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"Prof. Dr. P. Stoyanov" - Varna.

FACULTY OF PUBLIC HEALTH
DEPARTMENT OF HEALTH CARE

Maria Mladenova Georgieva

HEALTH AND PSYCHOLOGICAL SUPPORT FOR PATIENTS WITH HEART FAILURE

ABSTRACT

of a dissertation for obtaining the educational and scientific degree of "Doctor"

Specialty
Healthcare Management

Academic Supervisor
Prof. Silvia Borisova, PhD, DSc
Academic Consultant:
Prof. Dr. Yoto Yotov, M.D.

Official Reviewers:
Prof. Diana Ivanova, M.D.
Assoc. Prof. Nevyana Feschieva, M.D.

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The dissertation consists of 172 pages and is structured into five chapters. It includes 36 figures, 10 tables, 2 schemes, and 7 appendices.

The bibliography contains 208 sources, out of which 31 are in Cyrillic and 177 in Latin script.

The dissertation has been discussed and recommended for defense by an extended departmental council at the Department of Health Care, Medical University "Prof. Dr. P. Stoyanov", Varna, on January 13, 2023.

The public defense of the dissertation will be held on 20.04.2023 in the virtual hall of the online platform Webex at the Medical University - Varna, at an open session of the Scientific Jury. The defense materials are available at the Doctoral School department of MU-Varna and have been published on the website of MU-Varna.

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USED ABBREVIATIONS:

SBP systolic blood pressure
DBP diastolic blood pressure
ECG electrocardiography
LV left ventricle
LA left atrium
MU Medical University
AHF acute heart failure
MAP mean arterial pressure
HF heart failure
CVD cardiovascular disease
HFpEF heart failure with preserved ejection fraction
HFrEF heart failure with reduced ejection fraction
HR heart rate
BW body weight
UMHAT University Hospital for Active Treatment
EF ejection fraction
CHF chronic heart failure
FPH Faculty of Public Health
ACC American College of Cardiology
ACE Angiotensin-Converting Enzyme inhibitors (inhibitors of the renin-angiotensin-aldosterone system)
AHA American Heart Association
QOL Quality of Life
KCCQ Kansas City Cardiomyopathy Questionnaire
NYHA New York Heart Association

I. INTRODUCTION:

The diseases of "modern life" are the main cause of morbidity and mortality in developed countries. The transition from infectious diseases to the dominance of non-infectious diseases as the leading cause of premature death occurred after the end of World War II. Antibiotics and vaccines, along with improved living conditions, hygiene, food, access to clean water, led to a decrease in mortality from infectious diseases and an increase in life expectancy. All of these factors also lead to higher survival rates and an increasing number of people who live to an age when the frequency of malignant diseases and cardiovascular diseases increases. However, changes in lifestyle lead to an increase in the influence of risk factors for socially significant diseases, such as smoking, lack of physical activity, a diet rich in unhealthy fats and carbohydrates, and a tendency towards risky occupations, which also changes the frequency of diseases and mortality associated with them.

Cardiovascular diseases are socially significant diseases and the leading cause of morbidity and mortality on a global scale, with the problem being particularly relevant to our country. Heart failure is the final stage of the development of a preceding cardiovascular disease characterized by high levels of mortality, disability, and morbidity among the population, with an unfavorable trend.

Heart failure affects a large portion of people in their active age, has a high share in the structure of causes of death in the population, in treatment and rehabilitation costs, and requires the intervention of highly qualified and specialized medical care. Among patients with heart failure, accompanying diseases (anemia, iron deficiency, diabetes, renal failure, chronic obstructive pulmonary disease) are observed, which complicate therapeutic management and lead to an adverse prognosis.

One of the ways to cope with the severe and progressive course of the disease is the observation and monitoring of the condition of patients with heart failure. This provides an opportunity to optimize disease management, positively influence prognosis, and reduce hospital readmissions. Factors that exacerbate the disease can be controlled and optimized. Early detection, cardiovascular disease prevention, and support for patients and their families would improve their survival and quality of life.

In many European countries, heart failure clinics have been developed and various models of specialized nursing care are being implemented. The main trend in modern treatment is the collaborative care model combined with patient screening, which can be quickly and easily carried out by a nurse who coordinates the treatment of these disorders. Collaborative care is an effective model that allows for monitoring and control of patients' conditions, more frequent meetings with them, which increases the possibility of identifying the problem on time.

In Bulgaria, the issue of nurses' participation in the prevention and treatment of cardiovascular diseases has not been studied and examined in the aspect of scientific research. The role of the nurse in outpatient control and monitoring of heart failure has not been investigated so far, and there are no separate structures for providing cardiological nursing care in practice.

The relevance of the dissertation topic is determined by the possibility of the nurse, independently or in a multidisciplinary team, to monitor, observe, and educate patients with heart failure, as well as to carry out activities related to secondary and tertiary prevention of cardiovascular diseases. The search and creation of organizational models for cardiological nursing care is an innovative approach for the clinical and theoretical development of healthcare professionals with the possibility of specialization and certification.

II. OBJECTIVE, TASKS, MATERIALS AND METHODOLOGY OF THE STUDY

2.1. Objective, tasks and working hypotheses

Objective: To improve the well-being and quality of life of patients with heart failure through the application of an outpatient nursing care model.

The following **tasks** have been set to achieve the main objective:

1. To study the epidemiology of heart failure in Bulgaria and Europe.
2. To study international experience in providing nursing care in the management of heart failure.
3. To identify the factors favoring the progression of heart failure - adherence to the therapeutic plan, control of body weight, control of blood pressure, dietary and exercise regimen, etc.
4. To determine the biological and psycho-social determinants of quality of life in patients with heart failure, through validated questionnaires and scales for determining complex care and improving indicators.

5. To monitor the functional capacity of patients with heart failure by applying a 6-minute walk test, functional class according to NYHA, improving functional capacity, and getting accustomed to a specific physical activity.
6. To objectify the health status of patients through laboratory studies of the NTproBNP biomarker.
7. To assess the psychological state and tendency towards depression and anxiety of patients through psychological support in the short and long term.
8. To analyze the results of the applied complex care for patients with heart failure, by evaluating rehospitalization rates.
9. To develop a model for applying outpatient nursing care in priority areas of activity for patients with heart failure.

Working hypotheses

Based on the reviewed literature and the aim of the dissertation study, the following working hypotheses were formulated:

1. Ambulatory care nursing will contribute to the preservation, improvement, and restoration of health, achieving an increase in the well-being and satisfaction of patients with heart failure.
2. The participation of a nurse in comprehensive care for patients with heart failure does not affect the improvement of functional capacity and the number of readmissions.
3. The assessment of the condition, the implementation of therapeutic and nursing interventions lead to a favorable impact on the symptoms of heart failure and a decrease in serum levels of NTproBNP.

We developed the hypotheses, taking into account the need to optimize cardiological care with active participation of the nurse in the outpatient control of patients with heart failure.

2.2. Material and methodology

2.2.1. Object of the study

The subject of this study is the health well-being of patients with heart failure.

Depending on the subject of the research activity, the dissertation includes two main components of scientific research - prospective and empirical research.

2.2.2. Research objects

- Medical documents objectifying the condition of patients with heart failure;
- Literature/online sources on good practices, organization of nursing activities and care for patients with heart failure;
- Patients with heart failure, hospitalized in a cardiology clinic and after discharge.

2.2.3. Clinical contingent

The current study includes a total of 72 patients with II-IV functional class heart failure according to NYHA, who have been treated at the Second Cardiology Clinic, Department of Non-Invasive Cardiology at University Hospital "St. Marina" - Varna.

Inclusion criteria:

- Patients with heart failure, regardless of etiology and ejection fraction;
- Age over 18;
- Ability to perform a 6-minute walking test;
- Able to complete quality of life questionnaires;
- Able to complete a questionnaire on psychological status;
- Voluntarily expressed willingness to be followed up;
- Provided informed consent to participate in the study.

Exclusion criteria:

- Patients with severe comorbidities (advanced malignancies with expected survival of less than 1 year);
- Patients with mental disorders;
- Patients with impaired physical activity;
- Age under 18;
- Distant residence, which would make regular participation in follow-up visits difficult.

2.2.4. Study design

The study of quality and duration of life, functional and psychological status of patients with heart failure, including rehospitalizations, was conducted through a prospective and empirical study.

I. Prospective study

Each patient was followed up for a period of 6 months, from February 2020 to September 2022.

Observation groups

All participants are conditionally divided into two subgroups depending on the person leading the observation.

Group A - the main organizer of the observation is a nurse (M.G.), who selects the patients, contacts them and their relatives, and provides written informed consent. After examination and consultation with a specialist physician, she takes demographic characteristics, performs basic anthropometric and hemodynamic measurements, and determines the functional class with the help of a physician. After taking blood for laboratory tests and an electrocardiogram (ECG), M.G. conducts a 6MWT, assists the patient in completing questionnaires on quality of life, depression and anxiety. She trains the patients and their relatives. The nurse schedules follow-up visits and contacts other specialists after consulting with a cardiologist if necessary. She monitors the treatment and its results with the help of the cardiologist. She records readmissions and deaths. At the end of the follow-up, she analyzes the results of the follow-up with the patient and his/her relatives with the help of a specialist physician.

Group B - the main factor in the selection, inclusion and follow-up of patients with heart failure is a cardiologist. He performs clinical examinations, electrocardiography and echocardiography on all participants. The physician schedules consultations with other specialists if necessary. The role of the nurse is supportive in the observation team - she assists in the clinical examination, 6MWT, completion of questionnaires on quality of life, depression and anxiety. She takes blood for laboratory tests, records the ECG, and measures the patients' anthropometric and hemodynamic measurements.

The study includes an analysis of demographic, clinical, biochemical, electrocardiographic and echocardiographic indicators.

1. ***Prospective study of patients with HF for morbidity and mortality for a period of 6 months.***

The patients are followed up in terms of the occurrence and period of occurrence of adverse cardiovascular events: readmission for decompensated chronic heart failure, hospitalization for cardiovascular disease or other hospitalization, as well as overall mortality within a 6-month follow-up period.

2. ***A prospective study among patients hospitalized with heart failure regarding physical, mental state, and quality of life.***

During the observation period, data on the physical, psychological state,

and quality of life of patients with heart failure were prospectively collected. The data were analyzed and compared between the information at the patient's discharge from the cardiology clinic and at the end of the 6-month observation period.

For the purposes of analyzing the content of the collected information, a framework was developed, including: demographic data; physical examination; physical indicators - blood pressure, heart rate, and body weight; biological and psychosocial determinants of quality of life; self-assessment of health.

The information was collected through a physical examination at the Department of Non-Invasive Cardiology at the Second Cardiology Clinic of UMBAL "Sveta Marina" - Varna, medical documentation, and questionnaires.

The study identified factors favoring the progression of heart failure - body weight control, blood pressure control, dietary and exercise regimen, etc. The following tools were used to achieve the objectives and tasks of the study: Card for monitoring patients with heart failure; Patient's passport; standard questionnaires for quality of life - Heart Failure Questionnaire (Kansas City Cardiac Questionnaire); Generalized Anxiety Disorder Questionnaire (GAD7); Patient Health Questionnaire - 9 (PHQ-9); EQ-5D Health Questionnaire; Visual Analog Scale (VAS).

Data collection was conducted by the researcher from February 2020 to September 2022. At the beginning of each meeting, the purpose was explained, and anonymity of the participants was guaranteed. Nursing records were prepared for each patient, which contain medical documentation related to past acute or chronic illnesses, patient discharge summaries, laboratory and instrumental results; patient monitoring chart reflecting all possible indicators for worsening of heart failure; questionnaires for assessing quality of life and level of depression and anxiety.

Assessing the patient's condition, identifying relevant health problems, enables identification of the patient's problems and planning of outpatient nursing care.

3. Prospective study including laboratory testing of creatinine, sodium, potassium, chloride for patient safety and NT-proBNP for objective assessment of improved health status

Electrolyte levels in the blood are tested to monitor the effectiveness of heart failure treatment as well as compliance with dietary and lifestyle

recommendations. Laboratory tests are used to assess the need for correction of comprehensive care in patients with heart failure.

NT-proBNP levels are investigated to detect changes in cardiac function in patients with heart failure. Analysis of serum levels of NT-proBNP will provide an assessment of the impact of symptoms from therapeutic and nursing interventions (diuretic dose adjustment, adequate medication dose, control of motor and dietary regimen, allowed fluid intake, etc.).

The laboratory test results analysis will allow for an assessment of the patient's condition, validation and development of guidelines for activities to optimize processes in cardiac care, aimed at achieving optimal opportunities for good quality of life and life expectancy, and for the safety of treatment.

4. Prospective study, including instrumental investigations - electrocardiography and echocardiographic evaluation, to determine cardiac function

Electrocardiography and echocardiography are applied as methods for evaluating the effectiveness of the applied cardiology nursing care. Retrospective tracking of the results of instrumental investigations allows for timely indication of markers for deterioration of the patient's condition and the possibility of organizing adequate intervention.

II. Empirical Study.

Observation of the condition of patients with heart failure during ambulatory nursing care.

During the period of 2020-2022, observation was conducted on data regarding the physical and psychological state of patients with heart failure. The data was analyzed and compared between information on the condition of patients who received ambulatory care from a nurse and patients who received ambulatory care from a team consisting of a doctor and a nurse.

For the purpose of systematic analysis of the collected information, a framework was developed, including physical indicators such as blood pressure, heart rate, and body weight; laboratory and instrumental tests; determinants of quality of life; assessment of anxiety and depression.

Data collection was formed through the analysis of results from conducted studies and a conversation held in a specialized cardiology care center, Non-invasive Cardiology Department. Conditions were created for

maximum freedom and spontaneous sharing of problems, concerns, opinions, and personal impressions by patients.

The study identifies the impact of ambulatory nursing care on the implementation of the therapeutic plan. The results of the observation are recorded in the Card for Observation of Patients with Heart Failure. The card was developed by an international team under the guidance of Professor Martin Cowie, UK, as part of the Heart Failure Optimization Program, of which the Cardiocare HF program is a part. The card is used in multiple countries on three continents, which creates standardization in the care of patients on a global scale.

For the purposes of the study, a ***Checklist for controlling heart failure*** has been developed.

2.2.5. Organization of the study

The study was conducted after approval by the Ethics Committee for Scientific Research at the Medical University of Varna, Decision No. 90 of January 30, 2020.

In order to achieve greater accuracy, the main part of the study was carried out by the doctoral student in the cardiology clinic, during each patient examination, using the same instrumentation and under the same conditions. Cooperation with doctors from the University Hospital "Sveta Marina" - Varna was used. The selected staff were previously familiarized with the purpose and methodology of the study.

The period for monitoring the condition of each patient is 6 months within 6 consecutive examinations. The sequence stages are presented in Figure 1.

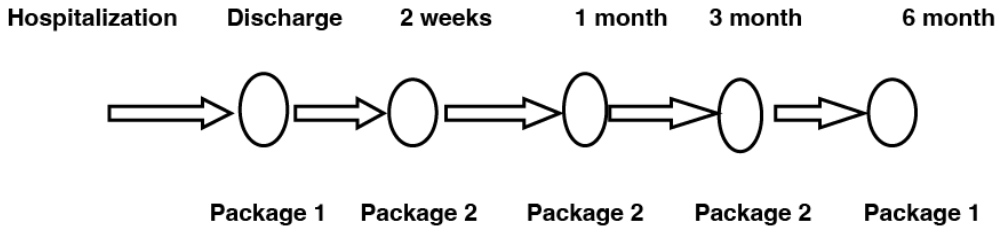


Figure 1. Stages of monitoring the patient's condition

The beginning of the follow-up starts upon the discharge of the patients from the Cardiology Clinic. Ambulatory nursing care is provided in two main packages of activities:

Package 1. Activities performed at the beginning and end of the follow-up

- Assessment of basic indicators (blood pressure, heart rate, and body weight);
- Determination of functional class according to NYHA;
- Assessment of echocardiographic indicators (electrocardiography and echocardiography);
- Evaluation of laboratory tests (creatinine, sodium, potassium, chloride, and NT-proBNP);
- Conducting a 6-minute walking test (in case of impossibility, a 4-meter walking test);
- Evaluation of quality of life by filling out standard questionnaires - Heart Failure Questionnaire (Kansas City), Generalized Anxiety Disorder Questionnaire (GAD7), Patient Health Questionnaire-9 (PHQ-9), EQ-5D questionnaire for assessing health status, Visual Analog Scale (VAS).
- Training of patients and their relatives on treatment and care guidelines (proper diet, fluid intake and quantity, physical activity, medication intake, monitoring body weight and blood pressure);
- Providing educational materials - information booklet on heart failure and a passport for follow-up.

Package 2. Activities performed in the second week, first and third months from the beginning of the monitoring:

- Evaluation of key indicators - blood pressure, heart rate, and body weight;
- Analysis of the patient's condition;
- Identification of existing or potential health problems;
- Patient and family education on treatment and care guidelines (proper dietary intake, fluid intake (quantity), physical activity, medication adherence, monitoring of body weight and blood pressure).

2.3. Research Methods:

2.3.1. Documentary method - to clarify the patient's condition regarding previous hospitalizations, consultations, and examinations (medical documentation).

2.3.2. Questionnaire method - an interview with patients including detailed data collection and evaluation of their condition. The social status, dietary habits, duration of heart failure, medication therapy, and information about a family history of chronic diseases were examined. Assessment of compliance with lifestyle changes recommendations was conducted.

2.3.2. Clinical examination - during each visit, a physical examination is performed to determine the objective condition of the patients, with particular attention paid to blood pressure, heart rate, and body weight. Previous and accompanying illnesses have been identified, medication intake, and plans for examination and treatment have been determined.

2.3.4. Electrocardiography

ECG was obtained from all subjects in a lying position. The ECG is recorded at a paper speed of 25 mm/s. A standard 12-lead ECG is performed on each patient at every visit to the office. It is performed after the patient has been at rest for at least 15 minutes in a seated position and before performing the 6MWT. Documentation is kept in the patient's file.

2.3.5. Echocardiographic assessment

All patients with heart failure underwent an echocardiographic examination to assess diastolic and systolic heart function. The echocardiographic examination was performed by a cardiologist using an Agilent 5500 (Phillips, ND) echocardiogram machine. The patient is in a lying, left semi-lateral position, with the left arm bent under the head and the right arm next to the body. A standard echocardiographic examination is performed. The dimensions of the LV and LA are measured, and the systolic and diastolic function, valvular lesions, and others are evaluated. The global pump function of the left ventricle is determined by the EF using the Simpson method (135a). The main indicator used to monitor patients is the change in ejection fraction.

2.3.6. Laboratory methods

All biochemical studies include ***creatinine, sodium, potassium, and chloride*** levels. The studies are conducted during the first visit to the office, which coincides with the patient's discharge from the department, at the first month of follow-up, and finally at the 6th month upon completion of the observation. The examination is taken with maximum sparing of the patient, venous blood, after atraumatic venipuncture of the cubital vein. All laboratory

methods are conducted in the Clinical Laboratory of University Hospital "Sveta Marina" Varna, on an automatic biochemical analyzer Olympus-400 (Beckman Coulter Inc., Brea, CA, USA).

In case of changes in creatinine, sodium, or potassium levels, steps are taken to adjust the medication therapy after consultation with a cardiologist.

Outpatient monitoring of the NT-proBNP indicator is performed at the beginning of patient follow-up for heart failure and at the 6-month mark. Comparing the two values provides information on the possible progression or improvement of the disease, as well as the effect of the applied medication therapy and changes in lifestyle. The biomarker test is performed in two ways: in the Clinical Laboratory of University Hospital "Sveta Marina" - Varna or using the COBAS 125 machine in the Department of Non-invasive Cardiology. To ensure repeatability and comparability, the NT-proBNP test for each patient is conducted using only one of the two methods.

2.3.7. Method for assessing functional capacity through a 6-minute walking test (6MWT)

A standard protocol is used to conduct the test:

A flat area with a length of 30 meters is provided for the six-minute walking test. The corridor is marked along its length every 3 meters. A marked starting line and endpoint at the 30-meter mark are available. Equipment with a timer, two small cones for marking the beginning and end of the corridor, as well as an instrument for measuring arterial pressure and the ability to perform emergency resuscitation procedures if necessary are provided.

Patient preparation is provided through comfortable clothing, appropriate footwear, and the use of their usual walking aids (crutches, etc.).

The patient's medication therapy is not interrupted. Patients do not engage in heavy physical exertion up to 2 hours before the start of the test and do not smoke cigarettes. The test can be repeated the following day under the same conditions.

Before the test, a 10-minute rest is provided. During the test, the patient is not verbally stimulated. However, at certain intervals, they can be informed of the remaining time until the end. After the test, the total distance traveled, rounded to 1 meter, is calculated and documented in written form in a form. The 6MWT is influenced by the patient's gender, age, weight, height, the presence of accompanying diseases, the need for O2 therapy, and the patient's motivation.

There are contraindications for conducting the test:

1. *Absolute contraindications* - unstable angina pectoris or myocardial infarction in the last month.
2. *Relative contraindications* - resting heart rate >120 bpm; blood pressure above 180/100 mm Hg.

In the present study, a 6-minute walking test is conducted at discharge from the hospital (enrollment in the program) and at the 6th month (end of follow-up).

The comparison between the two distances traveled has predictive value regarding the prognosis, the effect of therapy, and patient care within the 6-month observation period.

2.3.8. Evaluation of quality of life, anxiety, and depression

All studies are conducted by a nurse at each patient visit using the same instruments and under the same conditions.

- **Questionnaires for quality of life: KCCQ, EQ-5, Visual Scale**

Heart failure is a chronic condition without a real "cure" that has a huge impact on the quality and way of life of patients. Various questionnaires are used to assess the quality of life indicator. In the present observational project, 2 questionnaires and 1 self-assessment scale are used. The questionnaires are filled out by the patients themselves or with the help of relatives or the researcher at the start of the observation and at the 6th month.

The Kansas City questionnaire for heart failure is a disease-specific self-assessment questionnaire for quality of life consisting of 23 questions. It evaluates various aspects of the disease in 7 different domains, including physical activity, symptoms (frequency, severity, change over the past 2 weeks), social function, self-awareness, self-care, and quality of life.

To each question, there are a different number of answers provided, most commonly between 4 and 7, and only one correct answer can be chosen.

The completion takes approximately 5-15 minutes. The patient is offered a translated version of the questionnaire in Bulgarian by its creators.

The result is calculated by adding up the points on a special computer calculator, which presents the self-assessment as a number.

Written permission and consent for its use for the purposes of the study CV Outcomes, Inc., USA has been obtained.

Various scales are calculated - clinical, total, and self-assessment, each of which evaluates from 0 to 100 points. Depending on the result, the patient's condition is classified as: 0 to 24: very poor to poor; 25 to 49: poor to fair; 50 to 74: fair to good; and 75 to 100: good to excellent. An increase of more than 5

points is considered clinically significant improvement, and over 10 points - statistically significant. Conversely, a significant worsening of quality of life occurs when the score drops by at least 5 points (Spertus J. et al., 2005).

Health status questionnaire - EQ-5D. A non-disease-specific questionnaire consisting of 5 questions. They concern mobility, self-care, usual activities, pain or discomfort, and depressive thoughts. Each question provides three possible answers, with only one correct answer specified by the patient. A computer-based calculator is used to evaluate the generalized score of the patient's condition. The highest score is 1, and each change in condition receives a value less than 1.

Visual Analog Scale (VAS) for self-assessment of the current health status on the day of the examination. The patient indicates on a graph, marked as a measuring line from 0 to 100 with an arrow, how they feel at that moment. This way, the current state is evaluated at the beginning of the study and compared to that at 6 months, thus assessing any change in the patient's self-assessment for 6 months.

Assessment of depressive moods and anxiety.

A Patient Health Questionnaire-9 (PHQ-9) is attached. It contains 9 questions, and the answers are rated on a scale of 0 to 3. The maximum score is 27 points. The severity of depressive moods is graded as follows: 0-4 minimal, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe. A score of ≥9 points is considered to have 95% sensitivity and 84% specificity for detecting serious depression. Specifically for cardiovascular disease, a PHQ-9 score of >10 points has shown 70% sensitivity and 92% specificity for diagnosing depression.

The American Cardiology Association recommends using the PHQ-9 to screen patients with cardiovascular disease and HF for serious depressive states.

The Generalized Anxiety Disorder-7 (GAD-7) questionnaire seeks to assess the presence of anxiety moods in individuals through 7 questions.

The assessment is scored on a scale of 0 to 21, with scores of 0-4 indicating minimal anxiety and tension, 5-9 indicating mild anxiety, 10-14 indicating moderate anxiety, and scores in the range of 15-21 indicating severe anxiety disorder. A test result of ≥8 points has a sensitivity of 92% and specificity of 76% for detecting anxiety disorders, and ≥10 points has a sensitivity and specificity of over 80%, namely 89% and 82%, respectively (Spitzer RL, 2006).

2.4. Methods of medical-statistical data processing

The following analysis methods have been used:

- **Method of statistical grouping of data** - the characteristics are arranged according to their type in variational, interval, categorical, ordinal, and dynamic statistical series.
- **Method of statistical estimation**

A. Point estimates - to calculate the mean value of continuous characteristics, the formula $X = [\Sigma X] / n$ has been used.

B. Interval estimates

Significance probability (significance level) - p

For coefficients p = 0.95 (95%), the type I error is 0.05 (5%).

Confidence intervals (CI)

They are interpreted as the probability that the specified interval contains the real point estimate of the population. We have used 95% confidence intervals.

- **Graphic method** - linear and planar graphic images, circular and pie charts, volume charts, and symbolic diagrams are used.
- **Variational analysis** - when comparing continuous and interval indicators, grouped analyses were compared with analyses of independent subgroups - ANOVA test, Student's t-test, and in the case of non-normal distribution, non-parametric Mann-Whitney analysis was used. When comparing changes in indicators in the same patient at the beginning and end of the observation, they are compared using paired t-test or one-sample t-test. Differences in indicator parameters before and after completing the program were compared.
- **Non-parametric analysis** - for the analysis of categorical features, they are presented as absolute numbers and percentages. The Pearson $\chi 2$ (chi-square) criterion or Kendall's τ-analysis is used when dealing with ordinal categorical features. When the expected number in a given cell is less than 5, the exact Fisher's method is used instead of the chi-squared method. When there are more than two categories, the Cramer V test is used. Pairwise analysis is performed using the Wilcoxon method and sign analysis. Correlation analysis using the Pearson and Spearman (non-parametric) methods.
- **The correlation coefficient** calculated by both methods takes values between -1 and 1, with the sign depending on the direction of association, and values above 0.7 are considered strong correlation.

- **Linear regression analysis** - the method of multiple linear regression analysis was used to evaluate the independent predictive value of continuous variables, calculated by the formula: $y = \beta 0 + \sum \beta i xi$. Where:

  $\beta 0$ - constant, called the initial (intercept)

  βi - calculated regression coefficients of the variables

  xi - values of the n features included in the equation

Methods for assessing agreement used Cohen's κ (kappa) criteria. Values of kappa close to 1 indicate perfect agreement between the two methods, while values close to 0 indicate that the two methods diverge. Values of $\kappa = 0.61\text{-}0.80$ indicate good agreement between the different methods of investigation.

All data in the development are processed using a specialized standard statistical package for personal computer - **SPSS® for Windows, version 24.**

III. Results and Discussion

3.1. Comparative analysis by gender, age, arterial pressure, heart rate, 6MWT, laboratory indicators, and ejection fraction

Distribution of the subjects by gender and age

The study included a total of 72 patients with heart failure who underwent treatment at the Department of Non-Invasive Cardiology at the Second Clinic of Cardiology at UMBAL "Sveta Marina" Varna. Of these, 65.3% (n=47) were men and 34.7% (n=25) were women (Fig. 1).

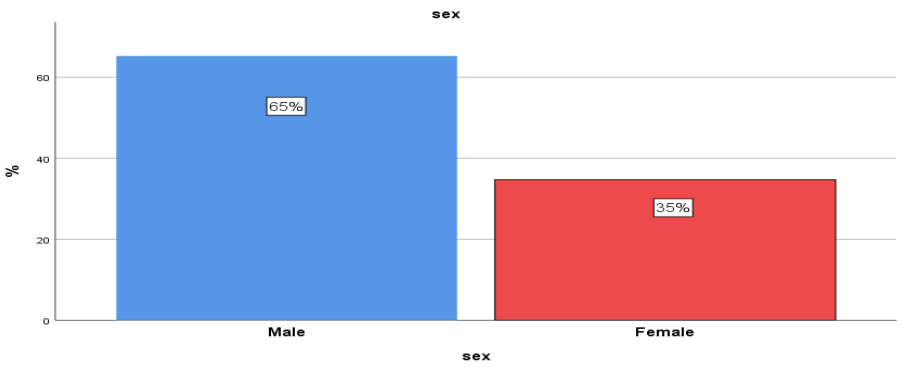


Figure 1. Distribution of patients by gender

In more than a quarter of the patients (29.17%), outpatient cardiology care was led by a nurse *(Group A)*, while in the remaining patients, 70.8% was led by a cardiologist and a nurse *(Group B)*. Both groups met the inclusion

criteria, and the same nursing care algorithm was applied. Women predominated more in Group A (43%) than in Group B (31%), p=0.25 (Fisher's test).

The average age of patients included in the program for monitoring heart failure patients was 66.85±11.06 years, 95% CI 64.25-69.45 years, median 69 years, range from 39-89 years. Women were significantly older than men (Table 1). The mean age difference was 7.34 years, 95%CI 2.45-12.24, p=0.004 (t-test) 29±.

Table 1. Source variables by gender

Indicator	Total	Men	Women	p
Number	72	47	25	-
Age (years)	66,85±11,06	64,30±11,26	71,64±9,07	0,004
Body weight (kg)	83,38±18,31	87,02±16,65	76,52±19,64	0,028
Systolic BP (mm Hg)	119,03±12,74	118,09±11,77	120,80±14,48	0,425
Diastolic BP (mm Hg)	71,10±8,66	71,04±8,61	71,20±8,93	0,943
HR (beats/min)	74,17±14,55	74,06±14,30	74,36±15,32	0,937
FEV (%)	42,78±14,23	39,45±14,24	49,04±12,14	0,004
NT-proBNP (ng/mL)	5325,75±3858,82	5568,52±3130,52	3984,28±2859,18	0,035
6MWT (m)	253,56±107,91	276,09±118,89	211,20±67,04	0,004
Creatinine (μmol/L)	105,73±55,30	114,83±63,89	89,00±28,63	0,022
Na+ (mmol/l)	139,45±7,10	139,57±8,24	139,24±4,43	0,325
K+ (mmol/l)	3,89±0,46	3,84±0,44	3,99±0,47	0,188
Cl- (mmol/l)	102,51±4,41	101,85±3,88	103,72±5,11	0,118

Regarding the total number of participants, the number of men (n=47) is greater compared to women (n=25). This largely explains the higher number of women suffering from heart failure with preserved ejection fraction but with worse control, as well as the fact that women are less represented in clinical studies on heart failure, which explains the higher number of men participating

in the heart failure program. There is no evidence or scientific studies to explain the mechanisms and reasons for the more severe course of heart failure in women.

There is no significant difference in age - 68.81±9.00 years compared to 66.04±11.79 years, p=0.29, t-test.

Rehospitalizations and mortality.

Patients were observed for an average of 171±50.67 days, with a median of 184 days and an interquartile range (IQR) of 168-189 days. There was no significant difference between those observed by a nurse and those observed by a specialist physician.

A total of 62 patients completed the follow-up, 6 died, 3 withdrew, and 1 did not complete the 6-month cycle. There were 6 fatalities out of 72 patients (8.3%). Readmissions over a period of 6 months were observed in 8 (11%) patients. A total of 12 (16.7%) of all study participants experienced a clinical event - death or hospitalization (Figure 2).

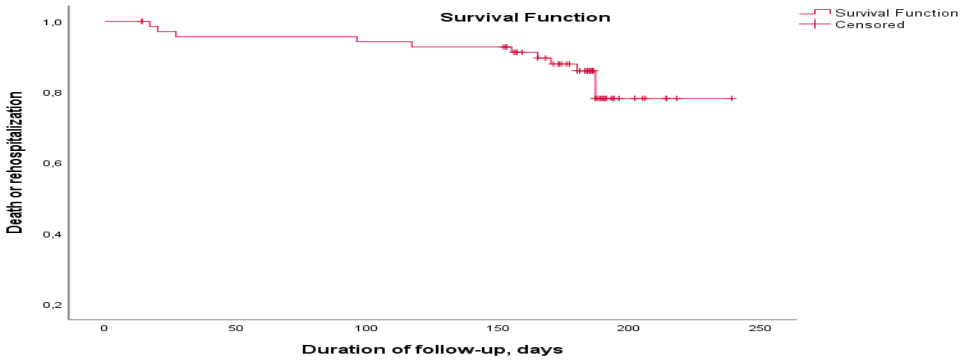


Figure 2. Kaplan-Meier curve of mortality for all patients

The group of patients followed up by a nurse are more frequently rehospitalized - 4 (19%) compared to the group observed by a doctor and nurse - 4 (7.8%), p=0.197. A favorable outcome is that in the group monitored by a nurse, there are fewer deaths - 1 (4.8%) compared to the group led by a team of doctor and nurse - 5 (9.8%), p=0.66 (Fisher's exact test). Regarding the higher number of rehospitalizations, it is important to note that hospitalizations for other reasons are included here as well.

The frequency of rehospitalizations and fatal cases in the study is similar to our previous studies.

Patients are referred to other specialists due to comorbidity and the need for a specialist with a different specialty than cardiology. Hospitalizations due to acute incidents and the Covid-19 epidemic are also included (Fig. 3).

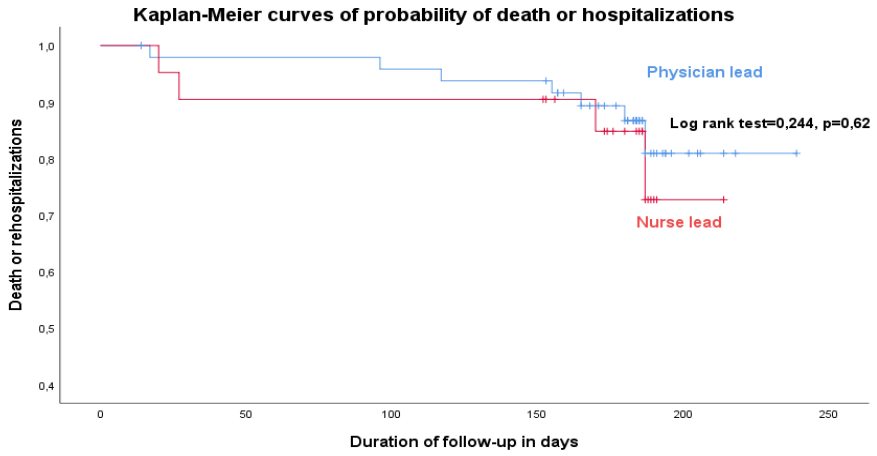


Figure 3. Kaplan-Meier curves for rehospitalization or mortality (according to the group of patients with HF depending on the leading specialist)

3.2. Clinically monitored indicators

Body weight (BW)

One of the easiest measurable parameters included in the patient follow-up, both in hospital and outpatient settings, is the change in body weight. It is recommended as a reliable method for controlling fluid retention in patients with heart failure. Measuring BW in a home setting is recommended. The change in weight over a short period of time can be used as a marker for fluid retention and for adjusting the dose of diuretics. In this study, body weight was measured and documented at every patient visit to the office, and patients were trained to monitor and record their BW in a home setting. It was recommended that if an increase in BW of more than 2 kg above stable weight for a period of 48-72 hours was observed, the diuretic dose should be increased or contact should be made with the physician or nurse from the office.

The results for changes in BW show that there is a consistently slight decrease in BW over time in patients, from an average of 83.38±18.31 kg at the beginning to 81.96±16.36 kg after 6 months (Fig. 4).

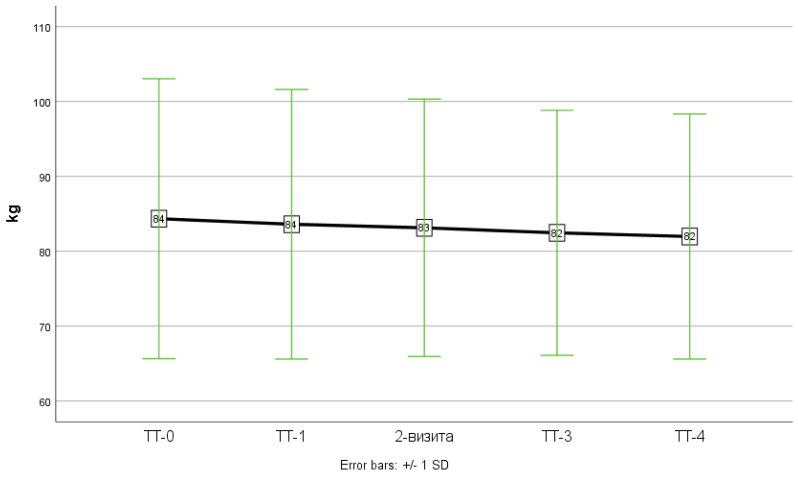


Figure 4. Dynamics of body weight of patients during the follow-up period

The difference in BW becomes significant from the 2nd visit (p=0.024) and remains significant until the end, exceeding 2 kilograms (p=0.004). There is no difference in achieved BW between the group of GPs and the specialist physician group, as well as between men and women.

Body weight is one of the first signs of worsening of the condition in patients with HF, providing information on impending fluid retention due to poor diet, irregular medication intake, excessive fluid consumption, or decreased physical activity. The study data show a delay in BW stability in the first two visits, V-0 and V-1, and a more significant decline in the subsequent three, with an average reduction of 2 (two) kilograms at the end of the follow-up period (6 months), indicating no significant decompensation of heart failure and the positive effect of monitoring.

Blood pressure (BP)

Systolic blood pressure (SBP) values remain stable throughout the study period, regardless of gender and regardless of the primary factor for observation of patients (Fig. 5).

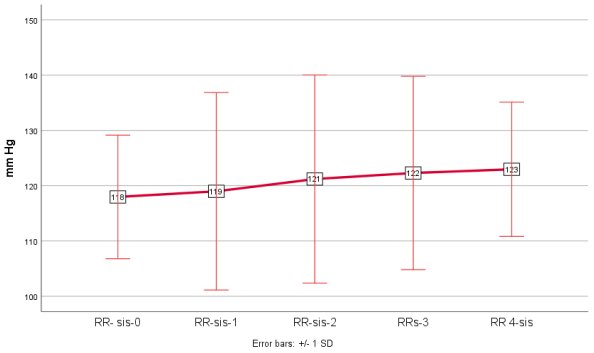


Figure 5. Dynamics of arterial blood pressure during the follow-up period

The achieved average difference of 3.5 mm Hg at the end of the 6th month is statistically significant (p=0.028). Although the values of systolic blood pressure gradually increase over time, there is no statistical significance compared to the initial blood pressure in the remaining comparisons.

Diastolic blood pressure shows a similar trend, with a constant increase in DBP over time, reaching 4.35 mm Hg at the end of the 6th month (Table 2).

Table 2. Average levels of DAN and SAN for the follow-up period

	Mean value	Number (N)	Standard deviation	Standard error	p
Original data	71,12	66	8,860	1,091	-
Data Visit 1	72,92	66	11,418	1,406	0,193
Original data	71,06	65	8,872	1,100	0,268
Data Visit 2	72,85	65	11,421	1,417	-
Original data	70,71	56	7,887	1,054	**0,013**
Data Visit 3	74,29	56	9,314	1,245	-
Original data	71,13	62	8,561	1,087	**0,001**
Data Visit 4	75,48	62	7,450	1,946	-

The data are largely explained by the fact that the patients were prescribed antihypertensive therapy, through which they maintain optimal MAP and DBP levels in the hospital. However, when they are returned to their usual daily environment, dose adjustments are often necessary.

Heart rate (HR)

Heart rate is an important hemodynamic parameter in patients with heart failure. The goal is to maintain a lower HR, preferably <70 beats/minute. Stable HR indicates a lack of activation of the sympathetic and RAAS systems, which is a compensatory reaction in worsening. In the group of patients observed in the program, HR remained stable throughout the observation period (Figure 6).

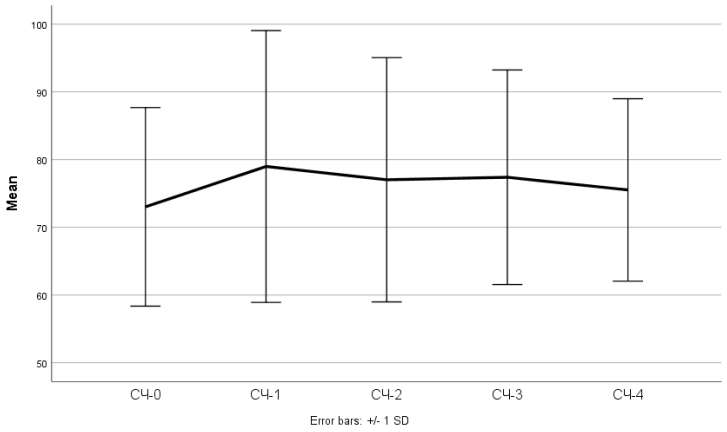


Figure 6. Dynamics of heart rate during the follow-up period

At the first visit after discharge, HR significantly increases (p=0.04), but then gradually stabilizes, and at the end of the observation, it is insignificantly higher by 1 beat/minute. There was no significant difference in the achieved HR during the individual visits between the group led by a nurse and the group led by a doctor.

In a comparative analysis of arterial pressure, heart rate, and BW (time of thrombin clotting), between patients led by a nurse and a team of a cardiologist and a nurse, there is a similar MAP (systolic arterial pressure) - 122.62±21.19, p=0.401, SCH (systolic heart rate) - 78.43±19.35 versus 78±18.76, p=0.978, BW - 82.00±17.55 versus 82.48±17.23, p=0.918, and significantly higher DBP (diastolic arterial pressure) - 78.33±13.07 versus 70.40±9.72, p=0.019.

3.3. Safety of observation by a nurse

The reduced cardiac output in patients with SN (systemic hypertension) affects the renal blood flow, resulting in oliguria and increased levels of serum creatinine and urea, leading to acute renal failure. On the other hand, the decrease in glomerular filtration leads to hypervolemia and left-sided heart failure. In chronic renal failure, especially with the progression of the disease,

there is a vicious circle of mutual deterioration of kidney and heart function. Therefore, it is important to monitor serum creatinine levels in patients with SN.

The main biochemical parameters monitored in patients are renal function and serum electrolytes, which do not change significantly during the observation period.

Serum creatinine remains relatively constant over time - from 105.73 μmol/l to 105.70 μmol/l, p=0.92 (paired one-sample t-test). The baseline creatinine levels do not differ in Group A and B - 104.43±42.02 versus 106.28±60.29, p=0.883. At the end of the observation, patients observed by a nurse have statistically insignificantly lower serum creatinine levels compared to the group observed by a physician - 97.58±34.66 versus 109.38±92.00 μmol/l.

Almost equally, patients improved or worsened renal function within 6 months, with a slightly small number showing no change - 44%, 49%, and 7%, respectively. In the group of patients led by a nurse, there were more people with improved renal function, while in the group of patients led by a physician, there were slightly more people with worsened creatinine values (Table 3). The difference is not statistically significant (uncertainty coefficient=0.009, p=0.675).

In the group led by the specialist, there are slightly more patients with a more severe course of heart failure (mainly right-sided heart failure, more men, with poorer average ejection fraction), and the correlation between renal function and severity of heart failure is well-known. On the other hand, the average age of patients in the group led by the nurse is over 2 years higher, and age is also a known factor in the worsening of renal function over time. Another explanation for the majority of patients with improved renal function in the nurse-led group may be the special care for adequate hydration of the patients, as well as less aggressive diuretic treatment.

Table 3. Change in creatinine values with different types of follow-up

Creatinine value	**Led by a nurse n (%)**	**Led by a specialist doctor n (%)**
Worsening	8 (42)	22 (52)
No change	1 (5)	3 (7)
Improvement	10 (53)	17 (41)

Some of the important electrolytes necessary for maintaining homeostasis and dynamic stability, despite the continuous exchange of substances and energy between the extra- and intracellular fluid environments, are potassium and sodium. The balance between intracellular and extracellular fluids is influenced by the concentration of electrolytes, mainly potassium and sodium. Patients with heart disease are vulnerable to electrolyte imbalances, as the main treatment is diuretic, and the likelihood of eliminating or retaining these electrolytes is high. Therefore, it is important to examine the levels of Na+ and K+ in patients with heart disease.

In the heart disease program, these markers are included for monitoring during the second and final visit to achieve optimal control.

Initially, the serum Na+ in patients in group A was similar to that in group B - 137.19±9.45 vs. 140.40±5.69, p=0.159. Regarding serum sodium, there was a tendency for a slight decrease in the entire group - from 139.45±7.1 mmol/l to 135.26±12.01 mmol/l (p=0.064, paired one sample t-test). This decrease in serum Na+ values can be explained by the more significant natriuresis resulting from diuretic treatment. There was no difference in the laboratory indicator between the two groups, observed by different leaders in the team - 136.1 vs. 134.9, p=0.79.

Another important safety indicator in patients with heart disease is serum potassium. The initial levels of K+ in the two compared groups were similar - 3.87±0.52 vs. 3.89±0.49, p=0.851. After 6 months of treatment, it did not change - from 3.89±0.46 mmol/l initially to 3.85±0.55 mmol/l, p=0.43. There was also no difference between the two compared groups - 3.74 vs. 3.89, p=0.15.

These results show that the observation of patients with heart disease, guided by the heart failure clinic, is safe for them and does not carry significant risks. It is comparable to that guided by a cardiologist.

Remaining symptoms and recommendations for non-pharmacological behavior

21.5% of the patients had residual complaints of shortness of breath after being included in the program, and edema in the extremities was still present in 43.1% at discharge. Significant clinical improvement was observed at the end of the follow-up. Only 1 patient (1.4%) reported mild shortness of breath, and edema persisted in only 6 patients (8.3%). Regarding adherence to diet and physical activity during the program, 78% of patients with heart failure strictly

followed the recommended dietary regime, and 62.5% performed the recommended physical activity. This largely explains the positive results at the end of the scientific study.

In 50% of cases, the patients included in the study were referred to another specialist for consultation. They were most often referred for psychological support with a psychiatrist/psychologist - 23.8%, with 6 cases (8.4%) being related to chronic alcoholism. Help from a dietician was sought in 4 cases (5.6%), a gastroenterologist was consulted in 2 cases (2.8%), and one case was referred for placement of a resynchronization device by an invasive cardiologist. A rehabilitation/physiotherapist was necessary for 3 patients (4.2%). The nurse less frequently referred patients to another specialist compared to the follow-up group of cardiologist and nurse - 57.1% versus 47.1% (p=0.028).

These data provide information about the role of the nurse in the multidisciplinary team of specialists and the group care focused on the patient's needs. Data from clinics working with heart failure patients show care primarily in outpatient or inpatient settings, using a multidisciplinary team that includes doctors, nurses, pharmacists, dietitians, social workers, physiologists, physiotherapists, psychologists, and other health specialists with specialized training and skills in managing heart failure.

Analysis of pharmacological therapy

Pharmacological therapy is of paramount importance in the treatment of patients with heart failure. The combination of pharmacological and non-pharmacological treatment, accompanied by a change in lifestyle, is extremely important for successful control and remission of heart failure. Therefore, it is of utmost importance to control the proper intake of medications prescribed by the doctor, as well as to monitor the objective condition of the patient and their complaints, with a view to changing the dose (e.g., increasing or decreasing the dose of a diuretic, beta-blocker, or ACE inhibitor) prescribed by the doctor.

Therapy was prescribed in 59 patients (82%). Beta-blockers were prescribed to 52 out of all patients (72%), diuretics were taken by the majority - 61 (85%), and ACE inhibitors - by 47 (65%). Ivabradine medication was prescribed to 18 patients (25%). *No differences were found in the type of heart failure, beta-blocker, diuretic, ACE inhibitor, or Ivabradine prescriptions.*

Patients mainly led by a nurse receive BB less frequently - 62% vs. 76.5% (p=NS), diuretics - 76% vs. 88% (p=NS), and Ivabradine - 19 vs. 27.5% (p=NS), but with no difference in ACE inhibitor prescriptions - 67 vs. 66% (p=NS).

Therapeutic behavior and influence

58 patients (93.5%) continue their treatment regularly, which shows a slight increase compared to the initial 82%. The recommended dietary regimen by the nurse is followed by a large proportion of patients, 54 (87%). The instructions for physical activity are followed by most patients, 54 (87%). Only one patient did not change their level of physical activity, and only 7 do not perform their prescribed physical activity (11%).

Seven patients (11%) do not take beta-blockers, and the dosage of beta-blockers is reduced after six months for two patients. The dosage of beta-blockers is increased for one patient and remains unchanged for 20 patients (32%). *There is no difference in adherence between patients observed by a nurse and a doctor (p=0.121).*

All patients included in the study take diuretics (98.4%), and the dosage of diuretics is decreased for 4 of them (6.4%), while it is increased for the same number of patients after six months. The dosage remains unchanged for 27 patients (43.5%).

Only 10 patients (16%) do not take ACE inhibitors. There is an increase in the use of these beneficial medications compared to the initial intake. The dosage is decreased for 4 patients (6.4%) and increased for 1 patient (1.6%). *There is no statistically significant difference in the therapeutic approach between the nurse and the doctor (p=0.44).*

20 patients (32%) take Ivabradine, a medication for reducing HR, which shows a slight increase from the initial intake. Information is not available for 3 patients, and 39 patients do not take it.

Assessment of the change in ejection fraction (EF)

Ejection fraction is the ratio between stroke volume (blood entering the aorta during one contraction of the heart muscle) and the end-diastolic volume of the ventricle (blood entering the chamber during the relaxation or diastole phase). The patient's ejection fraction can be improved or decreased. It is a dynamic parameter that provides information about the patient's condition. An ejection fraction of less than 40% is a consequence of changes in the

functionality of the heart muscle due to the progression of the underlying disease. It is a sign of a worsened quality of life, the need for hospitalization, a poor prognosis, and an increased risk of sudden cardiac death.

In the present study, the average FEV1 is 42.78±14.23%, ranging from 21% to 75%, with a 95% confidence interval of 39.43-46.12. The median is 41.5%, with most patients having a suppressed (reduced) FEV1 of less than 40%, and one third having preserved FEV1 greater than 50% (Fig. 7).

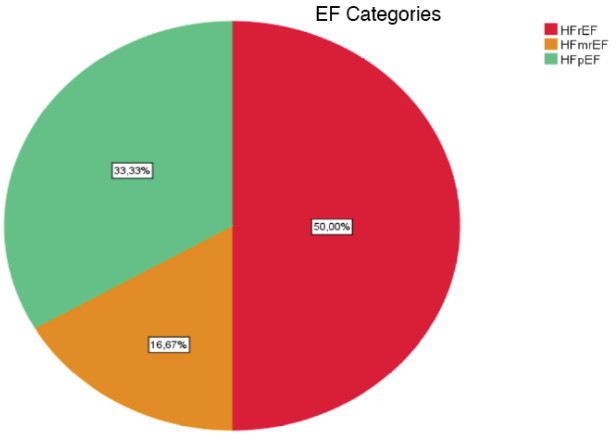


Figure 8. Distribution of patients by ejection fraction

Men have a significantly lower baseline EF by almost 10 points (Table 1) - the mean difference between genders is 9.6%, 95% CI 3.19-15.99%, p=0.004 (t-test for independent variables). Men are more likely to have a reduced ejection fraction - 64% versus 24% for women, while women are more likely to have a preserved EF - 56% versus 21% for men, p=0.003 according to the $\chi 2$ test.

The mean EF is not significantly higher in the group led by the nurse - 46.19±13.12% compared to 41.37±14.55%, p=0.19. Patients with reduced EF are more in the group led by the nurse, and conversely, more patients with preserved EF are in the group led by the doctor. The difference is not statistically significant, p=0.095 (Kendall's tau-b test).

The data from the study also have a positive effect in that there is no observed progression of the disease during the six-month follow-up period and show the effect of the heart failure program.

Evaluation of changes in NT-proBNP

This biomarker reacts to increased pressure in the heart chambers and to increased neuro-hormonal activation. It has diagnostic and prognostic value in patients with HF and complements clinical observation and changes in patients' symptoms. Reduction in serum levels of NT-proBNP indicates clinical improvement during treatment.

In the studied group of patients, the baseline levels of the biomarker are high, indicating the presence of a serious disease (Table 1). Baseline levels of NT-proBNP - 5018.5±3112.83 pg/ml, range 183-9000, median 4820, IQR 2436.50-9000. In men, NT-proBNP levels are significantly higher than in women. The same applies to those with reduced EF compared to those with preserved EF, as shown in Figure 9, nonparametric Kruskal-Wallis test p=0.012.

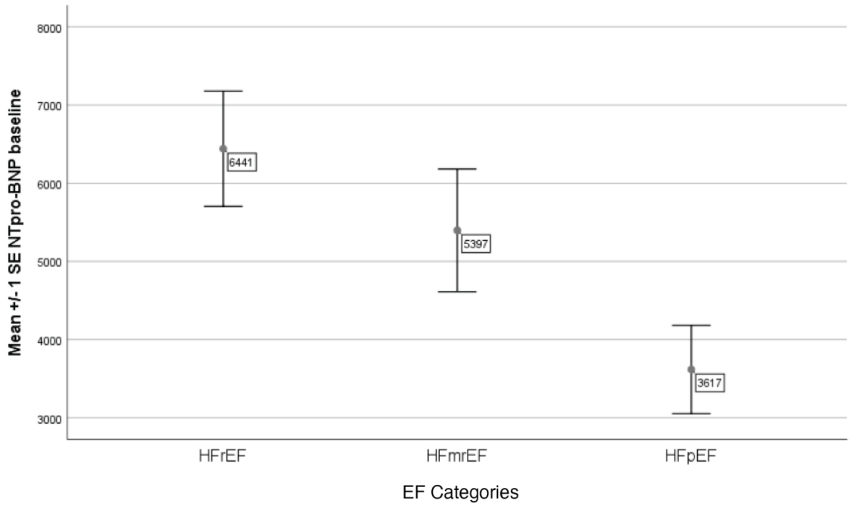


Figure 9. Average levels of NT-proBNP±SE according to EF categories

Regardless of the fact that NT-proBNP levels decrease with age and in our group, the correlation is weak and insignificant - nonparametric Spearman correlation coefficient rho = -0.16, p = 0.17.

There is no difference in the baseline levels of NT-proBNP between the nurse-led and physician-led groups - 4937.49 ± 2861.86 vs 5051.86 ± 3237.19, p = 0.85. After 6 months of follow-up and intervention in the heart failure clinic, a significant decrease in NT-proBNP levels was observed - from 4697.04 ± 3072.85 pg/ml to 3622.18 ± 3091.31, with a mean difference of 1072.29 ± 2107.14 over 6 months, p <0.0001.

NT-proBNP levels increase with increasing functional class according to NYHA, but the dependence is not statistically significant, r = 0.155 (Table 4).

Table 4. Baseline levels of NT-proBNP according to functional class according to NYHA

NT-proBNP initial.								
	N	Mean	Standard deviation	Standard error	95% confidence interval of the mean		Min.	Maximum
					Lower limit	Upper limit		
II	4	3609,50	2114,821	1057,410	244,35	6974,65	1024	5432
II-III	2	3631,00	2544,170	1799,000	-19227,46	26489,46	1832	5430
III	46	4691,72	3153,504	464,959	3755,24	5628,19	606	9000
III-IV	12	5799,58	3093,370	89 2,979	3834,15	7765,02	183	9000
IV	8	6777,25	3083,224	1090,084	4199,61	9354,89	2690	9000
Total	72	5018,50	3112,829	366,850	4287,02	5749,98	183	9000

More than 80% of patients have lower levels of NT-proBNP after 6 months of observation, and worsening is observed in only 14.5%.

In the group of patients mainly followed by a nurse, the improvement is even more pronounced - the majority of them have an improvement in the biomarker - 94.7% compared to 74.4% in the group led mainly by a doctor and a nurse. Worsening is less common in the first group - 5.3% compared to 18.6%. The difference is statistically significant - p=0.024 (Kendall's tau b test) (Fig.10).

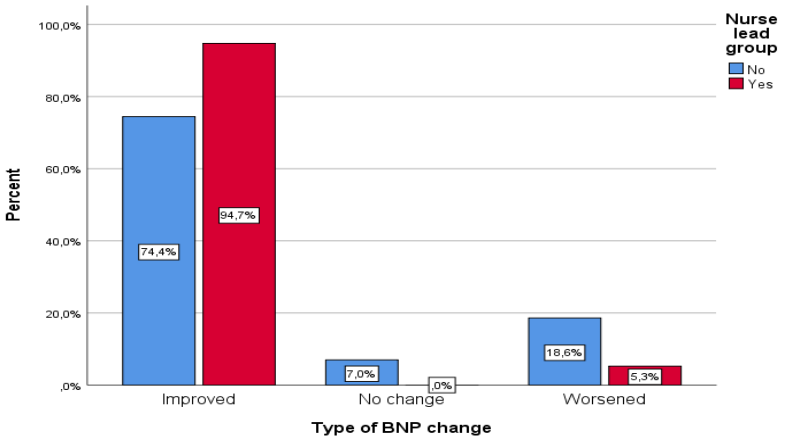


Figure 10. Change in NT-proBNP levels in patients led by a nurse and a doctor, and only by a nurse

Observation of the patients shows improvement in the results due to the impact of outpatient nursing care.

Assessment of changes in physical activity through the 6-minute walking test (6MWT)

The six-minute walking test is an excellent and reliable method for evaluating exercise tolerance and the effects of treatment in patients with CHF. It is easy to perform and well-tolerated. The distance covered in 6 minutes is the only parameter measured during the test. This parameter could allow for an assessment of the severity and prognosis of CHF.

The mean value of 6MWT initially for the entire CHF group is 253.56±107.91 m, range 90-780 m, 95%CI 228.2-278.91 m, median 250 m (Table 1). More than 2/3 of the patients cannot walk more than 300 m, and more than 1/3 walk less than 200 m, which predicts a high risk of an unfavorable outcome (Figure 11).

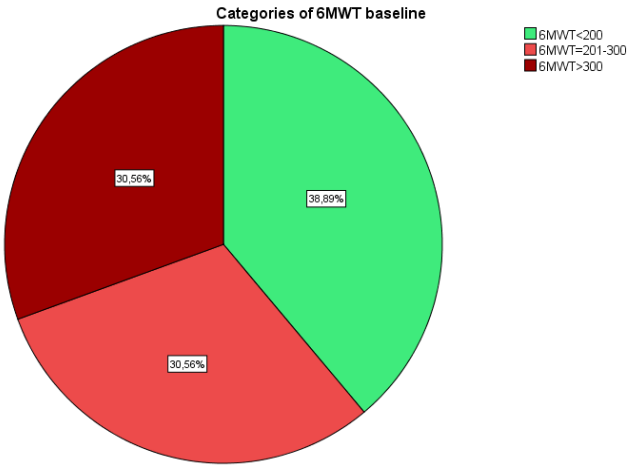


Figure 11. Physical activity of patients with heart failure

Women, despite having a better EF, walk a shorter distance in 6 minutes compared to men in the initial test. There is no statistically significant difference according to EF, p=0.14. Even patients with reduced EF have a better physical capacity because a large proportion of them are men. This is confirmed in linear regression analysis, where the relationship between the 6MWT distance and ejection fraction remains insignificant after correction for gender and age (p=0.507). There is no significant correlation between the initial distance covered in 6MWT at the beginning of the observation and the initial values of

NT-proBNP - partial Pearson correlation coefficient r=-0.19, p=0.114, after correction for the effects of gender and age.

After 6 months, we found a significant positive correlation between the levels of change in physical capacity after 6 months of active observation, assessed with the 6-minute walk test, and the change in levels of NT-proBNP - r=0.53, p<0.0001. Overall, 76% of participants improved both their test and biomarker, while only 3.2% worsened in both parameters (p=0.055, $\chi 2$ test).
There is a good correlation between the functional class according to NYHA and 6MWT, albeit statistically insignificant - p=0.079, ANOVA test (Figure 12).

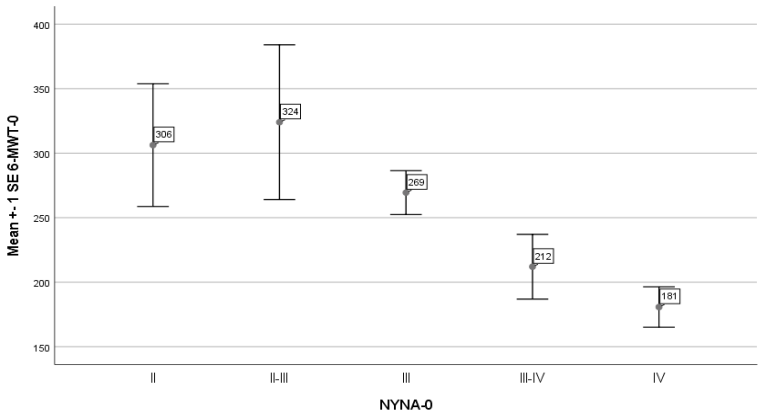


Figure 12. Correlation between NYHA and 6MWT

The correlation between NYHA class and 6MWT at the first visit is moderate and significant - Spearman's rho = -0.38, p = 0.001.

Patients with heart failure from the group led mainly by a nurse walk insignificantly more for 6 minutes at the baseline visit - 274.95 ± 149.39 m compared to 244.75 ± 86.35 m, p = 0.39. Those who cover >300 m are insignificantly more - 38% compared to 27.5% and fewer who cover 200-300 m initially - 24% vs. 33%, with no difference in the worst functional group - <200 m.

After 6 months of follow-up, patients have significantly improved the distance they walk for 6 minutes. The mean difference from the baseline visit is +58.19 ± 68.06 m, 95%CI 40.91-75.48 m, p <0.0001 compared to the baseline distance (Wilcoxon's sign rank test). The majority of patients have significantly improved their walked distance, with only 6.4% worsening their test results (Fig. 13).

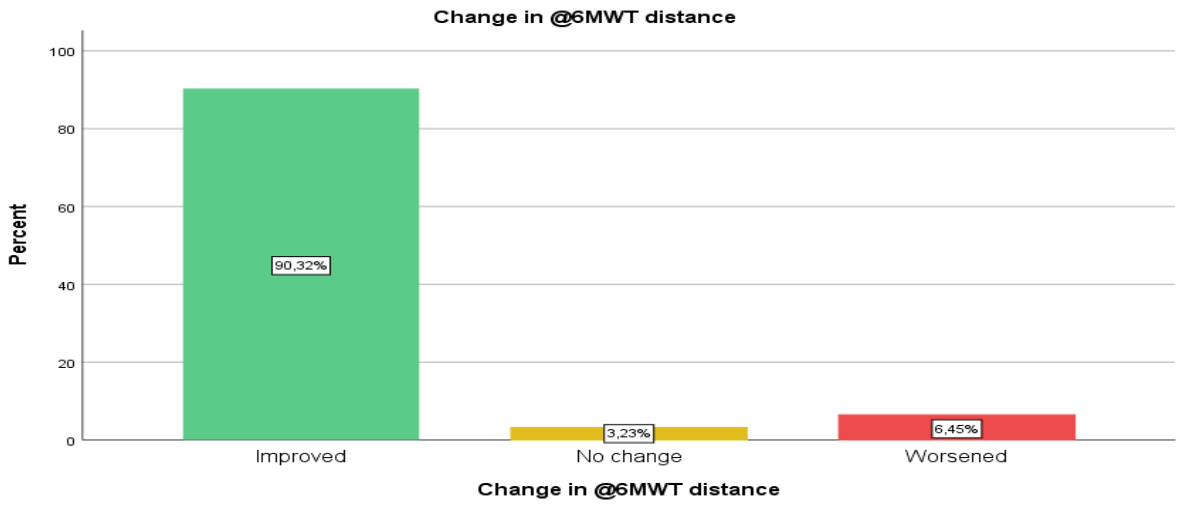


Figure 13. Change in physical activity through a 6-minute walking test in patients with heart failure

The group followed by the nurse showed a significantly weaker improvement compared to the patients in group B - the mean difference between the two groups was 40.6 m, p=0.029. We assume that this difference may be due to the fact that the patients in the group followed by the nurse were mostly women and older, with comparable EF. This is also supported by multiple linear regression analysis, where the difference became statistically insignificant after correction for gender, age, and EF (p=0.66 for the effect of the observation group). After correction for other factors using the generalized linear model, the predicted difference in 6MWT between the two groups with different coordinators was only 10 m - 306.2 vs. 316.9 m.

A little over 1/3 of the patients who had a very poor initial result (<200 m) showed the same result after 6 months (36%). All others have covered a greater distance in 6 minutes. There is not a single patient from the other two categories who has worsened their results.

Evidence of objective clinical improvement is the significant negative correlation between the increase in distance in 6MWT and the decrease in serum levels of NT-proBNP as a biomarker of hemodynamic change in patients with HF after treatment - Spearman's rho = -0.25, p=0.04.

There is also a very good correlation between the change in NYHA functional class after 6 months and the greater distance covered in 6MWT - Spearman's rho 0.56, p<0.0001 (Figure 14).

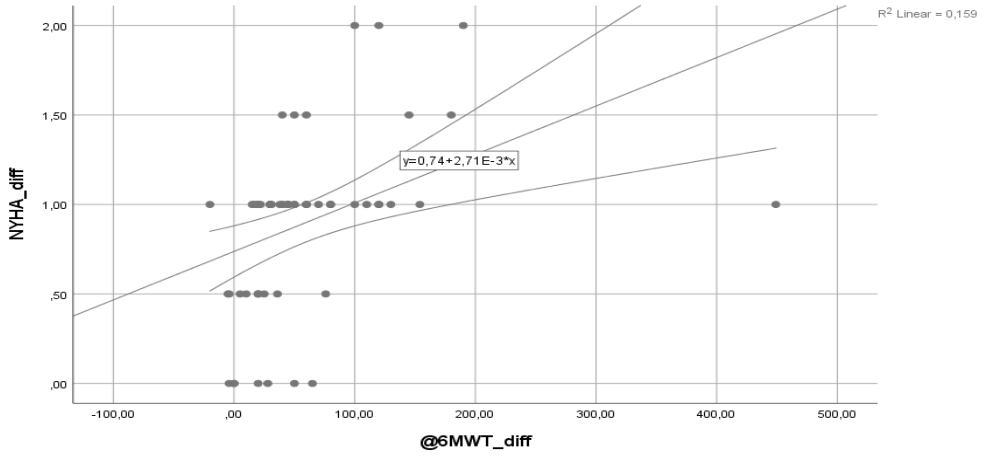


Figure 14. Change in NYHA functional class and walked distance in 6MWT after 6 months

There is a correlation established when comparing the 6-minute test with the NYHA functional class.

Distribution of the functional class according to NYHA

The average NYHA class in the entire group at discharge from the medical institution and at the beginning of the observation is 3.125 ± 0.45, ranging from II to IV, with a median of 3. Most patients at discharge from the hospital and at the beginning of the follow-up were in NYHA class III and III-IV, indicating a significant burden of symptoms of heart failure in the enrolled patients. The correlation between NYHA class and 6MWT is moderate and significant - Spearman's rho = -0.38, p = 0.001. As the NYHA class increases, indicating worsened symptoms and decreased physical capacity, patients walk less (Figure 15).

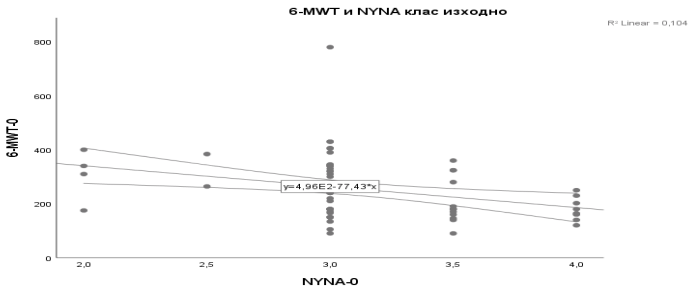


Figure 15. Correlation between 6MWT and NYHA

Although some studies show a reverse correlation between NYHA II-IV and 6MWT, there is significant heterogeneity in the published results. When comparing 6MWT with the individual classes of NYHA, some overlap between 6MWT and NYHA classification is observed. NYHA classification performs well in more symptomatic patients (NYHA class III/IV) but less well in asymptomatic/mildly symptomatic patients (NYHA I/II). Patients observed by a nurse had a slightly lower functional class at discharge from the hospital - 2.91 vs 3.21 ($p = 0.023$, t-test). This difference in functional status at enrollment in the program is clinically insignificant, although formal statistics show significance.

Change in NYHA class

Symptom severity is most commonly categorized using the New York Heart Association (NYHA) functional classification. According to the results of the present study, a significant improvement in the NYHA functional class was observed. At the end of the study, there were no patients in class IV, only 8 (13%) of the participants were in class III or III-IV. The majority were mainly in class II, and one participant was assessed as class I. The average improvement was 0.9 class, 95%CI 0.78-1.01. 87% of the patients showed an improvement of at least 1 class, with 3 of them improving their functional status by 2 classes. The individual changes in the functional class at the end of the observation for each patient are shown in Figure 16.

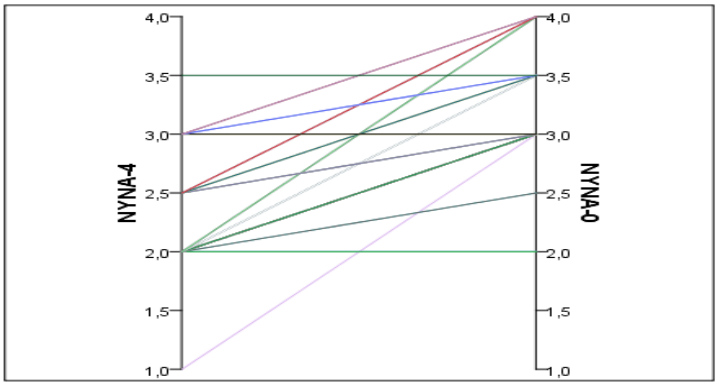


Figure 16. Individual changes in functional class at the end of the observation period for each patient

There were no significant differences observed between the groups followed by a nurse and a doctor. Patients followed by a nurse showed improvement of at least 1 NYHA class - 95% versus 84%, but the difference was not statistically significant (p=0.23, $\chi 2$ test).

3.4. Quality of life assessment through analysis of quality of life questionnaires

As part of the heart failure program, each patient completes and responds to quality of life questionnaires: *Kansas City Cardiomyopathy Questionnaire, Generalized Anxiety Disorder 7-item Scale, Patient Health Questionnaire-9, EQ-5D Health Questionnaire, and a Visual Analog Scale (VAS)*. At the end of the program (6th month), patients complete the questionnaires again and perform a self-evaluation. A comparative analysis and assessment of the patients' quality of life is made at the start of the program and after the care provided at the end of the program.

Kansas City Cardiomyopathy Questionnaire

68 patients with heart failure were studied at the beginning of the observation. The mean value of the Total Symptom Score (TSS) was 38.63±29.03, 95%CI 31.61-45.66, median 34.38, IQR 12.50-63.02. The Clinical Summary Score (CSS) was initially 43.92±27.60, 95% CI 37.24-50.60, with a median of 41.15, IQR 24.09-80.73, and the Overall Summary Score (OSS) was 40.99±24.73, 95%CI 35.01-46.98, median 37.11, IQR 22.46-60.09.

Despite the fact that digitally monitored patients have better quality of life indicators, these differences are not statistically significant. There was no initial difference observed in all assessment scales by gender and according to the EF.

After 6 months of active monitoring and treatment, the Total Symptom Score (TSS) reached an average of 80.80±21.30 points, 95%CI 75.52-86.04, with a median of 87.5, IQR 66.15-100. The mean difference from the initial TSS was 39.50±31.71 points, 95%CI 31.71-47.29 ($p<0.0001$, one-sample t-test).

The relative proportion of patients who have achieved good to excellent quality of life increases significantly, and those with very poor quality of life decrease according to the KCCQ questionnaire, p=0.027.

The Overall Summary Score (OSS) at the end of the observation reached 72.13±21.23 points, 95%CI 66.87-77.39, median 77.60, IQR 53.91-91.93. The

mean difference from the initial levels was 28.29±22.57 points, 95%CI 22.70-33.89 (p<0.0001). The OSS result also significantly improves over time in patients (p<0.0001; Fig.17).

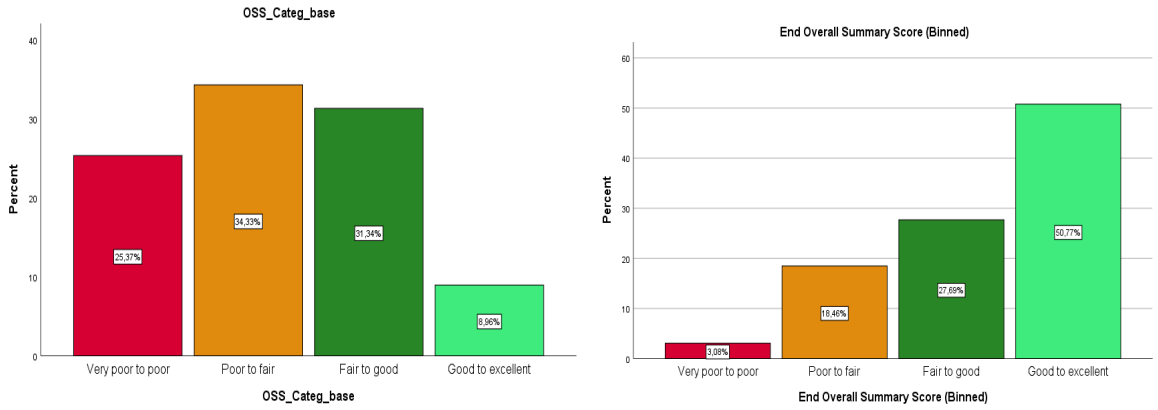


Figure 17. Initial and final overall total score at the end of follow-up

Similar improvement is observed in the Clinical Summary Score (CSS), which has become an average of 78.96±21.28, 95%CI 73.68-84.23, median 85.42, IQR 58.85-98.96 at the 6th month. The average improvement from the initial values is 31.99±25.21, 95%CI 25.74-38.24 points (p<0.0001). This quality of life indicator also shows significant improvement - 25% had very poor to poor quality of life at the beginning of the observation compared to 3% at the end, while those with good to excellent quality of life increased from 15.5% to 51% (p<0.0001, Sommer's d and Kendall's tau b tests).

Clinical symptoms also show significant improvement during the observation. CSS has increased by >5 points in 57 (87.7%) of the completed patients with CHF, >10 points in 55 (84.6%), and >20 points in 46 (70.8%). Deterioration in the quality of life in the clinical symptoms section was only recorded in 2 (3.1%) of the completed 6-month observations of 65 patients with CHF.

The results of the OSS quality of life test correlate weakly to moderately with the improvement in functional class by NYHA - r=0.41, p=0.001 (Figure 18).

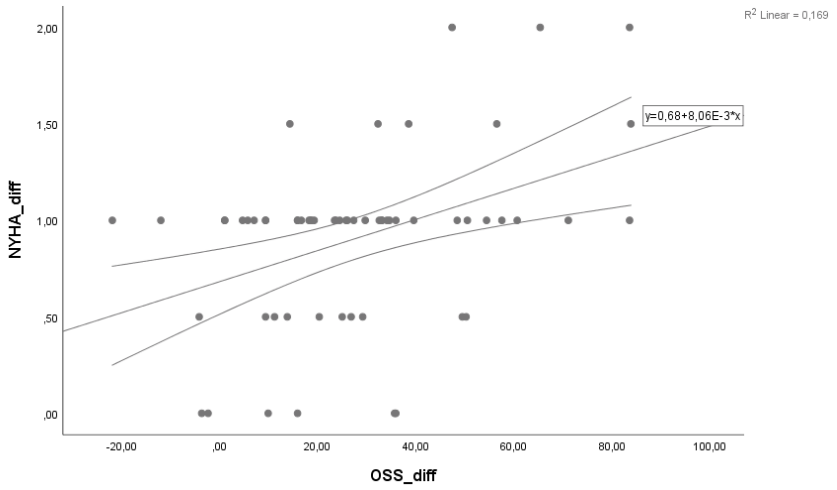


Figure 18. Correlation between NYHA class and 6-minute walking test

Similar correlations were observed with functional class and other KCCQ questionnaire indicators - TSS and CSS, with correlation coefficients of 0.29 and 0.35, respectively ($p < 0.0001$). Slightly weaker but statistically significant correlations were found between TSS and CSS and changes in 6MWT - $r = 0.33$ ($p = 0.009$) and 0.30 ($p = 0.017$), respectively.

EQ-5D Health Status Questionnaire

The mean value of the EQ-5D-3L index at baseline was 0.59 ± 0.28, 95% CI 0.52-0.66, median 0.59, IQR 0.48-0.78.

Patients led by a nurse had significantly better quality of life according to the EQ-5D scale - 0.71 vs 0.54 for group B, although not significant, $p = 0.27$ (Mann-Whitney U non-parametric test for independent variables). Gender did not have such an effect. After 6 months of follow-up, there was a change in the quality of life according to the European Quality of Life questionnaire EQ-5D. During the observation period, it increased from an average of 0.61 ± 0.27 to 0.81 ± 0.25, with a mean difference of 0.2 ± 0.24, 95% CI 0.15-0.26, $p < 0.0001$. There was no significant difference in the achieved level of quality of life between patients observed by a nurse and those seen by a specialist physician - 0.80 ± 0.22 vs 0.82 ± 0.27, $p = 0.73$ (t-test). In a univariate analysis, the difference in the achieved level of EQ-5 is significantly smaller for patients in the nurse-led group compared to the physician-led group - 0.09 vs 0.26, $p=0.015$. However, in a multivariate linear regression analysis with EQ-5 at 6 months as the dependent variable, after accounting for the effect of the baseline test result, which is higher in the nurse-led group, no significant difference is

found between the two groups. Such a difference is only found with respect to gender, but not age.

There is a good correlation between the assessment of the quality of life of patients with heart failure at the end of the observation period, made through the two questionnaires - KCCQ (OSS) and EQ5: r=0.51, p<0.0001. The correlation in the achieved difference between the beginning and the end of the observation period using the two methods is also satisfactory - r=0.38, r=0.002 (Figure 19).

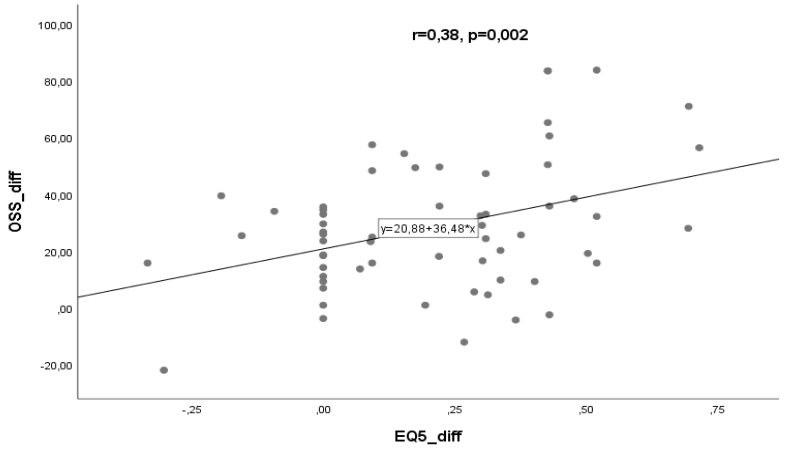


Figure 19. Assessment of the quality of life of patients with HF according to KCCQ (OSS) and EQ5

Applying concepts of care that meet the needs of patients with chronic heart failure (CHF) remains a challenge. In this context, psycho-emotional well-being is not routinely assessed and is insufficiently researched, despite indications that it is of great importance for, for example, acceptance, adherence, and prognosis. This study underlined the importance of risk factors for the quality of life of patients with CHF, particularly the differentiation of health-related QoL according to the severity of CHF.

In this new analysis, it was found that particularly mobility, self-care, and usual activities are prognostic factors associated with changes in EQ-5D-5L™ elements during follow-up.

Visual analog scale (VAS)

The initial mean value of the visual analog scale (VAS) was 0.49±0.15, 95% CI 0.45-0.52, median 0.50, IQR 0.40-0.60. Male patients have a significantly better self-assessment of their health status than female patients - VAS 0.51 vs. 0.44, p=0.04. Patients with SN who are managed by a nurse have

a worse initial visual assessment than those managed by a doctor - 0.445 vs. 0.50, possibly because they are more women, but the difference is not statistically significant (p=0.10, Mann-Whitney U non-parametric test for independent variables). The SF does not have a significant impact on the visual assessment of quality of life - 0.50; 0.50, 045 for reduced, slightly reduced, and preserved SF (p=0.5, Kruskal-Wallis test for independent categorical variable with more than 2 categories).

The initial self-assessment of health status only for the 65 patients who completed the 6-month observation is 0.50±0.15, assignable higher than that of all included patients, and increases positively to 0.65±0.14. This represents a difference of 0.15±0.12, 95% CI 0.12-0.1, p<0.0001. Even the one-factor analysis of VAS shows no significant difference between the two groups - the nurse and the doctor, in the achieved improvement in health status at 6 months, the intergroup difference is only 0.03, p=0.42. There is a moderate significant correlation between EQ-5D and VAS - r=0.41, p<0.0001. Accounting for the effect of who is responsible for patient management on the correlation even strengthens it - the partial correlation coefficient increases to 0.49, p<0.0001 when adding a variable group of investigated.

Generalized Anxiety Disorder Questionnaire (GAD7)

GAD-7 is an easy-to-use questionnaire that can be applied to patients as a screening method and measure of the severity of generalized anxiety disorder. The occurrence of depression in patients with GAD is associated with poorer clinical outcomes. Attempts to therapeutically influence and improve the overall condition, symptoms of anxiety and depression (despair, denial, lack of motivation, doubts about the favorable course of the disease), lead to a lack of cooperation in the treatment and non-compliance with therapeutic guidelines, which further worsens the overall condition of the patients.

The mean initial value for the entire study group is 5.7 ± 5.77, 95% CI 4.32-7.08, median 4, IQR 0-10. The mean value of the GAD7 anxiety questionnaire at the end of the observation period is 2.84 ± 3.35 points, 95% CI 1.99-3.68, median 2, IQR 0-6. This makes a mean difference from the initial value of 2.35 ± 3.90 points, 95% CI 1.37-3.33, p <0.0001 (Wilcoxon sign rank test and paired samples t-test).

There is no difference between patients observed by a nurse and a doctor in achieving the final anxiety score - 3.75 ± 3.19 vs 2.42 ± 3.37, mean

difference 1.33, p = 0.13 (nonparametric Mann-Whitney test). The percentage of patients without anxiety increases significantly - from 52.3% to 69.8%.

At the beginning of the study, the data on anxiety according to GAD-7 show that 47.14% of the patients had a tendency towards depressive attitudes, although some of them had mild to moderate symptoms and only 7.14% of them had a severe form of anxiety and depression, which shows the need for screening. At the end of the observation period, a reduction in depressive attitudes is observed, with the percentage of severe depression being eliminated or reduced to a moderate or low percentage of moderate anxiety and depression. The data from the clinical study show positive results from the follow-up of patients with GAD and the manifestation of depression and anxiety, as well as the need for screening methods, as a possibility for preventing symptoms of worsening of the overall condition and improving the quality of life (Fig. 20).

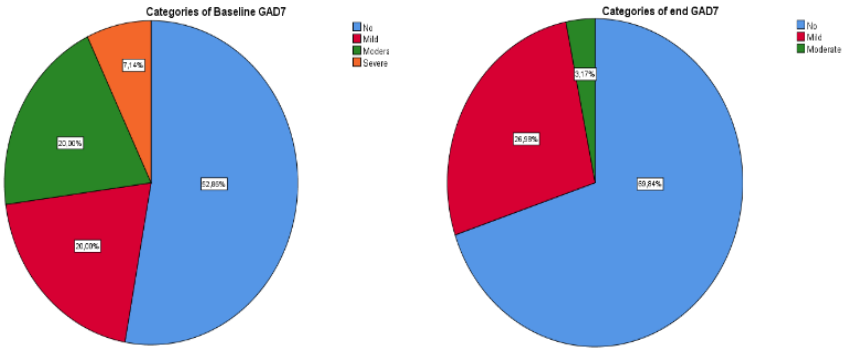


Figure 20. Level of depression in patients with heart failure at the beginning and end of the study.

Only 3 of all the patients who completed the observation worsened their anxiety status after 6 months - from no anxiety to mild anxiety. All others improved their status or did not change it. The initial application of the questionnaire found that 37% of all participants had a GAD7 score ≥8 points. At the end of the observation, the number of patients with clinically significant anxiety (GAD7>8 points) was significantly lower than at the beginning - 6 (9.5%) versus 26 (37%) initially, p=0.017 (Fisher's exact test). There was no difference in the relative proportion of patients in Group A and Group B by GAD7 categories at the end of the observation, nor in those with >8 points on the questionnaire.

Patient Health Questionnaire - 9, PHQ - 9

The Patient Health Questionnaire - 9 (PHQ-9) is one of the instruments used to assess the likelihood of depressive symptoms in people. The average PHQ-9 score at the beginning of the study in our group was 6.09±5.99, 95% CI 4.66-7.52, median 4.00, IQR 1-9. The distribution of PHQ-9 by groups is presented graphically (Fig. 21).

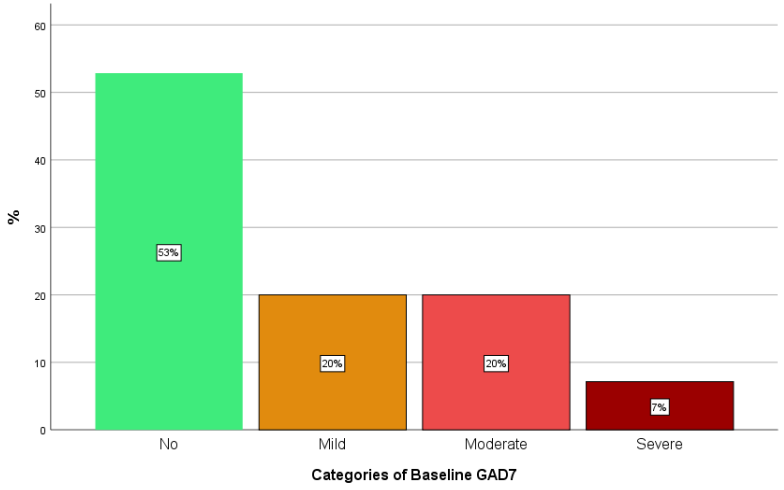


Figure 21. Mean PHQ9 score at the beginning of the study

Patients with PHQ9 ≥ 10 points account for over 1/5 of all patients with CHF. At the end of the observation period, a significant improvement in depressive moods was observed in patients with heart failure. The mean value of the responses is 3.65 points, SD 6.05, 95%CI 2.13-5.18, median 2 points, IQR 0-5. Among those who participated until the end of the study, there was a decrease in the depression score from a mean of 5.47 ± 5.22 at the initial visit, which is a significant decrease of 2.35 ± 3.9 on average, 95%CI 1.37-3.33, p <0.0001 (by paired samples t-test and Wilcoxon sign rank test). There was no difference in the level of depressive mood between patients observed by a nurse and those observed by a doctor. The mean value of the PHQ9 responses is 3.55 ± 4.16 in the CHF group compared to 3.70 ± 6.80 in the control group, p=0.99 (non-parametric Mann-Whitney U test).

Overall, 47 of the CHF patients studied have minimal or no depressive mood (75%), 12 have mild (19%), and only 4 (6%) have moderate depressive mood after 6 months of follow-up.

Only 5 of the patients have worsened their psychological condition - 3 from minimal to mild depressive mood and 1 from minimal to moderate depressive mood, as well as 1 from mild to moderate depressive mood. All other patients either remained unchanged or improved their psychological condition (Figure 22).

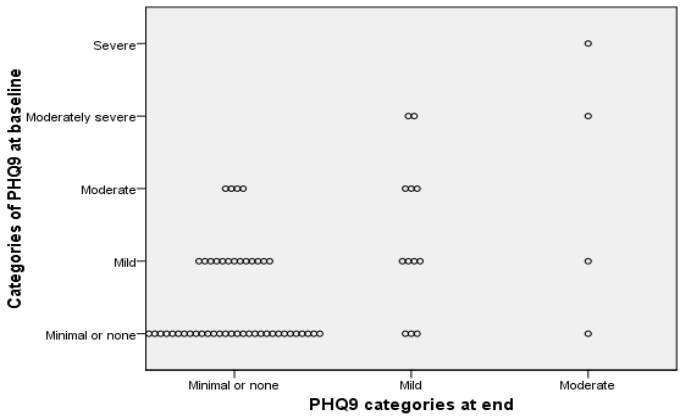


Figure 22. Assessment of PHQ9 during the follow-up period

Only 5 (7.8%) of all patients who completed 6 months of observation showed a score >10 on the PHQ9 questions (Figure 23).

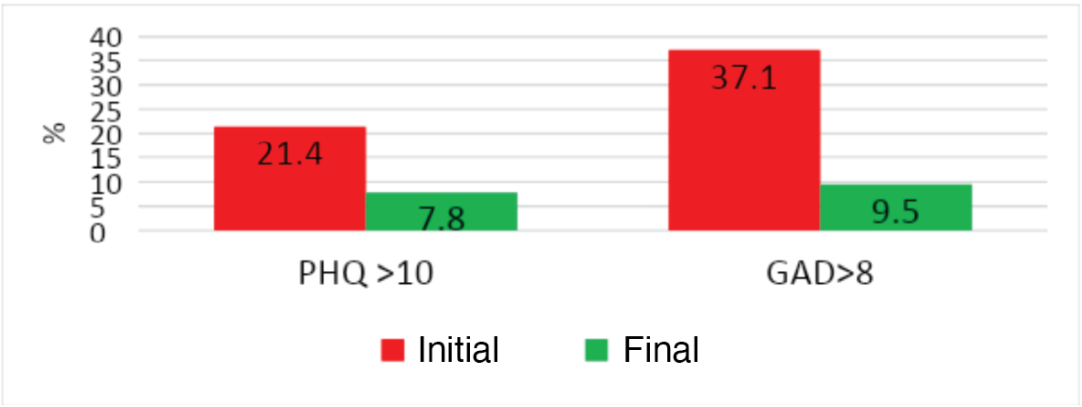


Figure 23. Comparison of PHQ and GAD 7

Only 2 (3.1%) of those who completed the study had worsened their psychological state and showed a score >10 points on the PHQ9 test at the end,

while at the beginning their score was <10 points. Conversely, 8 (14.1%) had improved their condition and had become low-risk, from high-risk for depression >10 points, p=0.04 (Fisher's exact test).

There was no difference found between the two groups (nurse and doctor) in the distribution of categories on PHQ9 at the end of the study, as well as in the frequency of those with >10 points after 6 months - 10% compared to 7%, p=0.64 (Fisher's exact test).

3.5. Assessment of the condition of patients following guidelines for physical activity and diet

In order to evaluate the effectiveness of the model for monitoring and outpatient care of patients with CVD by a nurse, we use as a measure of adherence to the program at the end of the follow-up period the self-reported readiness of patients to adhere to dietary and physical activity guidelines.

Advice on diet and physical activity for all patients was provided by the nurse according to an established protocol and in accordance with current recommendations for non-pharmacological behavior in CVD at the beginning of follow-up and at each visit.

Overall, there is information on adherence to the monitoring team's guidelines at the end of follow-up for 61 participants. Of these, the majority followed the advice for diet and physical activity (81.7%), and a small proportion reported that they did not follow some of the advice (0.18%). There was no significant difference in this indicator between the group of patients managed by the nurse and that by the physician, p=0.48 for the difference between the two groups. All patients were receiving drug therapy at the end of the follow-up, regardless of their compliance with the advice.

In the group that followed the lifestyle change guidelines, a numerical improvement was observed at the end of follow-up in all observed indicators:

- **6MWT** - the mean difference in improvement for those strictly following the guidelines was 39.36 m more (p=0.016). Overall, 94% of the group of guideline followers improved their 6MWT results, 4% had no change, and only 2% worsened their test results. In the group of non-compliant patients, 73% improved their walking distance, but 27% worsened. The difference is statistically significant.

- **NYHA** - improvement on average by 0.9 from 0.7 functional class, although statistically insignificant (p=0.19).
- **NT-proBNP** - for those who follow the guidelines, there is an average decrease of 1347.41 pg/ml, while in the other group, there is an average increase of 203.27 pg/ml, with a mean difference of 1550.68±677.35 pg/ml between the two groups, p=0.026. In the strict lifestyle group, improvement in biomarker levels is observed in 88%, and deterioration is only 9.8%, while in those who do not follow the guidelines, improvement is only 45%, but there is deterioration in 36% (p=0.003, $\chi 2$ test).
- **KCCQ** quality of life test: all indicators show greater improvement in the group that follows the diet and physical activity guidelines:
    - OSS - improvement in the compliant group is on average 30.88 points from 16.17 between the first and last visit, with a mean difference of 14.71±7.50 between the two groups, p=0.055.
    - CSS - 34.26 from 20.41 points, mean difference - 13.85±8.51, p=0.11.
    - TSS - 42.94 from 19.22, mean difference - 23.71±10.07, p=0.022.

Improvement with 5 or more points in OSS score is observed in 92.8% of patients on a diet and physical activity regimen compared to 63.6% in the group who do not follow the nurse's guidelines, p=0.029. Improvement with more than 10 points in OSS is 82% compared to 54.5%, p=0.05, and with more than 20 points - 64% compared to 36%, p=0.09. Deterioration with more than 5 points in the result after 6 months is observed in 18% of those who do not follow the guidelines compared to none in the strict group, p=0.03, (Fisher's exact test).

Similar results are observed for the other domains - CSS and TSS, with greater improvement in the group that follows the dietary and physical activity guidelines:

- The changes in the EQ5 index between the two groups are insignificant, while in the visual self-assessment scale, the average improvement at 6 months is greater in those who follow the guidelines than in those who do not - the mean difference between the two visits is 0.17 in the first group compared to 0.09 in the second, with a mean difference between the two groups of 0.075, with borderline statistical insignificance of p = 0.06;
- Even though EF has improved significantly in the group that follows the diet and physical activity, with an average of 6.82% compared to no real

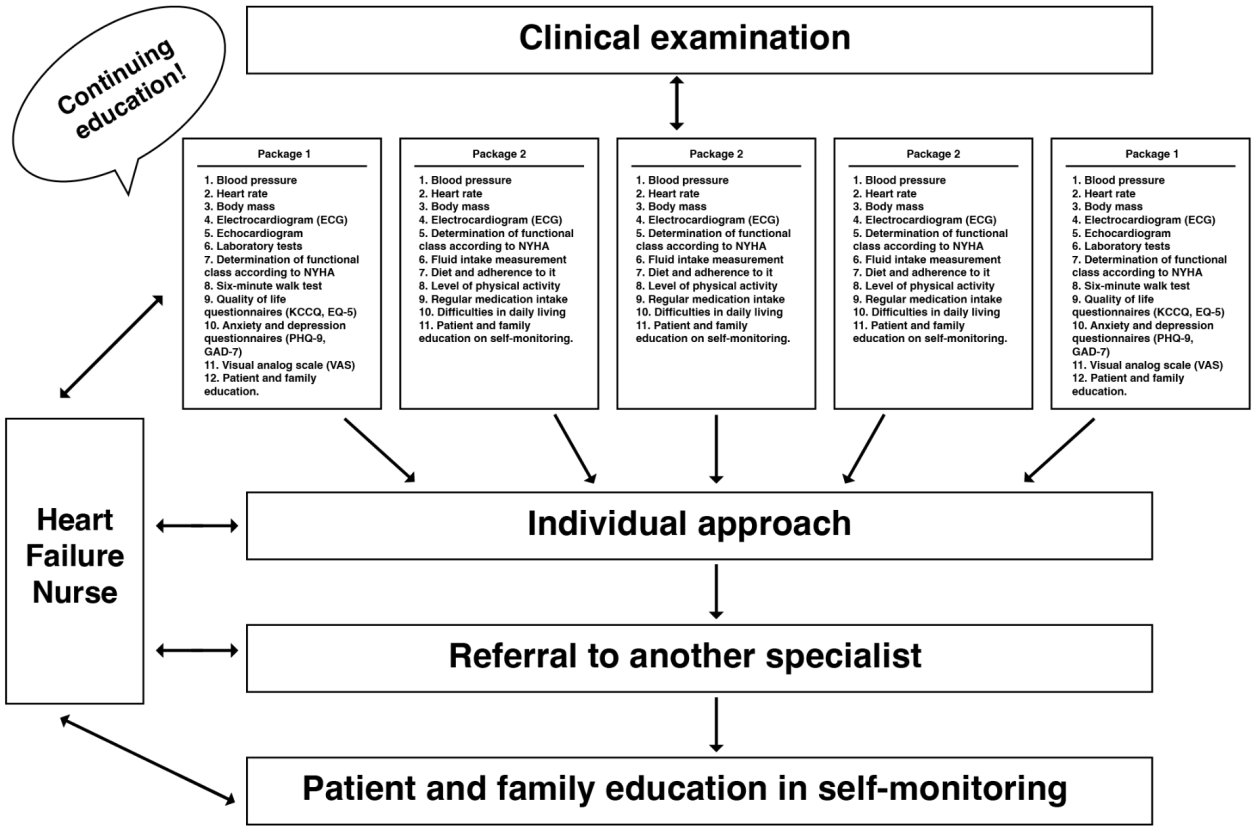
change in the other group (-0.36%). This represents a mean intergroup positive difference of 7.19%, p = 0.007;

- The improved functional status and greater quality of life have positively affected the psychological health of those who follow the lifestyle guidelines. They have reduced their anxiety by an average of 2.69 points according to the GAD7 questionnaire, while in those who do not follow the guidelines, this change is only 0.36 points. The mean intergroup difference is 2.33 points, p = 0.032. The change in depressive attitudes is similar, although the difference is not so strongly expressed. Those who follow the guidelines have reduced their depressive attitudes by an average of 1.73 points, while in the other group, the change is minimal - only 0.18 points. The intergroup difference here is 1.55 points, which is not statistically significant (p = 0.39).

IV. Management of Heart Failure - A Challenge in Nursing Practice

4.1. Model of Nursing Care for Patients with Heart Failure

- The results of the clinical study show improved condition and increased quality of life among patients with heart failure. The role of the nurse is focused on providing coordinated care that encompasses health and educational aspects. In partnership with medical specialists, comprehensive cardiology care is provided, which gives us the basis to propose the establishment of the Model of Nursing Care for Patients with Heart Failure introduced for the purposes of the study (Scheme 1.).



Scheme 1. Model of nursing care for patients with heart failure

The results of the study show that multidisciplinary care to support patients with heart failure has a positive impact on the well-being and quality of life of these patients. The care model ensures that every patient with heart failure has access to an appropriate specialist, medical examination and disease management, as well as coordinated nursing care.

The model for outpatient cardiology care is coordinated by an experienced nurse in caring for patients with heart failure. The model includes two main packages of healthcare distributed in five visits, tailored to the specific nature of the disease and the necessary tools for assessing the patient's condition.

Package 1 includes activities performed during the first and fifth visits: measurement of basic indicators such as blood pressure, heart rate, and body weight; evaluation of echocardiographic parameters by a physician, including electrocardiography and echocardiography; laboratory tests for creatinine, sodium, potassium, chloride, and NT-proBNP; determination of functional class according to NYHA; a 6-minute walking test (or a 4-meter walking test if the former is impossible); assessment of quality of life using standardized questionnaires (Kansas City Cardiomyopathy Questionnaire - KCCQ; 5-level

European Quality of Life questionnaire - EQ5; Patient Health Questionnaire-9 for depression assessment - PHQ 9; Generalized Anxiety Disorder-7 questionnaire with a visual analog scale - GAD 7 (VAT)); training for patients and their relatives on treatment and care guidelines, including proper diet, fluid intake (amount), physical activity, medication intake, monitoring of body weight and blood pressure; provision of training materials, including an information booklet on heart failure and a passport for monitoring the patient's condition.

Package 2 includes activities performed during the second, third, and fourth visits: measurement and recording of blood pressure, heart rate, and body weight; analysis of the patient's condition, identification of actual or potential health problems; training for patients and their relatives on treatment and care guidelines, including proper diet, fluid intake (amount), physical activity, medication intake, monitoring of body weight and blood pressure.

During each follow-up visit, patients receive advice on nutrition, fluid intake, salt consumption, etc. Patients and their relatives are trained to recognize signs of deterioration and ways to deal with them. All patients receive a patient passport that is created according to the standards of the Optimize Heart Failure Care program for outpatient monitoring. Patients and their relatives also receive a contact phone number for the outpatient clinic. Demographic data and data from physical examinations are tracked, including basic demographic data such as gender and age. The date of discharge from the hospital, which coincides with the first examination or enrollment in the monitoring program, is documented. Height and body weight are also recorded.

Patient information is collected on the symptoms of heart failure - fatigue at rest or during physical exertion, shortness of breath when lying down, abdominal swelling, and peripheral edema. Based on the data, the NYHA functional class is determined at the start of the 6-month observation period.

Patient information is also collected through a **checklist** developed for the purposes of the study. It is a specially designed list of significant indicators for controlling heart failure. The document provides information on the patient's behavior when adhering to conditions for living with heart failure and serves as a tool for planning nursing care. The checklist is individualized for the patient and is completed during each visit.

CHECKLIST

FOR THE CONTROL OF HEART FAILURE

Visit No. .....

Name, middle name, last name: .....

Age: .....

Diagnosis: .....

Accompanying illnesses: .....

Indicator	Yes	No	Comment
Understanding of the disease Heart failure			
● Understands the significance of the disease			
● Evaluates their condition correctly			
● Identifies changes in their condition			
● Risk of low self-esteem			
● Risk of role changes			
Medication therapy			
● Knows the prescribed medications			
● Indicates the correct time of intake			
● Indicates the correct dosage for intake			
Dietary regimen			
● Appetite			

• Number of meals			
• Meal times			
• Preferred type of food			
• Quantity of food per intake			
• Adheres to the recommended amount of salt (2 grams per day)			
• Adheres to the recommendation to limit fats			
• Intake of fresh fruits and vegetables			
• Nausea			
• Vomiting			
Fluid control			
• Type of fluids			
• Adheres to recommendations for fluid intake (1.5 liters per day)			
• Swelling in the lower extremities			
• Weight gain			
• Skin turgor			
Physical activity			
• Daily activity up to 30 minutes			
• Daily activity over 30 minutes			

● Exercises			
● Walk			
Healthy sleep			
● Daytime rest			
● Nighttime sleep (hours)			
● Sleep disturbances			
● Orthopnea			
● Paroxysmal nocturnal dyspnea			
● Nocturia			
● Arrhythmia			
● Obstructive sleep apnea			
● Psychological problems			
Impact of nicotine			
● Smoking			
● Use of e-cigarettes			

Patient condition analysis provides an opportunity to determine care directions and improve quality of life. Continuous care at different levels is necessary in the management of heart failure. The overall assessment of the patient's condition includes symptom control; management of medication therapy; risk factors for cardiovascular disease; functional activity; functional status according to NYHA; nutritional status; fluid intake; lifestyle and habits; psychosocial problems; social support.

For the purposes of the study, a **File** has been created for each monitored patient, which includes: questionnaires for assessing quality of life; questionnaires for assessing levels of depression and anxiety; medical documentation; results of instrumental and laboratory studies; patient observation card; condition assessment checklist.

The created nursing care model allows for an individual approach to each patient for faster adaptation to the change in lifestyle imposed by the disease.

The multidisciplinary care approach is a priority in the created model, in which the nurse is the main driver and coordinator in interaction with other specialists - doctor, physiotherapist, psychologist, psychiatrist, dietitian.

Patient and caregiver education is an essential component of the care model. Awareness about dietary regimes, physical activity, fluid intake, proper and continuous medication adherence as prescribed by the doctor, and many approaches to cope with daily challenges are crucial stages of managing a disease. The results of studies conducted have established insufficient awareness, knowledge, and skills for care and disease management.

Patients with heart failure often have significant needs for both complex and self-care. Poor knowledge and understanding of these needs lead to inadequate self-care and poorer outcomes.

Training patients and their caregivers in self-monitoring and care, as part of the Nursing Cardiology Care Model, leads to better outcomes and understanding of the disease. Information is presented in an accessible and understandable way to help patients and their caregivers recognize the signs and symptoms of heart failure, make adequate and timely decisions, and know when to contact their doctor for primary care and when to signal for emergencies. The training is related to risk behavioral factors, manifestation of symptoms of exacerbation of heart failure, self-monitoring of physical activity, dietary regimes, and fluid intake. The results show a positive change in the condition of patients with heart failure included in the tracking program, significantly improving their overall condition and quality of life. Patients lack the necessary information, skills, and knowledge to cope with recognizing symptoms of exacerbation and potential complications. Therefore, training in self-care and coping has shown significant success among patients with heart failure.

All activities and care related to tracking patients with heart failure and quality of life are most effective when provided by trained or certified cardiac nurses. Continuing education is a requirement for improving and enhancing patient care and a necessity for continuous implementation. The teams that provide care for patients with heart failure are important partners in the overall process.

4.2. Cardiology nursing care office

Based on a functioning office, with a main coordinating doctor - a cardiologist, for outpatient monitoring of patients with heart failure, located at the Second Clinic of Cardiology, Department of Non-Invasive Cardiology at UMBAL "St. Marina" - Varna, the activity of monitoring patients with heart failure is reorganized into an outpatient monitoring office, led by a nurse (Fig. 24).

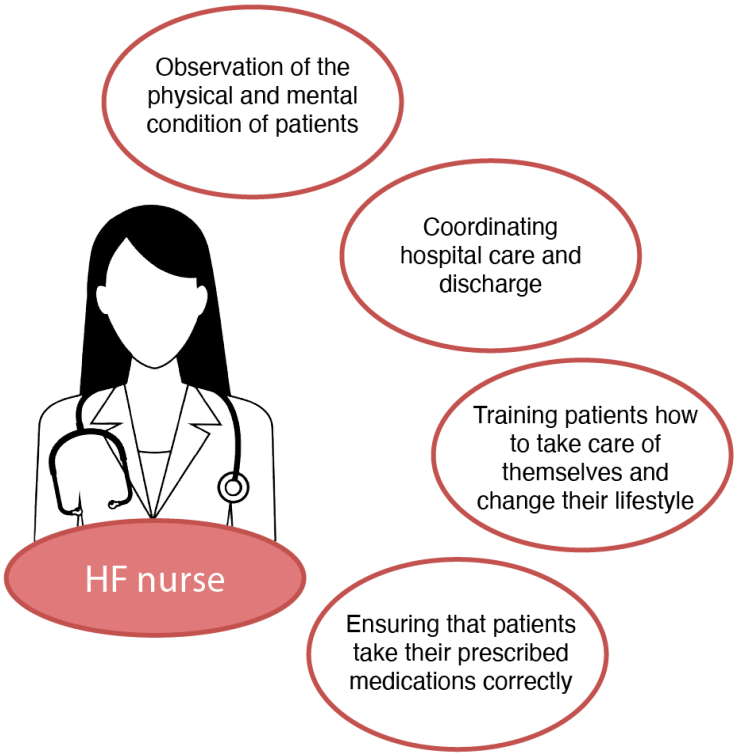


Figure 24. Main aspects of the heart failure clinic

Basic aspects of the activity of the Heart Failure Clinic, led by a nurse, are focused on:

1. **Clinical monitoring of patients with heart failure** - reducing factors that favor exacerbation of heart failure; monitoring and maintaining hemodynamic indicators responsible for worsening of the general condition; performing functional and physical tests as a measure of patients' physical abilities; tracking laboratory indicators that provide information on the need for changes in behavior and treatment; educating patients and their families; completing questionnaires related to quality of life, anxiety, and depression levels.

The practical health value of the heart failure clinic is to help provide effective comprehensive health care for patients with heart failure. The developed model of behavior, individual approach, and organization of nursing activities and care are aimed at improving the well-being and quality of life of patients with heart failure. Comprehensive care in this area is aimed at delaying and slowing down disability, reducing rehospitalizations, and providing psychological support.

Patient monitoring can take place in the clinic, over the phone, through home visits, in clinics led by a nurse, group rehabilitation, or a combination of methods.

2. **Scientific-educational activity** - the applied model for monitoring patients with heart failure laid the foundation for cardiological nursing care, which requires ongoing and developing education, expanding knowledge in the field of cardiological health care and public health. The need for ongoing and specialized training is outlined in order to improve and enhance the competencies of nurses. The activities provided in the cardiological nursing care clinic create conditions for training, participation in scientific forums to popularize the results of the activity.
3. **International partnership -** Heart Failure Clinics date back more than 25 years in many European countries in Central and Eastern Europe. This creates opportunities for international cooperation and exchange of experience with healthcare professionals, leaders of similar heart failure clinics. Partnership helps integrate the health skills and care of nurses into the overall European space and improve the quality of care for patients with heart failure, as they incorporate the best practices in Europe and the world. Exchange of useful practices creates conditions for conducting international joint research and projects.

The main task of the nurse providing activities and care for patients with heart failure is to achieve the best possible quality of life within the limitations imposed by the disease.

4.3. Nursing process in heart failure

The specificity of heart failure poses a number of challenges and requirements for the nurse in the monitoring of patients. Implementing the nursing process (including organization, planning and training) is an important

stage in multidisciplinary care and a framework for providing professional and quality healthcare by a trained nurse. This allows the entire team participating in the therapeutic and supportive process to become familiar with the specifics of heart disease, proper behavior and timely and accurate intervention.

The increasing needs of patients in all aspects of daily life affected by the disease lead to requirements related to the organization and management of heart failure, which are mainly aimed at organizing care with two main aspects:

- Application of a care model for patients with heart failure
- Application of a holistic approach and patient-centered care

Organizing patient-centered care meets the needs of the disease and the possibilities for overcoming difficulties in daily life.

Patients with heart failure use many different medications, which must be taken at different times relative to meals. The organization of the hourly intake is a prerequisite for regular intake and compliance with the prescribing physician's instructions. The nurse responsible for heart failure patients must ensure that they take their medications correctly and understand the importance of regular intake.

For heart failure patients, there is a need to change the organization of activities that promote overall well-being. Overcoming daily challenges in the best way possible reduces the risk of deterioration in the patient's general condition and increases their confidence and ability to cope with the disease.

Healthcare professionals take responsibility for assessing and caring for patients within the scope of professional nursing practice, communicating with the team, and administering prescribed medical care. The rapid changes in practice related to maintaining the health and quality of life of heart failure patients require the nurse to maintain knowledge and skills in managing outpatient cardiology care. The key roles of the nurse in treating heart failure are largely focused on monitoring and observing high-risk patients (for readmission to the hospital). All of this has prompted the development of **Guidelines for caring for heart failure patients**, which guide the nurse's activities in assessing patient conditions and managing heart failure. The nurse's actions ensure proper management of cardiac nursing care. The nurse shares responsibility for treatment outcomes with other medical specialists and patients. The guidelines for professional practice in heart failure describe the

competent level of care that nurses in cardiology practice should follow. The guidelines define professional values, knowledge, skills, and behavior that the nurse can apply in accordance with their professional competence. They provide a framework for setting goals, planning, implementing, and evaluating care for patients in cardiology. The main goals are to ensure evidence-based professional management, continuity of care, documentation, and systematic collection of data to establish good practices in the field of non-invasive cardiology.

GUIDELINES FOR CARE OF PATIENTS WITH HEART FAILURE

1. Initial clinical evaluation

- Basic indicators (breathing, blood pressure, heart rate, body weight)
- Appearance and general condition (patient's consciousness, position in bed, facial expression, skin condition, color of nails and visible mucous membranes, presence of edema)
- Signs and symptoms (dyspnea, orthopnea, wheezing, paroxysmal nocturnal dyspnea, acute chest pain, fatigue, weakness, edema, bloating of the abdomen, distension of the jugular vein, loss of appetite, and changes in weight)
- Sleep (quality, disruptions - sudden interruption due to dyspnea)
- Anxiety
- Previous diseases (coronary artery disease, myocardial infarction, hypertension, heart valve disease, myocarditis, congenital heart defects, heart arrhythmias or other long-term, chronic conditions that are poorly managed, such as diabetes, HIV, hyperthyroidism or hypothyroidism)
- Health needs and risk factors (coronary artery disease, myocardial infarction, hypertension, atrial fibrillation, diabetes, overweight, tobacco smoking, alcohol use disorder, thyroid disease, congenital heart disease, aortic stenosis)

2. Ongoing monitoring and management

- Hemodynamic parameters.
- Symptoms and signs (dyspnea upon exertion, orthopnea, fatigue/weakness, swelling in the lower extremities, anasarca, tachycardia, irregular heartbeat, low tolerance for physical activity, persistent cough, wheezing, abdominal distension, rapid weight gain, nausea, loss of appetite, chest pain).
- Effectiveness of therapy.

- Monitoring of kidney function, fluid balance, and urine output.
- Instrumental investigations (electrocardiography, echocardiography).
- Laboratory investigations (complete blood count, serum electrolytes, blood urea nitrogen, creatinine, liver function test, brain natriuretic peptide (BNP) or NT-proBNP).
- Patient's ability to understand and implement self-management strategies.
- Assessment of the patient's ability to manage potential risks

3. Analysis of information and data, identification of potential or actual patient problems.

- Reduced cardiac output (fatigue, weakness)
- Intolerance to activity
- Excess fluid volume (dyspnea, orthopnea, edema, pain from hepatic congestion and ascites).
- Risk of skin integrity impairment (orthopnea)
- Ineffective tissue perfusion
- Ineffective breathing pattern (shortness of breath at rest and/or upon exertion, paroxysmal nocturnal dyspnea)
- Impaired gas exchange
- Fatigue
- Poor memory and impaired cognition (confusion or impaired attention)
- Anxiety.
- Weakness
- Ineffective management of therapeutic regimen

4. Strategy for achieving the best possible outcome for the patient

4.1. Formulation of care goals - short-term and long-term

- By the end of the hospital stay, the patient should recover hemodynamic stability with vital signs, cardiac output, and renal perfusion within normal limits.
- By the end of the first month, the patient's clinical results should be improved.
- Change in lifestyle through activities that reduce the workload on the heart.
- By the next visit, the patient should report no chest pain or shortness of breath.
- Within 3 months, the risk of readmission should be reduced.

4.2. Care planning

- Encouraging physical activity

- Reducing fatigue
- Symptom relief
- Reducing anxiety
- Increasing the patient's ability to manage anxiety
- Educating the patient on self-control and proper behavior (dietary regime, limiting sodium intake to 2-3 g/day, daily fluid restriction to 2 L/day, self-monitoring of symptoms, daily tracking of body weight, adhering to medication therapy, control of comorbidities)
- Educating the patient's family members about treatment and care guidelines (proper dietary intake, fluid intake and quantity, physical activity, medication intake, monitoring of body weight and blood pressure)
- Adherence to the dietary regime.
- Following a motor mode
- Following medication treatment

5. Execution of the care plan (performing activities and care - dependent, interdependent, and independent)

5.1. Priority activities and care

- improving the patient's overall condition and heart function.
- reducing fluid intake.
- preventing complications.
- providing information about the disease, therapy needs, and preventing relapses.

5.2. Direct and indirect care and activities

- maintaining patient comfort - positioning in the Fowler position in the hospital bed, providing an additional pillow (if needed).
- measuring, recording, and evaluating vital signs.
- tracking and recording laboratory tests, manipulations, and health care.
- supporting breathing.
- recognizing life-threatening conditions and taking timely action.
- prophylaxis and counseling the patient for heart failure.
- advising individuals at increased risk of rehospitalization.
- educating the patient and their relatives - developing a training program, involving the patient in the therapeutic regimen, explaining the rules and the need for strict adherence to medication intake, adhering to a low-sodium diet - limiting fluid intake, recommendations for physical

activity, quitting smoking, learning to recognize signs and symptoms of worsening heart failure.

- Anxiety control - taking care of mental, physical, and social health, providing psychological support, training in techniques and methods for controlling anxiety, avoiding psychological risks, and support in decision making.
- Fluid management - assessment of edema, daily monitoring of body weight, through recording at the same time, on the same scale, advice on hygiene and nutrition, maintaining a low-sodium diet regimen, control of fluid intake for the day, advising on placing the water in a container from which the amount of fluid intake can be easily determined.
- Documentation of the amount of fluid intake, the amount of intravenous infusion solutions administered, and the amount of urine output.
- Management of physical activity - together with the treating physician, developing a daily physical activity program, creating a schedule, setting priority activities, and providing support and control during implementation.
- Assistance in avoiding dangers - ensuring patient safety by avoiding psychological and physical risks.
- Providing a peaceful environment.
- Emotional support.
- Assistance in strengthening, adapting, and reintegrating individuals into the family and social environment.

6. Observation and evaluation of the patient's progress towards expected outcomes or goals.

- Increased physical activity
- Maintaining fluid balance
- Reduced anxiety
- Accurate assessment of the situation and self-care
- Compliance with medication treatment
- Normal body weight
- No peripheral edema detected.
- The patient names the recommendations for the dietary regime and fluid restrictions to be followed.

The care guidelines for heart failure, led by a nurse, provide individualized care, continuous collaboration with the patient, effective training,

implementation of a holistic approach, and flexibility in choosing specialists for consultations.

4.4. Planning and organizing care related to unforeseen situations in the follow-up of patients with heart failure

Planning activities and disease prevention find wide application in the monitoring of patients with heart failure. Immunization, vaccination, and prevention of infections are important measures aimed at preventing deterioration of heart failure symptoms, which are discussed in the provided Package 1 and Package 2 activities in the applied care model for patients with heart failure. Patients are at risk of bacterial and viral infections, which can exacerbate the symptoms of chronic illness. In the heart failure clinic, prevention and planning of prevention-related activities are an important stage of monitoring. Patients are informed about the risks and at least once a year (due to seasonality), influenza vaccination is planned, including against COVID-19.

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. COVID-19 is a highly infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2), which spreads rapidly worldwide. COVID-19 is a risk factor for patients with heart failure, requiring hospitalization, including the need for mechanical ventilation and a higher risk of death. This required all stable ambulatory patients with heart failure (without sudden cardiac events, without clinical deterioration and without symptoms) to refrain from visiting the heart failure clinic, unless it is very urgent, in order to minimize the risk of infection. At this point in the program, there was a need to apply various forms of telemedicine - consulting with patients included in the study from a distance through an internet-connected device such as a computer, tablet, or smartphone. Remote monitoring by phone (telemonitoring), the use of electronic health tools, and digital health applications were a reliable method for tracking routine activities and providing advice, especially during an epidemic, living remotely, or being unable to visit the heart failure clinic. The use of remote telemonitoring assisted in the effective tracking of patients by providing information on the clinical condition and hemodynamic parameters measured by patients at home through the device or apparatus they routinely use. Patients provided data on body weight, blood pressure, heart rate, the presence of edema, or new symptoms that cause concern. The data were entered into the Tracking Card, compared to previous data, and an assessment of the overall condition according to the NYHA class of heart failure was performed. Factors

predisposing to hemodynamic deterioration were also evaluated and timely discussed with patients. The approach used also allowed for the discussion of issues that concerned patients, having a significant positive effect on their psycho-emotional state. It provided reliable and fast communication with a medical specialist in case of an acute condition, without losing time waiting and searching for the appropriate specialist. Remote monitoring allowed the heart failure patient to maintain contact with the monitoring center by phone. This was a way to reduce the number of planned or unplanned visits to the heart failure clinic during an epidemic, as well as to provide easier access to patients living in more remote areas, which provided greater patient safety and peace of mind, knowing that they have direct contact with a medical specialist in case of an acute condition.

4.5. The Role of Healthcare Professionals in Monitoring Patients with Heart Failure

With the development of medicine, the importance of healthcare services related to continuous improvement of the knowledge and skills of the nurse in their provision is increasing. Trained nurses have the opportunity to meet the growing needs of patients with heart failure by providing specialized and quality nursing care.

The objective assessment of the patient's condition enables the heart failure nurse to plan and anticipate their actions regarding control, the impact of risk factors, and the education of patients with heart failure.

The introduced specialized nursing documentation, in which the heart failure nurse accurately and clearly reflects hemodynamic indicators, symptoms, laboratory indicators, observes dynamics, monitors symptoms, enables the application of a nursing process, clear and accurate reporting of the activities carried out and the recommendations given.

The observation card, the heart failure control Checklist, as well as the specialized questionnaires for quality of life and tendencies towards depression and anxiety, are the main specialized methodology in monitoring patients with heart failure, which has shown excellent results in providing specialized care.

Cardiovascular diseases are a global health problem, and nurses working in the field of cardiology have a vital role in reducing the global burden and contributing to improving outcomes for patients and the community suffering from cardiovascular diseases.

Good managers in the care of patients with heart failure can create and manage care teams, set appropriate goals and tasks for their teams and patients, make effective decisions, and plan and prioritize tasks. This results in better quality of care for patients and their families or caregivers.

The role of the nurse manager is particularly important because, working as part of a multidisciplinary team, it is necessary to create good work organization. Knowledge and skills are necessary for the training of patients, tailored to their individual needs, in order to identify and make the most appropriate choice for each individual case.

The heart failure nurse, taking a leading role in the multidisciplinary team, organizes activities related to the health of the patients, aimed at:

- reducing the number of unplanned and premature hospitalizations and the length of stay in the medical facility;
- improving the quality of care, and respectively, the quality of life of the patient;
- providing support to heart failure patients, teaching them to care for and manage their illness independently, following the doctor's instructions;
- establishing links with other specialists and facilitating communication, as the driving force behind the multidisciplinary team;
- maintaining an individual approach to patient care;
- encouraging a holistic approach to care, which takes into account the psychological and social needs of the patient;
- providing psychological support to patients and their families.

The participation of the nurse, independently or in a multidisciplinary team, in the monitoring, prevention, treatment, and rehabilitation of patients at risk or with cardiovascular disease is well popularized and advocated in many European countries. A similar care model has been developed in Poland, where specialists in heart failure continue to optimize and improve the condition of patients.

The developed and implemented ***Model for Ambulatory Nursing Care*** in a Cardiology Care Unit has created the opportunity for organization in line with the competencies of nurses in Bulgaria. According to the researched sources in different countries, the methodology, organization of work, and monitoring of patients with heart failure have varying levels of organization based on the authority of nurses, qualifications, and level of service.

The Patient Assessment Chart is a valuable methodological guide for nursing practice in registering and tracking the specific needs and requirements

of heart failure patients. It helps to fully and consistently account for the individual characteristics and needs of specific patients within a comprehensive clinical and complex systematic observation framework. The entire process of organizing, planning, and training also provides opportunities for continuous optimization of care for heart failure patients and seeking new ways to deal with the challenges imposed by the disease. The assessment of healthcare professionals includes a clinical analysis with the identification of relevant health problems and the development of an individual approach based on the patient's needs. All measures related to the monitoring and well-being of patients with cardiovascular disease lay the scientific foundation for nursing practice in heart failure patients and broaden the theoretical and practical knowledge of healthcare professionals in this area.

V. Conclusions, proposals, and contributions

5.1 Conclusions

The results of the conducted study provide a basis for the following conclusions:

1. Different countries around the world have established practices for caring for patients with heart failure. There is a key role of trained heart failure nurses observed.
2. The model for ambulatory nursing care shows a positive effect in symptom management for patients with heart failure.
3. The practical application of the Model for Ambulatory Nursing Care improves the quality of life of patients with heart failure, improves ejection function, physical capacity, which is confirmed by the positive results from NT proBNP and 6-minute walk test.
4. Cardiological nursing care reduces the risk of recurrent or subsequent hospitalization of patients with heart failure.
5. The hypothesis that ambulatory nursing care will help maintain, improve, and restore health, achieve increased well-being and satisfaction of patients with heart failure, has been confirmed.
6. The positive effect of disease monitoring and the absence of significant decompensation of heart failure are confirmed by the data in the study, which show a retention of consistency in body weight in the first two visits and a more significant decrease in the following three, with a

reduction in body weight by an average of 2 (two) kilograms at the end of the follow-up (6 months).

7. In the group of patients followed by a nurse, there is a predominance of individuals with improvement in renal function (53%), improvement in NT-proBNP biomarker (94.7%), adherence to a dietary regime (78%), and physical activity (62.5%), thus supporting the role of healthcare professionals in the ambulatory control of the disease.
8. The nurse less frequently directed patients to another specialist (57.1%) compared to the group followed by a cardiologist and nurse 47.1% (p=0.028).
9. Improvement in the quality of life of patients is established within 6 months, which correlates with the other results for improvement in the distance covered in 6 minutes and improvement in the functional class according to NYHA.
10. Patients monitored by a nurse have significantly better quality of life according to the EQ-5D scale (0.71).
11. The degree of manifestation of depression and anxiety (GAD7>8 points) at the end of the follow-up is lowered or completely eliminated compared to the initial data, 6 (9.5%) versus 26 (37%) initially, p=0.017.
12. Patient and family education has a favorable impact on adaptation to the changes and limitations imposed by the illness.
13. Compliance with the nurse's instructions for dietary and exercise regimes during the monitoring of patients with heart failure leads to significant improvements in hemodynamics, self-confidence, functional status, quality of life, and anxiety-depressive moods (regardless of medication treatment provided to all patients).

5.2. Proposals

1. **Proposals to the Ministry of Health:**

- To establish a specialization program "Heart Failure Nurse" under Regulation No. 1 of 2015 for acquiring a specialty in the healthcare system;
- To establish a standard for nursing activities and care in heart failure;
- To regulate the nursing process in cardiology practice.

2. **Proposals to Medical Universities regarding increasing the competencies of nurses in cardiology practice:**

- To develop and propose for approval a specialization program "Heart Failure Nurse" under Regulation No. 1 of 2015 for acquiring a specialty in the healthcare system;
- To develop a curriculum in the field of cardiology healthcare for individual or group training of healthcare professionals in the healthcare system;
- To organize seminars and workshops for developing new competencies and specific professional behavior of nurses in the field of cardiology practice for the clinical follow-up of patients with heart failure.

3. Proposals to healthcare institutions regarding the activities and care of the nurse in the field of cardiology:

- To develop and implement rules for good nursing practice in cardiology;
- To develop and introduce specific nursing documentation for monitoring the condition of patients with heart failure;
- To develop and propose programs for training patients and their relatives in the control and management of cardiovascular diseases;
- To encourage continuing education of nurses in the field of cardiology by providing opportunities for training and professional development;
- To create conditions for independent activity of the nurse for the clinical follow-up of patients with heart failure.

5.3. Contributions

Based on the conclusions, suggestions, and results from our own research, we would like to note the following elements of a contributory nature:

Theoretical and cognitive:

- A systematic review of the epidemiology of heart failure has been conducted.
- For the first time, the management of cardiological care has been researched and analyzed.
- The beginning of theoretical and clinical nursing in the field of cardiology has been established.
- Scientific foundations have been laid in nursing practice for providing activities and care to patients with heart failure, which leads to the

expansion of theoretical and practical knowledge of healthcare professionals.

- Observations and evaluations of the condition of patients have been conducted through a self-developed clinical research methodology.
- Data on the physical condition of patients with heart failure have been presented.
- For the first time, a model for the organization of cardiological nursing care in outpatient settings has been developed.

Practical-applied:

- Guidelines for care of patients with heart failure have been developed, optimizing processes in cardiac healthcare.
- A Checklist for control of heart failure registration has been developed, providing information on patient behavior when complying with conditions for living with heart failure.
- The first in the country clinic for monitoring patients with heart failure led by a nurse has been established.
- The first of its kind comprehensive, targeted, and in-depth cardiac care model for patients with heart failure in an outpatient clinic has been developed and implemented in practice.
- The role and significance of the nurse in heart failure as the main driver in a multidisciplinary team have been outlined.
- Factors favoring the progression of heart failure in a specific patient have been identified - non-compliance with the therapeutic plan, difficult control of body weight, poor control of blood pressure, incorrect diet and exercise regimen.

PUBLICATIONS AND PARTICIPATION IN SCIENTIFIC FORUMS RELATED TO THE DISSERTATION WORK

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2. Georgieva M., M. Rushid, S. Borisova, K. Genova, L. Mircheva, Y. Yotov (2020). Depression and anxiety in patients with heart failure. Healthcare. VIII (3):18-24.
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4. Georgieva M., M. Rushid, S. Borisova, L. Mircheva, Y. Yotov (2020). Good nursing practice in an ambulatory office for heart failure management, Asklepios, International Annual of History and Philosophy of Medicine, vol. XVI, 108.
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7. Georgieva M., M. Nankova, Y. Yotov, S. Borisova (2020). Physical activity in patients with heart failure: in the Seventh National Student Scientific Session - Pleven "Trends in healthcare in the 21st century". Proceedings of the Medical University of Pleven.