure are at a grave danger.

Old people are faced with a loss of autonomy and physical inactivity. Falls are a major cause of dependence in old people and can result in disability, loss of mobility, reduced quality of life and even death (Tiedemann et al., 2013). Furthermore, there is clear evidence that specific exercise programs that challenge balance are more effective in preventing falls (Sherrington et al., 2008). Exercises especially that incorporate elements of balance, gait, and strength training have been shown to reduce the activity levels and the incidence of falls among old adults (Gillespie et al., 2012; Kenny et al., 2011). It is known that muscle weakness and balance deficit are intrinsic risk factors leading falls. In the literature, a regular, planned physical exercise is emphasized in connection with the independence and balance of the geriatric population (Lunsford B, Wilson, 2015; McAllister et al., 2012; Villareal et al., 2017).

Fall can be reduced by effectively monitoring activity levels of old people and conducting early interventions for those with possible loss of balance. There are various systems which can monitor individuals’ activities and balance and provide alerts in emergency situations, but these systems generally involve equipment such as cameras which violate the privacy of the individual (Cardile et al., 2010). In additions, nurses play a key role in improving the exercise capacity and preventing fall in old adults. The American Nurses Association identified patient falling down as a nurse-sensitive indicator (Lunsford and Wilson, 2015).

The importance must be stressed of a theoretical basis for programs relating to fall and its’ prevention in order to improve balance and exercise capacity and to promote preventive behavior. Indeed, literatures of many studies of educational programs of fall prevention are based on theory (John JAst et al., 2015; Frieson et al., 2012). The Empowerment Model was developed for health-protection and improving behavior such as exercise, self-care, self-monitoring. The European Society of Cardiology (ESC) also emphasize that the treating patients with heart failure play a key role in their own care and treatment (ESC/EAS, 2011). Developing self-confidence, and enabling patients to cope with the problems they encounter is the key concept in achieving this empowerment, which include’s creating a feeling of success in people who need continuous treatment and care, especially because of chronic illness (McAllister et al., 2012). Studies on empowerment are usually involved in diabetic individuals. A statistically significant reduction in HbA1C and blood pressure values were seen after the empowerment training had been given to individuals with diabetes (Castillo et al., 2010; Naik et al., 2011; Tang et al., 2010; Tekir and Esen, 2011). Despite the strong evidence supporting some exercise modalities for preventing falls in old adults, there is uncertainty especially about the effects of exercise programme in old people with heart failure.

Aim of the Research: This study aimed to investigate the effects of a fall prevention exercise program based on the empowerment model for senior citizens. The goals of the exercise program were to increase participants balance and activity level, empowerment level, their exercise capacity, during the weekly exercise regiment.

Materials and Methods: This randomized controlled study including pre-test/post-test and follow-up trials were performed between January-November 2014 at a university hospital in Izmir, Turkey. The RCT number was obtained (NCT 04022369).

Study population: The study population comprised of patients being treated in the cardiology outpatient clinic or cardiology inpatient unit of the hospital, and the sample consisted of patients with HF who met the inclusion criteria. A total of 21 patients (11 exercise, 10 control) completed the study. The patients’ addresses and telephone numbers were noted, and home visits were conducted approximately one month after discharge. All individuals eligibility for exercise were assessed by a cardiologists. The inclusion criterias were aged 60 years or older, independent, literate, able to communicate verbally, and participating voluntarily in the study. Exclusion criterias were having a diagnosis of psychiatric illness, a visual or auditory impairment, previously participated in another exercise program, and any contraindication to exercise (uncontrolled arrhythmia, hypertension and metabolic illness, ejection fraction <30%, abnormal hemodynamic response, ischemic cardiogram changes at the exercise tolerance testing, advanced cerebrovascular and peripheral vascular insufficiency, pulmonary emphysema).

Ethical Issues: The study protocol was approved by the Institutional Review Board of the University . The participants provided their written informed consent in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

Randomization: A simple layered randomization method was used in the selection of the study sample. Sixty patients were examined to determine their eligibility for participation in the study. The selected patients (n=30) were assigned to the exercise group (n=15) and the control group (n=15). The final sample size cosistes of 21 old people (exercise group n=11 and control group n=10) (Figure 1).

Exercise Group: The intervention group received 45-60 minute of individual training and a handbook for the exercise program was given. These patients were followed for a total of 12 weeks. The weekly motivational phone calls structured according to the empowerment model and home visits when necessary were repeated. The exercise program was developed by reviewing the literature part on physical activity for senior citizens with heart failure. The program was established on evidence-based recommendations for the cardiac rehabilitation of patients with HF. Each session included warm-up and cool-down exercises, moderate walking, and balance exercises (McAllister et al., 2012; Demirsoy and Taskiran, 2010). Details of the education program based on Empowerment model can be seen in Table 2 (Kaldoudi, 2012). Visual tools and repetition methods were used by the researcher to facilitate patients understanding and to increase their knowledge. Weekly motivational telephone interviews structured according to the empowerment model were conducted with the patients, and the home visits and telephone interviews were repeated when belived necessary. The purpose of the study were explained to all individuals involved in the study. Body movements, balance levels, exercise durations, and strengths of individuals before exercise program (T0) and after exercise program (T1) were evaluated. A booklet demonstrating the exercises was given to the patients to enhance their understanding, and they were allowed to ask questions about the exercise program during the training. The content validity index of the booklet was found to be adequate when assessed by five experts. In the exercise group, data collection forms were given to patients in the first month and 12 weeks after discharge (after completion of the exercise program).

Control Group: The patients in the control group continued their standard treatment and care.

Data collection forms were applied to the patients in the control group at the first month and 12 weeks after discharge. After the study was completed, all patients in the control group were provided with home-based exercise training booklets.

Measures: In this research, a sociodemographic data questionnaire (including age, education level, marital status etc.), a pedometer, an accelerometer, the Berg Balance Scale, the HF Empowerment Scale, a monitoring form for estimated weekly exercise and Exercise Booklet were used.

Pedometer:Pedometers provide objective measurement of physical activity and is a potential remedy to the problem of inaccurate activity recall. This was used to evaluate individuals weekly activity and their exercising status. In our study, a simple type pedometer was used.

Accelerometer: Body movements of individuals were monitored with an accelerometer (Texas Instruments Chronos eZ430). At the beginning of the study period and at the end of the procedure (after 12 weeks), each patient was monitored with an accelerometer for an average of 3 days. This device is small and functional enough not to interfere with the daily activities of the individual (Figure 2). As shown in Figure 3, it has been used with a chest strap. The device operates with an ultra-low power panel (3V); the data is transferred to the computer that is used as the receiver through the wireless connection method. It follows the amount of acceleration (x, y, z) on the three movement axes that occur when performing the activities of the individual. This device can be used in a variety of situations, such as the "LLA-Low Level Acceleration" (15-25) in the normal daily activities of the individual, the "MLA-Middle Level Acceleration" (26-35) moderate level activity requiring daily activities and the sudden movements requiring a higher level of daily life activities "HLA-High Level Acceleration"(36 and over) classification (Figure 4) (Sahin et al., 2013).

Fig. 1 CONSORT flow diagram

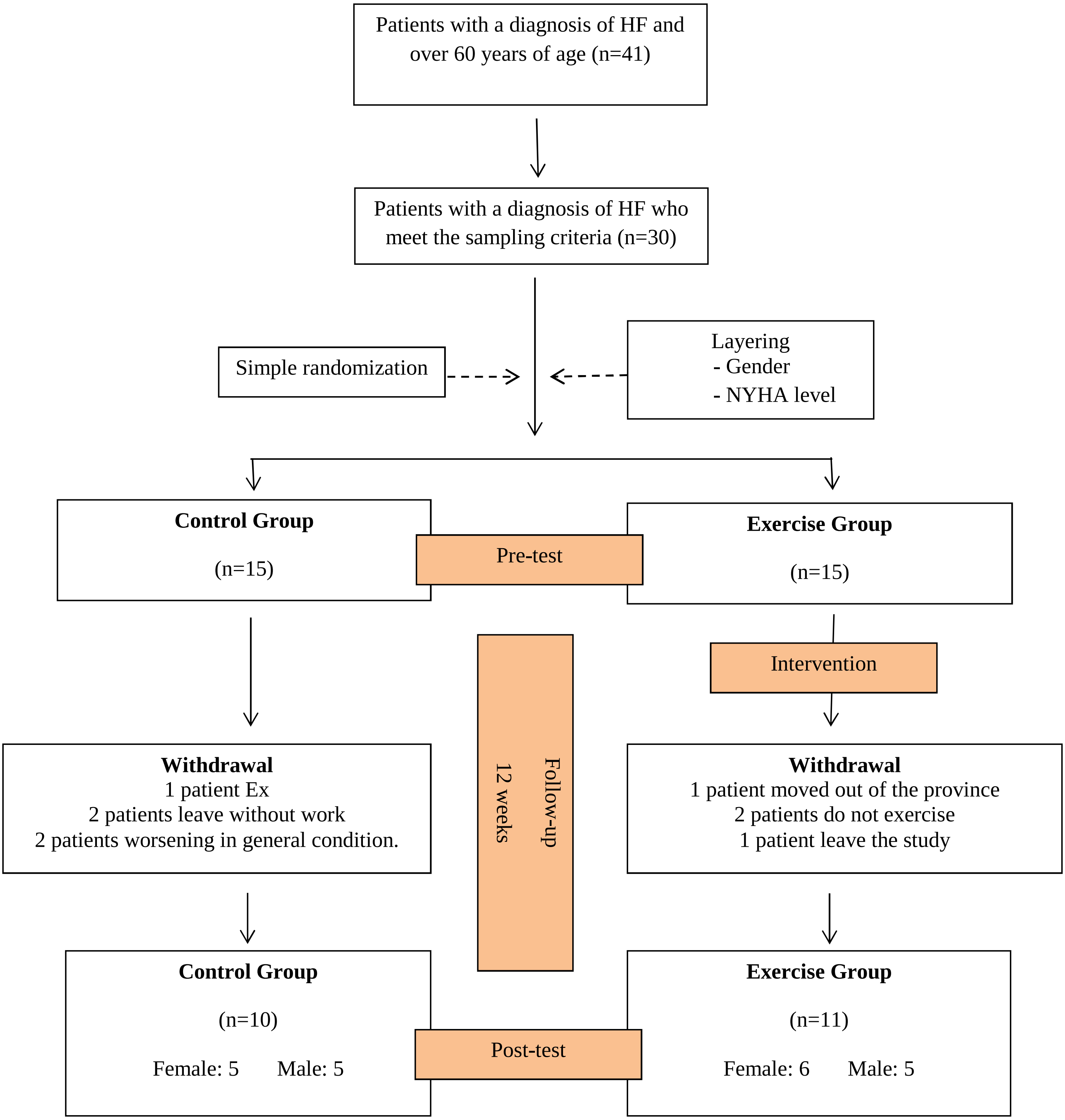


Fig. 2 Accelerometer

Fig. 3 Accelerometer body position

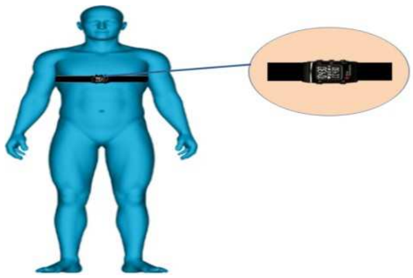
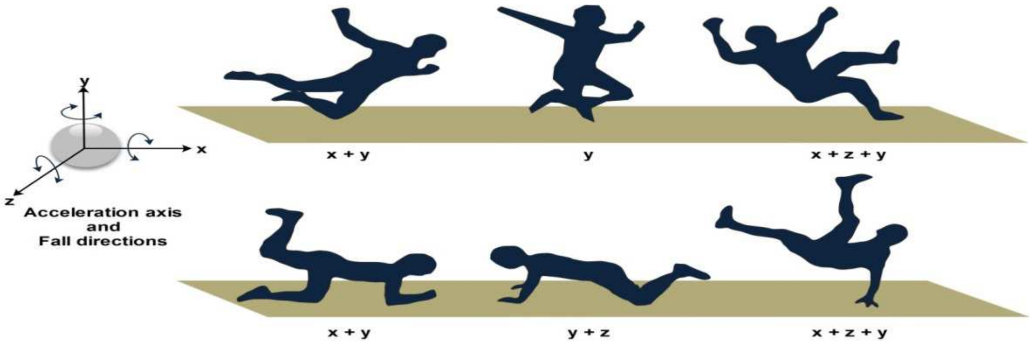


Fig. 4 Body movement oscillations



A custom software program was developed for the device to analyze the collected data. At the same time, the program interface collected the individual's movement data for analysis. The most important feature of the program was that possible daily movements and activities (eating, walking, etc.) of each individual were recorded into the system at the beginning, allowing the software to recognize potential changes in patterns.

The Berg Balance Scale: Validity and reliability studies of this scale were conducted (Sahin et al., 2013). The balance test consists of 14 items and each part is assessed between 0 and 4. It measures the level of dependence or independence in a series of positions, such as standing up from sitting position, standing with both feet together, standing in a fully balanced position, remaining balanced on one leg, and the ability to change position. Higher scores indicate better balance. Patients are placed into three categories based on their score: at high risk of falling, balance disorder (0-20 points); at medium risk of falling, acceptable balance (21-40 points); and at low risk of falling, good balance (41-56 points) (Sahin et al., 2013). Berg Balance Scale was preferred because of its validity, reliability and widespread use. Furthermore the scale was recommended by the thesis monitoring committee.

HF Empowerment Scale: The original version of the Diabetes Empowerment Scale (DES) was adapted for patients with HF, and later converted to the Turkish version (Anderson et al., 2000; Ozcan and Korkmaz, 2012; Karaman et al., 2017). The form of the scale has 28 items and five-way likert-type scale. Scores range from 28 to 140, with scores of 28-65 classified as low, 66-103 as medium, and 104-140 as high empowerment (Anderson et al., 2000).

Weekly Exercise Monitoring Form: This form asks duration (minutes/week) in order to determine weekly exercise such as how the participants do their exercises (balance-walking) which were recommended them.

Analysis of Data: Data were collected immediately before the exercise program as pretest (T0), post-test (T1) 12 weeks after the end of the education programme. Details of the study process can be seen in Figure 1. The SPSS statistical package program was used to analyze the data. The Shapiro-Wilk test was first used to test numeric data for normal distribution. Chi-square and the Mann-Whitney U tests were used to test the homogeneity of the groups. The Mann-Whitney-U test was used to evaluate the significance of changes in study parameters during the study period in groups. Statistical results were evaluated within a confidence interval of 95% ($p<.05$).

Results

Study participants: m45.4% of the exercise group were in the age group 60-64, 54.5% were female, 45.4% were educated to primary school level; 81.8% were married, and 63.6% have three or more children. A 50.0% of the control group was in the age group 70 and above, 50.0% was female, 70.0% had attended primary school level; 70.0% was married, and 60.0% have three or more children. There were no statistically significant differences in measuring the demographic variables between the two groups (p > .05) (Table 1).

Exercise capacity and balance level: None of the participants fell down during the study. At T1, the exercise group showed significant improvements in exercise capacity and balance level compared to baseline values (p<.05) (Table 3). Data obtained from the accelerometer were also used to assess balance. Although these data indicated a small increase in movement capability at the end of exercise program, it was not statistically significant (p>.05) (Table 4). The only significant improvement observed was on the x axis of MLA movements in the exercise group (p<.05) (Table 4). Data obtained from the accelerometer were also used to assess balance. Although these data indicated a small increase in movement capability at the end of exercise program, it was not statistically significant (p>.05) (Table 4). The only significant improvement observed was on the x axis of MLA movements in the exercise group (p<.05) (Table 4).

Table 1 Baseline Characteristics and Homogeneity of Study Participants, According to Study Group (n = 21)

Characteristic	Exercises (n=11)	Control (n=10)	χ^2	p
	n (%)	n (%)		
Age				
60-64	5 (45.4)	1 (10.0)		
65-69	4 (36.4)	4 (40.0)	3.91	.141
70 and over	2 (18.2)	5 (50.0)		
Gender				
Female	6 (54.5)	5 (50.0)	0.041	1.000
Male	5 (45.5)	5 (50.0)		
Education Status				
Primary School and under	5 (45.4)	7 (70.0)		
High School	3 (27.3)	1 (10.0)	1.48	.475
University	3 (27.3)	2 (20.0)		
Marital Status				
Married	9 (81.8)	7 (70.0)	0.38	.635
Single	2 (18.2)	3 (30.0)		
Number of Children				
2 and under	4 (36.4)	4 (40.0)	0.02	.864
3 and over	7 (63.6)	6 (60.0)		
NYHA** Level				
Level I	3 (27.3)	4 (40.0)		
Level II	8 (72.7)	5 (50.0)	1.792	.408
Level III	0 (0.0)	1 (1.0)		
Level IV	0 (0.0)	0 (0.0)		

*Pearson Chi-Square **NYHA= New York Heart Association

Table 2 Contents of the Exercise Program Based on Empowerment Model

	Topics for Program
1st Interview	Medical information about heart failure, old age, falls Measures to be taken to prevent falls Benefits of exercise and walking, effect on balance level Practice for exercise thoughts about exercise and the expression of fears about exercise
12 weeks	Telephone calls were held once a week in order to support the individuals and motivate them to exercise.

Table 3 Berg Balance Level of Patient (n = 21)

Balance Score		Exercises (n=11)	Control (n=10)		
		M ± SD	M ± SD	t	p
Berg Balance Score	Z^0	42.91 ± 3.33	35.70 ± 2.52	5.50	<.001
	Z^1	46.00 ± 3.26	35.50 ± 2.59	8.11	<.001
		t=-4.73 p=.001	t=1.00 p=.343	Z	t

Z^0: I. Measurement Z^1: II. Measurement

Table 4 Results of Patients According to Activity Level (n = 21)

		15-25 Activity Level					
		Exercises (n=11)		Control (n=10)			
		M±SD	Median (Min-max)	M±SD	Median (Min-max)	Z	p
X Axis	Z^0	.143 ± .13	.08 (.03-.40)	.05 ± .04	.04 (.01-.16)	-1.81	.070
	Z^1	.06 ± .06	.04 (.02-.22)	.02 ± .02	.01 (01-08)	-1.72	.085
		Z=-1.71	p=.086	Z=-1.71	p=.086		
Y Axis	Z^0	.95 ± .08	.05 (.02-.22)	.09 ± .08	.040 (.02-.22)	-.83	.402
	Z^1	.10 ± .15	0.03 (.03-.50)	.10 ± .15	.04 (.03-.50)	-.22	.825
		Z=-.17	p=.859	Z=-.88	p=.374		
Z Axis	Z^0	.21 ± .21	0.13 (.05-.62)	.21 ± .21	.10 (.05-.62)	-1.19	.233
	Z^1	.13 ± .17	.07 (.03-.58)	.13 ± .17	.06 (.03-.58)	-.66	.508

		Z=-1.00	p=.314	Z=-1.24	p=.214		
26-35 Activity Level							
X Axis	Z⁰	.00 ± .00	.00 (.00-.01)	.00 ± .00	.00 (.00-.01)	-1.77	.076
	Z¹	.00 ± .00	.00 (.00-.00)	.00 ± .00	.00 (.00-.00)	-.04	.964
		Z=-2.36	p=.018	Z=-1.40	p=.161		
Y Axis	Z⁰	.09 ± .08	.00 (.00-.32)	.00 ± .00	.00 (.00-.02)	-1.45	.145
	Z¹	.00 ± .01	.00 (.00-.04)	.00 ± .00	.00 (.00-.01)	-.39	.691
		Z=-1.24	p=.213	Z=-.88	p=.374		
Z Axis	Z⁰	.01 ± .01	.00 (.00-.03)	.00 ± .00	.00 (.00-.03)	-.44	.659
	Z¹	.00 ± .00	.00 (.00-.03)	.00 ± .00	.00 (.00-.03)	-.92	.354
		Z=-.65	p=.515	Z=-.77	p=.441		
36 ↑ Activity Level							
X Axis	Z⁰	.00 ± .00	.00 (.00-.00)	.00 ± .00	.00 (.00-.00)	-1.94	.052
	Z¹	.00 ± .00	.00 (.00-.00)	.00 ± .00	.00 (.00-.00)	-1.28	.198
		Z=-1.18	p=.236	Z=-.10	p=.916		
Y Axis	Z⁰	.00 ± .02	.00 (.00-.07)	.00 ± .00	.00 (.00-.00)	-1.95	.050
	Z¹	.00 ± .00	.00 (.00-.01)	.00 ± .00	.00 (.00-.00)	.00	<.001
		Z=-1.719	p=.086	Z=-.708	p=.483		
Z Axis	Z⁰	.00 ± .00	.00 (.00-.00)	.00 ± .00	.00 (.00-.00)	-1.54	.122
	Z¹	.00 ± .00	.00 (.00-.01)	.00 ± .00	.00 (.00-.00)	-.95	.342
		Z=-1.60	p=.109	Z=-.84	p=.400		

Z⁰: I. Measurement Z¹: II. Measurement

Table 5 Empowerment Level of Patient (n = 21)

Empowerment Sub dimensions		Exercises (n=11) M ± SD	Control (n=10) M ± SD		p
1. Sub dimension	Z^0	36.40 ± 4.57	27.18 ± 3.45	-5.24	<.001
	Z^1	37.30 ± 3.12	12.54 ± 3.50	-17.00	<.001
		t=-1.18 p=.279	t=7.99 p=.000		
2. Sub dimension	Z^0	27.30 ± 3.71	25.54 ± 2.33	-1.30	.206
	Z^1	29.20 ± 3.45	16.54 ± 2.80	-9.24	<.001
		t=-2.17 p=.058	t=10.17 p=.000		
3. Sub dimension	Z^0	39.80 ± 4.61	36.72 ± 3.79	-1.67	.111
	Z^1	42.00 ± 5.39	16.90 ± 3.75	-12.47	<.001
		t=-1.46 p=.178	t=12.00 p=.000		
Total	Z^0	103.50 ± 9.92	89.45 ± 7.59	-3.66	.002
	Z^1	108.50 ± 8.78	46.00 ± 9.11	-15.96	<.001
		t=-2.47 p=.035	t=11.18 p=.000		

Z^0: I. Measurement Z^1: II. Measurement

Empowerment level: As shown in Table 5, there were no statistically significant differences between the two groups in empowerment level at T0 (p>.05). There was a slight increase in the empowerment level subscale in the exercise group at T1, but the difference did not reach statistically significance level (p>.05). However, when the general empowerment level was examined, the improvement in the exercise group was significant (p<.05) (Table 5).

Effectiveness of the exercise program: Details of the exercise program based on Empowerment model can be seen in Table 2.

Discussion

An evident finding of our study was that the HF patients in both groups had inadequate exercise levels at the beginning of the study. This study presents an important contribution to the literature regarding the efficacy of exercise program for old patients with HF.

Exercise capacity and balance level: The exercise group showed improved exercise capacity and balance level after the program (Table 3). Exercise capacity is directly related to an individual's activity level. It has been reported that regular aerobic exercise results in improvements in skeletal muscle function and cardiopulmonary performance (Senuzun et al., 2006). However, individuals with heart disease generally adopt a sedentary lifestyle due to the misconception that activity or exercise will damage their heart, thus entering a counterproductive cycle in which their activity levels and exercise capacity progressively decline. Similarly, the literature reports that patients with HF typically avoid activity, reinforcing the significance of inactivity as a factor in the deterioration of functional capacity (Villareal et al., 2017; Senuzun et al., 2006). In the present study, patients' exercise capacity based on the time required to walk three meters was comparable in the two groups at the beginning of the study. This result supports the view that most individuals with HF avoid exercise. However, at the end of the study, the exercise group walked three meters in significantly less time, indicating that exercise improves activity levels and exercise capacity, even for old people. Our findings highlight the importance of cardiac rehabilitation in increasing the exercise and activity capacities of HF patients.

There is significant evidence in the literature that exercise performed by HF patients increases exercise capacity (Villareal et al., 2017; Senuzun et al., 2006; Ashe et al., 2009). However, in their study of a large population of old adults, Ashe et al determined that among those without chronic illness, less than 30% were engaging in physical activity (Ashe et al., 2009).

Acceleration values are another parameter that reflects balance. The accelerator data obtained while monitoring balance and movement capability in our study indicated a small but statistically nonsignificant increase in movement capability at the end of exercise program (Table 4). Age-related reduction in balance and activity are to be expected in old patients; however, the improvement observed in our exercise group, although small, suggests that exercise plays a role in maintaining or restoring balance and exercise capability. Similarly, it has also been emphasized in the literature that exercise increases functional independence in the geriatric community (Demirsoy and Taskiran, 2010).

Balance is necessary for many activities of daily life. During movement, the body's center of mass moves; when a person is standing still or in motion, it is important to compensate for this shift in order to prevent falling (Winter, 1995). Henwood et al implemented an 8-week resistance exercise program with healthy individuals aged 60-80 and reported significant increases in physical performance (Henwood and Taaffe, 2005). The results of the present study are consistent with the literature.

Empowerment level: General empowerment level improved in the exercise group after the exercise program. Failure to achieve significant improvement in the empowerment subscale may be related to the research duration. However, we believe the increase in general empowerment level was a significant finding nonetheless. Empowerment is a model aiming to protect patients' rights and develop the quality of care (Cooper et al., 2008). In the literature, researches on empowerment have mostly been carried out with individuals with diabetes mellitus (Castillo et al., 2010; Tekir and Esen, 2011).

While our exercise group showed a slight (though nonsignificant) improvement with therapeutic interviews and counseling services structured on the empowerment model, the control group showed a significant decline in empowerment level over the course of the study. This model is aimed at giving individuals a feeling of success and improving their self image, and is intended to make necessary lifestyle changes easier and more lasting. The study was conducted only on patients discharged from the university hospital. For this reason the results of the study can only be generalized to individuals who participated in the research. The study was conducted with a limited number of patients because of the precised number of computers and the accelometers used to monitor individuals' body oscillations in the study. Evaluation of the effectiveness of the exercise program was limited to 3 months. The fact that the individuals' physical activity duration were assessed by means of their own written reports was another limitations.

Conclusion: The study findings supported all our hypotheses. Participants level of activity, balance and empowerment increased in this research. The results provide important evidence demonstrating the effectiveness of exercise programs based on the empowerment model conducted by nurses. We recommended that exercise program should be applied to prevent fall based on different theoretical model. However, long-term studies including larger sample sizes are necessary for better evaluation of the effects of these programs on exercise capacity.

Study limitations: The most important limitation is that the study includes patients in the western region of Turkey were selected as the sample group of this study. Therefore, these results cannot be generalized for other individuals living in other regions of Turkey.

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Abbreviations: RCT: Randomized controlled trials; HF: Heart failure; ESC: The European Society of Cardiology; HbA1C: Hemoglobin A1c; T0: Before exercise program; T1: After exercise program; LLA: Low Level Acceleration; MLA: Middle Level Acceleration; HLA-High Level Acceleration; DES: Diabetes Empowerment Scale.

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