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Remote Monitoring of Patients with Chronic Heart Failure NYHA Class II–III Using the Mobile Application 'M-cardio' in Kyrgyzstan

Aim	Development and implementation of the M-Cardio mobile application for remote monitoring of patients with chronic heart failure (CHF) at the outpatient stage with an assessment of clinical effectiveness.
Material and methods	This study included 244 patients with NYHA functional class (FC) II-III CHF of ischemic etiology. During the inpatient phase, the patients were taught the basics of self-monitoring and self-care in CHF. In addition, patients of the main group were trained in using the M-Cardio mobile application. Patients were randomized into 2 groups: Group 1 was the main group, with further remote monitoring using the mobile application (n = 127), Group 2 was a control group, with standard outpatient monitoring at the patient's residence (n = 117). The original version of the mobile application was downloaded to the smartphones of the participants in the main group. The app contained a developed algorithm of clinical indicators, which allows real-time assessment of the patient's condition based on the quantitative deviations above or below threshold values. This algorithm includes 7 items, shortness of breath, position in bed, palpitation, edema, body weight, blood pressure (BP), and heart rate (HR), which the patient fills in twice a week or every day if necessary. A possibility is also included for automated information of the doctor and the patient to specify recommendations and timely adjust the treatment. The follow-up period was 12 months.
Results	244 patients with NYHA FC II-III CHF of ischemic etiology were selected and enrolled in the study, including 155 (63.5%) men and 89 (36.5%) women (mean age, 61±7.4 years). NYHA FC II CHF was detected in 50 (20.4%) patients and NYHA FC III CHF in 194 (75.5%) patients. The mean left ventricular ejection fraction was 41.6±10.7%.
Conclusion	Preliminary results of the study indicated that the use of remote monitoring of CHF patients was significantly associated with an improvement in their quality of life, ability for self-care, and the functional status. The effectiveness of the M-Cardio mobile application in the remote monitoring of outpatients is based on a decreased frequency of rehospitalizations and an increased survival.

Keywords	Chronic heart failure; remote monitoring; mobile application; mHealth
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Chronic heart failure (CHF) is one of the key healthcare problems worldwide, that has a global socioeconomic dimension. CHF is a complex, life-threatening clinical syndrome characterized by acute episodes of decompensation leading to repeated hospitalizations, which is associated with a threefold increase in the risk of death [1, 2]. However, up to 40% of readmissions can be prevented [3] by improving the coordination and continuity of patient care at the outpatient stage [4]. In addition, one of the solutions to the problem of frequent readmissions is to improve patient education, for example, immediately before discharge [4, 5]. High mortality and readmission rates, low patient adherence to treatment, staffing shortages, and problems in the outpatient and polyclinic sector necessitate a comprehensive approach to the management of this category of patients throughout the course of their disease [6, 7]. The development of remote patient monitoring (RPM) tech-

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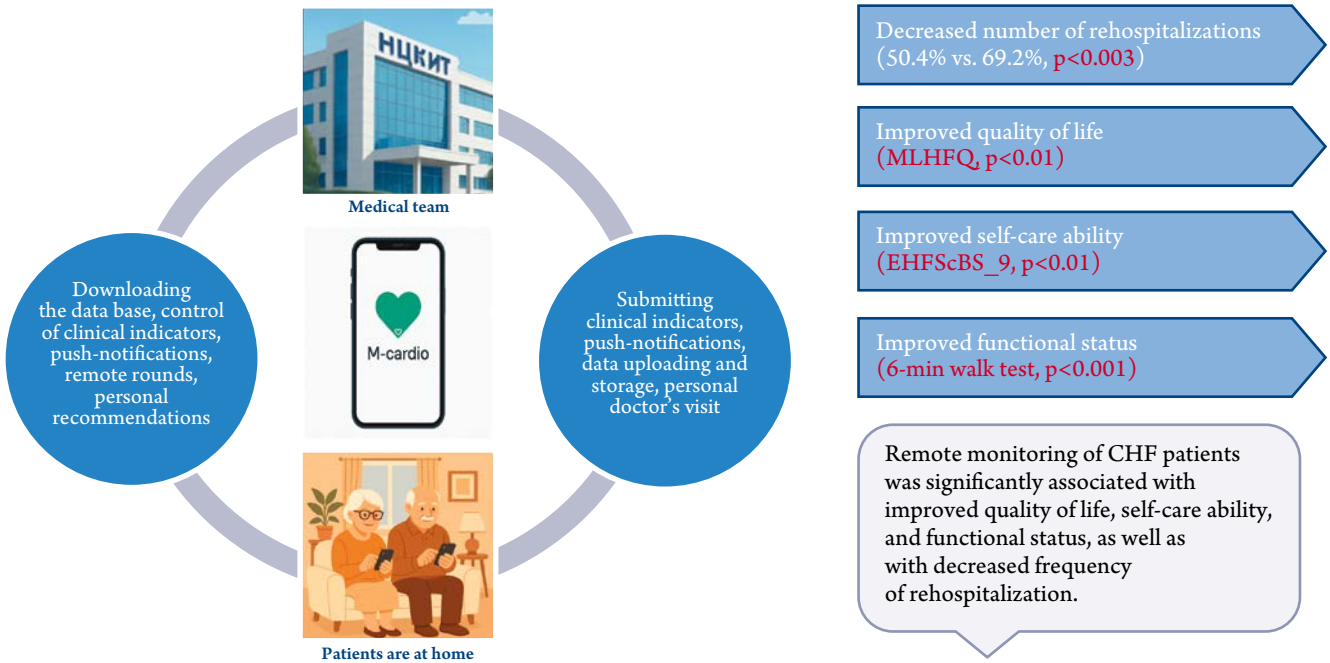
Central illustration.
Remote monitoring of patients with CHF using the M-cardio mobile application: Key results



nologies can help reduce the frequency of rehospitalization and mortality in patients with CHF. According to the literature, the most preferable type of non-invasive monitoring is the use of mobile applications for monitoring the CHF patients' condition [8]. Thus, in the latest clinical guidelines, 2021 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure, RPM was defined as an effective method for educating and motivating patients, as well as for providing medical care (class II, level of evidence B recommendation) [9]. A meta-analysis of 26 randomized trials, that assessed the effectiveness of non-invasive RPM, demonstrated a 40% reduction in all-cause mortality within 180 days [10]. The RPM using the approach presented in the Telemedical Interventional Management in HF-2 (TIM-HF2) study [11], as well as in one of the recent randomized clinical trials OSICAT, can be considered for use in CHF patients to reduce the frequency of rehospitalization and mortality [12]. At the same time, studies conducted in recent years have reported conflicting results due to differences in the study populations, health care systems, and monitoring types, which requires standardization of intervention methods, including according to the structure of the health care system in each individual country. The development of a model for managing CHF patients through RPM programs is a potentially effective solution for improving the quality of life, adherence to therapy, and the self-care ability of patients.

Aim

The aim of the study was development and implementation of the M-cardio mobile application for remote monitoring of patients with CHF at the outpatient stage with an assessment of clinical effectiveness.

Material and methods

Study protocol

All patients provided written informed consent to participate in the study. The study was conducted in consistency with the Rules of Clinical Practice and the World Medical Association Declaration of Helsinki on ethical principles for medical research involving human participants. The study protocol was approved by the Bioethics Committee of the Academician M. Mirrakhimov National Center of Cardiology and Therapy (NCCT) (Protocol #4 dated October 13, 2020). This study, entitled "Effects of Remote Monitoring of Patients with Heart Failure Based on Mobile Application" (ERICA-HF) was an open-label randomized clinical trial registered on the website of the International Registry of Randomized Clinical Trials (RCTs), ClinicalTrilas.gov (https://clinicaltrials.gov/Identifier: NCT04591964). The study design was an open, prospective, randomized, controlled trial. The inclusion criteria were NYHA FC II-III CHF of ischemic etiology; glomerular filtration rate (GFR) >30 ml/min/1.73 m^2; age from 30 to 75 years; and voluntary informed consent to participate in the study. The exclusion criteria

were pregnancy; implanted cardiac devices (resynchronization therapy, implantable cardioverter-defibrillator); mental illness or disability; alcohol and drug abuse; lack of a smartphone with Android software. Randomization was performed using a random number table. The study included patients successively admitted to the CHF Department of the NCCT from June 2021 through May 2022.

In addition to standard laboratory and instrumental evaluations, patients were assessed for quality of life, self-care ability, and functional status.

Quality of life was assessed using the Minnesota Heart Failure Quality of Life Questionnaire (MLHFQ). This questionnaire consists of 21 questions conditionally divided into 4 subgroups: factors determining the patient's physical capabilities or limitations; emotional factors; general factors; and medical factors. The highest quality of life score was 0, the lowest is score was 105.

Self-care ability was assessed using the European Heart Failure Self-care Behavior Scale-9 (EHFScBS-9). This scale includes 9 items related with various aspects of self-care. The answers were rated on a 5-point scale ranging from "completely agree" (1 point), "almost agree" (2 points), "rather agree than disagree" (3 points), "rather disagree than agree" (4 points) to "completely disagree" (5 points). The total score was calculated by summing up the points for each item and ranged from 9 to 45. The lower the total score, the better the self-care ability.

Functional status of CHF patients was assessed by the results of the 6-minute walk test (6MWT).

During the inpatient treatment, starting from the moment of admission, all patients were given two classes with presentation of materials containing general information about CHF, symptoms of CHF progression, features of diet, physical activity, drug control of the course of CHF, and the need for self-monitoring and self-care. In addition, after randomization, patients of the main group were trained to use the M-cardio mobile application developed by us. Upon discharge, the original version of the M-cardio application was loaded to the patients' mobile phones (Android OS) in the main group. After discharge, patients of the main group began submitting values of their clinical indicators in real time twice a week or every day if necessary. If the data were not submitted before 10:00 am, reminders of the need to submit the values were sent to the patients' mobile phones. If more than two values deviated from the normal, the supervising physician received automatic notifications of the patients with the parameter deviations from the threshold values. The doctor then contacted the patients via WhatsApp online chat or by phone to assess the condition further and, if necessary, made adjustments and assessed adherence to the therapy. In addition, the reasons for deviations (violation of diet, water-salt regime) and adherence to drug therapy were clarified. If a patient failed to submit the data more than two times, he/she was contacted by phone or WhatsApp to clarify the reasons for the problem with data recording. In addition to filling in the clinical indicators, patients could also contact the supervising physician via WhatsApp online chat or by phone to ask questions about their current condition. Patients of the control group were on standard outpatient management. The follow-up visit for monitoring of clinical and laboratory data in both groups took place at 12 months after inclusion in the study. Endpoints were recorded every month.

A model for managing a patient with CHF developed and implemented in the study group using the M-cardio mobile application

The original version of the mobile application with the algorithm of clinical indicators we developed was downloaded to the smartphones of the main group. The algorithm determined the current state of patients based on the quantitative deviations above or below the threshold values. The algorithm included 7 items: shortness of breath, position in bed, palpitations, edema, body weight, blood pressure (BP), and heart rate (HR). The patient submitted these items twice a week or every day if necessary. Both the physician and the patient can be automatically notified to specify recommendations and timely adjust the treatment. In addition to the indicators, the application interface also includes a database, self-monitoring diaries, automatic notifications (in the absence of submission of the required parameters or in case of deviations from threshold values), an information block for patients, two-way contacts in the form of structured telephone support and via the WhatsApp online chat, a handbook on CHF for patients. The M-cardio mobile app provides the possibility to download, store and review the patient's baseline data while ensuring the security of personal data.

Endpoints

The primary endpoint was the incidence of death. The secondary endpoint was the composite incidence of rehospitalization (for decompensated CHF) and deaths; changes in quality of life (Minnesota Questionnaire) and self-care ability (EHFScBS-9); and the functional status (6MWT).

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Statistical analysis was performed with a SPSS software package (IBM Inc., USA, version 23). Quantitative variables are presented as mean ± standard deviation. Qualitative variables are presented as percentage of the total number of observations. Qualitative variables were compared using the chi-square test. For comparison of quantitative variables between the main and control groups, the unpaired Student's t-test was used. For comparison of quantitative variables at baseline and after 12 months, the paired Student's t-test was used. Differences were considered statistically significant at $p<0.05$.

Results

By the present time, 244 patients with NYHA FC II–III CHF of ischemic etiology have been selected and included in the study. The 1st (main) group included 127 patients in whom, along with the standard practice of medical care, other treatments were administered according to the study protocol with subsequent remote monitoring via the mobile application. The 2nd (control) group that initially included 117 patients was on a standard outpatient monitoring at the place of residence. The main group included 80 (63%) men and 47 (37%) women aged 60.8±7.2 years. The control group included 75 (64.1%) men and 42 (35.9%) women aged 62.2±7.6 years. The groups did not differ in gender and age. The remaining characteristics of the groups are presented in Table 1. The groups were comparable in clinical parameters, laboratory data, and the treatment with major disease-modifying drugs for coronary heart disease (CHD) and CHF.

In this study, the preliminary results of using the RPM program with the mobile application in CHF patients were as follows. Initially, 244 patients were enrolled, 127 in the main group and 117 in the control group. At 12 months, the main group had a lower death rate compared to the control group although the difference did not reach statistical significance (3.9 and 7.7% in the main and control groups, respectively; p=0.2). During the follow-up period, 14 patients died (5 in the main group and 9 in the control group). Furthermore, 7 of them died within the first 3 months after discharge from the hospital. The frequency of the secondary endpoint (fatality or readmission) was significantly lower in the intervention group (50.4 and 69.2% in the main and control group, respectively; p=0.003), as shown on Figure 1.

Table 2 and Figure 2 show the changes in quality of life (MLHFQ), self-care ability (EHFScBS-9), and exercise tolerance (6MWT). At baseline, there were no statistically significant differences between the groups.

Table 1. Baseline clinical and laboratory characteristics of study groups of patients with NYHA FC II-III CHF of ischemic etiology

Parameter	1st group (main), n=127	2nd group (control), n=117	p
SBP, mm Hg	137.0±24.7	134.8±27.0	0.51
DBP, mm Hg	84.6±12.9	84.1±15.2	0.78
HR, beats/min	79.7±16.4	82.9±17.6	0.14
Smoking, n (%)	31 (24.4)	34 (29.0)	0.42
Obesity, n (%)	59 (46.4)	52 (44.4)	0.75
AH, n (%)	113 (89.0)	101 (86.3)	0.52
Type 2 DM, n (%)	50 (39.4)	34 (34.2)	0.40
COPD, n (%)	19 (14.9)	20 (17.0)	0.65
Anemia, %	22 (17.3)	23 (19.6)	0.64
LV EF, %	42.1±11.6	40.9±9.4	0.38
FC II CHF, n (%)	30 (23.6)	24 (20.5)	0.56
FC III CHF, n (%)	97 (76.4)	93 (79.5)	0.56
ACE inhibitors/ARBs, n (%)	120 (94.4)	107 (91.5)	0.33
MCRAs, n (%)	127 (100)	115 (98.1)	0.12
Diuretics, n (%)	109 (85.8)	105 (89.7)	0.36
Beta-blockers, n (%)	122 (96)	109 (93.2)	0.33
Statins, n (%)	127 (100)	117 (100)	0.98

CHF, chronic heart failure; FC, functional class; SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; AH, arterial hypertension; DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; LV EF, left ventricular ejection fraction; ACE, angiotensin-converting enzyme; ARBs, angiotensin receptor blockers; MCRAs, mineralocorticoid receptor antagonists.

The improvement in quality of life in the main group compared to the control group became noticeable after 6 months of observation, and remained through 12 months (scores 44.8±6.7 and 56.5±7.9; p<0.001 in the main and control group, respectively). The same was observed for the self-care ability (scores 17.5±5.1 and 22.4±4.2; p<0.001 in the main and control group, respectively). Statistically significant differences were also found for exercise tolerance in the main and control group at 12 months (6MTX): 319±79 m and 233±64 m, respectively (p<0.001).

Figure 3 shows the proportion of patients who discontinued the major drugs after 12 months of follow-up. The most frequently discontinued drugs were mineralocorticoid receptor antagonists (16.1 and 15.7% in the main and control group, respectively; p=0.92) and angiotensin-converting enzyme (ACE) inhibitors or sartans (2.2 and 17.3% in the main and control group, respectively; p<0.001). In addition to ACE inhibitors/sartans, statistically significant differences between the groups were found in the frequency of discontinuation of beta-blockers (1.1 and 8.2% in the main and con-

Table 2. Comparison of dynamic evaluations of quality of life, self-care ability, and functional status

Parameter	Baseline		p	At 12 months		p
	Main group	Control group		Main group	Control group	
MLHFQ, score	51.9±8.5	51.9±8.1	1.0	44.8±6.7	56.5±7.9	<0.001
EHFScBS-9, score	28.5±3.7	27.5 ±5.3	0.09	17.5±5.1	22.4±4.2	<0.001
6MWT, m	272±86	263±73	0.38	319 ±79	233±64	<0.001

MLHFQ, Minnesota Living with Heart Failure Questionnaire; EHFScBS-9, European Heart Failure Self-care Behavior Scale 9; 6MWT, 6-minute walk test.

Figure 1. Comparative incidence of primary and secondary endpoints in study groups

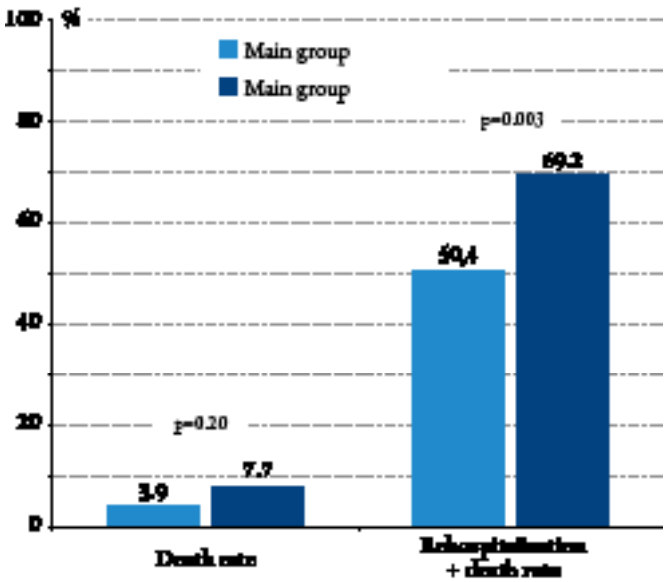
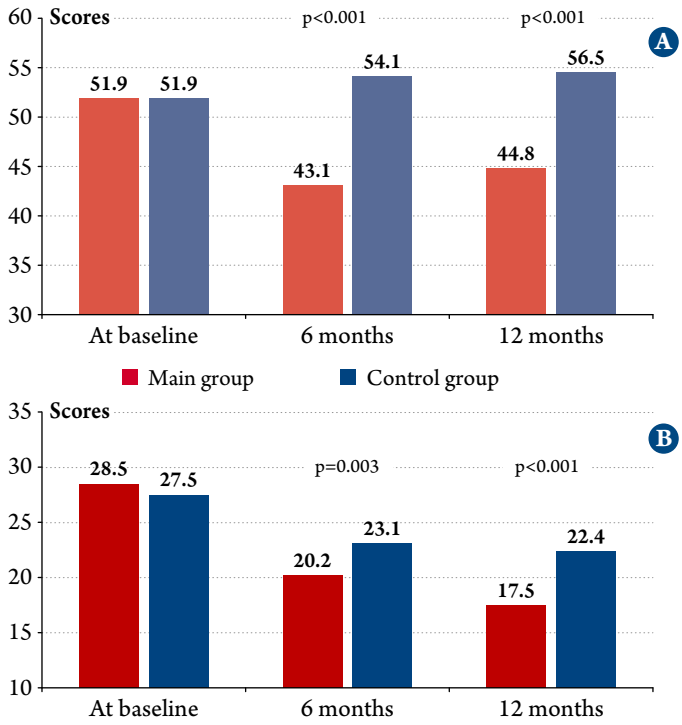


Figure 2. Changes in MLHFQ (A) and EHFScBS-9 (B) values at 6 and 12 months



trol group, respectively; p=0.008). These differences apparently demonstrate better adherence to treatment by patients of the main group.

Table 3 shows the changes in biochemical parameters during 12 months. In both groups, there was a statistically significant decrease in low-density lipoprotein (LDL) cholesterol from 2.71±1.11 to 2.36±1.25 mmol/l (p=0.042) in the main group and from 2.73±0.97 to 2.35±1.03 mmol/l (p=0.023) in the control group. It should be noted that the target LDL values were not achieved in either group. Changes in other lipid panel values, as well as in glucose and hemoglobin, did not reach statistical significance. Noteworthy is the significant decrease in GFR in the control group (from 81.8±20.7 to 73.3±21.5 ml/min; p=0.016), which was an indirect marker of a more severe course of CHF. At the same time, GFR was unchanged in the main group.

Discussion

This article presents preliminary results of a study that compared RPM with standard care for patients with CHF. The patient care model we developed and implemented includes individual training in the hospital and before discharge, followed by personal RPM twice a week, or daily, if necessary. Daily self-monitoring of clinical symptoms by recording them in a self-monitoring diary, regular submission of the data to the supervising physician, and the possibility to predict the development of decompensated HF and rapidly adjust the main treatment for CHF allowed us to reduce the frequency of rehospitalization and to achieve improvements in the quality of life and the ability to self-care in the RPM group. The advantage of our study is the creation of clinical indicators that include the major data of CHF patients for a comprehensive assessment of their current condition with automatic notification of both the physician and the patient, while most studies included an assessment of only body weight or other clinical indicators separately. Thus, L. Bezerra Giordan et al. [13] studied potentialities and effectiveness of using mobile apps by patients

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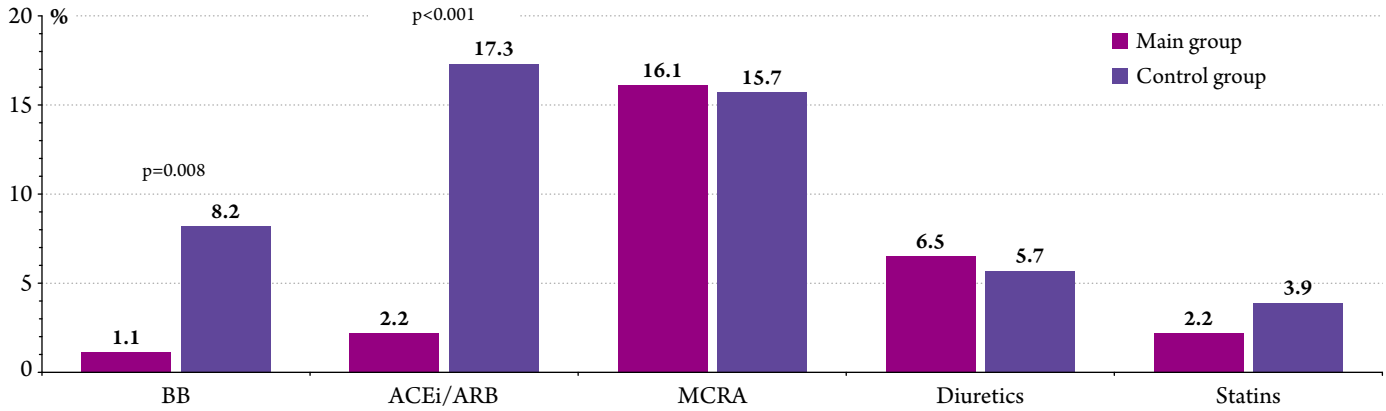
Figure 3. Proportion of patients who discontinued their drug treatment in the main and control groups



BB, beta-blockers; ACEi, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers; MCRAs, mineralocorticoid receptor antagonists.

Table 3. Dynamics of biochemical indexes in both groups

Index	Main group		p12 months	Control group		p12 months
	At baseline	At 12 months		At baseline	At 12 months	
Hemoglobin, g/l	146±18	147±17	0.66	145±20	143±22	0.46
Glucose, mmol/l	6.97±2.97	6.63±2.53	0.36	6.69±2.60	6.82±2.83	0.71
Total cholesterol, mmol/l	4.67±1.35	4.37±1.32	0.32	4.58±1.36	4.22±1.98	0.10
TG, mmol/l	1.96±1.25	1.91±1.14	0.58	1.87±1.40	1.78±1.17	0.59
LDL, mmol/l	2.71±1.11	2.36±1.25	0.042	2.73±0.97	2.35±1.03	0.023
HDL, mmol/l	1.14±0.28	1.200.61	0.23	1.12±0.25	1.10±0.32	0.58
Creatinine, μmol/l	83.5±23.2	85.6±21.5	0.47	85.0±26.1	94.1±25.2	0.009
GFR, ml/min	80.3±17.8	79.5±18.5	0.73	81.8±20.7	73.3±21.5	0.006

TG, triglycerides; LDL, low-density lipoproteins;
HDL, high-density lipoproteins; GFR, glomerular filtration rate.

with CHF based on an analysis of 10 RCTs and reported the most effective apps for RPM. In addition, that study identified the aspects to be focused on in further studies, namely, automated self-monitoring and feedback, personalization, direct collaboration with clinicians, and automatic notifications and reminders. Another study [14], in which body weight values were submitted and monitored three times a week, also did not show a reduction in the frequency of hospitalizations or deaths. RPM studies have reported conflicting results. Thus, a large RCT conducted by F. Koehler et al. [11] demonstrated a reduction in all-cause mortality and duration of hospital stay. However, 3 previous large trials failed to identify any benefits of RPM [15-17]. In a review, P. Ware et al. [18] hypothesized that discrepancies between the results of different RPM studies may also be largely due to the lack of adaptation of the RPM programs to target patients and to the differences in the interventions. The authors of the TIM-HF2 study reported that RPM of CHF patients resulted in a decrease in rehospitalizations and the number of all-cause deaths compared to standard management. However, the RPM model used in TIM-HF2 is difficult to implement in clinical practice, since it requires a telemedicine center with physicians and nurses specialized in HF on a 24/7 basis. In addition, patients submitted their data (body weight, BP, HR, electrocardiography (ECG) data, and peripheral oxygen saturation) to the telemedicine center. Finally, patients regularly received information about HF [17]. That study confirmed that more thorough monitoring is beneficial in terms of rehospitalizations. The Better Effectiveness After Transition (BEAT-HF) study with 1,437 participants used health-related phone calls and monitoring using special equipment that collected information on BP, HR, symptoms, and body weight. That study did not find a decrease in the readmission rate during 6 months of follow-up. However, parameters of quality of life were significantly better in the monitoring group at 6 months. The follow-up period lasted only 6 months [17], while according to a systematic review [19], the RPM benefits were observed in studies with long-term follow-up. The recent HERPMeS study [20] showed that the simulta-

neous use of combined telemonitoring and structured teleintervention in the early posthospital period in CHF patients resulted in statistically significant improvements in self-care and adherence to therapy and a decrease in the frequency of rehospitalization, regardless of LV ejection fraction, age, and comorbidities. The data from the HERPMeS study confirmed the results of our study and justified the inclusion of the mHealth management model in clinical guidelines on the management of patients with CHF. In the national three-year cohort analysis TELESAT-HF, the adaptive RPM program Satelia Cardio including 5357 matched patients reduced all-cause mortality by 36% (odds ratio, OR: 0.64; 95% confidence interval, CI: 0.59-0.70; p<0.0001) and emergency visits by 17% (relative risk, RR: 0.83; 95% CI: 0.75-0.92; p=0.001), while the hospitalization rate for CHF remained unchanged but the total time of hospital stay was shorter by 2.1% (p<0.0001). These results once again emphasize the importance of flexible symptom monitoring and rapid intervention to optimize outpatient management of CHF [21]. However, N. Pierucci et al. [22] noted that scaling RPM is difficult due to the lack of unified validation standards, data on robustness of the programs and their cost-effectiveness. The authors call for the development of unified protocols, conducting multicenter RCTs with cost analysis, and adopting regulatory standards for the widespread implementation of RPM in the management of patients with CHF.

It follows from the large body of publications, that the interest to RPM of CHF patients is growing. The use of RPM programs in general will only expand and can be a useful tool for managing patients at the outpatient stage. The issue of CHF patients' adherence to the use of mobile technologies remains relevant. Since patients spend on average less than 0.001% of their time (about 10 hours annually) at medical institutions, they mainly perform the treatment and monitoring of their condition independently at home. The use of adapted mHealth applications with two-way communication with a doctor and automated reminders provides significant improvements of patients' adherence to therapy, their motivation, and quality of life [23]. A study by M. Ziacchi et al. [24] showed that younger patients with a higher level of education are more likely to accept the technology, despite the fact that they are less diligent in using it, and, thus, represent a group in which adherence to treatment can be significantly improved. Older patients are more motivated to use mobile applications that allow them to maintain contact with their doctor. These data provide compelling evidence for the need for specialized training of both patients and caregivers in the skills needed to effectively use RPM mobile technologies and to raise awareness of the RPM potential benefits. Also, the importance of adherence to the treatment should be emphasized, since poor adherence to drug therapy is one of non-cardiac causes for decompensated CHF [25]. Poor adherence to therapy is observed in 15.3-25% of patients with CHF; in older patients, the proportion of low adherence reaches 50%. A limitation of our study is the lack of the application ability to assess and monitor medication adherence, but this monitoring is conducted indirectly through phone calls and online chat. In addition, technical features, such as mandatory availability of the Internet access and stable cellular communication, may restrict the RPM implementation in distant regions. In addition, the use of a RPM platform based on a mobile app helps titrating doses of major drugs taken by CHF patients to achieve the target doses at the outpatient stage. It is also important to provide data to supervising physicians, which will allow timely identification of patients with early signs of decompensation [26] and give them recommendations remotely, thereby preventing the risk of rehospitalization. All of the above confirms the need for further research in this area. In the future, the introduction of standardized and validated RPM programs to clinical practice based on mobile technologies may become a breakthrough in the modern strategy of patient management, optimization of CHF therapy and more.

Conclusion

Preliminary results of the study show that the use of a mobile application for remote monitoring at the outpatient stage in combination with standard therapy provides effective control and prevention of decompensated chronic heart failure and reduces the frequency of rehospitalization. The study also shows that remote monitoring of the condition of patients with chronic heart failure significantly improves their quality of life and ability for self-care and self-control. A significantly less frequent discontinuation of the treatment with angiotensin-converting enzyme inhibitors/sartans (2.2% vs. 17.3%; p = 0.008) and beta-blockers (1.1% vs. 8.2%; p<0.001) in the main group apparently became a key factor in reducing the number of rehospitalizations.

Conflict of interest is not declared.

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СОСТАВ*. 1 капсула с пролонгированным высвобождением содержит триметазидина дигидрохлорида 80 мг. **ПОКАЗАНИЯ К ПРИМЕНЕНИЮ*.** У взрослых пациентов в качестве дополнительной терапии для симптоматического лечения стабильной стенокардии при неадекватном контроле или непереносимости антиангинальной терапии первой линии. **СПОСОБ ПРИМЕНЕНИЯ И ДОЗЫ*.** Внутрь, по 1 капсуле 1 раз в сутки, утром во время завтрака. Оценка пользы от лечения должна быть проведена после трех месяцев приема препарата. Прием триметазидина следует прекратить, если за это время улучшения не наступило. *Пациенты с нарушением функции почек/пожилые пациенты:* у пациентов с умеренным нарушением функции почек (КК 30-60 мл/мин) рекомендуется снижение дозы наполовину, т.е. 1 таблетка, содержащая 35 мг триметазидина, утром во время завтрака. **ПРОТИВОПОКАЗАНИЯ*.** Гиперчувствительность к действующему веществу или к любым вспомогательным веществам, входящим в состав лекарственного препарата. Болезнь Паркинсона, симптомы паркинсонизма, тремор, синдром «беспокойных ног» и другие связанные с ними двигательные нарушения. Тяжелая почечная недостаточность (КК <30 мл/мин). Период беременности и кормления грудью. **ОСОБЫЕ УКАЗАНИЯ*.** Предуктал® ОД не предназначен для купирования приступов стенокардии и не показан для начального курса терапии нестабильной стенокардии или инфаркта миокарда на догоспитальном этапе или в первые дни госпитализации. В случае развития приступа стенокардии следует вновь оценить степень поражения коронарных артерий и при необходимости пересмотреть лечение. Триметазидин может вызывать или ухудшать симптомы паркинсонизма (тремор, акинезию, повышение тонуса), поэтому следует проводить регулярное наблюдение пациентов, особенно пожилого возраста. Могут отмечаться падения, связанные с неустойчивостью походки или артериальной гипотензией, особенно у пациентов, принимающих антигипертензивные препараты. **ВЗАИМОДЕЙСТВИЕ*. ФЕРТИЛЬНОСТЬ*. БЕРЕМЕННОСТЬ И ЛАКТАЦИЯ*.** Не следует использовать. **УПРАВЛЕНИЕ ТРАНСПОРТНЫМИ СРЕДСТВАМИ, МЕХАНИЗМАМИ*.** Наблюдались случаи головокружения и сонливости, что может повлиять на способность управлять транспортными средствами и работать с механизмами. **ПОБОЧНОЕ ДЕЙСТВИЕ*.** *Часто*: головокружение, головная боль, боль в животе, диарея, диспепсия, тошнота, рвота, кожная сыпь, кожный зуд, крапивница, астения. *Редко*: ощущение сердцебиения, экстрасистолия, тахикардия, артериальная гипотензия, ортостатическая гипотензия, которая может сопровождаться общим недомоганием, головокружением или падением, особенно при одновременном приеме антигипертензивных препаратов, «приливы» крови к коже лица. *Частота неизвестна*: симптомы паркинсонизма (тремор, акинезия, повышение тонуса), неустойчивость походки, синдром «беспокойных ног», другие связанные с ними двигательные нарушения, обычно обратимые после прекращения терапии, нарушения сна (бессонница, сонливость), вертиго, запор, острый генерализованный экзантематозный пустулез, ангионевротический отек, агранулоцитоз, тромбоцитопения, тромбоцитопеническая пурпура, гепатит. **ПЕРЕДОЗИРОВКА*. ФАРМАКОЛОГИЧЕСКИЕ СВОЙСТВА*.** Триметазидин предотвращает снижение внутриклеточной концентрации аденозинтрифосфата (АТФ) путем сохранения энергетического метаболизма клеток в состоянии гипоксии. Антиишемический эффект достигается без сопутствующих гемодинамических эффектов. **ФОРМА ВЫПУСКА*.** По 10 капсул в блистер. По 3 или 6 блистеров в пачку картонную.
**Смотрите полную информацию о препарате в общей характеристике лекарственного препарата.*

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