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Development and implementation of a heart failure telemonitoring system: the single centre experience

Aim	To evaluate the efficacy of remote monitoring by the compliance with body weight control and drug therapy in patients with CHF, using a specially developed software module for chronic heart failure (CHF) monitoring.
Material and methods	During 2018–2020, 79 patients with dilated cardiomyopathy (mean age, 36.1 [34.2; 38.4] years) and NYHA II–IV functional class CHF were included in the outpatient telemonitoring (TM) program.
Results	The duration of monitoring was 965 [768; 1065] days. During the monitoring time, the compliance with outpatient body weight control significantly improved: 73.3 [70; 80] % at baseline vs. 86.7 [76.7; 86.7] % at the end of the 31st month ($p<0.001$). The proportion of patients measuring their body weight at least 6 times a week significantly increased: 8.9% at baseline vs. 58.1% by the end of the monitoring ($p<0.001$). There was no significant association between the time-related changes in the compliance with body weight control and drug therapy and the patient's gender. In addition, during long-term TM, a small but statistically significant increase in left ventricular ejection fraction was noted (36.3 [35.5; 37.2] % at baseline vs. 37.2 [35.8; 38.3] % at the end of monitoring; $p=0.0008$). The involvement of staff physicians in the remote correction of therapy for CHF decreased during the study: the number of system notifications that required a physician's response reduced over two years from 26.6 to 13% ($p=0.011$).
Conclusion	Participation of patients with dilated cardiomyopathy and CHF in the structured TM program was associated with a significant increase in the compliance with regular self-control of body weight and drug therapy for heart failure.

Keywords	Heart failure; telemedicine; compliance with therapy
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Current recommendations and clinical guidelines for the management of patients with chronic heart failure (CHF) [1, 2] offer self-monitoring of CHF symptoms by patients as a factor in improving the prognosis. Daily weighting is included in clinical guidelines for the diagnosis and treatment of CHF, such as the 2016 European Society of Cardiology guidelines [1] and the Practical Guidelines of the Cardiac Society of Australia and New Zealand [3], but patients' adherence to monitoring their well-being is often significantly lower [4, 5]. Similarly, the lack of adherence to drug treatment can be as low as 20–50% in patients with CHF [2]. The lack of adherence to self-monitoring and drug treatment may delay seeking medical attention and increases the risk of hospitalization and death [4, 6].

We made an attempt in this study to analyze the adherence of patients to self-monitoring of CHF using a dedicated software suite that provides simple registration of vital signs and early detection of the progression of CHF and allows the physician to have continuous access to the patient's clinical score.

Material and methods

The study protocol was prepared in accordance with the Declaration of Helsinki of the World Medical Association [7], GOST R 52379–2005 and approved by the ethics committee. The open-label prospective study included patients according to the following criteria:

- Signed informed consent form;
- Age of 18 years and older; CHF of NYHA functional class II–IV;
- Dilated cardiomyopathy (DCM) diagnosed based on the following criteria [8]: left ventricular end-diastolic dimension more than 117% of the normal dimension, adjusted to the age and body surface area [more than 2.7 cm/m2 body surface];

- Left ventricular ejection fraction (LVEF) less than 45% and/or fractional shortening less than 25%; coronary atherosclerosis ruled out by coronary angiography;
- Montreal Cognitive Assessment score ≥26 [9].

Exclusion criteria were neuromuscular diseases, mental pathology, uncorrected loss of vision. Patients included in the DCM register generated from January 2018 to June 2020 were invited to take part in the study. The follow-up was scheduled for at least 8 months. After signing the informed consent, all patients were trained in the CHF school on the use of the CHF control module developed by the Volgotech Scientific Development and Production Center. The software suite used in this study is not a medical device, but a medical information system aimed at remote health management for high-risk patients. Depending on the characteristics of a particular patient at a face-to-face visit, a physician assesses the risk of developing adverse cardiovascular events and schedules the follow-up in accordance with the National Guidelines for the Prevention of Adverse Cardiovascular Events [10, 11]. When the treatment is prescribed, the patient receives a reminder on his/her smartphone or computer to confirm that he/she has been familiarized with the medical recommendation and later receives the schedule of drug administration. The physician can periodically make reports for the patient on the progress of treatment and changes in the parameters of interest. The physician can attach his/her recommendations to the report.

The system includes «patient schools»: small blocks of useful information are sent to the patient in accordance with a predetermined time schedule. The patient can correspond with the physician and add documents to his/her diary to complete the medical record.

The system can be connected to commercial scales equipped with a Bluetooth interface, which simplifies the communication of body weight (two choices of household scale model having declarations of compliance with the EAEU technical regulations were provided to the patients). The telemonitoring system generated notifications based on the received data for the physician and the patient on the changes in body weight: (a) a rapid increase in body weight (more than 2 kg per 3 days [10–12]); (b) a slow change in body weight (a decrease or increase by 5 kg within 30 days); (c) a minimum change in body weight (a decrease or increase by 1 kg within 24 hours) [5]. Notifications of the first type were grounds for an additional contact with the patient, a correction to the treatment regiment, or a face-to-face visit. Notifications of the second and third types involved contact with the patient for an additional assessment of symptoms and direction of an additional CHF Compensation Questionnaire to the patient by the telemedicine system.

The telemonitoring data were evaluated by four cardiologists and three nurses trained in CHF management. The incoming data were initially assessed by nurses; if deemed necessary, notifications were subsequently provided to the physician.

The primary endpoints were adherence to weight control and adherence to drug treatment of CHF. Adherence to weight control was assessed monthly as the ratio of patient measurements entered into the telemonitoring system to the recommended control frequency in percent. The weekly weight control frequency, defined as the mean number of days a week on which weighing was performed, was considered throughout the follow-up period. The number of patients performing weighing at least four times a week (as an equivalent of preferential compliance with the recommendations for the frequency of control [4, 5]) and the number of patients performing weighing at least six times a week, which is closer to the best possible recommendation of daily weighing, were taken into account [5].

The adherence to drug treatment for CHF was determined based on the confirmation made by the patient on a daily basis in response to the telemonitoring system's reminder to administer drugs (reminders were generated automatically depending on the frequency of drug administration indicated by the physician). Monthly adherence was defined as the mean of 30 consecutive daily values. Patients were able to identify a specific time interval as impossible to weigh or confirm drug administration. Adherence was assessed as zero for such time intervals in the analysis.

Secondary endpoints included adherence to blood pressure (BP) monitoring; changes in the Symptomatic Hospital and Outpatient Clinical Score (SHOCS) [10]; clinical outcomes potentially associated with CHF (frequency of hospitalizations and emergency visits due to decompensated CHF; rhythm disorders; clinically significant changes in BP; conditions associated with coagulation disorders; symptoms of acute coronary syndrome); number of notifications generated by the telemonitoring system for the physician regarding the need for additional patient contact. Patients monitored BP using home blood pressure monitors. The telemonitoring system generated automatic reminders to measure BP at a frequency specified by the physician.

Evaluations using SHOCS and assessment of LVEF were performed at the scheduled face-to-face visits once every 6 months and additionally at the end of follow-up.

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The sample size was calculated for the primary endpoint (changes in the adherence to weight control) using G*Power Version 3.1.9.6 (Franz Faul, Universität Kiel, Germany). The statistical criteria planned for the analysis of the primary endpoint were specified in the program. These included ANOVA with repeated measurements; the effect magnitude (the difference between the compared means expressed by the ratio) of 0.25, which, according to J. Cohen, corresponds to the mean value; and the correlation value of 0.5, as the mean value expected in the biomedical studies [13].

Statistical analysis of the data obtained was performed using Statistica 12 (StatSoft, 2014) following the guide [14]. The independent groups were compared by the continuous variable using the Mann-Whitney U-test. The chi-squared test and Fisher's exact test were used to compare the categorical variables. The dependent samples were compared by binary and frequency variables using the McNamara-Bowker test and Wilcoxon's signed rank test for the dependent samples [15] in IBM SPSS Statistics version 26.

The Wilcoxon test was used to compare the dependent groups by quantitative variable, while the Friedman test was used to evaluate the difference of multiple dependent groups by quantitative variable. The effect of individual predictors on adherence was evaluated by constructing a linear regression model. The 95% confidence interval (CI) was used to calculate the relative risk (RR). The critical significance value p was 0.05. The data are expressed as the median and interquartile range (Me [25%; 75%]); absolute values and percentages are indicated where applicable.

Results

Patients were recruited over a period of 20 months and the maximum duration of follow-up was 1,151 days. Of the 94 patients included in the DCM register at baseline, 74 (79%) agreed to take part in the study, but 2 patients met exclusion criteria, i.e., 72 patients were included in the study. Additionally, 7 patients with newly diagnosed DCM were included during the first 20 months of the study. Thus, a total of 79 patients were included in the study: 69 (87.3%) patients during the first year of recruitment, 6 (7.6%) patients during the second year, and 4 (5.1%) patients at a later date. 54% of patients were included in the study during the treatment of CHF in hospital, while 46% were included at the outpatient visits. However, patients of both subgroups underwent the same 1.5-hour training at the CHF school. The analysis of results was performed based of the data of all patients included in the study.

The study lasted for 965 [768; 1,065] days. During the follow-up period, all-cause mortality was 16 cases or 20.2% of the patients included in the study. During the study, two patients underwent heart transplantation (indications were defines after the beginning of follow-up), while three patients had triple-chamber pacemakers with cardioverter-defibrillator function (CRT-D) implanted. Those patients continued to use telemonitoring and were included in the analysis.

The main characteristics of patients are presented in Table 1. The age of the male and female patients included in the study did not differ statistically significantly: 35.9 [34; 38.5] years versus 36.3 [34.7; 38.2] years. Baseline median LVEF was 36.1 [34.8; 37.1] %. The baseline distribution by functional classes (FC) of heart failure was as follows: 5 (6.3%), 57 (72.2%), and 17 (21.5%) patients had FC II, III, and IV, respectively.

All classes of drugs used to treat CHF were used for patients included in the study at maximum tolerated doses. The administration of sacubitrile/valsartan increased during the study; the percentage of patients administering angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers decreased simultaneously.

Of the 12,334 cases of missed body weight measurements, 4,438 (36.0%) episodes were reported by patients as scheduled (e.g., departure from home, hospitalization); 986 (8.0%) episodes were due to technical problems, and 6,910 (56.0%) episodes were not explained. Missed body weight measurement due to technical problems included 784 (79.5% of the subgroup) episodes were caused by failure of the Internet connection; 183 (18.6%) episodes were caused by problems of the wireless connection of scales; 19 (1.9%) cases were due to broken scales.

Changes in the adherence to weight control were calculated using the baseline values (at the end of month 1 of follow-up) and values measured at the end of month 31 of the study, i.e., the study stage, which was completed by 43 (54.4%) of 79 patients. An increase in the adherence to weighing was observed: 73.3 [70; 80] % at baseline versus 86.7 [76.7; 86.7] % at month 31; $p<0.001$ (Figure 1) along with a Kendall's coefficient of concordance being 0.639, which corresponded to a significant effect value. The achieved «plateau» of weight control frequency was maintained for a larger part of the study. The adherence at month 7 of the study did not differ from that at month 31: 83.3 [76.7; 86.7] % versus 86.7 [76.7; 86.7] %; $p=0.48$.

No influence of these factors on adherence was shown by a regression model constructed for each month of follow-up, including the value of adherence to weighing

Table 1. Characteristics of patients examined

Parameter	Value		
Male/female	47 (59.5)/32 (40.5)		
Age, years	36.1 [34.2; 38.4]		
Arterial hypertension	23 (29.1)		
Dyslipidemia	10 (12.7)		
CKD IIIb	3 (3.8)		
Atrial fibrillation	11 (13.9)		
Ventricular arrhythmia	13 (16.5)		
Pacemaker	1 (1.3)		
QRS > 120 ms	5 (6.3)		
Smoking	19 (24.1)		
Parameter	**Beginning of follow-up (n=79)**	**End of follow-up (n=63)**	**p**
Beta-blockers	69 (87.3)	57 (90.5)	0.75*
Loop diuretics	77 (97.5)	60 (95.2)	0.66**
Spironolactone	64 (81.0)	54 (85.7)	0.6*
ACE inhibitors, sartans	62 (78.5)	39 (61.9)	0.048*
Sacubitril + valsartan	16 (20.3)	24 (38.1)	0.03*
Oral anticoagulants	11 (13.9)	8 (12.7)	0.5*

The data are expressed as the absolute numbers and percentages of patients (n (%)), unless otherwise specified.
* – Yates chi-squared test; ** – Fisher's exact test.
CKD – chronic kidney disease;
ACE – angiotensin converting enzyme.

as a dependent variable, the sex of the patient, and the fact of hospitalization in the CHF therapy department prior to inclusion in the telemonitoring program as independent variables.

During the study, the majority of patients consistently measured body weight at least four times a week: the percentage of such patients varied from 95.2% to 100.0%. At the same time, the number of patients who weighed themselves six times a week or more increased. At baseline, 7 (8.9%) of 79 patients reached the initially indicated control rate, while 25 (58.1%) of 43 patients reached the control rate at month 31; p<0.001. The percentage of 53.2% was achieved in month 8 of the study did not differ from that of month 31: 42 (53.2%) of 79 patients versus 25 (58.1%) of 43; p=0.375.

Adherence to drug treatment of CHF increased significantly during the study (Figure 2): 85.0 [81.7; 88.3] % after 1 month of follow-up versus 91.7 [88.3; 95.0] % after 31 months; p<0.001. The adherence plateau, which was reached at month 11 of the study, did not differ statistically significantly from month 31: 92.5 [88.3; 96.7] % versus 91.7 [88.3; 95.0] %; p=0.92. The regression model did not confirm the role of sex, LVEF, or previous hospitalization in the CHF therapy department as predictors of adherence to drug treatment (Figure 2).

Adherence to BP control also tended to increase: 40.0 [36.7; 40.0] % of patients measure BP with a recommended frequency after month 1 of follow-up and 53.3 [50.0; 56.7] % at month 31; p<0.001.

The distribution of CHF FCs changed significantly during the study: the number of patients with FC IV decreased, while the number of patients with FC II increased. At the end of month 31, 7 (17.1%) patients had FC II, 29 (70.7%) patients had FC III, and 5 (12.2%) patients had FC IV, while the baseline incidence was 6.3%, 72.2%, and 21.5%, respectively; p=0.043.

Comparison of LVEF determined at baseline and after 31 months showed a statistically significant increase in this indicator: 36.1 [34.8; 37.1] % versus 37.2 [35.8; 38.3] %; p=0.0007. After excluding the baseline LVEF

Figure 1. Changes in adherence to weight control, Me [25 %; 75 %]

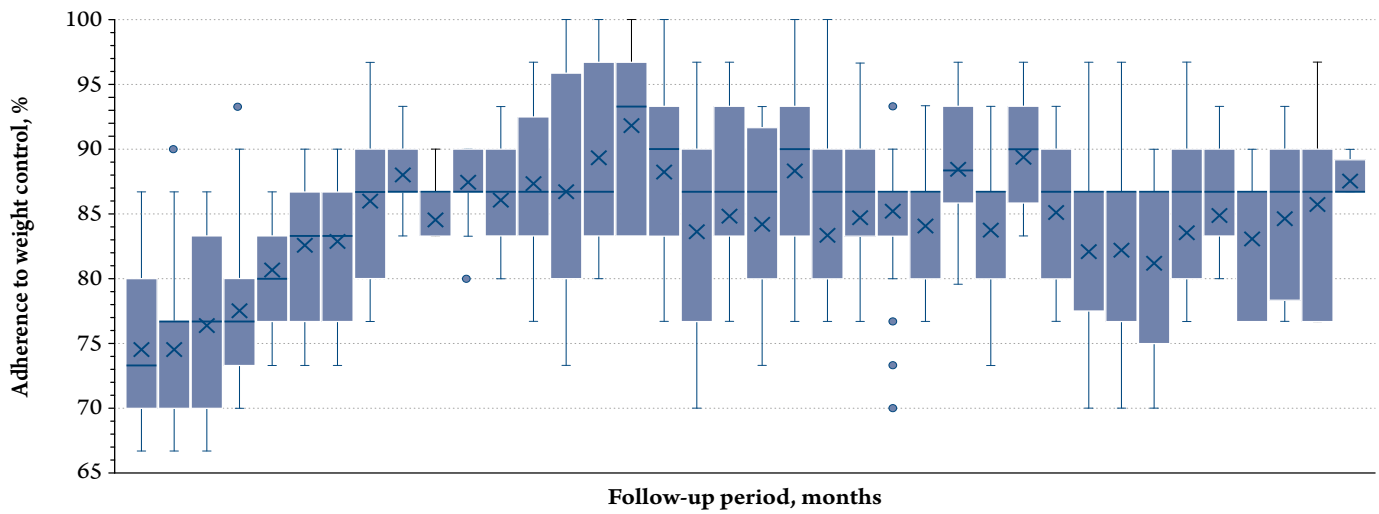

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Figure 2. Changes in adherence to drug treatment of CHF, Me [25 %; 75 %]

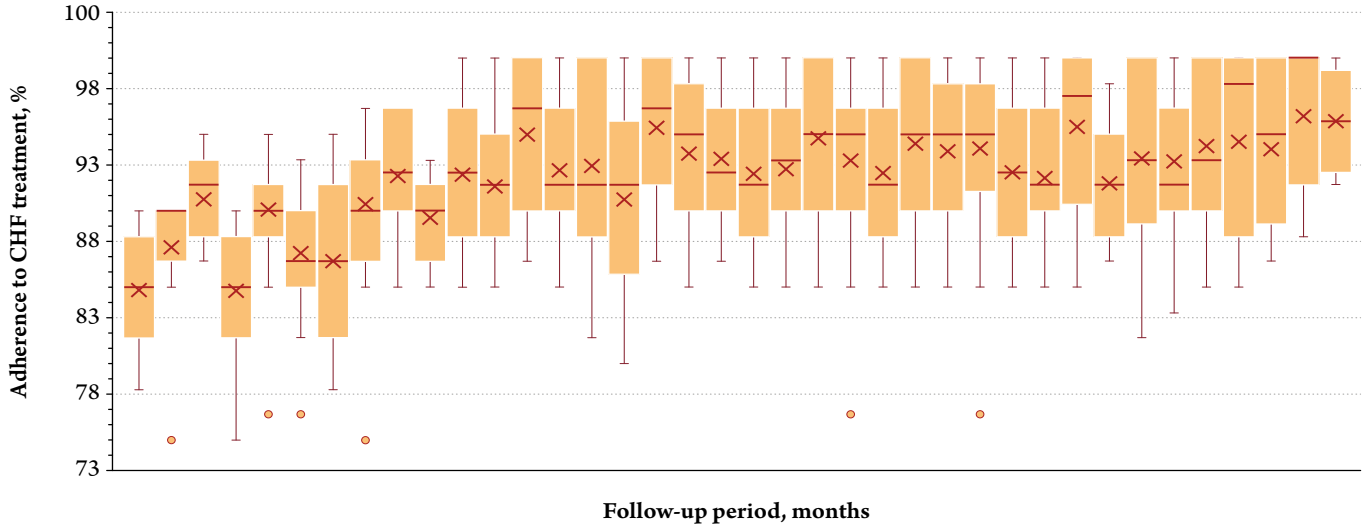

Table 2. Patient distribution by the SHOCS scores

Study period	SHOCS, score				p*
	6	7	8	9	
Month 1, n=79	5 (6.3)	8 (10.1)	48 (60.8)	18 (22.8)	0.003
Month 31, n=41	6 (14.6)	11 (26.8)	15 (36.6)	9 (22.0)	

The data are presented as the absolute numbers and percentages of patients (n (%)). * – McNemar-Bowker test.

values of patients who had died by the time of repeated determination of LVEF from the analysis, the statistical significance of the difference did not change (36.3 [35.5; 37.2] % versus 37.2 [35.8; 38.3] %; p=0.0008). Since the only reason for LVEF changes during the study, this allows us to object to the idea of excluding patients with the most severe CHF forms from the study group.

The clinical significance of changes in LVEF was assessed using the analysis of the distribution of patients according to the clinical condition in CHF (SHOCS); the results are presented in Table 2. Patients with SHOCS 7–9 prevailed at baseline; only 6.3% of patients had SHOCS score 6. At the end of month 31, the number of patients with SHOCS 8 decreased, while the number of patients with SHOCS 6–7 increased; p=0.003.

The frequency of unscheduled medical visits and the frequency of hospitalizations due to conditions that could be related to CHF were analyzed by comparing the data collected in the first 12 months of the follow-up, i.e., the study period completed by 76 (96.2%) of 79 patients, with similar data collected anamnestically for the period of 1 year prior to inclusion in the study (Table 3). An additional consideration in choosing such a time frame was the intention to rule out any potential effects on the outcomes of the SARS-CoV-2 infection. In the first 12 months of the study, the relative risk of seeking unscheduled medical attention (including hospitalization) for conditions that might have been related to CHD was 0.86. (95% CI 0.74–1.0; p=0.0498).

During the first 12 months of follow-up, the telemonitoring system generated 21 notifications of rapid weight gain (more than 2 kg in 3 days); based on results of remote patient visits, drug treatment was corrected in 8 cases to compensate the deviation; in 13 cases, face-to-face visits were scheduled; 4 cases involved hospitalization.

In comparison to the first year of follow-up, decreased notifications of rapid weight gain were statistically significant over the second year: 8 (13.0 percent) notifications were generated per 60 patients who finished the second year of follow-up versus 21 (26.6 percent) notifications per 79 patients in the first year; p=0.011.

Discussion

The present study investigated the long-term use of the dedicated CHD telemonitoring module in young patients (36.1 [34.2; 38.4] years) with DCM (median duration of follow-up 956 [768; 1,065] days). Body weight comprising the biological indicator most frequently used in the telemonitoring algorithms

Table 3. Number of unscheduled visits, including hospitalizations

Period of time	Visits for medical attention, n (%)	No emergency visits, n (%)	p*
12 months prior to examination, n=79	19 (24.0)	60 (76.0)	0.012
12 months of examination, n=76	9 (11.8)	67 (88.2)	

* Wilcoxon signed rank test.

for correcting CHF therapy was used as a marker of decompensated CHF [16–19]. However, it should be mentioned that the available evidence on the effect of body weight monitoring on the prognosis of CHF remains inconclusive. No statistically significant difference was discovered between the telemonitoring group and the standard monitoring groups in the randomized trial WISH [17], which included daily monitoring of body weight with automatic data transfer. As the review authors correctly noted [18], this effect in the WISH trial may, however, result from the implementation in the standard monitoring group of a patient action algorithm, which allowed for more frequent telephone contacts with medical personnel than in real-world outpatient practice.

The majority of patients participating in the study maintained long-term frequency of weight control at least four times a week. Moreover, the number of patients who measured body weight at least six times a week grew during telemonitoring. With targeted weight measurement four times a week, this approach is stricter than that applied in the majority of earlier studies [4, 20]. In this connection, while the process of increasing adherence to weighing frequency required a significant amount of time, the eventually achieved level was maintained until the end of the study. This result is comparable to that of the randomized study by Ding et al. [5], in which 45% of patients in the telemonitoring group weighed themselves at least six times a week. Unlike Celler et al. [21], we did not observe a period of decrease in the frequency of body weight control and BP control during follow-up. This may be explained by the use of a technically easier method of automatic transfer of body weight measurements to the telemonitoring system.

According to Ueda et al. [5], the telemonitoring group showed a statistically significant increase in adherence to drug administration and diet, which was consistent with the increase in patient adherence to drug treatment of CHF and BP control in our study.

There was a statistically significant, albeit marginal, decrease in the overall need for unscheduled medical attention for conditions that might have been related to CHF: in the first 12 months of the study HR=0.86 (95% CI 0.74–1.0; p=0.0498). This result is consistent with the findings of the meta-analysis [19], in which the risk of hospitalizations due to CHD reduced when telemonitoring was used (RR=0.71; 95% CI 0.60–0.83). Similar findings were made in the study [22], in which there were fewer hospitalizations in the telemonitoring group (OR=0.29; 95% CI 0.11–0.75; p<0.001). According to Ueda et al. [5], telemonitoring did not have a significant effect on the frequency of hospitalizations and seeking emergency attention; however, patients taking part in that study were older and had significant comorbidities. The study [5] only lasted for six months, which might have not been long enough for the effects of telemonitoring to transfer into clinical outcomes.

The study was limited by the relatively small number of included patients, the cohort design, and the participation of physicians and nurses of the specialized CHF department in the telemonitoring system, whose recommendations to patients might have been more thorough than those made by primary care providers [21]. The number of patients included in the study had sufficient power for the primary endpoints (adherence to weight control and adherence to drug treatment of CHF), for which the study was designed, but not for the secondary endpoints of hospitalization and seeking emergency attention. In this regard, regardless of their statistical significance, the effects of telemonitoring shown in this study on the specified secondary point, should be interpreted with great caution. It should also be mentioned that the sample size restricts the analysis of endpoints adjusted for changes in the frequency of using sacubitrile/valsartan. The high rate of patient retention in the study and its long-term duration, which allowed the detection of changes in patient adherence to treatment in the real-world clinical practice, are the positive aspects of the study.

Conclusion

A statistically significant increase in adherence to both weight control and drug treatment of chronic heart failure was observed when the dedicated telemonitoring

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module for chronic heart failure was used to monitor the health of patients with dilated cardiomyopathy.

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No conflict of interest is reported.

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