

Effect of home-based cardiac rehabilitation programmes on the social health of patients with an Implantable Cardioverter Defibrillator (ICD): a semi-experimental study

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A – Study Design, B – Data Collection, C – Statistical Analysis, D – Data Interpretation, E – Manuscript Preparation, F – Literature Search, G – Funds Collection

Summary Background. Shocks caused by an Implantable Cardioverter Defibrillator (ICD) affect the social health of patients. Implementation of Home-Based Cardiac Rehabilitation (HBCR) by trained nurses can be effective in preventing or reducing these effects.

Objectives. The aim this study was to determine the effect of implementation of HBCR programmes on the social health of patients with ICD.

Material and methods. This study was conducted as a semi-experimental and randomised study with two groups of control ($n = 35$) and experimental ($n = 35$) patients receiving ICD in the Shahid Chamran Heart Centre of the Isfahan University of Medical Sciences (IUMS). Data collection tools included Keys Social Health questionnaire and the HBCR programmes checklist. In four educational sessions, patients were introduced to the practical concepts of HBCR programmes.

Results. At the beginning of the study, there was no significant difference between the two groups in terms of social health score ($p = 0.056$), but immediately after the intervention and three months after the intervention, there was a significant difference in the social health score in the two groups ($p < 0.001$). The experimental group had a higher social health score than the control group.

Conclusions. The findings of this study represent the positive impact of implementing HBCR programmes on the social health of patients with ICD and the role of nurses in providing healthcare services at home, the gap of which is quite noticeable in the health system of our country.

Key words: cardiovascular diseases, cardiac rehabilitation, implantable defibrillators, social determinants of health.

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Background

Cardiovascular diseases (CVD) are the most common cause of mortality worldwide, and 17.9 million people die from this disease annually. According to the statistics of the World Health Organization (WHO), some 32% of all mortality rates in the world are caused by CVD. More than four out of five cardiac deaths are caused by heart attacks and strokes, and one third of these deaths occur prematurely in people under the age of 70 [1]. In the last 20 years, important advances have been made in diagnostic, therapeutic and surgical technologies for CVD patients.

The ICD is one of these progresses in treatment technologies and is the primary treatment for patients with ventricular tachycardia and fibrillation. The use of an ICD is preferable to anti-dysrhythmic medications in reducing the mortality caused

by cardiac dysrhythmias, as well as the risk of Sudden Cardiac Arrest (SCA). This device returns the heart rhythm to normal by identifying potentially dangerous heart rhythms and discharging a shock. However, this may lead to psycho-social discomfort in patients, and if they are not compatible with the device, it may affect their QoL and social health [2]. Age, gender, ethnicity, family history, smoking, high blood pressure, high cholesterol, diabetes, physical inactivity, overweight/obesity, unhealthy diet, depression and poor social health are considered as the important risk factors for CVD [3].

Poor social health is the most recent and poorly understood CVD risk factor. The results of a systematic review and meta-analysis of 23 longitudinal observational studies (a total of 4,628 coronary heart disease and 3,002 stroke events) indicated that poor social health increased the risk of coronary heart disease by 29% and stroke by 32% [4]. Social health is a personal as-



assessment of how someone functions in society and the type of attitude of a person towards other members of society. Low social health status affects patients' psychosis and causes adverse health outcomes and negative health-related behaviours as well [5]. In the study of NasrAbadi et al., the effect of the continuous care model on the social health status of caregivers of patients undergoing coronary artery bypass surgery was evaluated. The results showed that follow-up care as a cheap and available intervention is an effective step in reducing the care burden of caregivers of patients with coronary artery disease in terms of social health status [6].

Implementing the CR programme was considered as one of the best approaches to improve activity tolerance, control disease symptoms, improve and control hyperlipidaemia, lose weight, reduce smoking and improve mental and social health status, reduce stress and improve social function adaptation, return to work and reduce mortality [7, 8]. Moreover, CR is performed in heart transplant patients, heart valve surgery patients, heart attack patients, chronic heart failure patients and those with cardiac devices; nurses play a prominent role in its formulation and implementation [9, 10].

HBCR programmes include a series of interventions used by nurses to improve the health of patients and help the patient to achieve the best possible physical, mental and social conditions, which continues at the patients' homes with continuous follow-up by nurses. These interventions include performing sports exercises at home, adjusting cardiac risk factors at home and supporting, counselling and strengthening the knowledge of patients regarding heart diseases [11]. Home-based interventions are cheaper and less expensive than hospital and institutional treatments and allow the patient to stay at home and receive care along with other family members [12]. One of the effective ways for secondary prevention is HBCR programmes, where health workers, especially nurses, play an effective role in its implementation [13].

The three categories of respect, support and participation are the key components of HBCR programmes. A large number of researchers in the field of health believe that the approach of HBCR programmes has a better future than traditional care methods that only focus on the disease and the resulting defect, because traditional methods mainly rely on care methods and technology and environments. Treatment is considered separate from the families and the society they should serve [14].

In a study conducted in the US, almost half of the people preferred receiving HBCR programmes [9]. The superiority of the CR programme at home to CR in rehabilitation centres is that the CR programme at home can be done 24 hours a day/7 days a week, while CR in rehabilitation centres is limited to 3 to 4 hours per week [9]. On the other hand, the increase in hospitalisation costs, distance from family and the risk of hospital infections have made nursing care at home more popular day by day, and considering that recovery from chronic diseases is not easily and prematurely achieved, the continuation of care at home has been considered [15]. Furthermore, the coronavirus pandemic has highlighted the value and experiences of home care models as physicians search for approaches to continue medical services. Continuous review and standardisation of HBCR models is necessary to care for a wide range of patients and current conditions [16]. Therefore, in this study, the researchers intended to measure the effect of implementing HBCR programmes on the level of the social health of patients with ICD.

Material and methods

Study design

The research population in this randomised semi-experimental study included ICD patients referred to the Shahid Chamran Heart Centre of IUMS in a period of 6 months in 2021.

Using the available easy sampling method, among a total of 160 patients who had ICD devices, 70 patients were included in the study from 2020.

Ethical approval

After approval of the study by the Ethics Committee of Shahrekord University of Medical Sciences with the ethics code of IR.SKUMS.REC.1399.098 and filling out the informed consent form, the subjects who met the inclusion criteria were included in the study.

The inclusion criteria were that the patient or his/her main companion should be literate, the patient should not have cognitive problems or anxiety disorders treated with medications, the patient has access to a landline or mobile phone, the patient does not have any physical damage and specific movement restrictions, absence of life-threatening arrhythmias and uncontrolled arrhythmias in the analysis performed after inserting the device, performed by the attending physician, not suffering from unstable and stable angina and unstable haemodynamic conditions according to the evaluation of the attending physician and the continuous evaluation and follow-up of the researcher, the participant should not be in class III or IV according to the classification of the New York Heart Association, the patient or one of his/her family members does not have medical education, does not have speech and hearing disorders, being in the age range of 35 to 75 years old and, in order to prevent damage and displacement of the ICD leads, one month should have passed since the installation of the Medtronic device. Exclusion criteria included the patient's reluctance to continue participating in the study, hospitalisation for any reason, patient death during the intervention, infection at the device insertion site, stroke or suffering from any type of movement-limiting disease during the study.

Data collection

Data was collected using a demographic information form, Keyes social health questionnaire and a home visit checklist and was analysed in SPSS/22 using chi-square, independent *t* and repeated variance tests. The demographic information form included gender, age, education, marital status, number of children, employment, underlying medical history and the reason for implanting a cardiac defibrillator. In order to determine the social health level of the patients, the Keyes social health status questionnaire was used.

Keyes Social Health Status Questionnaire

This questionnaire was compiled by Keyes at the MacArthur Science Foundation of the US in 2004, and its validity and reliability have been tested in several periods. This questionnaire refers to components such as social prosperity, solidarity, cohesion, acceptance and social participation, and its reliability and validity have been confirmed in studies conducted in Iran [17]. The home visit checklist for patients with CVD based on the components of the American Heart Association (AHA) statement on home CR on 19 May 2019 was confirmed with Cronbach's alpha of 0.88. This questionnaire includes 6 parts of walking control, recognising and complying with risk factors, complying with medication and food regimen, psychological support and referring the patient to a specialist if needed. In addition, the reliability of this questionnaire was confirmed with Cronbach's alpha of 0.93 in the current study.

The selected samples were then randomly assigned into two groups: control ($n = 35$) and experimental ($n = 35$). In addition to hospital care programmes, the patients in the experimental group received dedicated HBCR programmes in four sessions for 30 to 40 minutes per week and were followed up weekly by telephone. Patients in the control group received only hospital

care plans. The content of the training sessions was according to the scientific literature and indicators of the statement of rehabilitation at home in the US in 2019. The walking programme of the patients in the experimental group was started one month after ICD implantation in the newly implanted patients, and the walking programme protocol was based on the Schwartz heart patient walking programme, which is suitable for the low functional level of patients with heart problems. Patients were instructed to take account of their pulse before, during and 5 minutes after walking. It should be noted that the patient should reach his/her maximum heart rate (HR), which is about 60–80% of the maximum of his/her age, and it is necessary to calculate the maximum HR range in these patients to 20 beats of the programmed rate for the ICD device [18].

A trained nurse was also used as a research assistant in the implementation of the HBCR programmes. The aforementioned questionnaires were filled out before the intervention, immediately after the trainings and three months after the intervention in the presence of the proposal's colleague and during the last visit at home. In the control group, patients filled out the questionnaires by visiting the hospital or at home.

Data analysis

After data collection, descriptive and inferential statistics, such as chi-square, independent *t*-Test and analysis of variance, as well as SPSS/21, were used to analyse the data. Descriptive statistics describing the existing conditions were used to determine the central and dispersion indicators, such as the mean and standard deviation and to set the absolute and relative frequency tables.

Results

All the samples in both groups had the necessary participation during the study, and no patients were excluded from the study (the participation rate was 100%). Examining the demographic characteristics of the research samples showed that 29 patients were women (41.42%), and 41 patients (58.57%) were men. Most of the participants in the study were in the age group of 65–75 years. Most of the studied patients in both groups were married (88.5%), and in terms of education level, 35.7% had a bachelor's degree, 32.8% were at a reading and writing level, 20% had a university education, and 11.4% were illiterate. In terms of job type, housekeeper with 27.14% and self-employed job with 20% were the most frequent, and the job of employee (1 person) was the least frequent with 1.4%. The clinical characteristics of the studied patients in terms of diabetes, blood pressure, history of heart attack, hyperlipidaemia and severity of heart failure and duration of disease are shown in Table 1.

The chi-squared statistical test did not show any significant difference in terms of distribution of samples in the two groups according to background variables. After examining the level of social health amongst the research samples, the average and standard deviation of the social health score in three intervals before, immediately and three months after in the intervention and control groups were reported as 5.5 ± 1.6 , 6.8 ± 5.61 , 72.02 ± 5.70 and 4.8 ± 6.64 , 6.7 ± 6.63 , 63.4 ± 6.63 , respectively. At the beginning of the study, there was no significant difference between the two groups in terms of social health scores ($p = 0.056$), but immediately after the intervention and three months after the intervention, there was a significant difference in the social health score in the two groups ($p < 0.001$). In fact,

Table 1. Demographic characteristics of the participants (n = 70)

Variable		Control group		Experimental group		p
		n	%	n	%	
Having diabetes	yes	19	54.3	12	34.3	0.092
	no	16	45.7	23	65.7	
Having high blood pressure	yes	19	54.3	11	57.1	0.053
	no	16	45.7	24	42.9	
History of previous MI	yes	28	80	26	74.3	0.569
	no	7	20	9	25.7	
High cholesterol level	yes	17	48.6	10	28.6	0.086
	no	18	51.4	25	71.4	
Other diseases	yes	16	45.7	18	51.4	0.632
	no	19	54.3	17	48.6	
Severity of heart failure	class I	24	68.6	17	48.6	0.089
	class II	11	31.4	18	51.4	
Duration of disease	> 6 months	3	8.6	11	31.4	0.059
	6 months – 1 year	7	20	9	25.8	
	1–3 years	8	22.8	4	11.4	
	≥ 3 years	17	48.6	11	31.4	

Table 2. Mean social health score of patients with ICD

Social health	Experimental group (n = 35)	Control group (n = 35)	p
	M ± SD	M ± SD	
Before	63.8 ± 6.4	61.5 ± 1.6	0.054
Immediately	63.7 ± 6.4	70.8 ± 5.5	> 0.001
After three months	63.4 ± 6.6	72.02 ± 5.6	> 0.001
Intragroup p	0.413	> 0.001	> 0.001
Changes during the study	-0.40 ± 1.56	-10.48 ± 0.99	> 0.001

a higher social health score was reported for the experimental group. In both groups, the social health score increased significantly. Nevertheless, there was a significant difference in the social health score in the two groups, so that the average changes in the experimental and control groups were increased by 10.5 and 0.4 units, respectively (Table 2). In the experimental group, the social health score increased more and significantly, and in the control group, the changes and the slight increase were more statistical, and in the control group, there were very slight changes.

Discussion

The results of this study indicate that the implementation of HBCR programmes improved the social health status in the experimental group, and the mean score of the social health status in the control and experimental group before, immediately and three months after the intervention showed a statistically significant difference. Lima et al., in a similar randomised controlled clinical trial study, evaluated the impact of HBCR programmes on public health care in Brazil. The HBCR programmes included health education, physical exercises and providing guidance over the phone. Moreover, in this research, the new method was compared with the traditional method of CR provided in most of the hospitals [19]. In this research, as with the previous study, telephone counselling and follow-up and health education methods were used.

The findings of this research did not show a statistically significant difference between the two groups of HBCR programmes and rehabilitation in the traditional way, and in this sense, it is not aligned with the present study; the only difference between these two groups was the improvement of the QoL score in the group that benefited from the HBCR programmes. Du et al. investigated the effect of doing home exercises to improve the physical movements of children with congenital heart disease and reduce anxiety and improve the QoL of parents in China whose children with congenital heart disease have been catheterised, and 300 children were assigned into two groups [20].

The findings of the research showed that performing sports exercises at home led to the improvement of modified indicators and heart function, the growth rate in the tibia, the functions related to childhood and the QoL of parents, as well as decreasing the anxiety level, which is consistent with the findings of the current study. The results of a study by Vanhees et al. in Belgium were consistent with our study; in their study, the effect of exercise in patients with ICD was evaluated in a two-group clinical trial on a total of 565 cardiac patients [21]. This research was conducted in two groups, and the target group of interventions was patients with ICD, which is similar to the present study. Their exercise programmes were the same as well. The results of this study showed that patients with ICD could safely participate in sports training programmes with favourable results. In a randomised clinical trial study conducted by Oerkild et al. in Denmark under the title of "HBCR programmes as an attractive alternative to non-CR for elderly patients", the patients were divided into two groups of 20 people, experimental and control, and for the experimental group, physiotherapists performed home examinations. In the aforementioned study, two goals including walking for six minutes and improving blood pressure, cholesterol, number of times of smoking, QoL and worry and anxiety state were examined. Although there was a significant increase in the first achievement in the experimental group, there was no statistically significant difference in the second goal [12], which is not consistent with the results of the present study. Although the findings of this research are not aligned with the present study and no statistically significant difference was observed between the groups after the intervention, the above study is similar to the present study in terms of its two-group nature and the type of intervention.

The aforementioned study is in line with the present study in terms of the intervention model and the studied variable, i.e.

social health status, but in terms of the number of patients participating in the study and the duration of the intervention, it is not similar to our study. Limoe et al. aimed to investigate the effect of HBCR programmes on the QoL of 102 patients after coronary artery bypass surgery in Ahvaz, Iran. For the experimental group, four training sessions were conducted in the hospital followed by six sessions of home visits once every two weeks for three months. The results of this study, which are in line with the present study, showed that the average of the areas and the total score of the QoL in the experimental group increased more than the control group ($p < 0.0001$) [22].

Given the aforementioned literature, it is very important to use non-pharmacological treatments to better help patients with an ICD. The implementation of HBCR programmes is actually a kind of implementation of community-based rehabilitation programmes. These programmes might solve an important part of patients' problems, such as the distance and dispersion of specialised rehabilitation centres, the unwillingness and acceptance of patients, the high costs of CR programmes in centres, as well as improve the communication between different treatment departments. Increasing one's sense of hope and life expectancy and reaching the desired goals in patients by learning HBCR programmes might increase the social health level and improve their disease status. Using HBCR programmes, which is a simple method to train patients, could be a reminder that healthcare providers might take a significant step in improving the health of the society by using simple methods in training patients in the fields of health and treatment.

Limitations of the study

This research was carried out under the specific conditions of COVID-19; in order to solve this problem, training in an open environment with a small number of patients or individually was attempted. In the implementation of educational programmes in a group, coordination for the formation of classes and the presence of research units in all classes was also one of the basic problems for the researcher. In order to solve this problem, if the research units were not coordinated, the trainings were done individually. Another limitation was that sometimes it was difficult to convince the patients to attend the training classes, and their cooperation was obtained by stating the importance and purpose of the research and telephone follow-ups. The individual differences of the patients and the medications used could also affect the results of the research. In this case, we tried to minimise these differences by randomly replacing the samples or using a special statistical test.

Conclusions

The results of several studies have shown that participation in a CR programme reduces mortality by up to 25% over an average of 5 years when compared with usual treatment and care, such as medical therapy alone. The findings of this study indicate the positive impact of implementing HBCR programmes on the social health status of patients with ICD and the role of nurses in providing healthcare services at the home level, the gap of which is quite noticeable in the health system of our country. Providing care in HBCR programmes will provide for the care needs of the patient and their family and will increase their satisfaction with the care system. Undoubtedly, rehabilitation nurses could play a vital role in the effectiveness and continuity of rehabilitation team services at home for patients with chronic disorders.

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