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The Efficacy of the Smart-Rehabilitation Program in Patients After the Correction of Valvular Heart Diseases

Aim	Comparative analysis of the effectiveness of a new approach, «SMART rehabilitation of patients after heart valve replacement», which includes, in addition to face-to-face training, Internet technologies in the form of video conferencing, the mobile application «Calculation of the warfarin dose», and a traditional program for educating patients after correction of valvular defects.
Material and Methods	The study included 190 patients with prosthetic heart valves. The main group consisted of 98 patients who completed a distance learning course. The control group included 92 patients participating in face-to-face training. Clinical and instrumental examinations (electrocardiography, echocardiography, determination of international normalized ratio (INR)), and surveys to evaluate awareness, compliance with treatment, and quality of life (QoL) were performed.
Results	At baseline, the awareness, compliance and QoL did not differ between the compared groups. After 6-month follow-up, the mean score of awareness increased by 53.6% (p=0.0001). The compliance with treatment increased 3.3 times in the main group and 1.7 times in the control group (p=0.0247). Patients of the main group were more prone to self-management (p=0.0001), had better medical and social awareness (p=0.0335), medical and social communicability (p=0.0392), confidence in the therapeutic strategy of the attending physician (p=0.0001), and treatment effectiveness (p=0.0057). Analysis of QoL showed increases in living activity 2.1 times (p=0.0001), social functioning 1.6 times (p=0.0001), and mental health 1.9 times (p=0.0001).
Conclusion	The novel approach of distance learning, «SMART rehabilitation of patients after heart valve replacement», provides improvements in awareness, compliance with treatment and QoL.

Keywords	SMART-rehabilitation; awareness; compliance with treatment; quality of life; prosthetic heart valves
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Introduction

Training sessions for patients with various diseases is one of the elements of secondary rehabilitation in practical medicine. There are training programs for patients with hypertensive heart disease [1], chronic heart failure (CHF) [2], atrial fibrillation (AF) [3] and after heart surgery [4]. Such programs increase adherence to treatment, improves quality of life (QoL) and reduces the incidence of complications of the underlying disease [5].

Many papers by foreign and Russian authors are devoted to the issues of rehabilitation after heart surgery. However, the improvement of approaches to outpatient management of patients aimed at raising awareness and adherence to treatment, improving the quality and prognosis of life after high-tech interventions. Particular attention should be paid to the development of e-training modes using the Internet technologies or mobile phones.

In 2010, an in-person training mode including inpatient and outpatient stages of patient management was developed and implemented in our center and proved effective in increasing adherence to treatment and improving QoL [6]. A new mode of outpatient management after heart surgery SMART Rehabilitation of Patients after Heart Valve Replacement has been developed with the support of the Presidential Grant Fund. It includes a set of remote technologies aimed at monitoring patient's health and increasing knowledge about the disease using mobile application Calculation of Warfarin Dose.

The hypothesis of this study was the assumption that a new approach to training patients using Internet technologies will better contribute to raising awareness, adherence to treatment, and improving QoL after correction of valvular heart disease (VHD).

Objective

Perform a comparative analysis of the effectiveness of the new SMART Rehabilitation of Patients After Heart Valve Replacement approach, which includes, as well as in-person

training, such Internet technologies as video conferencing, mobile application Calculation Warfarin Dose, and the traditional patient training program after correction of VHD.

Material and methods

The study included 190 patients who underwent surgery for VHD. The main group consisted of 98 patients who completed the training course SMART Rehabilitation of Patients after Heart Valve Replacement. The control group included 92 patients who visit the School for Patients with Prosthetic Heart Valves for in-person training (Table 1).

The groups were comparable in age, sex, level of education, primary diagnosis, type of heart valve prosthesis, clinical manifestations of CHF, and the frequency of AF. All patients participating in the study were followed up by a cardiologist or local primary care physician. They underwent clinical examinations (electrocardiography, echocardiography and laboratory test to calculate international normalized ratio (INR) at least once a month (more often if there were relevant indications). Patients received standard drug therapy including warfarin in relevant therapeutic doses considering the target INR range.

Before discharge from the hospital, Calculation of Warfarin Dose application was installed on the smart phones of patients of the main group acquired thanks to the Presidential Grant Fund. It allowed calculating the recommended daily dose of warfarin in tablets based on the target range and INR calculated on the corresponding day, and the analysis of the drug and food interaction.

The application was synchronized with local information resource Medportal of the Research Institute of Complex Problems of Cardiovascular Diseases in order to monitor patients participating in the SMART Rehabilitation program over time. The attending cardiologist or nurse reviewed the automatically calculated INR values. If the value high or low, a phone call was made to the patient to find out the causes of hypocoagulation instability and the dose of warfarin was adjusted.

In-person training was conducted in the main and control groups for 6 months, included 5 sessions on the prevention of hemorrhagic and thrombotic complications, special aspects of anticoagulant therapy, prevention of prosthetic valve endocarditis; lectures on psychological and physical rehabilitation. Additionally, video lectures were uploaded to the private YouTube channel accessible by link for in the main group of patients so that they could rewatch them and learn more effectively. The mobile application was used in the main group.

Under this project, a register of patients with prosthetic heart valves was created and included all clinical and anamnestic data, all registered INR values and questionnaires to assess the levels of patient awareness, adherence to treatment, and QoL, which was carried out at the stage of inclusion of patients in the SMART Rehabilitation program and at the end of the project (after 6 months of follow-up). Patients of the control group who attended the patient school after the discharge from the hospital were also questioned before and after training in 6 months.

The integral indicator of adherence to treatment (IIAT) was determined using the method by S. V. Davydov [7], QoL was assessed using the SF-36 questionnaire [8]. A questionnaire was developed to assess the effectiveness of the patient training program, which includes 14 multiple choice question and is implemented as the online application. The correct answer scores 2, the incomplete answer scores 1, and the incorrect answer scores 0. The patient's knowledge was assessed by the total score. The maximum score for all correct and complete answers was 28.

The statistical processing of the obtained data was performed using Statistica version 12.0. The normality of distribution was evaluated using the Kolmogorov-Smirnov test. Non-parametric Wilcoxon and Mann – Whitney tests were used for the non-normal distribution; the medians and the interquartile ranges (Me [Q1; Q3]) were calculated. Pearson's chi-squared test was used to compare qualitative variables. The intergroup differences were statistically significant with p value ≤0.05.

Results

Baseline level of knowledge did not differ between the groups. After 6 months of follow-up, the mean score of

Table 1. Comparative characteristics of the patient groups

Parameter		Group: Main group (n=98)	Group: Control group (n=92)	p
Age, years		59.7±10.6	62.2±12.3	0.1344
Sex	Female, n (%)	52 (53.1)	51 (55.4)	0.7428
	Male, n (%)	46 (46.9)	41 (44.6)	0.4327
Rheumatic heart disease, n (%)		51 (52)	57 (61.9)	0.1679
Infective endocarditis		15 (15.3)	15 (16.3)	0.8504
Connective tissue dysplasia, n (%)		15 (15.3)	10 (10.9)	0.3659
Calcinosis, n (%)		17 (17.4)	10 (10.9)	0.2013
Prosthetic heart valve	Mechanical, n (%)	71 (72.4)	65 (70.6)	0.7838
	Biological, n (%)	27 (27.6)	37 (40.2)	0.0649
Atrial fibrillation, n (%)		36 (36.7)	24 (26.1)	0.1146
CHF	CHF NYHA class II, n (%)	70 (71.4)	59 (64.1)	0.2816
	CHF NYHA class III, n (%)	28 (28.6)	33 (35.9)	0.2816
Education	Higher, n (%)	14 (14.3)	12 (13.0)	0.8034
	Vocational	61 (62.2)	53 (57.6)	0.5145
	Secondary, n (%)	23 (23.5)	27 (29.4)	0.3578

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the level of awareness after correction of VHD was higher in the main group, where a new training approach was applied (p=0.0001). At the same time, the awareness of the administration of warfarin did not differ statistically significantly between the two groups (Table 2).

The level of awareness in the sections of physical (p=0.0001) and psychological (p=0.0001) rehabilitation, the prevention of prosthetic valve endocarditis (p=0.0025) was lower in the traditional training group than in the main group. Baseline adherence to treatment did not differ between the groups. After 6 months of training, IIAT increased 3.3 times in the main group and 1.7 times in the control group (Table 3). The analysis of the factors that form adherence to treatment showed no differences in willingness to pay for treatment, medical and social adaptation, and the treatment schedule. However, the tendency to self-control was higher in the main group (p=0.0001), that is, patients who used the Calculation of Warfarin Dose application could independently make decisions on adjusting the dose of anticoagulant.

The main group had a higher level of medical and social awareness (p=0.0353) and medical and social communication (p=0.0392). At the same time, the medical and social distance (p=0.0046) was lower in the main group than in the control group, in which the training was conducted in person without the mobile application. Moreover, such factors of adherence as trust in the treatment strategy applied by the attending physician (p=0.0001) and treatment efficacy (p=0.0057) scored more in the main group after 6 months of training.

Baseline QoL did not differ between the groups, a statistically significant improvement in QoL was observed over time (Table 4). The comparison of the QoL indicators in the main group showed a statistically significant (p=0.0001) increase in Vitality (VT), Social Functioning (SF) (p=0.0001), and Role Emotional Functioning (RE) after 6 months of follow-up.

Thus, the analysis of awareness, adherence to treatment, and QoL in this study shows the effectiveness of the new approach implemented in the School for Patients with Prosthetic Heart Valves using a mobile application that include, as well as the warfarin dose calculator, the possibility of conducting remote training program via video conferencing.

Discussion

The use of healthcare mobile applications provides patients with personalized support and ensures compliance with the prescribed treatment regimen [9]. A group of authors led by Yu. M. Lopatin [10] carried out a study to assess the effectiveness of a remote follow-up platform based on using a mobile application for CHF patients, which allowed monitoring changes in the prescribed therapy, conducting a self-assessment of health status, and transferring information on blood pressure, heart rate, weight gain, diet, and physical activity to health professionals.

According to Miller et al. [11], video conferencing and videos on the prevention of the adverse effects of risk factors contribute to greater patient engagement in the training program for patients. It was shown that the patient training by phone, text messaging, via web pages, and mobile applications reduces modifiable risk factors in patients with coronary artery disease [12]. New opportunities associated with telemedicine training of patients surely open up prospects for improving specialized preventive care [13]. Foreign literature confirms high motivation of patients taking warfarin in achieving the target INR range during online training [14, 15].

According to our findings, the awareness of patients of the administration of anticoagulant therapy did not differ in the two groups. Patients were equally aware of the advantages of regular and correct administration of warfarin. In the main group, in which a new mode of training using Internet technologies was used, patients had a higher level of knowledge of the main issues of prevention of prosthetic valve endocarditis (p=0.0025) and physical and psychological rehabilitation (p=0.0001). Physicians of different specialties were engaged in the training of patients of this group. Physician's role in

Table 2. Changes in the knowledge level scores of patients with prosthetic heart valves

Issue	Duration of follow-up	Main group (n=98), Me [Q1; Q3]	Control group (n=92), Me [Q1; Q3]	p for intergroup differences	p for the main group	p for the control group
Special aspects of anticoagulant therapy	Baseline	1.17 [0; 1.89]	1.11 [0.08; 1.89]	0.7118	0.0001	0.0001
	In 6 months	2 [2; 2]	2 [2; 2]	0.3471		
Prevention of infective endocarditis	Baseline	0 [0; 1]	0 [0; 1]	0.9368	0.0001	0.0001
	In 6 months	2 [2; 2]	2 [1.5; 2]	0.0025		
Physical rehabilitation	Baseline	1 [0; 1]	1 [0; 1]	0.7673	0.0001	0.0001
	In 6 months	2 [2; 2]	1 [1; 1]	0.0001		
Mental rehabilitation	Baseline	1 [1; 1]	1 [1; 1]	0.9966	0.0001	0.0001
	In 6 months	2 [2; 2]	1.5 [1; 2]	0.0001		
Mean score of all issues	Baseline	15 [5; 19]	15 [5.75; 19]	0.8826	0.0001	0.0001
	In 6 months	28 [27; 28]	25 [25; 26]	0.0001		

Table 3. Changes in factors influencing treatment adherence

#	Adherence factors, scores	Duration of follow-up	Main group (n=98) Me [Q1; Q3]	Control group (n=92) Me [Q1; Q3]	p for intergroup differences	p for the main group	p for the control group
1.	Willingness to pay for treatment	Baseline	1 [–2; 2]	1 [0; 2]	0.0685	0.0001	0.0177
		In 6 months	2 [0.25; 2]	2 [1; 2]	0.8319		
2.	Medical and social adaptation	Baseline	1 [–2; 2]	1 [0; 2]	0.3402	0.0001	0.0919
		In 6 months	2 [1; 2]	2 [0; 2]	0.0923		
3.	Medical and social awareness	Baseline	0 [–1; 1]	0 [–1.25; 1]	0.8312	0.0001	0.0006
		In 6 months	2 [0; 2]	1 [–1; 2]	0.0353		
4.	Tendency to self-control	Baseline	1 [–2; 2]	1 [–1; 2]	0.3693	0.0001	0.1443
		In 6 months	2 [2; 2]	2 [1; 2]	0.0001		
5.	Medical and social communication	Baseline	1 [–1; 2]	1 [–1; 1]	0.9204	0.0030	0.2588
		In 6 months	1 [0; 2]	1 [0; 1]	0.0392		
6.	Administered treatment scheme	Baseline	1 [–1; 2]	0 [–1; 1]	0.0915	0.5530	0.0675
		In 6 months	0 [–1; 2]	1 [–1; 2]	0.4194		
7.	Medical and social distance	Baseline	2 [0; 2]	1 [–0.25; 2]	0.4244	0.0518	0.1122
		In 6 months	2 [0.25; 2]	2 [1; 2]	0.0046		
8.	Trust in the attending physician's treatment strategy	Baseline	1 [0; 2]	1 [0; 2]	0.9520	0.0102	0.8250
		In 6 months	2 [0; 2]	1 [0; 1]	0.0001		
9.	Efficacy of treatment	Baseline	0 [–1; 1]	0 [–1; 0]	0.1240	0.0001	0.0062
		In 6 months	1 [–1; 2]	1 [–1; 1]	0.0057		
10.	IIAT	Baseline	3 [1; 6.75]	4 [0; 7]	0.5699	0.0001	0.0010
		In 6 months	10 [5; 13]	7 [2; 13]	0.0247		

IIAT, integral indicator of adherence to treatment.

Table 4. Changes in indicators of quality of life (SF-36)

Item, score	Duration of follow-up	Main group (n=98) Me [LQ; UQ]	Control group (n=92) Me [LQ; UQ]	p value for intergroup differences	p value for the main group	p value for the control group
PF	Baseline	45 [35; 55]	40 [35; 50]	0.9714	0.0001	0.0001
	In 6 months	77.5 [70; 85]	80 [50; 80]	0.3383		
RP	Baseline	40 [34.25; 50]	45 [35; 50]	0.7380	0.0001	0.0001
	In 6 months	70 [52.5; 80]	60 [50; 65]	0.0627		
BP	Baseline	40 [30; 50]	35 [25; 50]	0.1660	0.0001	0.0001
	In 6 months	70 [40; 80]	70 [40; 80]	0.4501		
GH	Baseline	35 [30; 40]	40 [35; 50]	0.1340	0.0001	0.0001
	In 6 months	75 [65; 80]	75 [50; 80]	0.3602		
VT	Baseline	37.5 [30; 60]	40 [35; 60]	0.4914	0.0001	0.0001
	In 6 months	85 [70; 85]	70 [60; 85]	0.0001		
SF	Baseline	55 [40; 70]	55 [40; 65]	0.3979	0.0001	0.0001
	In 6 months	90 [75; 95]	74.5 [55; 80]	0.0001		
RE	Baseline	45 [35; 55]	40 [35; 50]	0.2152	0.0001	0.0001
	In 6 months	70 [65; 85]	65 [60; 70]	0.0001		
MH	Baseline	40 [30; 50]	40 [30; 55]	0.6720	0.0001	0.0001
	In 6 months	75 [70; 90]	72.5 [65; 100]	0.1882		
Physical component of health	Baseline	34.0 [30.0; 36.9]	33.2 [29.7; 36.1]	0.2472	0.0001	0.0001
	In 6 months	43.9 [39.2; 48.0]	44.9 [40.7; 48.6]	0.3645		
Psychological component of health	Baseline	40.1 [36.5; 44.5]	40.3 [36.5; 44.6]	0.6956	0.0001	0.0001
	In 6 months	52.9 [48.2; 61.0]	49.2 [47.2; 52.5]	0.0001		

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increasing adherence to treatment is particularly important, as he/she makes a significant contribution to increasing the motivation of patients to achieve the goal, primarily the regular intake of drugs, the correction of modifiable risk factors of cardiovascular complications [16]. The non-randomized design was the limitation of this study. Randomized trial will be conducted when enough data is collected. The new developed approach including, as well as traditional training, the Internet technologies and mobile application Calculation of Warfarin Dose can be used for the outpatient follow up of other categories of patients receiving anticoagulant therapy.

Conclusion

Numerous studies show that digital means of increasing adherence to the recommendations of health professionals are effective in various nosologies [17, 18]. In our study, we demonstrated the effectiveness of a new mode of outpatient training for patients with prosthetic heart valves, including, as well as in-person training, the use of the mobile application and the Internet technologies that increased awareness of the prevention of prosthetic valve endocarditis and physical and psychological rehabilitation. A more significant increase in treatment adherence and quality of life was shown, mainly due to the psychological component of health.

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