

# Physical activity in patients with grown-up congenital heart defects after comprehensive cardiac rehabilitation



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## Abstract

**Introduction:** The group of grown-up patients with congenital heart defects (grown-up congenital heart – GUCH) complains of a number of specific medical and non-medical problems. The presented program of comprehensive cardiac rehabilitation (CCR-GUCH), dedicated to the above mentioned group, can potentially improve the physical activity of GUCH patients.

**Aim:** The aim of the study was to assess the effect of the comprehensive cardiac rehabilitation program on the physical activity of GUCH patients.

**Material and methods:** The invitation to take part in the CCR-GUCH program was addressed to a group of 57 patients (mean age:  $23.7 \pm 4.1$  years) who had undergone the surgical correction of ventricular septal defects (VSD) or atrial septal defects (ASD) at least 12 months earlier. The patients were divided into two groups: A – patients undergoing rehabilitation, and B – patients who did not participate in the program. The patients were initially examined using functional and stress tests, and the program of comprehensive cardiac rehabilitation was started in group A. After 30 days, the patients from both groups underwent further testing using the same methods as during the initial evaluation.

**Results:** After one month of rehabilitation, the physical activity parameters of patients participating in the CCR-GUCH program (group A) were significantly better than those observed among non-participants (group B).

**Conclusions:** The introduction of the comprehensive rehabilitation program improves the physical activity and, consequently, the quality of life of GUCH patients. The CCR-GUCH program appears to be a justified supplement to holistic care

## Streszczenie

**Wstęp:** Wśród wielu problemów sygnalizowanych przez dorastających pacjentów z wrodzonymi wadami serca (*grown-up congenital heart* – GUCH) podstawowym wydaje się – powszechne w społeczeństwie – przekonanie o bliżej nieokreślonym ograniczeniu ogólnej sprawności związanym z wadą serca i jej wcześniejszym leczeniem. Poprawie aktywności fizycznej pacjentów z GUCH może służyć odpowiednio przygotowany program kompleksowej rehabilitacji kardiologicznej (KRK-GUCH) stanowiący kolejny, odległy etap leczenia.

**Cel:** Ocena wpływu KRK-GUCH na aktywność fizyczną pacjentów w odległym okresie po chirurgicznej korekcji wrodzonych wad serca.

**Materiał i metody:** Do badania włączono 57 pacjentów (30 kobiet, 27 mężczyzn) w wieku  $23,7 \pm 4,1$  roku, będących minimum 12 miesięcy po korekcji operacji ubytku w przegrodzie międzykomorowej (*ventricular septal defects* – VSD) lub w przegrodzie międzyprzedsionkowej (*atrial septal defects* – ASD). Wszystkim pacjentom zaproponowano udział w programie KRK-GUCH. Utworzono dwie grupy: poddaną rehabilitacji – grupa A ( $n = 31$ ), oraz nieuczestniczącą w programie rehabilitacji – grupa B ( $n = 26$ ). U wszystkich pacjentów wykonano wstępne badania czynnościowe, po czym wdrożono program KRK-GUCH. Po 30 dniach od badania wstępnego ponownie oceniono pacjentów z obu grup, stosując takie same narzędzia badawcze jak we wstępnym badaniu.

**Wyniki:** U pacjentów z grupy nierehabilitowanej (grupa B) stwierdzono istotnie niższą aktywność fizyczną po miesiącu od badania wstępnego niż w grupie pacjentów rehabilitowanych w ramach programu KRK-GUCH (grupa A).

**Wnioski:** Wdrożenie programu kompleksowej rehabilitacji kardiologicznej KRK-GUCH poprawia aktywność fizyczną i tym sa-

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in the late rehabilitation of patients after the surgical correction of congenital heart defects.

**Key words:** GUCH, cardiac rehabilitation, physical activity.

## Introduction

Adolescents and young adults after surgery of grown-up congenital heart (GUCH) defects constitute a growing group of patients requiring cardiac care and multifaceted support. The reduction of early mortality and the prolongation of survival among patients with congenital heart defects (CHDs) may appear as a tangible success [1, 2]. However, apart from good short-term results and long-term survival, to fully assess the efficacy of the interventional treatment of cardiac defects, a broadly understood quality of life evaluation of adolescent patients with cardiac issues that were successfully treated during childhood is needed [3].

Among the many issues raised by adolescent GUCH patients, the widespread belief concerning unclearly defined restrictions in general fitness, associated with congenital heart defects and their previous treatment, appears to be fundamental. It directly impacts the patients' everyday life and reduces their physical activity.

Undergoing cardiac surgery in childhood leads to a decrease in expectations, which naturally reduces the readiness of the patients themselves to take up various forms of physical activity. Notwithstanding, the physical activity of GUCH patients may be improved by a properly prepared comprehensive cardiac rehabilitation (CCR-GUCH) program, serving as another stage of treatment with proven influence on exercise tolerance and quality of life [4].

The present study evaluates the impact of comprehensive cardiac rehabilitation on the physical activity of GUCH patients participating in a specially developed authorial program dedicated to this group of patients. Its basic premise is that the low physical activity of GUCH patients increases their predisposition to cardiovascular diseases proportionally more in the case of those less active, similarly to the general population [5]. The issue appeared especially interesting due to the potential for increasing the activity of adolescent patients with congenital heart diseases, which could consequently improve their general condition and reduce the risk of additional cardiovascular problems natural for this age in long-term observation [6].

The aim of this study was to evaluate the influence of the CCR-GUCH program on the long-term physical activity of adolescent patients after CHD surgery.

## Material and methods

Fifty-seven patients with CHDs (30 women and 27 men) at the mean age of  $23.7 \pm 4.1$  years, who met the inclusion criteria and provided their free and informed consent, were

mym najprawdopodobniej jakość życia pacjentów w późnym okresie po chirurgicznej korekcji wrodzonych wad serca. Zaproponowany program KRK-GUCH może stanowić uzupełnienie holistycznej opieki w opisywanej grupie pacjentów po korekcji wrodzonych wad serca.

**Słowa kluczowe:** GUCH, dorastający pacjenci z wrodzonymi wadami serca, rehabilitacja kardiologiczna, aktywność fizyczna, wrodzone wady serca.

invited to participate in the program of comprehensive cardiac rehabilitation designed at the Chair and Clinic of Rehabilitation of the Medical University of Gdańsk in the years 2007-2009. All the patients had undergone cardiac surgery procedures in childhood (at the age of 6 on average); these included either the correction of ventricular septal defects (VSD) or the repair of atrial septal defects (ASD). Out of all patients invited to participate in the CCR-GUCH program, 31 patients (17 women and 14 men) were ultimately included in the program. The remaining 26 patients, who did not participate in the rehabilitation program due to logistic, economic, or social reasons, were provided information about the program as well as about the expected positive results of the involved controlled physical exertion and its importance for normal functioning. The CHD patients constituting the study group were divided into two subgroups: those participating in rehabilitation (A) and non-participants (B). The control group consisted of 30 healthy students (15 women and 15 men) at the mean age of  $24.4 \pm 1.97$  years, free of any additional comorbidities, or physical/mental limitations, who provided their free and informed consent for their participation and the anonymous use of the obtained results for the purpose of the present study (group C).

Identical inclusion criteria were used for the examination of GUCH patients (groups A and B): clinical diagnosis – condition after the repair of shunt-related cardiac defects (ASD or VSD) employing median sternotomy; time from the cardiac surgery – over 12 months. The inclusion criteria for all three groups (A, B, and C) were: age over 18 years as well as free and informed written consent for participation in the study. The exclusion criteria included: active inflammatory diseases, life-threatening cardiac dysrhythmias, impaired motor function preventing the patients from performing the tasks of the rehabilitation program, coexistence of other heart defects (congenital or acquired), significant deterioration of clinical condition within the past month, acute cardiac or neurological events within the past 6 months, positive results of the cardiac diagnostic test, lack of consent, or mental illnesses precluding patient cooperation.

No statistically significant differences between groups A and B were observed in terms of the distribution of sex, height, body mass, or the basic functional indicators of the circulatory system. There were 30 patients after VSD repair and 27 after ASD repair. The mean age of the patients at the time of surgery was  $5.18 \pm 2.8$  years. The mean value of BMI was  $21.9 \pm 2.9$  kg/m<sup>2</sup>. The resting heart rate (HR<sub>rest</sub>) was 90 bpm on average; right bundle branch block (RBBB)

was revealed on resting electrocardiograms of 15 patients, premature ventricular contractions (PVC) were diagnosed in 4 patients, and premature supraventricular contractions (PsVC) were diagnosed in 2 patients. No statistically significant differences were noted between groups A, B, and C in terms of selected initial anthropometric indices (Table I).

All patients (groups A, B, and C) underwent physical examination, and their medical histories were obtained. The patients underwent cardiopulmonary exercise testing on a cycloergometer using the MetaSoft Studio software (CORTEX); the selected ramp protocol consisted of an initial load of 20 W increasing by 10 W per minute. Limits of maximal fatigue were put in place along with the standard indications for test termination; the following parameters were evaluated:  $HR_{rest}$ ,  $HR_{max}$ , exercise time, exercise load in Watts,  $VO_2$  peak.

The evaluation of physical activity was based on the Stanford Questionnaire, which served as a tool for the objective assessment of patients with different parameters [7]. It was composed of questions concerning the patients' current lifestyle and was divided into two parts, including questions about everyday exercise of low-activity (Stanford I) and high-activity exercise (Stanford II). Each test item was worth one point, and the final score reflected the current physical activity of the respondents.

Additionally, a written questionnaire was drawn up especially for the purposes of the CCR-GUCH program. The subjects from both study groups (A, B) and the controls (C) were asked to answer questions about their lifestyle (whether they considered themselves physically active and whether they were apprehensive of engaging in some forms of physical activity). They were also asked about their participation in physical education classes during their school years and about tobacco use. The GUCH patients (A, B) were also asked whether they had ever participated in cardiac rehabilitation and whether they saw the need for engaging in controlled physical training sessions.

After 30 days following the initial examination and after completion of the CCR-GUCH program, the physical activity of patients in groups A and B was evaluated again, using the same methods as during the initial examination (Stanford I and II questionnaires, own questionnaire).

### Comprehensive cardiac rehabilitation program

The CCR-GUCH program was implemented during the course of four weeks and was based on recommendations

concerning comprehensive cardiac rehabilitation in adults [4]. It consisted of kinesitherapy, psychological influence, and education.

The kinesiatic program involved a cycle of half-hour monitored cycloergometer training sessions and general fitness training with elements of aerobics and Nordic walking. At the gym, the subjects engaged in exercises with and without equipment as well as resistance exercise. They performed coordination, relaxation, strengthening, and stretching exercises. Breathing exercises were introduced in order to strengthen the respiratory muscles and to teach proper breathing both during exertion and in situations requiring the improvement of ventilation, e.g. dyspnea or fatigue. Resistance training was performed 2-3 times per week on fitness stations using weights up to 20 kg; the sessions consisted of no more than 4 series of 15 repetitions.

The psychological influence consisted of emotional support, the stimulation of self-confidence, and the improvement of self-esteem.

During the educational part of the program, which included classes conducted by a cardiologist, a psychologist, and a dietician, the patients learned methods of coping with emotional stress and changing the habits adversely affecting their predisposition to cardiovascular diseases. The patients were instructed how to measure their pulse (monitoring the pulse and assessing potential cardiac dysrhythmias) and arterial pressure. Moreover, the participants were instructed in the proper use of everyday exercise, including proper respiration during various forms of activity (walking, running, resistance training). They also received advice concerning the optimal selection, planning, and performance of exercises and were shown various forms of physical activity, including sports and recreational activities which exert favorable effects on the cardiovascular system and facilitate the achievement of good short-term and long-term results [8, 9].

### Results

The performed analysis of the initial Stanford questionnaire results demonstrated that the GUCH patients (A and B) were less physically active than their healthy peers (mean scores: Stanford I – 1.9 vs. 2.9 points,  $p < 0.001$ ; Stanford II – 0.21 vs. 1.2 points,  $p < 0.001$ ) (Table II).

Subsequently, the GUCH patients undergoing rehabilitation (A) were compared with the group that did not undergo the CCR-GUCH program (B). Both groups were char-

**Tab. I.** Patient characteristics for the study groups (A – undergoing rehabilitation, B – no rehabilitation) and controls (C)

| Trait          | Groups A and B (n = 57) |      |           | Group C (n = 30) |      |           | p     |
|----------------|-------------------------|------|-----------|------------------|------|-----------|-------|
|                | Mean                    | SD   | Range     | Mean             | SD   | Range     |       |
| Age (years)    | 23.7                    | 4.1  | 18-36     | 24.4             | 1.97 | 21-30     | 0.35  |
| Body mass (kg) | 62.1                    | 10.3 | 44-98     | 69               | 14.4 | 40-90     | 0.021 |
| Height (cm)    | 168                     | 7.1  | 150-184   | 173              | 11   | 147-190   | 0.04  |
| BMI            | 21.9                    | 2.9  | 18.3-31.6 | 22.8             | 2.7  | 18.5-27.2 | 0.049 |

BMI – body mass index, SD – standard deviation

**Tab. II.** Preliminary results of the physical activity examination among the study groups – GUCH patients (A and B) and the controls – healthy students (C) before the start of the CCR-GUCH program

| Trait       | Groups A and B (n = 57) |      |       | Group C (n = 30) |      |       | p       |
|-------------|-------------------------|------|-------|------------------|------|-------|---------|
|             | Mean                    | SD   | Range | Mean             | SD   | Range |         |
| Stanford I  | 1.9                     | 1.1  | 0-4   | 2.9              | 1.1  | 1-6   | < 0.001 |
| Stanford II | 0.29                    | 0.45 | 0-2   | 1.2              | 0.99 | 0-3   | < 0.001 |

GUCH – grown-up congenital heart, CCR – comprehensive cardiac rehabilitation, Stanford I – low-activity exercise, Stanford II – high-activity exercise

**Tab. III.** Results of the Stanford questionnaire among the study groups (A – undergoing rehabilitation and B – no rehabilitation) before the start of the CCR-GUCH program

| Trait       | Group A (n = 31) |      |       | Group B (n = 26) |      |       | p     |
|-------------|------------------|------|-------|------------------|------|-------|-------|
|             | Mean             | SD   | Range | Mean             | SD   | Range |       |
| Stanford I  | 1.97             | 1.2  | 0-4   | 1.8              | 0.98 | 1-4   | 0.605 |
| Stanford II | 0.13             | 0.34 | 0-1   | 0.31             | 0.55 | 0-2   | 0.171 |

CCR – comprehensive cardiac rehabilitation, GUCH – grown-up congenital heart, Stanford I – low-activity exercise, Stanford II – high-activity exercise

**Tab. IV.** Results of the Stanford questionnaire among the study groups (A – undergoing rehabilitation and B – no rehabilitation) after the end of the one-month CCR-GUCH program

| Trait       | Group A (n = 31) |     |       | Group B (n = 19) |      |       | p       |
|-------------|------------------|-----|-------|------------------|------|-------|---------|
|             | Mean             | SD  | Range | Mean             | SD   | Range |         |
| Stanford I  | 3.2              | 0.8 | 2-5   | 1.8              | 1    | 1-4   | < 0.001 |
| Stanford II | 1.2              | 0.4 | 1-2   | 0.13             | 0.34 | 0-1   | < 0.001 |

CCR – comprehensive cardiac rehabilitation, GUCH – grown-up congenital heart, Stanford I – low-activity exercise, Stanford II – high-activity exercise

acterized by similar baseline physical activity according to the initial Stanford questionnaire (Table III).

Forty-seven GUCH patients (82%) did not participate, while all students (100%) did participate in physical education during their school years. Apprehension concerning engaging in physical exertion in everyday life was reported by 35 GUCH respondents (61%), while all students declared that they felt no fear of exercise. Twenty-six GUCH patients (45.6%) declared themselves to be physically active in everyday life; all the students answered this question in the same manner. All the GUCH patients (100%) declared the need to improve their physical capacity and activity. Similar answers were given to the question concerning the readiness to participate in controlled CCR-GUCH training sessions; however, 26 patients (45.6%) did not ultimately participate in the program. None of the GUCH patients had participated in any previous cardiac rehabilitation programs.

No significant differences were noted concerning the use of tobacco. Three of the GUCH patients (5.2%) and 2 students (6.4%) reported tobacco use.

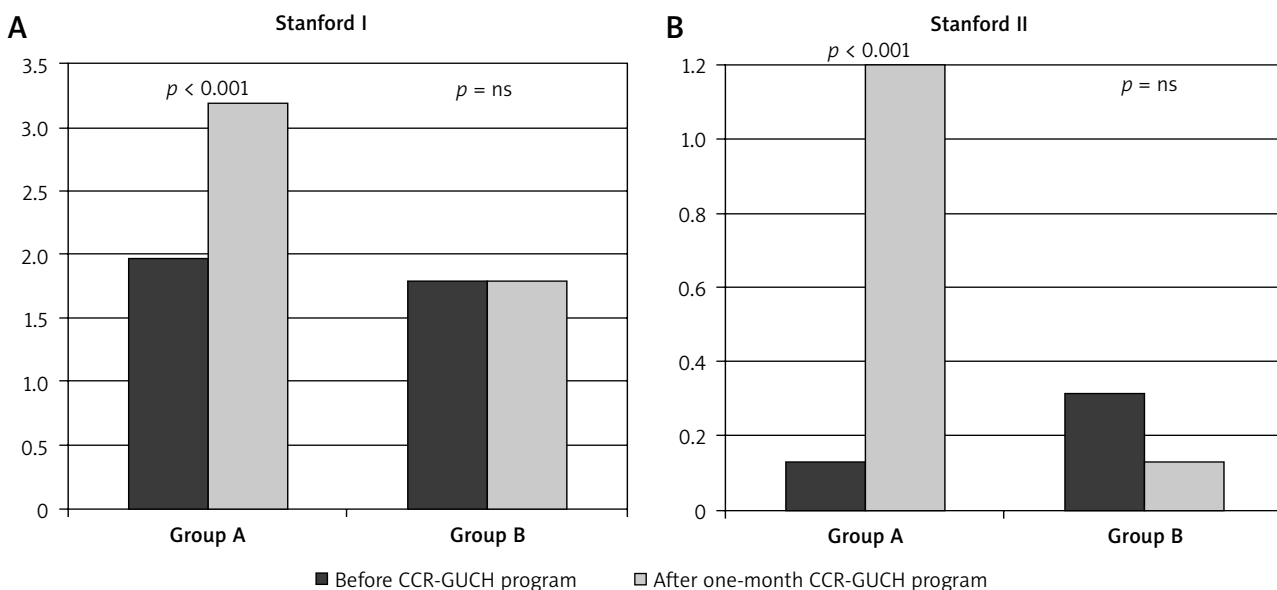
After the intensive rehabilitation program conducted over the course of 1 month, the subjects were again asked to fill out the Stanford questionnaire. Seven patients who did not undergo rehabilitation (group B) did not answer the questions. The analysis of the remaining 50 questionnaires demonstrated that, after the period of 1 month, the patients who were not included in the CCR-GUCH program (group B) were characterized by significantly lower physical

activity in comparison to the patients participating in the training sessions (group A) (mean scores: Stanford I – 1.8 vs. 3.2 points,  $p < 0.001$ ; Stanford II – 0.13 vs. 1.2 points,  $p < 0.001$ ) (Table IV).

The analysis of both parts of the questionnaire also revealed that, after the completion of the CCR-GUCH program, the 31 patients from group A engaged in both low-activity (Stanford I) and high-activity exercise (Stanford II) much more frequently ( $p < 0.001$  and  $p < 0.001$ ) (Fig. 1). The results of the Stanford questionnaire in group A before the start and after the completion of the CCR-GUCH program are presented in Table V.

The unequivocally positive opinion of the effects of the CCR-GUCH program, expressed by 24% of the GUCH patients, should be underscored at this point. Asked about the benefits that they believed were achieved by participating in the program, 20 group A patients (64.5%) responded that their subjective well-being was much better, 5 patients (16.1%) wrote that they tired less during everyday activities, 2 patients (6.4%) no longer feared increasing the load of physical exercise, and 3 patients (9.6%) felt safer during their everyday activity.

Their descriptive answers to the questionnaire handed out after the completion of the rehabilitation program were more likely to include information that they tended to use the stairs more often than the elevator, that they tended to walk rather than drive for short distances, and that they would more frequently go out for walks after dinner or supper. The questionnaire score reflecting improvements in



**Fig. 1.** Results of the Stanford questionnaire among the study groups (A – undergoing rehabilitation and B – no rehabilitation) before the start and after the end of the one-month of the CCR-GUCH program; A) Stanford I; B) Stanford II

**Tab. V.** Results of the Stanford questionnaire in study group A (undergoing rehabilitation) before the start and after the end of the CCR-GUCH program (n = 31)

| Trait       | Before the start of the CCR-GUCH program (n = 31) |      |       | After the end of the one-month of the CCR-GUCH program (n = 31) |      |       | p       |
|-------------|---|------|-------|---|------|-------|---------|
|             | Mean  | SD   | Range | Mean  | SD   | Range |         |
| Stanford I  | 1.97  | 1.2  | 0-4   | 3.2   | 0.88 | 2-5   | < 0.001 |
| Stanford II | 0.13  | 0.34 | 0-1   | 0.74  | 0.63 | 0-2   | < 0.001 |

CCR – comprehensive cardiac rehabilitation, GUCH – grown-up congenital heart, Stanford I – low-activity exercise, Stanford II – high-activity exercise

everyday physical activity corresponds with the results of the Stanford I questionnaire, assessing the same type of activity: the mean Stanford I score changed from 1.97 points before CCR-GUCH to 3.2 after completion of the program.

**Discussion**

Congenital heart defects surgery is typically performed during the patient’s childhood; the age of patients undergoing these operations is increasingly lower, and increasingly younger children undergo successful cardiac surgical treatment using state of the art technology. The dominant group among adolescents and young adults with CHDs is formed by those who had undergone cardiac surgery, but, unfortunately, have predominantly sedentary lifestyles or undertake exercise that is not recommended for their health condition. This often results from the lack of precise information concerning the type and intensity of exercise that they could engage in. Telling these patients: “You can do everything, but in moderation” or “You should not overexert yourself” is clearly insufficient. The basis for the selection of physical activity for individuals with CHD is constituted by the standards of sports cardiology included in the recommendations of consecutive sports conferences in Bethesda [11].

The newest recommendations concerning the use of physical exercise by individuals with CHD were listed in the

“European Society of Cardiology guidelines for the management of grown-up congenital heart disease (new version 2010)” [12]. Regrettably, many adolescents and young adults after the surgical treatment of simple shunt-related cardiac defects avoid intense physical activity [13, 14].

The Bethesda recommendations permit any kind of exercise after the successful and uneventful repair of simple intracardiac shunts [11]. The guidelines of the European Society of Cardiology (ESC) also contain no contraindications for physical exercise in this patient group [12]. The decided majority of patients operated on due to simple shunt-related heart defects (atrial and ventricular septal defects) may perform physical exercise of any kind and intensity starting from the 6th postoperative month, provided no complications, pulmonary hypertension, or dysrhythmias are observed.

It should be stressed that information concerning the physical exercise recommended to this patient group is still lacking; as a result, many patients are unsure what types of activities are truly safe. The patients are unfamiliar with their capacity or the potential risks and restrictions; therefore, it appears necessary to create professional teams dedicated to managing patients after CHD repair [15].

Physical activity may be objectively assessed using a questionnaire including questions concerning the use of various exercise types of different intensity. For the pur-

poses of this study, i.e. determination of the current physical activity profiles of patients, the data obtained from the Stanford I and II questionnaires were immensely useful in evaluating GUCH patients, even though the test was originally designed for other purposes [7, 16]. The conducted analysis of the questionnaire's results demonstrated that, after the completion of the rehabilitation program, the everyday physical activity of our patients increased. After the program ended, the subjects tended more often to report engaging in high-activity exercise (the average Stanford II scores increased from 0.13 before the rehabilitation to 0.63 after the rehabilitation). It is, therefore, to be expected that, owing to this active attitude, the patients will be able to maintain the improvement of physical capacity and exercise tolerance achieved during the comprehensive cardiac rehabilitation program for a longer period of time.

It should be underscored that the ultimate examination with the Stanford questionnaires demonstrated that the patients undergoing comprehensive rehabilitation had statistically better results than the patients who refused to participate in the rehabilitation program (mean scores: Stanford I – A: 3.2 vs. B: 1.8; Stanford II – A: 1.2 vs. B: 0.13,  $p < 0.001$ ). This may indicate that the elements of the program were properly selected and may confirm the program's effectiveness, including in terms of the increase in awareness concerning the need for developing basic health-oriented habits and an active lifestyle.

When analyzing the obtained responses, one should pay attention to the subjective opinions of patients concerning the benefits resulting from participating in the rehabilitation program. After completion of the training cycle, the patients declared that they felt much better, tired less, felt safer during physical activity, and did not fear engaging in types of activities that used to constitute an "impassable" barrier of their capabilities. Thus, it should be expected that, in the future, the group of patients who underwent the CCR-GUCH program will be more aware of their capabilities and will be better able to see their limits without overexerting themselves, which, unfortunately, tends to happen in the group of young adults with CHDs [14].

The final results of the young adult GUCH patients were closer to the results of the controls, recruited (as in previous studies conducted by the authors) among young, healthy students [14]. In accordance with the study's methodology, cardiac rehabilitation conducted in the study group significantly improved the physical activity of over half of the participants. Based on the obtained data, it can be surmised that the expected positive results of training and an improvement of the cardiovascular system's adaptation to physical exercise were achieved during the program. The results confirm previously published literature data; however, there are still few comprehensive studies devoted to the physical capacity of GUCH patients despite the growing number of such patients in the population [17, 18].

The CCR-GUCH rehabilitation in the study group was designed in accordance with the guidelines for conducting

physical training, published by the American Heart Association [21] and with the experience of the authors in providing treatment and conducting physical training sessions for cardiovascular patients [3, 14, 22]. One limitation of the study was the lack of randomization during group selection; however, the authors deemed refraining to invite the patients to participate in the program unethical. The number of patients included in the program was also restricted by the financial limits of the study. The intensity of physical exercise was determined based on the initial CPET. In order to maintain safety, the patients were monitored with electrocardiography during cycleergometer training, while the intensity of general fitness training and Nordic walking sessions was controlled only by pulse measurements. In accordance with the premises of the CCR-GUCH program, acquiring self-control reduced anxiety related to continuing the activities and physical training in home conditions, without the supervision of physical therapists or physicians.

In conclusion, it should be underscored that the improvement of the initially lowered physical activity of GUCH patients undergoing rehabilitation documented in this study, contrasted with the results of patients who did not undergo rehabilitation, confirms the need to qualify and include GUCH patients in comprehensive programs of late rehabilitation [19, 20].

## Conclusions

Engaging in the comprehensive program of late cardiac rehabilitation improves the physical activity of patients after the surgical correction of congenital heart diseases.

Comprehensive cardiac rehabilitation reduces the fears concerning various forms of physical activity that are often encountered in this group of patients, and, in consequence, improves the patients' quality of life.

It appears justified to introduce the comprehensive rehabilitation program as a supplement to holistic care in the group of adolescent patients after congenital heart diseases.

## Disclosure

Authors report no conflict of interest.

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