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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

THE ROLE OF INSTRUCTION, SELF-MONITORING, AND "HOTLINE" IN THE REGULATION OF ARTERIAL HYPERTENSION AND METABOLISM IN TYPE 2 DIABETES

Speciality: 3205.01 - Internal Diseases

Branch of Science: Medicine

Applicant: **Kubra Alik Garibova**

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The work was performed at the Department of Internal Diseases 1 of the Azerbaijan Medical University and at the Azerbaijan Association of Endocrinology, Diabetology, and Therapeutic Guidance.

Scientific Supervisor: Doctor of Medical Sciences, Professor
Vasadat Ali Azizov

Scientific Advisor: Doctor of Medical Sciences,
Associate Professor
Valeh Aghasafa Mirzazade

Official Opponents: Doctor of Medical Sciences, Professor
Azar Alijabbar Karimov

Doctor of Medical Sciences,
Associate Professor
Eldar Mursal Hatamzade

Doctor of Philosophy in Medicine
Gunay Aliheydar Ismayilova

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Alihuseyn Alishan Hidayatov

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Nazim Adil oğlu Pənahov
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GENERAL CHARACTERİSTİCS OF THE WORK

Relevance of the Topic: Type 2 diabetes (T2D) and arterial hypertension (AH) are two of the most critical cardiovascular risk factors, leading to a high number of cardiovascular events and deaths worldwide. Both conditions are widespread chronic pathologies. According to the 2019 IX edition of the International Diabetes Federation, the number of people with diabetes worldwide is 463 million.[1] This number is expected to rise to 578 million by 2030 and 700 million by 2045, representing a 51% increase. An analysis of the dynamics of the changes in the number of diabetic patients from 2000 to 2019 raises strong concerns: a threefold increase. Nearly 5 million deaths annually are related to diabetes[2].

The number of patients with arterial hypertension was 600,000 in 1980, rose to 1 billion in 2008, and is expected to reach 1.5 billion by 2025. In untreated patients with arterial hypertension, the risk of hospitalization, re-hospitalization, and early death increases by 5.4 times. Annually, 9.4 million deaths are linked to arterial hypertension.[3]

In patients where both pathologies coexist, the risk of microvascular and macrovascular complications is higher.[4] Elevated blood pressure in T2D significantly increases the risk of developing ischemic heart disease, stroke, nephropathy, and retinopathy.

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[1] IDF Diabetes Atlas, 9-th ed, International Diabetes Federation. 2019. 176 p.

[2] F.Cosentino, P.J. Grant, V. Aboyans et al. 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD. The Task Force for diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD) // European Heart Journal, - 2019. – p.1-69.

[3] V.Peberty (IFPMA). Hypertension: Putting the Pressure on the Silent Killer. 2016, https://www.ifpma.org/wpcontent /uploads/2016/05/2016 - Hypertension - putting-the-pressure-on-the-silent- killer.pdf

[4] Pavlou, D.I., Paschou S.A., Anagnostis P. et al. Hypertension in patients with type 2 diabetes mellitus: Targets and management // Maturitas, - 2018 .112 - p.71-77.

Approximately 40% of deaths in diabetic patients are associated with elevated arterial tension.[5]

Currently, there is substantial evidence supporting the benefits of effective glycemic control and blood pressure regulation in diabetic patients.[6] Unfortunately, despite the development of a wide range of pharmacological preparations for the management of diabetes and arterial hypertension, the effectiveness of therapy cannot be considered optimal. This is because some patients do not take their medications on time, and others fail to adjust their doses correctly. In this scenario, therapeutic education should form the basis for managing chronic diseases, including diabetes and arterial hypertension, as patients with chronic diseases directly control their conditions, determining the adequacy and utilization of therapeutic measures.[7]

Methods that ensure the continuity of education and foster interaction between patients and medical personnel are increasingly being used.

Objective of the Study: The aim of the research is to determine the impact of a therapeutic complex, which includes training, self-monitoring, and a "hotline" for patients with Type 2 Diabetes (T2D) and coexisting arterial hypertension (AH), on the effectiveness of metabolic and blood pressure management.

Research Tasks:

1. To study the dynamics of glycated hemoglobin levels in patients with Type 2 Diabetes mellitus combined with arterial hypertension who have not undergone structured training.

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[5] Wannamethee S.G., ShaperA.G., Whicup P.H. Impact of diabetes on cardiovascular disease risk and all-cause mortality in older men: influence of age at onset, diabetes duration, and established and novel risk factors // Archives of Internal Medicine., - 2011, 171. 5. - p.404–410.

[6] Zoungas S., de Galan B.E, Ninomiya T. et al. The combined effects of routine blood pressure lowering and intensive glucose control on macrovascular and microvascular outcomes in patients with type 2 diabetes; new results from ADVANCE. // Diabetes Care, -2009. 32 (I1). –p. 2068-2074.

[7] Zhang Y., ChuL. Effectiveness of Systematic Health Education Model for Type 2 Diabetes Patients. International Journal of Endocrinology, v.2018, Article ID 6530607, 9 p., https://doi.org/10.1155/2018/6530607

2. To study the dynamics of blood pressure indicators in patients with Type 2 Diabetes mellitus combined with arterial hypertension who have not undergone structured training.

3. To study the impact of structured training on glycated hemoglobin levels in patients with Type 2 Diabetes mellitus combined with arterial hypertension.

4. To study the impact of structured training on systolic and diastolic blood pressure indicators in patients with Type 2 Diabetes mellitus combined with arterial hypertension.

5. To study the impact of a "hotline" on glycated hemoglobin, systolic, and diastolic blood pressure indicators in patients with Type 2 Diabetes Mellitus combined with arterial hypertension.

Scientific Novelty of the Research:

■ A structured training system for patients with Type 2 Diabetes Mellitus combined with arterial hypertension was developed based on international experience and lifestyle characteristics.

■ It has been determined that conducting structured training for patients with Type 2 Diabetes Mellitus combined with arterial hypertension significantly reduces glycated hemoglobin levels, increases the frequency of achieving target parameters for glycated hemoglobin, and reduces the variability of glycated hemoglobin indicators.

■ Conducting structured training for patients with Type 2 Diabetes Mellitus combined with arterial hypertension significantly reduces SAP and DAP levels and increases the frequency of achieving target parameters for blood pressure.

■ It was determined that the use of a "hotline" system necessary for resolving acute situations does not lead to an improvement in glycated hemoglobin and blood pressure indicators.

The practical significance of the research:

■ Information indicating the need for optimization of pharmacotherapy in T2D patients has been obtained;

■ It has been determined that a structured training program based on international experience and lifestyle characteristics

reduces the level and variability of glycated hemoglobin and increases the frequency of target glycated hemoglobin levels in T2D patients with AH combination;

■ It has been found that a structured training program based on international experience and lifestyle reduces the levels of SAP and DAP and increases the frequency of target indicators in T2D patients with AH combination;

■ A “hotline” is an integral part of the general care for patients with diabetes and arterial hypertension and plays a significant role in resolving acute situations, although the existence of the “hotline” does not improve the indicators of glycated hemoglobin and arterial pressure. Moreover, the need for a “hotline” is higher when diabetes and arterial hypertension are poorly controlled.

Application of the research results. The results of the research have been applied in the practical activities of the Teaching-Therapeutic Clinic of the Azerbaijan Medical University and the Association of Endocrinology, Diabetology, and Therapeutic Instruction of the Republic of Azerbaijan.

Main provisions put forward for defense:

1. Specialized medical supervision significantly reduces HbA1c levels in T2D patients with AH. Within three years, it allows achieving "<7.0%" HbA1c indicators in 9.3% of cases and "<6.5%" in 1.9% of cases.

2. Specialized medical supervision significantly reduces SAP levels ("<140 mm Hg" in 31.5% of cases and "<130 mm Hg" in 3.7% of cases) and DAP levels ("<90 mm Hg" in 29.6% of cases and "<80 mm Hg" in 3.7% of cases) in T2D patients with AH.

3. The combination of structured training with specialized medical supervision statistically significantly reduces the average HbA1c level and its variability in comparison with those who did not receive structured training for T2D patients with arterial hypertension. At the end of the study, the frequency of achieving "<6.5%" HbA1c indicators was 1.9% in the first group and 25.3% in the second group ($p = 0.0002$). At point 7, the frequency of

achieving "<7.0%" HbA1c indicators was 9.3% in the first group and 52.4% in the second group ($p < 0.0001$). At the end of the study, the frequency of achieving "less than the HbA1c at point 1" was 64.8% in the first group and 100.0% in the second group ($p < 0.0001$).

4. The combination of structured training with specialized medical supervision statistically significantly reduces the average SAP and DAP levels compared to the group that did not receive structured training. In the first group, the average SAP level decreased from 148.8 ± 1.20 mm Hg to 143.3 ± 1.24 mm Hg ($p < 0.001$), while in the second group, it decreased from 148.3 ± 0.56 mm Hg to 133.6 ± 0.58 mm Hg ($p < 0.001$). Regarding diastolic arterial pressure, the average DAP level in the first group decreased from 96.1 ± 1.03 mm Hg to 91.7 ± 0.88 mm Hg ($p < 0.01$), and in the second group, it decreased to a more significant level – from 95.0 ± 0.53 mm Hg to 83.4 ± 0.41 mm Hg ($p < 0.001$).

5. The “hotline” is a necessary component of the diabetes and arterial hypertension treatment system and is considered important in resolving acute situations, but it does not affect changes in HbA1c, SAP, and DAP levels during planned treatment.

Published works. The main provisions and results of the research are reflected in 12 scientific works. 8 of them are scientific articles, with 5 published in local journals and 3 in foreign ones, while 4 are theses, 2 published locally and 2 in foreign languages.

Approval of the work. The results of the research were discussed at various scientific events: the scientific conference dedicated to the 75th anniversary of Prof. A. T. Aghayev. Public health and Healthcare. Baku, 2019; II International Congress of Applied Sciences Azerbaijan National Academy of Sciences, 8-10 November 2021; International congress “Actual problems of medicine” dedicated to the 100th anniversary of Professor Tamerlan Aliyev, Baku 2021. The dissertation was discussed at the interdepartmental scientific seminar on March 15, 2024, and at the meeting № 02 of the Dissertation Council`s Scientific Seminar

Approval Commission, operating under the Azerbaijan Medical University, held on May 22, 2024.

Volume and structure of the dissertation. The dissertation is recorded on 147 pages (195974 characteres) printed on a computer. Of which: " Introduction" (11777 marks), Chapter I (38841 marks), Chapter II (10746 marks), Chapter III (70947 marks), Conclusion (25596 marks), Results (2156 marks), Practical recommendations (916 marks). The references used in the dissertation include 174 literature sources. 4 of them in Azerbaijani, 11 in Russian and 159 in foreign languages. The work is illustrated with 32 tables and 44 diagrams.

RESEARCH MATERIALS AND METHODS

The patients involved in the study (n=224) were divided into two groups: the 1st group (patients who refused to receive structured training, n=54) and the 2nd group (patients who received structured training, n=170). The duration of the study for each participant was 3 years.

Inclusion criteria for the study were as follows:

- Concurrent presence of both T2D and AH in the patient;
- Age between 45 and 65;
- HbA1c level above 7.0%;
- Blood pressure (BP) below 180/110 mm Hg.

The criteria for exclusion from the study were as follows:

- The person under examination did not consent to participate in the study;
- Non-compliance with the examination conditions;
- The patient has previously undergone structured training;
- The necessity for insulin therapy;
- Presence of acute or chronic kidney pathology (GFR < 60 ml/min/1.73m²);
- Liver functional disorders (ALAT, ASAT > 80 U/L);

■ Presence of cardiovascular pathologies (previous myocardial infarction, previous coronary artery bypass grafting or stenting, clinically manifested heart failure);

■ Severe complications of T2D (significant vision impairment, amputations, clinical signs of autonomic diabetic neuropathy);

■ Presence of significant cognitive impairment;

■ Presence of other serious comorbid pathologies.

The study participants consisted of 50.0% (n=112) women and 50.0% (n=112) men. The patients' ages ranged from 45 to 65, with an average of 56.9±0.42 years. The average height was 167.5±0.44 cm (154-181 cm), the average weight was 85.7±0.81 kg (56-114 kg), and the average BMI was 30.6±0.28 kg/m² (22.1-40.7 kg/m²). Normal body weight was observed in 10.3% (n=23) of the study participants, overweight in 38.8% (n=87), and obesity in 50.9% (n=114).

The medical history of 179 (79.9%) patients who participated in the study included diabetes mellitus. The duration of diabetes mellitus ranged from 0 to 9 years, with an average of 3.9±0.20 years. 80 patients (35.7%) had a history of AH. The average ASAT levels were 27.2±0.58 U/L, ranging from 10 to 51 U/L. ALAT levels ranged from a minimum of 12 U/L to a maximum of 58 U/L, with an average of 30.6±0.65 U/L. The average creatinine level was 0.85±0.009 mg/dL, with a minimum of 0.45 mg/dL and a maximum of 1.2 mg/dL. The average GFR was 86.5±14.29 ml/min/1.73 m², with a minimum of 61 ml/min/1.73 m² and a maximum of 136 ml/min/1.73 m².

Structured Training of Patients

The training system was developed based on existing international recommendations. Typically, the training of patients was individualized. To increase the effectiveness of the training, family members living with the patient often participated in the process. In some cases, group training was applied (with a maximum

of 3 people per group, considering age, psychological, and intellectual compatibility).

"Hotline" System and Its Usage

The "hotline" system was created using both local and international experience. Each participant in the study was provided with a card containing the telephone number of the hotline of the Endocrinology, Diabetology, and Therapeutic Guidance Association of the Republic of Azerbaijan. It should be noted that the scope of the "hotline" was limited to providing support for resolving acute situations for patients participating in the study.

Examination Methods:

Participants in the study underwent the following examinations:

1. Passport section was recorded.
2. Information about the current treatment was recorded:

a. Antidiabetic therapy - no, yes, which;

b. Treatment for arterial hypertension - no, yes, which;

3. Height, body weight, body mass index (BMI = body weight/height^2);
4. Blood pressure was measured in the office setting.
5. Laboratory tests of patients were conducted.

The tests were performed after 8-12 hours of fasting. Venous blood was analyzed. Fasting glucose levels were determined using the Precision PCx Medi Sense device (Abbott, USA) and appropriate test strips for laboratory glucose testing. HbA1c levels were determined using the "SDA1c Care" (SD biosensor, Korea) express analyzer and expressed as a percentage. ALAT (in "U/l"), ASAT (in "U/l"), and creatinine (in "mg/dl") levels were determined using the "Reflotron Plus" automatic analyzer (Roche Diagnostics Corporation, Switzerland) with the appropriate test strips. The glomerular filtration rate (GFR) was calculated based on the CKD-EPI equation using a universal calculator available on the internet, known as the "calculator for calculating the Glomerular Filtration Rate and creatinine clearance."

RESULTS AND DISCUSSION

The Effect of Specialized Physician Supervision Combined with Therapeutic Training on the Management of Glucose and Blood Pressure in Type 2 Diabetes with Arterial Hypertension

The analysis of the impact of therapeutic training elements and specialized medical supervision on glycemic control in Type 2 Diabetes combined with Arterial Hypertension revealed that, primarily, the study highlighted the need for significant correction in various types of glucose-lowering therapy within the general patient group throughout the study. At the beginning of the study, 21.4% of patients were not receiving any glucose-lowering pharmacotherapy. By the end of the study, it was deemed essential to implement glucose-lowering pharmacotherapy for all patients. The proportion of patients receiving therapy with Metformin increased from 67.0% to 88.4% ($p<0.0001$). The frequency of therapy with secretagogues (sulfonylureas + non-sulfonylurea secretagogues) remained virtually unchanged (58.9% and 55.4%; $p=0.4547$). The number of patients receiving therapy with incretin-based medications (DPP-4 inhibitors and GLP-1 receptor agonists) increased from 10.3% to 44.2% ($p<0.0001$). The use of other non-insulin glucose-lowering agents increased from 2.2% of patients before the study began to 15.2% by the end of the treatment ($p<0.0001$).

At the start of the study, HbA1c levels in the general patient group fluctuated between 7.1% and 11.5%, with an average of 8.9±0.07% (see Figure 1).

Throughout the study, there were significant positive changes in the dynamics of HbA1c levels: the HbA1c level initially decreased from 8.9±0.07% to 7.3±0.06% (points 2 and 3), then increased to 7.4±0.06% at point 4, and subsequently returned to 7.3±0.06%. Differences in HbA1c levels between the first point of the study and all other points were statistically significant ($p<0.001$).

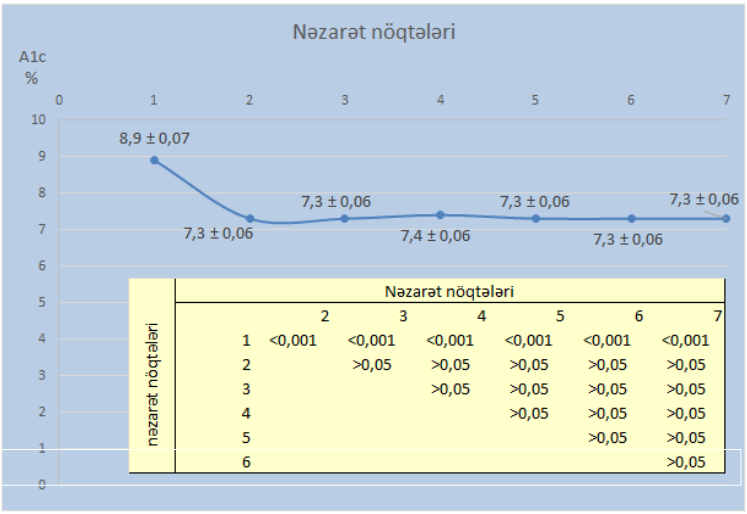

Figure 1. Dynamics of HbA1c in the Overall Patient Group During the Study

In these categorical patients, there was a serious need for adjustment of antihypertensive medications for proper blood pressure management: Pharmacotherapy for hypertension was not administered at all in 65.2% of the patients participating in the study.

By the end of the study, all patients had been required to receive antihypertensive treatment. The number of patients receiving ACE inhibitors or sartans increased from 30.8% to 96.9%. The frequency of therapy with diuretics rose from 22.3% to 92.9%. The number of patients receiving calcium channel blockers increased from 17.0% to 56.7%. Other medications for the treatment of hypertension were used by 5.8% of patients at the beginning of the study and 5.4% at the end of the study. At the beginning of the study, the average systolic arterial pressure (SAP) in the overall patient group ranged from 136 mm Hg to 168 mm Hg, with an average of 148.4±0.51 mm Hg. During the study, significant positive changes in SAP levels were observed due to the adjustment of antihypertensive

medications according to the patient's blood pressure levels (Figure 2).

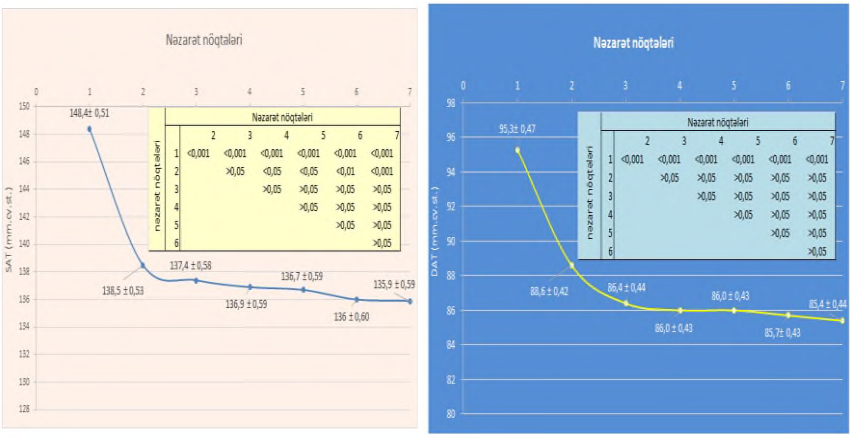

Figure 2. Dynamics of Blood Pressure in the Overall Patient Group During the Study

The average SAP decreased from 148.4±0.51 mm Hg at the beginning of the study to 138.5±0.53 mm Hg after 6 months, and then continued to decrease sequentially every 6 months: 137.4±0.58 mm Hg ⇒ 136.9±0.59 mm Hg ⇒ 136.7±0.59 mm Hg ⇒ 136.0±0.60 mm Hg ⇒ 135.9±0.59 mm Hg. Additionally, the difference between the first point and all subsequent control points was statistically significant ($p<0.001$ in all cases).

At the beginning of the study, the minimum diastolic arterial pressure (DAP) was 76 mm Hg, the maximum was 108 mm Hg, and the average value was 95.3±0.47 mm Hg. In 11.2% (n=25) of patients, DAP was below 90 mm Hg, and in 3.1% (n=7) of patients, it was below 80 mm Hg. During the study, DAP decreased to 86.6±0.42 mm Hg after 6 months and continued to decrease sequentially every 6 months: 86.4±0.44 mm Hg ⇒ 86.0±0.43 mm Hg ⇒ 86.0±0.43 mm Hg ⇒ 85.7±0.43 mm Hg ⇒ 85.4±0.44 mm Hg. Additionally, differences between the first point and all

subsequent control points were statistically significant ($p<0.001$ in all cases).

Thus, the analysis of data from the overall patient group showed that during the study, there was a significant enhancement in glucose-lowering pharmacotherapy and antihypertensive therapy, as well as a statistically significant reduction in HbA1c, SAP, and DAP levels.

The Effect of Structured Training on Glucose and Blood Pressure Management in Patients with Type 2 Diabetes with Arterial Hypertension

At the beginning of the study, groups 1 and 2 did not differ significantly in terms of key clinical-laboratory indicators and treatment administered. By the end of the study, the percentage of patients in group 1 not receiving hypoglycemic pharmacotherapy decreased from 20.4% to 0.0% ($p=0.0006$). The number of patients on metformin therapy increased from 66.7% to 87.0% ($p=0.0128$). The percentage of patients treated with secretagogues did not change significantly (57.4% and 55.6%, respectively; $p=0.8510$). The number of patients receiving incretin therapy increased significantly ($p=0.0002$) (11.1% and 42.6%, respectively). Additionally, the number of patients treated with other hypoglycemic agents increased (1.9% and 14.8%; $p=0.0159$).

In group 2, the percentage of patients not receiving hypoglycemic pharmacotherapy decreased from 21.8% to 0.0% ($p=0.0001$). The percentage of patients on metformin therapy increased from 67.1% to 88.8% ($p=0.0027$). The percentage of patients treated with secretagogues did not change significantly (59.4% and 55.3%, respectively; $p=0.5867$). The number of patients receiving incretin therapy increased significantly ($p=0.0001$) (10.0% and 44.7%, respectively). Additionally, the number of patients treated with other hypoglycemic agents increased (2.4% and 15.3%; $p=0.0081$).

Thus, the analysis of the hypoglycemic therapy conducted showed that the pharmacotherapy of diabetes mellitus significantly

strengthened during the course of the study in both groups 1 and 2. However, there was no difference between the groups at the beginning or the end of the study. At the beginning of the study, the HbA1c levels in groups 1 and 2 were 8.9±0.15% and 8.9±0.08%, respectively, and did not differ statistically significantly from each other (Figure 3).

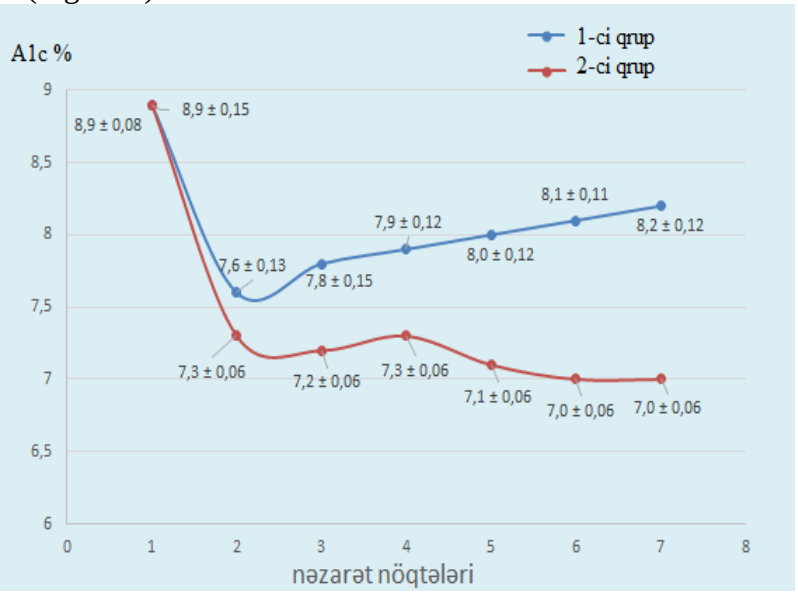

Figure 3. Changes in HbA1c in Groups 1 and 2 during the study

The image showing the changes in HbA1c levels over 3 years of the study shows that the average HbA1c level in Group 1 dropped to 7.6±0.13% after 6 months and gradually increased to 8.2±0.12% at the end of the study. In Group 2, the average HbA1c level dropped to 7.3±0.06% and 7.2±0.06% 6 and 12 months after the study, 7.3±0.06% after 18 months, and 7.1±0.06% after 24 months, and stabilized at 7.0±0.06% at the end of the study. The differences between the groups at the first point of the study were not statistically significant ($p>0.05$), but statistically significant at all other points ($p<0.001$).

Therefore, the combination of ST with doctor consultation showed more effectiveness in reducing HbA1c levels than doctor consultation alone throughout the study, and this trend was statistically significant throughout the study.

At the end of the study, the analysis of target HbA1c values showed that the frequency of HbA1c values of "<6.5%" was 1.9% in Group 1 and 25.3% in Group 2 ($p=0.0002$). At point 7, the frequency of HbA1c values of "<7.0%" was 9.3% in Group 1 and 52.4% in Group 2 ($p<0.0001$). The frequency of HbA1c values of "<HbA1c at point 1" was 64.8% in Group 1 and 100% in Group 2 ($p<0.0001$).

One of the indicators of variability of any value is standard deviation (SD). The average SD value was 0.58±0.258 in Group 1 and 0.25±0.014 in Group 2. The differences between the average values were statistically significant ($p<0.001$).

Thus, based on the given SD values, the variability of HbA1c values in the group of patients not receiving ST was significantly higher than in the group of patients receiving ST. The average variability coefficient was 7.45±0.349% in Group 1 and 3.42±0.187% in Group 2. The differences between the groups were statistically significant ($p<0.001$).

We also investigated another indicator that allows specifying the variability of HbA1c values. The average value of absolute differences between the nearest points of the study for each patient was calculated. We called this indicator Average Δ. The value of the Average Δ indicator was 0.52±0.19 in Group 1 and 0.21±0.008 in Group 2. In other words, the variability of HbA1c was higher in Group 1 compared to Group 2.

At the end of the study, the number of patients not receiving antihypertensive therapy in Group 1 decreased from 64.8% to 0.0%. The number of patients receiving therapy with ACE inhibitors or sartans increased from 29.6% to 96.3%. Patients receiving treatment with diuretics increased from 20.4% to 90.7%, and the number of patients receiving therapy with calcium channel blockers increased from 16.7% to 51.9%. The number of patients receiving treatment with other drugs remained unchanged. In Group 2, the percentage of patients not receiving pharmacotherapy for AH at the end of the

study decreased from 65.3% to 0.0%. Patients receiving therapy with ACE inhibitors or sartans increased from 31.2% to 97.1%, and patients receiving treatment with diuretics increased from 22.9% to 93.5%. The number of patients receiving therapy with calcium channel blockers increased (17.1% and 58.2%, respectively). The number of patients receiving treatment with other drugs changed slightly (5.9% and 5.3, respectively; $p>0.05$).

Thus, upon completing the analysis of antihypertensive pharmacotherapy, it can be said that, in both Group 1 and Group 2, the pharmacotherapy for hypertension significantly improved during the study, but there was no difference between the groups in pharmacotherapy neither at the beginning nor at the end of the study. In Group 1, the average systolic arterial pressure (SAP) was 148.8±1.20 mmHg, while in Group 2, it was 148.3±0.56 mmHg. There was no statistically significant difference between the groups ($p>0.05$). Throughout the study, it was possible to reduce the SAP level in both hypertensive type 2 diabetes patients who received structured training (ST) and those who did not (Figure 4). In Group 1, SAP decreased to 144.4±0.99 mmHg after 6 months, increased to 145.1±1.15 mmHg after one year, decreased to 144.8±1.21 mmHg after 1.5 years, to 144.0±1.25 mmHg after 2 years, and at the end of the study, it was 143.5±1.19 mmHg and 143.3±1.24 mmHg.

In Group 2, the SAP level decreased from 148.3±0.56 mmHg to 136.7±0.55 mmHg after 6 months, to 135.0±0.56 mmHg after one year, and then to 134.4±0.55 mmHg and 134.0±0.57 mmHg after 1.5 and 2 years, respectively. After 2.5 years, it was 133.6±0.60 mmHg, and finally 133.6±0.58 mmHg.

The differences between Groups 1 and 2 were statistically significant at all study points (2-7) ($p<0.001$). A significant portion of patients in both Group 1 (83.3%) and Group 2 (92.9%) reached the targeted parameter. Although there were more patients in Group 2 compared to Group 1 who achieved the "lower SAP value at the 7th point compared to the 1st point" target parameter, the difference between the groups did not reach the necessary statistical significance ($p>0.05$).

In Group 1, 31.5% of patients achieved the target systolic arterial pressure (SAP) value of "<140 mmHg." In Group 2, which received structured training (ST), 78.2% of patients reached the "<140 mmHg" SAP target, which is statistically significantly higher compared to Group 1 (p<0.0001).

Achieving the target SAP value of "<130 mmHg" was a more challenging problem, with only 3.7% of patients in Group 1 and 29.4% in Group 2 reaching this target. The differences between the groups were statistically significant (p<0.0001).

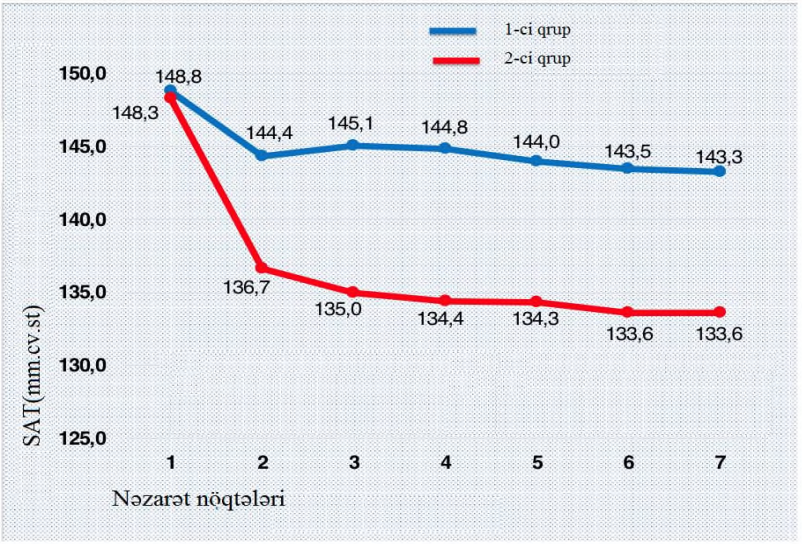

Figure 4. Changes in SAP in Groups 1 and 2 during the study

Thus, therapeutic training significantly increased the ability to achieve all the intended SAP target values and confirmed its importance in managing chronic conditions such as hypertension in combination with type 2 diabetes.

At the beginning of the study, Group 1 had a diastolic arterial pressure (DAP) of 96.1±1.03 mmHg, while Group 2 had 95.0±0.53 mmHg. During the study, in Group 1, DAP levels decreased to 94.4±0.66 mmHg over the first 6 months, 94.3±0.65 mmHg after one

year, further decreased to 93.3±0.75 mmHg after 1.5 years, 93.2±0.71 mmHg after 2 years, 92.6±0.70 mmHg after 2.5 years, and finally 91.7±0.87 mmHg at the end of the study. In Group 2, DAP levels decreased from 95.0±0.53 mmHg at the start of the study to 84.1±0.34 mmHg after 6 months, 83.8±0.38 mmHg after one year, further decreased to 83.7±0.37 mmHg after 1.5 years and 83.7±0.39 mmHg after 2 years, 83.4±0.39 mmHg after 2.5 years, and finally 83.4±0.41 mmHg at the end of the study (Figure 5).

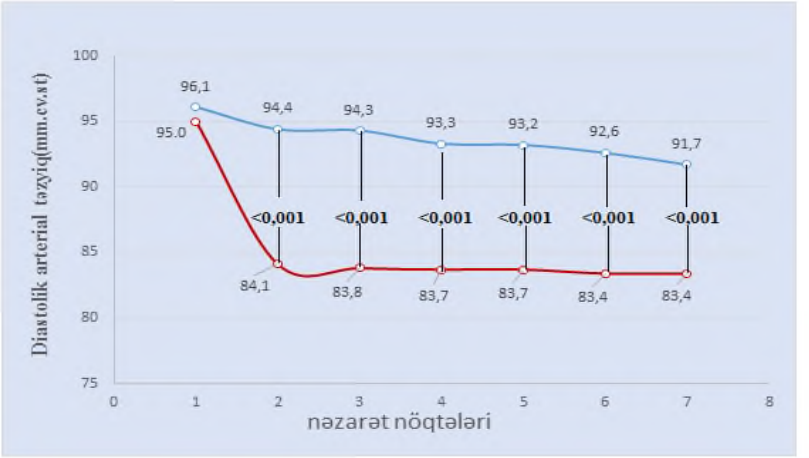

Figure 5. Changes in DAP in Groups 1 and 2 during the study

Although differences between Groups 1 and 2 were not statistically significant at the beginning of the study ($p>0.05$), they were highly significant at all other points throughout the study ($p<0.001$).

A significant portion of patients in both Group 1 (79.6%) and Group 2 (93.5%) achieved the intended target parameter. Additionally, while a higher percentage of patients in Group 2 achieved the target parameter of "lower DAP levels at the 7th point compared to the 1st point" compared to Group 1, this difference was statistically significant ($p=0.0029$).

For the target DAP value of "<90 mmHg," 29.6% of patients in Group 1 and 82.9% of patients in Group 2 achieved this target ($p<0.0001$). Achieving the target DAP value of "<80 mmHg" was less common, with only 3.7% of patients in Group 1 and 25.3% in Group 2 reaching this target ($p<0.0001$).

Thus, therapeutic training has proven to be significant in managing chronic conditions like hypertension in combination with type 2 diabetes.

Effect of the "Hotline" System on Glucose and Arterial Pressure in Type 2 Diabetes Patients with Arterial Hypertension

During the 3-year study period, 71 (31.7%) patients contacted the "hotline". The number of hotline contacts exceeded the number of patients contacting it. In the first year, there were 73 contacts; in the second year, 75; and in the third year, 84. In total, there were 232 hotline contacts over 3 years. On average, the number of hotline contacts per patient during the study was 1.2±0.14.

In the first analyzed part of the study, all participants (n=224) were divided into two groups:

"Hotline+" group (Hl+, those who contacted the hotline; n=71)

"Hotline-" group (Hl-, those who did not contact the hotline; n=153)

At the beginning of the study, there were no significant differences between the "Hl+" and "Hl-" groups in terms of clinical and laboratory indicators: the HbA1c level was 8.9±0.12% in the "Hl+" group and 8.9±0.09% in the "Hl-" group.

During the study, the average HbA1c level in the "Hl+" group decreased to 7.3±0.10% over the first 6 months, increased to 7.4±0.11% after one year, and then to 7.5±0.09% after 1.5 years, remaining at 7.4% by the end of the study. In the "Hl-" group, the average HbA1c level decreased to 7.4±0.07% and 7.3±0.07% at 6 and 12 months, respectively, increased to 7.4±0.07% after 18 months, decreased to 7.2±0.07% after 2.5 years, and remained at that level by the end of the study.

Overall, a significant decrease in HbA1c levels was observed at the second point, with levels remaining approximately the same thereafter. Differences between the groups were not statistically significant at any control point (in all cases, $p>0.05$).

Therefore, the dynamics of HbA1c levels throughout the study were not related to hotline contacts. At the end of the study, the frequency of the "<6.5%" HbA1c level was 11.3% in the "Hl+" group and 23.5% in the "Hl-" group. At the 7th point, the frequency of "<7.0%" HbA1c levels was 35.2% in the "Hl+" group and 45.1% in the "Hl-" group ($p=0.1633$). The frequency of "lower HbA1c than at the 1st point" was 88.7% in the "Hl+" group and 92.8% in the "Hl-" group ($p=0.3070$).

In the "Hl+" group, the average variability coefficient was 4.9±0.39%, while in the "Hl-" group, it was 4.2±0.23% ($p>0.05$).

Thus, the investigation into the impact of the “Hotline” system on glucose control did not reveal significant differences between the “Hl+” group and the “Hl-” group. Achieving the <6.5% HbA1c target was statistically more frequent in the “Hl-” group (23.5% vs. 11.3%; $p<0.05$).

The effect of the “Hotline” system on arterial pressure was also examined. At the beginning of the study, the systolic arterial pressure (SAP) was 148.6±0.91 mm Hg in the “Hl+” group and 148.3±0.61 mm Hg in the “Hl-” group ($p>0.05$). In the “Hl+” group, SAP decreased to 138.9±1.00 mm Hg after 6 months, increased to 138.5±1.08 mm Hg after 1 year, and then decreased to 138.1±1.07 mm Hg after 1.5 years, 138.0±1.03 mm Hg after 2 years, 137.9±1.03 mm Hg, and finally to 137.4±1.05 mm Hg by the end of the study.

In the “Hl-” group, SAP levels decreased to 138.3±0.62 mm Hg after 6 months, 137.0±0.69 mm Hg after 1 year, further decreased to 136.4±0.71 mm Hg after 1.5 years, 136.1±0.73 mm Hg after 2 years, and 135.1±0.74 mm Hg after 2.5 years, and then increased to 135.3±0.72 mm Hg by the end of the study. The differences between the groups were not statistically significant at any point of the study ($p>0.05$).

At the simplest target of “SAP at the 7th point lower than at the 1st point,” the “Hl+” group achieved this in 90.1% of cases, while

the “Hl-” group achieved it in 90.2% of cases ($p>0.05$). For the more stringent “SAP<140 mm Hg” target, 57.7% of patients in the “Hl+” group and 71.2% of patients in the “Hl-” group achieved this target ($p<0.05$).

For the most stringent “SAP<130 mm Hg” target, 15.5% of patients in the “Hotline+” group and 26.8% of patients in the “Hl-” group achieved it ($p>0.05$).

Thus, the data confirm that SAP levels were significantly reduced in both the “Hl+” and “Hl-” groups. No statistically significant differences were found between the SAP values in the two groups, but significant differences were observed in the “SAP<140 mm Hg” indicator in the “Hl-” group compared to the “Hl+” group.

At the beginning of the study, diastolic arterial pressure (DAP) was 95.5±0.85 mm Hg in the “Hl+” group and 95.2±0.57 mm Hg in the “Hl-” group. No statistical difference was found between the groups ($p>0.05$). During the study, DAP levels in the “Hl+” group decreased to 87.4±0.76 mm Hg after 6 months, remained at the previous level (87.4±0.79 mm Hg) after 1 year, further decreased to 87.2±0.79 mm Hg after 1.5 years, 87.1±0.78 mm Hg after 2 years, 87.2±0.76 mm Hg, and finally to 87.2±0.78 mm Hg by the end of the study.

In the “Hl-” group, DAP levels decreased to 86.2±0.50 mm Hg after 6 months, 86.0±0.52 mm Hg after 1 year, further decreased to 85.5±0.51 mm Hg after 1.5 years, and remained at 85.5±0.52 mm Hg after 2 years. After 2.5 years, DAP levels were 85.0±0.51 mm Hg, and at the end of the study, it was 84.6±0.53 mm Hg. Differences between the “Hl+” and “Hl-” groups were not statistically significant at points 1, 2, 3, 4, and 5 ($p>0.05$), but were statistically significant at points 6 and 7 (both $p<0.05$).

At the simplest “DAP at the 7th point lower than at the 1st point” target, the “Hl+” group achieved this in 85.9% of cases, while the “Hl-” group achieved it in 92.2% of cases ($p>0.05$). For the more stringent “DAP<90 mm Hg” target, 63.4% of patients in the “Hl+” group and 73.2% of patients in the “Hl-” group achieved it ($p<0.05$). For the most stringent “DAP<80 mm Hg”

target, 11.3% of patients in the “Hl+” group and 24.2% of patients in the “Hl-” group achieved it ($p>0.05$).

Thus, the obtained data confirm that there was a statistically significant reduction in DAP levels in both the “Hl+” and “Hl-” groups. However, the reduction in DAP levels was statistically more pronounced in the “Hl-” group compared to the “Hl+” group. A higher percentage of patients achieved all target parameters in the “Hl+” group compared to the “Hl-” group, and the difference in the “DAP<80 mm Hg” indicator was statistically significant ($p<0.05$).

Impact of the “Hotline” System on Glycohemoglobin Control in Type 2 Diabetes Patients with Arterial Hypertension, Considering the Structured Training Factor

In the first group, 23 patients (42.59%) used the hotline throughout the study period, whereas in the second group, 48 patients (28.2%) used it ($p<0.05$). Subsequently, patients in the first and second groups who contacted the hotline will be labeled as 1 “Hl+” and 2 “Hl+”, and those who did not contact will be labeled as 1 “Hl-” and 2 “Hl-”. In the first group, there were 94 calls over 3 years, while in the second group there were 138 calls. The average number of contacts per patient was 0.7 ± 0.13 in the first group and 0.4 ± 0.05 in the second group ($p<0.05$).

Throughout the study, the frequency of hotline contacts were higher in the first group: 31.5% in the first year, 33.3% in the second year, and 38.9% in the third year. In the second group, these figures were 17.6%, 18.2%, and 20.0%, respectively ($p<0.05$). There were no statistically significant differences in the frequency of annual hotline contacts within each group.

Both the first and second groups had hotline contacts due to hypoglycemia (5.3% and 7.2%; $p=0.5633$). Increased blood glucose levels led to hotline contacts in 20 (21.3%) cases in the first group and 15 (10.9%) cases in the second group ($p=0.0303$, i.e., $p<0.05$).

Decreased arterial pressure occurred in 3 cases (3.2%) in the first group and 3 cases (2.2%) in the second group ($p=0.6395$, i.e.,

p<0.05). Typically, this was related to the necessity of reducing the dose of received therapy.

Self-monitoring issues were observed in 15 (16.0%) cases in the first group and 24 (17.4%) cases in the second group (p=0.7801). Other issues led to hotline contacts in 29 (30.9%) cases in the first group and 68 (49.3%) cases in the second group.

Thus, the implementation of therapeutic training has reduced the necessity for urgent contacts due to acute conditions.

The average HbA1c levels calculated at control points 2-7 were 8.0±0.15% in the 1 “Hl+” group and 7.9±0.14% in the 1 “Hl-” group. Differences between the groups were not statistically significant (p>0.05). Throughout the study, the average HbA1c values in the 1 “Hl+” and 1 “Hl-” groups were excessively close at each of the 7 points. The observed differences were not statistically significant in any case (p>0.05).

The average HbA1c levels at control points 2-7 were 7.2±0.09% in the 2 “Hl+” group and 7.1±0.07% in the 2 “Hl-” group. Differences between the groups were not statistically significant (p>0.05). At all control points, the differences in average HbA1c values between the 2 “Hl+” and 2 “Hl-” groups were not statistically significant (p>0.05).

Thus, the use or non-use of the hotline in both the 1 “Hl+” and 1 “Hl-” groups did not have a statistically significant impact on the level of diabetes control.

Impact of the “Hotline” System on Arterial Pressure Control in Type 2 Diabetes Patients with Arterial Hypertension, Considering the Structured Training Factor

The average systolic arterial pressure (SAP) levels at control points 2-7 were 144.6±1.26 mm Hg in Group 1 “Hl+” and 143.9±1.72 mm Hg in Group 1 “Hl-”. The differences between the groups were not statistically significant (p>0.05).

The average diastolic arterial pressure (DAP) levels at control points 2-7 were 93.4±0.79 mm Hg in Group 1 “Hl+” and 93.2±0.96 mm Hg in Group 1 “Hl-” (p>0.05). Throughout the study, the

average SAP and DAP values in both Group 1 “Hl+” and Group 1 “Hl-” were very close at each of the 7 points. The differences were not statistically significant in all cases ($p>0.05$).

The average SAP levels at control points 2-7 were 135.0±0.96 mm Hg in Group 2 “Hl+” and 134.4±0.48 mm Hg in Group 2 “Hl-” ($p>0.05$). The average DAP levels at control points 2-7 were 84.2±0.58 mm Hg in Group 2 “Hl+” and 83.6±0.34 mm Hg in Group 2 “Hl-” ($p>0.05$). The differences between the groups were not statistically significant.

Thus, the use or non-use of the “Hotline” system did not have a statistically significant effect on SAP and DAP control levels.

RESULTS

1. Specialized physician supervision led to a decrease in HbA1c levels from 8.9±0.15% to 8.2±0.12% ($p<0.001$) in Type 2 Diabetes patients with arterial hypertension. By the end of the study, 9.3% of patients achieved HbA1c levels of "<7.0%", and 1.9% achieved levels of "<6.5%" [3,5].

2. Specialized physician supervision caused a decrease in systolic arterial pressure (SAP) from 148.8±1.20 mm Hg to 143.3±1.24 mm Hg ($p<0.001$); the target SAP of "<140 mm Hg" was achieved in 31.5% of cases, and the target "<130 mm Hg" was achieved in 3.7% of cases. Diastolic arterial pressure (DAP) decreased from 96.1±1.03 mm Hg to 91.7±0.88 mm Hg ($p<0.01$), with the target DAP of "<90 mm Hg" achieved in 29.6% of cases and the target "<80 mm Hg" achieved in 3.7% of cases [2].

3. Combining specialized physician supervision with structured training led to a reduction in average HbA1c levels from 8.9±0.08% to 7.0±0.06%. The HbA1c target of "<7.0%" was achieved in 52.4% of cases, and the target "<6.5%" was achieved in 25.3% of cases. Differences between this group and the group without structured training were statistically significant in all cases ($p<0.0001$). Variability in HbA1c levels was lower in the trained patients compared to those who did not receive training (VƏ=3.42±0.187% vs. 7.45±0.349%; $p<0.001$) [3,5].

4. Combining specialized physician supervision with structured training resulted in a reduction in average SAP from 148.3±0.56 mm Hg to 133.6±0.58 mm Hg ($p<0.001$). The target SAP of "<140 mm Hg" was achieved in 78.2% of cases, and the target "<130 mm Hg" was achieved in 29.4% of cases. DAP decreased from 95.0±0.53 mm Hg to 83.4±0.41 mm Hg ($p<0.001$), with the target DAP of "<90 mm Hg" achieved in 82.9% of cases and the target "<80 mm Hg" achieved in 25.3% of cases. Differences in average SAP and DAP levels and target indicators between this group and the group without structured training were statistically significant [7].

5. The “Hotline” is an essential component of the treatment system for diabetes and hypertension, contributing to the resolution of acute conditions. However, its use did not affect changes in HbA1c, SAP, and DAP levels and was -required more frequently in patients with poorly controlled comorbid conditions [6,10,11,12].

PRACTICAL RECOMMENDATIONS

1. Specialized physician supervision aimed at optimizing lifestyle and pharmacotherapy can effectively influence glycosylated hemoglobin, as well as systolic and diastolic blood pressure levels in Type 2 Diabetes patients with arterial hypertension.

2. Structured training for Type 2 Diabetes patients with arterial hypertension should be an absolute (essential) treatment method for this type of patients.

3. Specific training programs adapted to local conditions should be used for structured training of Type 2 Diabetes patients.

4. The “hotline” must be an integral component of general care for patients with hypertension and diabetes, addressing acute situations as they arise. Nevertheless, the presence of a hotline does not necessarily lead to improvements in glycosylated hemoglobin and blood pressure indicators. Additionally, the need for a hotline is greater in cases of uncontrolled diabetes and hypertension.

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LİST OF ABBREVİATİONS

HbA1c – glycohemoglobin
AH – arterial hypertension
ALAT – alanine aminotransferaza
ASAT – aspartate aminotransferaza
AP – arterial pressure
SAP -systolic arterial pressure
DAP – diastolic arterial pressure
Hl+ - hotline users
Hl- - hotline non-users
GFR – glomerular filtration rate
T2D – type 2 diabetes
ST – structured training
SD – standard deviation

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Address: Anvar Qasimzade Street, Building 14, Baku City Az1022

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