










‘The Weak Heart’: an educational model for patients hospitalised due to decompensation of heart failure with reduced ejection fraction

„W trosce o słabe serce” – model edukacji chorych hospitalizowanych
z powodu dekompensacji niewydolności serca ze zmniejszoną frakcją wyrzutową

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Abstract

Introduction. KONS (*Kompleksowa opieka nad chorymi z niewydolnością serca*) is the name of a Polish programme for the coordinated care for patients with heart failure that has been proposed as a complex heart failure management solution based on European Society of Cardiology (ESC) Heart Failure recommendations. The challenge is that there are currently no available systemic solutions for educating these patients. Our project aimed to evaluate the effectiveness of a pilot model of education and telemonitoring known as ‘The Weak Heart’ for patients hospitalised due to decompensation of heart failure with reduced ejection fraction (HFrEF).

Materials and methods. ‘The Weak Heart’ educational model consists of three phases: phase I – training and certification of nurses to perform the role of heart failure nurse specialists; phase II – checking the effectiveness of the model in a clinical setting; and phase III – implementation of patient education standards in cardiac centres. Data collected will be used to evaluate the impact of the programme on patients’ understanding regarding heart failure, their compliance with recommendations, and their pro-health behaviours in terms of self-care and self-control.

Conclusion. ‘The Weak Heart’ programme will allow conclusions to be drawn concerning the usefulness and effectiveness of the first targeted heart failure-based patient educational model in Poland. Positive results in this pilot project could become the basis for implementing systemic changes, and introducing the model into everyday clinical practice.

Key words: cardiology, disease management, educational model, heart failure, self-care

Folia Cardiologica 2020; 15, 2: 99–106

Introduction

Heart failure (HF) – which has been described as “the epidemic of the 21st century” – is a major clinical and public health concern, with high rates of mortality and morbidity, and it carries a very large financial burden [1]. It is the third most prevalent cardiovascular disease [2], and one of the main causes of hospitalisation of people aged over 65. It is also a major cause of premature mortality. Currently, 750,000 patients in Poland are affected by HF, and almost 6,000 Poles will die each year from the disease. Moreover, the incidence of HF is set to significantly increase over the next 10 years due to the ageing population, with the result that it will become the most prevalent of all cardiovascular diseases [2–4].

In Poland, the care of patients with HF still requires targeted and somewhat costly measures. Unfortunately, organised outpatient care is currently inadequate, leading to delayed diagnosis and insufficient control and/or therapy [5, 6]. Extended waiting times for a post-hospital visit, as well as the lack of well-functioning cardiac rehabilitation, significantly affect the overall care of patients with HF. Recurring decompensation of HF not only increases the financial costs of healthcare, but also contributes to disease progression, health deterioration, impaired physical and mental condition, and a poorer quality of life [2].

Due to the rapidly increasing prevalence of HF, and the complex care required for such patients, an active disease management system for the coordinated care of patients with HF was drawn up to be implemented in Poland. This was named *Kompleksowa opieka nad chorymi z niewydolnością serca* (KONS). This coordinated care model, funded by the National Health Fund (NFZ, *Narodowy Fundusz Zdrowia*), was designed to effectively prevent, treat, and provide comprehensive care for patients with HF. A detailed description of the assumptions behind the KONS model has been published elsewhere [7, 8].

The need to optimise the care of patients with HF in Poland has become clear in addressing several issues. Firstly, Polish hospitalisation rates of HF patients are one of the highest in Europe at 547/100,000 citizens. This is almost five times higher than in the United Kingdom, and double the rate in the countries of the Organisation for Economic Cooperation and Development (OECD) [9].

Indeed, as many as 83% of all hospital admissions in Poland are associated with acute HF.

Secondly, clinical registries indicate that patients with HF are often re-hospitalised following discharge: one in every four patients is re-hospitalised within three months of discharge. This increases to every second person after six months, reaching almost 70% after 12 months [10]. Moreover, patients with HF in Poland are younger than in other European countries [11]. The Ministry of

Health predicts the number of hospitalisations due to cardiovascular diseases, including HF, will increase by about 26% over the next decade [12].

Thirdly, the treatment of HF places a large economic burden on society. Indeed, according to NFZ data from 2016, the direct costs associated with HF treatment in Poland amount to nearly 900 million PLN. There is also a reduction in potential public revenues due to the high percentage of HF patients [13].

Data to be found in the literature emphasises that multi-specialist teams and multi-profile activities (*i.e.* education and self-control of symptoms) could effectively reduce mortality by 25%, and one in four patients could avoid hospitalisation. Furthermore, a telephone conversation with a trained nurse and simultaneous access to a family doctor could prevent hospitalisation for almost 25% of patients [14].

Along with the involvement of a multidisciplinary team, optimisation of pharmacotherapy, long-term follow-up, psychological support, and cardiac rehabilitation, the KONS programme highlights patient education [7, 8].

Therefore, a pilot educational programme, ‘The Weak Heart’, was designed as an independent project based on the proposed organisational solutions of KONS. The model supports patients with HF through in-patient education about the disease itself and self-control of symptoms, as well as post-hospital phone monitoring. These activities are all performed by an ‘HF nurse’ (as in other European countries, the HF nurse is defined as a specialist responsible for the education and monitoring of the patient’s condition). In Poland, no similar targeted model of supporting HF patients has been implemented previously, with patients still being incidentally educated by various healthcare professionals. The high rate of rehospitalisation indicates insufficient preparation of patients for self-care and self-control. Therefore, proving the effectiveness of the proposed model in clinical practice creates the possibility of standardising HF patient education.

This project aims to test the effectiveness of a new educational and telemonitoring model in clinical practice for patients hospitalised due to decompensation of heart failure with reduced ejection fraction (HFrEF). The aim of this paper is to present the design and methodology of the educational model constituting phase II of ‘The Weak Heart’ project.

Materials and methods

Project design

‘The Weak Heart’ is an educational and telemonitoring model for patients hospitalised due to decompensation of HFrEF. This is a multi-centre, prospective, non-randomised programme to evaluate the impact of the educational model on patients’ knowledge and understanding of the disease, and their compliance with recommendations. Adopting the

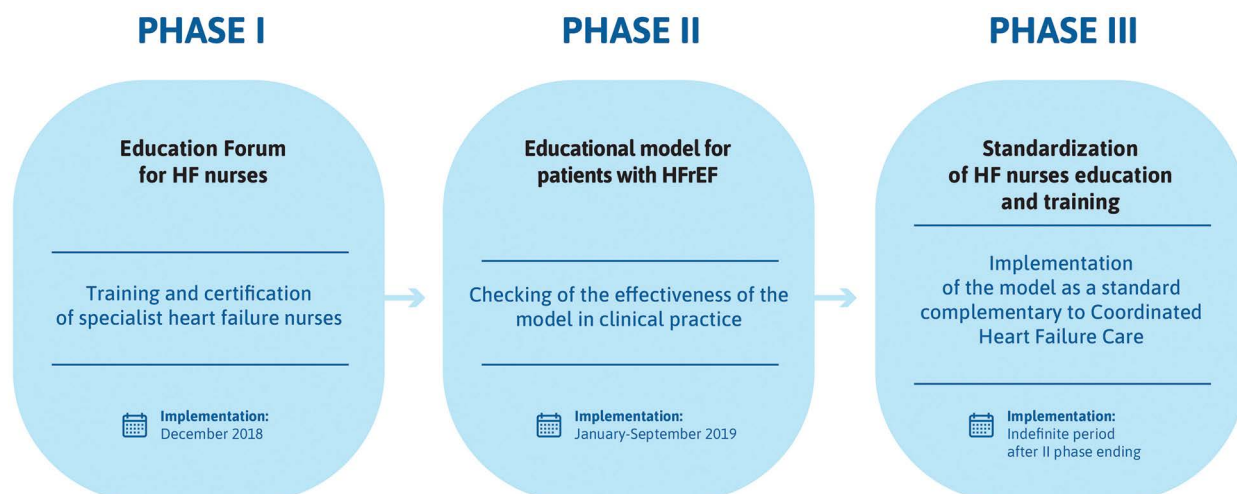


Figure 1. 'The Weak Heart' project phases; HF – heart failure; HFrEF – heart failure with reduced ejection fraction

practice of other European countries, the role of an 'HF nurse' has been created. This person is responsible for educating and monitoring patient conditions. The project consists of three consecutive phases (Figure 1).

Phase I of the project aims to educate HF nurses via the 'Education Forum for HF Nurses', a two-day theoretical and practical course organised by the academic centre and certified by the Polish Cardiac Society (PTK, *Polskie Towarzystwo Kardiologiczne*). The training covers the following topics: epidemiology, HF symptoms, early diagnosis of HF decompensation, control of symptoms at home, principles of post-hospital care, pharmacotherapy, nutrition, liquid and sodium intake, physical activity and principles of physical exercise, communication with the patient, and the principles of patient education based on the internet portal: www.slabeserce.pl [15]. To obtain an HF nurse certificate, it is necessary to pass a test constructed in accordance with current HF guidelines.

Phase II aims to check the effectiveness of the proposed model in clinical practice among patients hospitalised due to decompensation of HFrEF. The model consists of two elements: education and telephone monitoring of the patient's condition.

The education of an HF patient is conducted by the HF nurse via two 60-minute meetings. One during hospitalisation, and the second after stabilisation of his/her clinical condition. The online portal content on a tablet has been prepared by PTK experts in the form of short, easily-understood instructional videos [15]. The patient's knowledge is examined before and after via a questionnaire (comprising 10 questions) prepared for the project based on clinical management guidelines. Questions are put verbally to the patient, and the HF nurse scores responses from 0 to 2 (0 – incorrect response, 1 – partially correct, 2 – correct). The maximum score is thus 20 points. Detailed

information on the scope of the two educational visits is provided in Figure 2.

During the first educational visit, the patient is also equipped with a 'Passport of a Patient with Heart Failure', prepared by Polish Cardiac Society experts, which can be printed on the patient's portal [16]. This passport is essentially a diary of the patient's observations and self-control. The patient is educated on how to monitor symptoms daily, how to record the results of measurements in the passport, and how to recognise the early symptoms of decompensation. In addition, the patient receives a medication dispenser and is educated on how to properly receive the recommended treatment. The patient is also instructed on the role of the GP in the care of patients with HF, and in particular on the necessity of handing to the GP the letter from the cardiologist during the first visit after hospital discharge [17].

During the second educational visit, the patient is trained in the principles of post-discharge care and the necessity of regular post-hospital visits in accordance with the standards. For every patient, an individual outpatient appointment plan is prepared based on recommended visits. This is entered in the appropriate section of the passport.

After discharge, the HF nurse makes three 30-minute monitoring telephone calls (*i.e.* at the end of the first week, the first month, and the third month; Figure 3). During each call, the HF nurse evaluates compliance using a checklist comprising the following elements: patient condition, patient well-being, daily self-monitoring and documenting in the passport, accomplishment of an outpatient appointment with a cardiologist and the GP, compliance with lifestyle and pharmacotherapy recommendations, and monitoring of adverse effects. The HF nurse also reminds the patient about the necessity of visiting the GP and the cardiologist in accordance with the agreed individual

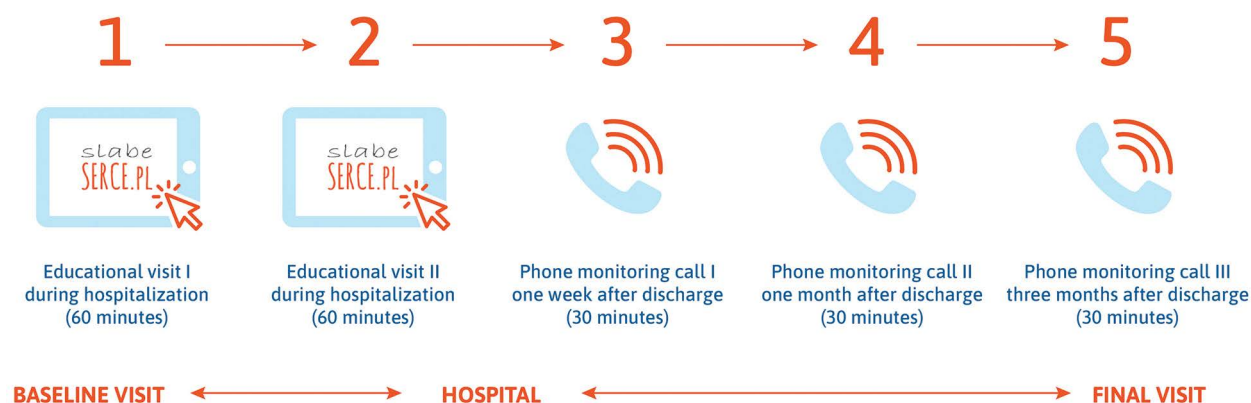


Figure 2. Diagram of patient educational model

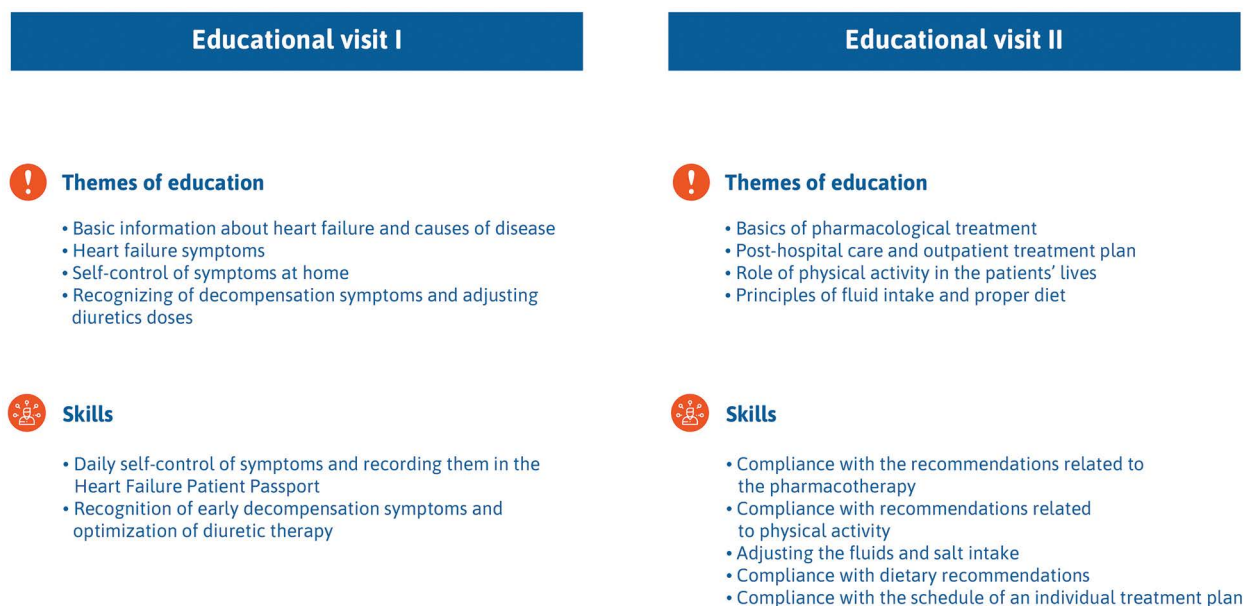


Figure 3. Details of intra-hospital educational visits

outpatient appointment plan, even though these visits are not part of the programme.

The project uses questionnaires and checklists designed specifically for the project in cooperation with Polish HF experts and materials owned by the PTK (e.g. the HF Patient Passport [16]), as well as materials published elsewhere, including:

- Heart Failure Nurses Survey;
- Knowledge Questionnaire about HF for Nurses;
- Knowledge Questionnaire about HF for Patients;
- Checklist, Educational Meeting 1;
- Checklist, Educational Meeting 2;
- Checklist, Monitoring Telephone Calls 1 and 2;

- Checklist, Monitoring Telephone Call 3;
- Letter to the GP [17];
- Heart Failure Patient Passport [16].

Setting

The programme has been performed in cardiac centres specialising in HF and which hospitalise at least 50 HF patients per month, with the main cause of hospitalisation according to the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) codes: I50.0, I50.1, and I50.9. The locations of the sites participating in the project are shown in Figure 4.



Figure 4. Location of sites participating in project

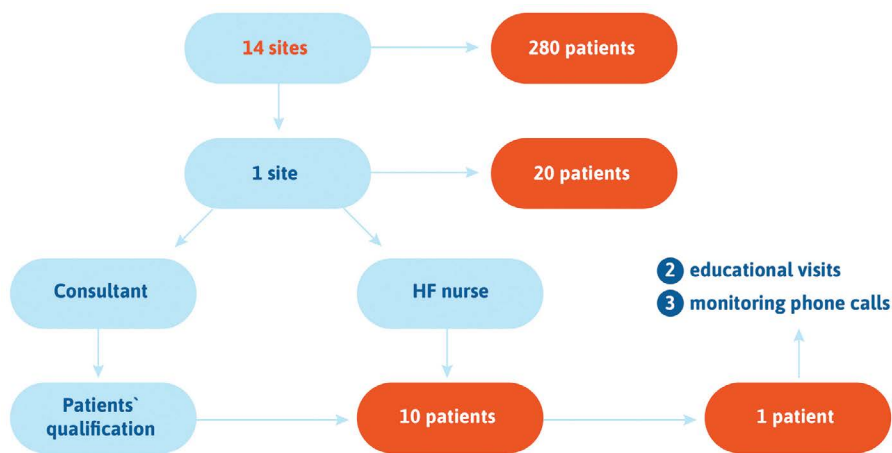


Figure 5. Patient qualification for programme; HF – heart failure

At each site, the programme is conducted by one or two HF nurses and a consultant (physician). The consultant qualifies patients in accordance with criteria for inclusion in the programme, and discusses the purpose and principles of the programme with the patient. After the patient has agreed to participate in the programme, the consultant asks them to sign an informed consent form and to agree to the processing of personal data. In addition, the consultant supports HF nurses with their clinical expertise.

Participants

The programme included consecutive patients hospitalised due to decompensation of HFrEF as the main cause according to the ICD-10 code, who met the following inclusion criteria: diagnosed HFrEF documented by echocardiography (ejection fraction [EF] < 40%), cognitive function enabling participation in the programme (as evaluated by the consultant), patients' involvement in the treatment, and their adherence to medical recommendations (as shown in Figure 5). Prior to inclusion in the programme, patients

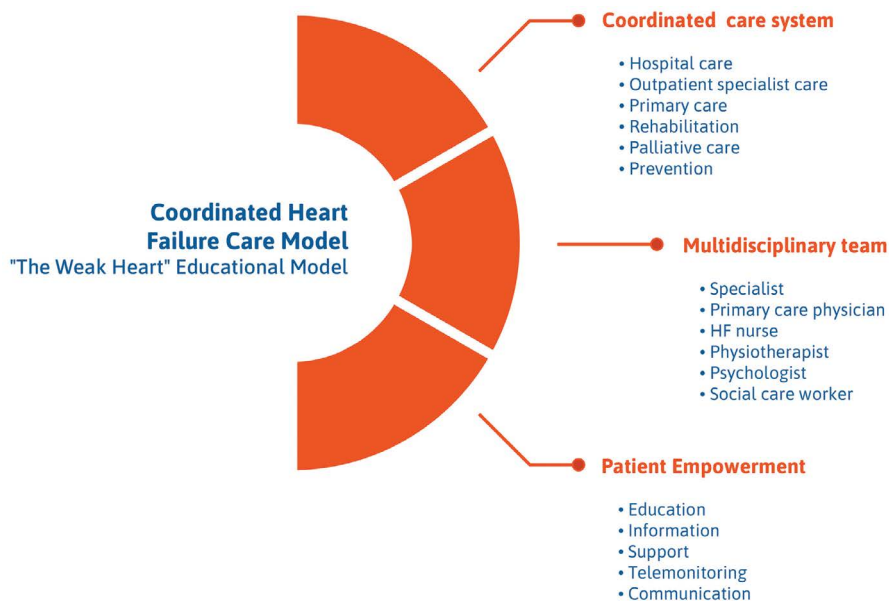


Figure 6. Comprehensive approach to treatment of patients with heart failure with reduced ejection fraction

had to give their consent to participate in the programme and had to agree to their personal data being processed. The programme was conducted between 1 February and 30 September, 2019 in 14 cardiology centres across Poland.

Data collection

Data was collected at five time points: during hospitalisation (*i.e.* after the patient's condition stabilised and they had provided written consent to participate in the project) but prior to educational activities (visit 1, baseline); during hospitalisation, before discharge (visit 2); in the first week after discharge (visit 3); in the first month after discharge (visit 4); and three months after discharge (visit 5).

Patients' knowledge about HF was evaluated by completing an HF knowledge questionnaire at three time points: before the patient's education (visit 1); after finishing education (visit 2); and after three months (visit 5). Patients' skills of self-control, compliance with recommendations in their individual treatment plan, physical activity, diet, and pharmacotherapy were assessed at four time points: during visits 1, 3, 4, and 5.

The data collected by the HF nurse was entered into the electronic database installed on a tablet.

Data analysis and sample size

Data will be analysed to evaluate the effectiveness of the programme based on previously established assessment measures. The primary endpoint of the programme is defined as the change in patient knowledge regarding HF relative to baseline, which will be evaluated based on the change in the average score of the knowledge

questionnaire immediately after education and after three months (*i.e.* the difference between visit 2 and visit 5 relative to visit 1). Secondary endpoints include compliance with recommendations relating to self-control, the individual treatment plan, physical activity, diet, and pharmacotherapy after three months relative to baseline (*i.e.* visits 3, 4, and 5 versus visit 1). A paired t-test will be used to compare the results.

A sample size of 199 patients is required to achieve a statistical significance of < 0.05 . This was calculated on the assumption that a patient has a baseline score of 10 points, and their knowledge improves by 10% (1 point) after three months, with a standard deviation of 5 points and a statistical power of 80%.

Due to the innovative nature of this study, and a lack of prior published results, this sample size calculation assumes a large diversity of results among the patients. Moreover, the loss of contact with some patients over the three-month follow-up has to be accounted for. If the loss to follow-up is estimated at 20%, the number of patients enrolled in the study should be 250.

Ethical aspects and recommendations

The project, classified as a Patient Support Programme (PSP), was approved by the Bioethical Commission at the Medical University of Warsaw No. KB/3/A/2019 on 14 January 2019. The investigation conforms with the principles outlined in the Declaration of Helsinki. The project received the recommendations of the PTK, Heart Failure Section of the Polish Cardiac Society (*Sekcja Niewydolności Serca Polskiego Towarzystwa*

Kardiologicznego), and the Nursing and Medical Technology Section of the Polish Cardiac Society (Sekcja Pielęgniarstwa i Techniki Medycznej Polskiego Towarzystwa Kardiologicznego).

Potential impact

The collected results will confirm the usefulness of the first targeted educational model for HF patients in Poland (summarised in Figure 6). Obtaining positive results in a pilot project would form the basis for implementing systemic changes and subsequent introduction into everyday clinical practice. The use of an effective model of supporting HF patients, including patients' education and monitoring, not only promotes the effective use of healthcare resources, but also delivers desired clinical results and a reduction in the presently alarming number of rehospitalisations.

Conclusions

According to European Society of Cardiology (ESC) guidelines, the goal of HF management is to provide an effective system of care throughout the patient's entire journey, including hospital and ambulatory pathways. Strategies based on patient education and monitoring should be considered to be a fundamental part of multidisciplinary disease management programmes, leading to a reduction in mortality and morbidity, as well as an improvement in quality of life. Currently in Poland, a comprehensive educational model for HF patients does not exist. The introduction of a standardised approach to education and post-discharge monitoring would fill current gaps in the HF management system, while having a positive effect on the prognosis for this group of patients in the longer term.

Acknowledgements

The formatting and preparation for submission of this paper was provided by Proper Medical Writing Sp. z o.o.

The authors would like to thank Joanna Wróblewska, Mariola Storczyk, Beata Tomaszewska, Agnieszka Nowak, Tacjana Struch, Paulina Grabka, Aurelia Stachowiak, Małgorzata Kania, Grażyna Gertig, Agnieszka Rodak, Kamila Daniluk, Agnieszka Kacperska, Krystyna Czapla, Beata Szeliga-Dańko, Beata Lech, Karolina Kopeć, Maria Łyżwa-Pączek, Anna Bajdzińska-Korona, Agnieszka Rutkowska, Dorota Gwóźdź, Karolina Cierpień, Agnieszka Tolarczyk, Aleksandra Tlałka, Marta Wleklík, Agnieszka Maj, Magdalena Lisiak, Iwona Kasprzak, Anna Frankiewicz, Bartosz Topoliński, Radosław Bartkowiak, Aneta Dudek-Górska, Łukasz Jodko, Alicja Nowak, Michał Konwerski, Grzegorz Słonka, Magdalena Frączek-Jucha, Aleksandra Bobel, Andrzej Przybylski, Jarosław Myszor, Michał Tkaczyszyn, and Ewa Kruszyńska for their contribution to the programme.

Conflict of interests

J. Kolasa: employee of Novartis Poland; M. Lelonek, A. Pawlak, and J. Nessler received honoraria and consulting fees from Novartis, and were involved in clinical trials sponsored by Novartis; E.A. Jankowska, I. Uchmanowicz, M. Grabowski received honoraria and consulting fees from Novartis; M. Wleklík, M. Lisiak declare no conflict of interest.

Funding

This work is fully supported by Novartis Pharmaceuticals Poland.

Streszczenie

Wstęp. Zgodnie z zaleceniami Europejskiego Towarzystwa Kardiologicznego (ESC) zaproponowano wdrożenie w Polsce programu skoordynowanej opieki nad pacjentami z niewydolnością serca. Program KONS (Kompleksowa opieka nad chorymi z niewydolnością serca) zakłada kompleksowe podejście do chorego z niewydolnością serca. Obecnie brakuje dostępnych systemowych rozwiązań służących edukacji tych pacjentów. Celem programu „W trosce o słabe serce” jest ocena skuteczności pilotażowego modelu edukacji i monitorowania pacjentów hospitalizowanych z powodu dekomensacji niewydolności serca ze zmniejszoną frakcją wyrzutową (HFrEF).

Materiały i metody. Przedstawiony model edukacyjny składa się z trzech faz: fazy I – szkolenie i certyfikowanie pielęgniarek specjalizujących się w opiece nad chorymi z niewydolnością serca, fazy II – sprawdzenie skuteczności zaproponowanego modelu edukacyjnego w warunkach klinicznych, fazy III – wdrożenie standardów edukacji pacjentów w innych ośrodkach kardiologicznych i internistycznych. Zebrane dane zostaną wykorzystane do oceny wpływu programu na wiedzę pacjentów o niewydolności serca, przestrzeganie przez nich zaleceń oraz ich zachowania prozdrowotne w zakresie samoopieki i samokontroli.

Wnioski. Zakładamy, że program pozwoli na wyciągnięcie wniosków o przydatności i skuteczności pierwszego w Polsce ukierunkowanego modelu edukacji pacjentów z niewydolnością serca. Pozytywne wyniki tego projektu pilotażowego mogą się stać podstawą do wprowadzenia zmian systemowych i wykorzystania modelu w codziennej praktyce klinicznej.

Słowa kluczowe: kardiologia, zarządzanie chorobą, model edukacyjny, niewydolność serca, samoopieka

Folia Cardiologica 2020; 15, 2: 99–106

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