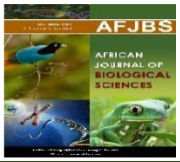
https://doi.org/10.48047/AFJBS.6.6.2024.9311-9317

African Journal of Biological Sciences



Research Paper Open Access

# Biologically Active Food Supplement for Treating Dyslipidemia and Hypertension: Clinical Trial

**Maria Mikhailovna Shamova[1], Valery Mikhailovich Poznyakovsky[1, 2], Alexander Nikolaevich Avstrievskikh[1], Galina Georgievna Cherentsova[3], Boisjoni Tokhiriyon[3]***

[1]Department of Technological Entrepreneurship, Kuzbass State Agricultural Academy, Kemerovo, Russia

[2]Scientific and Educational Center for Applied Biotechnology and Nutrition, Kemerovo State Medical University, Kemerovo, Russia

[3]Department of Management, Entrepreneurship and Engineering, Ural State University of Economics, Ekaterinburg, Russia

Corresponding Author: Boisjoni Tokhiriyon

Article History

Volume 6, Issue 6, 2024
Received: 03 Feb 2024
Accepted: 06 Apr 2024
doi:10.48047/AFJBS.6.6.2024.9311-9317

## Abstract

The importance of identifying affordable and effective ways of preventing cardiovascular diseases (CVDs) as well as reducing their outcomes is fully acknowledged by dieticians. To address the nutrition issues and correct nutrition deficiencies, dieticians explore different approaches. One of the approaches is employing biologically active food supplements (BAFSs) in combination with the main treatment. BAFSs are concentrated sources of various nutrients like minerals, vitamins, fibre, amino acids, essential fatty acids, as well as herbal and plant extracts. The current paper presents the findings of the clinical trial aimed to examine a new BAFS for patients with dyslipidemia and hypertension. Traditional methods of laboratory and clinical trials were used to monitor ailments and complaints and to assess physical health. The ingredients for the new BAFS include (mg per 1 capsule): L-carnitine – 22.5; polyprenols – 5; lycopene – 0.625; tocopherol acetate – 3.75; coenzyme Q10 – 3.75. The patients who received the new BAFS demonstrated improved memory, reduced headaches, fatigue, and dizziness. There were significant changes in the indicators for the health-related quality of life (physical activity, sleep, emotional state, social functioning). The Giessen Subjective Complaints List, which is a scientifically sound assessment of subjective health complaints, was applied to document exhaustion, gastrointestinal, musculoskeletal and cardiovascular complaints. Positive changes in blood pressure levels and lipid profiles were recorded. The findings of the trial revealed reduced cholesterol and triglycerides, improved overall health and well-being in patients prescribed the new BAFS along with the main treatment.

**Keywords:** dyslipidemia, hypertension, nutrition, supplement, clinical trial, efficacy

## Introduction

The importance of proper nutrition in preventing, delaying and treatment of many diseases is widely acknowledged and is frequently taken into account when disease treatment plans are drawn. Extensive research provides evidence on correlation between nutrition and common diseases [1-3]. Some studies, which examined the advantages of nutrition, highlight the adverse reactions associated with chemically synthesised drugs [4,5].

In many countries around the world CVDs remain the most common cause of death or disability [6]. Peripheral artery disease, coronary heart disease, and aortic atherosclerosis constitute a serious public concern. There are a number of factors contributing to the widespread development of CVDs, namely, the urban shift and rapidly growing megacities, work intensification with its effects on mental health, a faster pace of life with reduced physical activity and improper nutrition.

According to the data collected by World Health Organisation, the two most common causes of cardiovascular deaths are ischemic heart disease and stroke. An estimated 17.9 million people died from CVDs in 2019, representing 32% of all global deaths. In Russia, almost 56% of all deaths are attributed to CVDs and there is an alarmingly increasing number of younger patients suffering from high blood pressure [7].

Since the most frequent risk factors of CVDs include unhealthy diet (with excessive salt consumption, lack of fruits and vegetables, high intake of trans fats), physical inactivity, and tobacco use, it is of utmost importance to create health policies and educate people on how to develop and sustain healthy lifestyles.

Although CVDs have various causes and, therefore, different dietary patterns are required, available research indicates the efficacy of employing BAFSs in preventing, delaying and treating CVDs [8-11].

A clinical trial was carried out to examine the efficacy and functional properties of a recently developed BAFS based on polyprenols. The ingredients for the new BAFS include (mg per 1 capsule): L-carnitine – 22.6; polyprenols mixture 75% – 6.8 (total polyprenols – 6); lycopene 10% – 6.27 (lycopene – 0.626); tocopherol acetate 98% – 3.84 (tocopherol acetate – 3.76); coenzyme Q10 – 3.75.

The pharmacological properties of the selected ingredients address blood vessel stability, help lower the content of both low density lipoprotein and very low density lipoprotein, demonstrate an antiaggregation effect, inhibit the destructive effect of free radicals on cardiac muscle cells, and enhance the recovery of the myocardium functioning after operations [12-19].

The ingredients of the new BAFS supply the mitochondria in the cardiac myocytes with essential fatty acids. Polyprenols promote regeneration of cellular structures through the dolichol phosphate pathway, stimulate restoration of blood vessels and cardiac muscle, and assist in regenerating cell membranes [20-24].

The combined functional properties of the new BAFS provide for:

• the stabilisation and restoration of cardiomyocyte membranes, the prevention of myocardial ischemia and cell cytolysis;

• the inhibition of free radicals, the increase of blood supply to the myocardium;

•the regeneration of cell membranes, the protection of cardiomyocytes from negative effects;

• the supply the heart muscle with adenosine triphosphate and essential micronutrients.

## Materials and Methods

The clinical trial sample was comprised of 60 patients with dyslipidemia and hypertension (stages 1 and 2) divided into two groups (experimental and control). All patients received their main treatment with statins, antihypertensives, and diuretics. The participants of the experimental group were prescribed 1 capsule of the new BASF twice daily for the period of 30 days. Statistical testing was applied to determine a statistically significant difference ($P \leq 0.05$).

The clinical trial was performed in accordance with Guidelines for Good Clinical Practice of the International Council and the principles of the Declaration of Helsinki of the World Medical Association, the ethical provisions of the Directives of the European Union and the requirements of the laws of the Russian Federation. The subjects signed informed consents for their participation in the clinical trial. The average age of the participants was $56.8 \pm 5.3$.

The clinical trial was held by the central research laboratory of Kemerovo State Medical University of the Ministry of Health of the Russian Federation and City Hospital 2 of Kemerovo city.

The patients were diagnosed with dyslipidemia and hypertension with the help of laboratory and instrumental tests, physical examination and medical history.

The Giessen Subjective Complaints List was applied to document exhaustion, gastrointestinal, musculoskeletal and cardiovascular complaints. The questionnaire was completed before the treatment to assess somatic symptoms and then, on Day 30, to assess treatment effectiveness. The patients self-reported on exhaustion, heart pain, stomach pain, pains in other body parts, the intensity of complaints.

## Results and Discussion

During the initial assessment the participants complained about poor quality sleep, daytime exhaustion, headaches, dizziness, and problems with memory. Medical tests of blood samples indicated higher levels of cholesterol, low-density lipoprotein fractions and triglycerides. On Day 30, the patients from both experimental and control group demonstrated improvements. The improvements related to sleep, memory, and overall well-being were more noticeable for the patients from the experimental group. A statistically significant difference was also recorded in the severity and frequency of headaches, with the patients from the experimental group demonstrating better results. The intensity of complaints was also significantly lower for the patients from the experimental group **(Table 1).**

**Table 1.** The Giessen Subjective Complaints data for patients with dyslipidemia and hypertension.

| Variable | Before treatment, score | Day 30, score | |
|---|---|---|---|
| | | Control group, N=30 | Experimental group, N=30 |
| **Exhaustion** | 13.9±0.4 | 8.1+0.7* | 6.7+0.6* |
| **Gastrointestinal complaints** | 9.0±1.3 | 7.4+1.09 | 6.7+0.9 |
| **Pains in different body parts** | 11.6±2.3 | 9.3±1.3 | 7.0+0.7 |
| **Heart complaints** | 21.4±1.3 | 15.4+0.8* | 9.1+0.8* |
| **The intensity of complaints** | 55.8+2.3 | 40.1+1.4* | 29.9 +1.4* |

*Note:* * the difference is significant when compared with the data before therapy (P<0.05).

It should be highlighted that the results for the patients from the experimental group demonstrated positive trends in patients' overall function and well-being **(Table 2).**

**Table 2.** Quality of life.

| Variable | Before treatment, score | Day 30, score | |
|---|---|---|---|
| | | Control group, N=30 | Experimental group, N=30 |
| **Energy level** | 56.9±0.8 | 44.3+1.1 | 31.4+0.5* |
| **Pain sensations** | 89.3±1.6 | 62.1+1.1* | 49.3+1.0* |
| **Emotional state** | 46.3±1.2 | 32.3+1.4 | 28.4+1.1* |
| **Sleep** | 76.3+1.1 | 52.1+0.8* | 42.4+0.7* |
| **Social functioning** | 34.6+1.4 | 26.6+1.2 | 24.9+0.9* |
| **Physical activity** | 69.8+1.6 | 46.1+1.0* | 33.7+0.7* |
| **Total** | 373.2+4.2 | 263.6+5.0* | 210.4+3.5* |

*Note:* * the difference is significant when compared with the data before therapy (P<0.05).

As can be seen in Table 3, on Day 30 the patients from the control group demonstrated lower level of triglycerides as well as the reduced atherogenicity index and cholesterol. The levels were reduced by 5.0%, 18.5 and 11.5%, respectively.

At the same time, the new BASF enhanced the lipid-lowering effect of statins and, thus, for the patients from the experimental group the level of triglycerides, the atherogenicity index, and cholesterol decreased by 10.0%, 29.0% and 20.0%, respectively **(Table 3).**

**Table 3.** Lipid profile.

| **Variable** | **Before treatment, score** | **Day 30, score** | |
|---|---|---|---|
| | | Control group, N=30 | Experimental group, N=30 |
| **Cholesterol (total), mmol/l** | 6.5+0.4 | 6.3+0.7 (5%) | 5.7+0.3 (10%)* |
| **Low density lipoproteins, mmol/l** | 3.5+0.8 | 2.8+0.7 | 2.4+0.1 * |
| **High density lipoproteins, mmol/l** | 1.42+0.7 | 1.53+0.3 | 1.55+0.4 |
| **Triglycerides (TG), mmol/l** | 3.8+0.3 | 3.1 ±0.3 (18%) | 2.5+0.3 (29%)* |
| **Atherogenicity index** | 3.6+0.4 | 3.2+0.6 (11.5%) | 2.7+0.3 (20%)* |

*Note:* * the difference is significant when compared with the data before therapy ($P<0.05$).

On the average, the patients from the control group demonstrated a decrease of 5.4 mm Hg in systolic blood pressure as well as a decrease of 4.2 mm Hg in diastolic blood pressure. Whereas systolic blood pressure was reduced by 6.9 mm Hg and diastolic blood pressure was reduced by 5.5 mm Hg in the patients from the experimental group.

**Conclusion**

1. When the main treatment of patients with dyslipidemia and hypertension was supported by BASF, a positive increase in the metabolic processes was recorded.
2. There were significant changes in such indicators for the health-related quality of life as mood and general well-being.
3. Nutrition supplementation assists in reducing the atherogenicity index, cholesterol, and triglycerides.
4. During the clinical trial no undesirable effects related to the new BASF were registered.

The new BASF can be recommended to be used in combination with prescribed medications to help relieve the symptoms of dyslipidemia and hypertension. The new BASF can also be used to lower the risks of developing dyslipidemia and hypertension, to supplement the diet of patients who experience stressful situations or physical inactivity.

The recommended intake is 1 capsule twice daily for the period of 30 days. The courses should be repeated at least two times a year.

**Acknowledgments:** The team of authors thanks the administration of the « Art life» company for the opportunity to research its basis.

**Conflict of interest:** None.

**Financial support:** None.

**Ethics statement:** The study was conducted according to the guidelines of the Declaration of Helsinki.

## References

1. Chiu, H.F.; Venkatakrishnan, K.; Golovinskaia, O.; Wang, C.K. Impact of Micronutrients on Hypertension: Evidence from Clinical Trials with A Special Focus on Meta-Analysis. Nutrients 2021, 13, 588.
2. Tsai I-C, Hsu C-W, Chang C-H, Tseng P-T and Chang K-V. Effectiveness of Coenzyme Q10 Supplementation for Reducing Fatigue: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Front. Pharmacol. 13:883251. doi: 10.3389/fphar.2022.883251
3. Dimitra Karageorgou, Ulrika Rova, Paul Christakopoulos, Petros Katapodis, Leonidas Matsakas, Alok Patel,Benefits of supplementation with microbial omega-3 fatty acids on human health and the current market scenario for fish-free omega-3 fatty acid, Trends in Food Science & Technology, Volume 136,2023,Pages 169-180,ISSN 0924-2244, https://doi.org/10.1016/j.tifs.2023.04.018.
4. Gerasimenko N.F., Poznyakovsky V.M., N.G. Chelnakova Methodological aspects of nutritious, safe nutrition: importance in maintaining health and performance // Man. Sport. Medicine. – 2017. V. 17. No. 1. 79-86.
5. Poznyakovsky V. M. Evolution of nutrition and the formation of the nutriome of modern man // Nutrition Industry. 2017. No. 3. P. 5-12.
6. Mills, K.T.; Stefanescu, A.; He, J. The Global Epidemiology of Hypertension. Nat. Rev. Nephrol. 2020, 16, 223–237.
7. Fact Sheets on Cardiovascular diseases. [Internet] Available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)
8. Tutelyan, V. A., Pogozheva, V., Baturin A. K. Biologically active components of nutrition for cardiac patients.M.: SvR-ARGU; 2012. 380 p.
9. Shevchenko, V.P. Clinical dietology. M.: GEOTAR-Media;2014. 256 p.
10. Pogozheva, A. V., Bogdanov, A. R., Derbeneva, S. A. Diet therapy for cardiovascular diseases. General Guide. Practical Dietetics. 2015. No. 4 (16): 36-40.

11. Kochetkova, A.A., Vorobyova, V.M., Vorobyova I.S. Theoretical and practical aspects of the development of specialised food products for diet therapy for cardiovascular diseases. Food industry. 2016. No. 8:8-12.
12. J. H. Lee, H. O'Keefe, C. J. Lavie et al. Omega-3 fatty acids for cardioprotection. Mayo Clin. Proc. 2008. Vol. 83: 324-332.
13. Kromhout, D. Omega-3 fatty acids and cardiovascular events after myocardial infarction .N. Engl. J. Med. 2010. Vol. 363 (21): 2015-2026.
14. Lazarus, S., Garg, M. Tomato extract inhibits human platelet aggregation in vitro without increasing basal cAMP levels. Int. J. Food Sci. Nutr. 2004. Vol. 55: 249-256.
15. Yamamoto, J. Tomatoes have natural antithrombotic effects.Br. J. Nutr. 2003. Vol. 90:1031-1038.
16. Dorn, G. A., Lobach, E. Y., Ragozinnikova, E. V., Lapina, V. Y., Poznyakovsky, V. M., & Tokhiriyon, B. (2022). A Review of Antler Supplements: Benefits, Trends, and Potential. Journal of Biochemical Technology, 13(1), 81-85.
17. Sergun, V. P., Evgenia, B., Burkova, V. N., Poznyakovsky, V. M., Danko, N. N., & Tokhiriyon, B. (2023). Treatment of Menstruation Disorders at Puberty: A Plant-Based Dietary Supplement Efficacy and Safety. Journal of Biochemical Technology, 14(3-2023), 13-17.
18. Dorn, G. A., Danko, N. N., Vladimirovna, P. E., & Tokhiriyon, B. (2023). Pantohematogen Safety Study: Embryotoxicity or Teratogenicity. Entomology and Applied Science Letters, 10(3-2023), 42-50.
19. Nikolenko, M. V., Trigub, V. V., Popov, V. G., Ragozinnikova, E. V., Cherentsova, G. G., & Tokhiriyon, B. (2023). Plant Biotechnology Potential for Food Production: The Tyumen Region. Journal of Biochemical Technology, 14(3-2023), 1-5.
20. Mukhametova, Y., Tokhiriyon, B., Poznyakovsky, V., Pastushkova, E., & Toshev, A. (2023). Supplements with Polyprenols: Assessment of the Russian Market Potential. International Journal of Pharmaceutical Research and Allied Sciences, 12(2-2023), 128-132.
21. Kruk, J., & Szymańska, R. (2023). Synthesis of natural polyprenols for the production of biological prenylquinones and tocochromanols. RSC advances, 13(33), 23122-23129.
22. Boateng, I. D. (2023). Polyprenols in Ginkgo biloba; a review of their chemistry (synthesis of polyprenols and their derivatives), extraction, purification, and bioactivities. Food Chemistry, 136006.
23. Nwachukwu, S. C., Edo, G. I., Jikah, A. N., Emakpor, O. L., Akpoghelie, P. O., & Agbo, J. J. (2024). Recent advances in the role of mass spectrometry in the analysis of food: a review. Journal of Food Measurement and Characterization, 1-16.
24. Mohammadi-Cheraghabadi, M., & Hazrati, S. (2023). Terpenoids, steroids, and phenolic compounds of medicinal plants. Phytochemicals in Medicinal Plants: Biodiversity, Bioactivity and Drug Discovery, 105.