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Diet Therapy Fortified with Plant-Based Specialized Products to Prevent Cardiovascular Risk



Elena S. Simonenko^{1,*}, Sergey V. Simonenko¹, Tatiana S. Zaletova², Anatoly A. Khitrov³, Elena S. Semenova¹, Anna V. Begunova¹, Irina S. Samsonova¹

¹ Scientific Research Institute of Baby Food – a branch of the Federal State Budgetary Scientific Institution "Federal Research Center for Nutrition, Biotechnology and Food Safety", Istra, Russia

² Federal Research Center of Nutrition, Biotechnology and Food Safety, Moscow, Russia

³ Biomedical Innovation Technologies Ltd, Mednoye, Russia

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Abstract.

Cardiovascular disease remains the leading cause of death worldwide, largely due to unhealthy diet, obesity, and associated metabolic disorders. Formulating specialized food products incorporating milk fat replacers could help reduce these risks. Forty patients from the personalized diet therapy department were recruited for the study and randomized into two groups. The study group (n = 20) received a low-calorie diet fortified with a specialized preventative product, while the control group (n = 20) received an unfortified diet. The diagnostic tests included a clinical examination (medical history, physical examination, and anthropometric measurements such as body mass index, blood pressure, and heart rate), laboratory tests (clinical and biochemical blood tests, analyses of the lipid profile, carbohydrate metabolism, vitamin status, and antioxidant activity), instrumental methods (bioimpedance analysis, indirect calorimetry), as well as diet analysis, protein metabolism analysis, sensory evaluation, and monitoring of side effects. Statistical analysis was performed in StatTech v.3.0.4. Fortifying the diet with the specialized product resulted in a significant reduction in total cholesterol (by 13.5%), low-density lipoprotein cholesterol (by 12.1%), and fat mass (by 1.5%) with preserved muscle tissue. Significant improvements in metabolic parameters included a 13.0% decrease in homocysteine levels, lower oxidative stress (malonaldehyde down by 31.9%), and a 58.3% increase in vitamin B₁₂. The administration of this diet therapy was not associated with the development of any adverse reactions.

The specialized preventative product manufactured using cheese technology can be recommended for use in preventative nutrition to reduce cardiovascular risks.

Keywords. Milk fat replacers, dyslipidemia, bioimpedance analysis, cardioprotection, antiatherogenic

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Инновационные подходы к созданию специализированных продуктов на основе растительного сырья как ключ к профилактике кардиоваскулярных рисков

Е. С. Симоненко 1,* , С. В. Симоненко 1 , Т. С. Залетова 2 , А. А. Хитров 3 , Е. С. Семенова 1 , А. В. Бегунова 1 , И. С. Самсонова 1

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*e-mail: nir@niidp.ru © Е. С. Симоненко, С. В. Симоненко, Т. С. Залетова, А. А. Хитров, Е. С. Семенова, А. В. Бегунова, И. С. Самсонова, 2025



Аннотация.

Сердечно-сосудистые заболевания остаются ведущей причиной смерти в мире, во многом из-за распространенности нездорового питания, ожирения и сопутствующих метаболических нарушений. Разработка специализированных пищевых продуктов, включающих заменители молочного жира, может способствовать снижению этих рисков.

В исследование включили 40 пациентов отделения персонализированной диетотерапии, рандомизированных на две сопоставимые группы: основная (ОГ, n=20) получала специализированный продукт для диетического профилактического питания в дополнение к низкокалорийной диете, контрольная (КГ, n=20) – только диету. Диагностический комплекс включал клиническое обследование (анамнез, осмотр, антропометрию с ИМТ, АД, ЧСС), лабораторные анализы (клинический и биохимический анализы крови с оценкой липидного профиля, углеводного обмена, витаминного статуса и антиоксидантной активности), инструментальные методы (биоимпедансометрию, непрямую калориметрию), анализ рациона, исследование белкового обмена, органолептическую оценку и мониторинг побочных эффектов. Статистический анализ выполняли в StatTech v.3.0.4.

Исследование показало, что включение специализированного продукта в диету обеспечило значимое снижение общего холестерина на 13,5 % и холестерина ЛПНП на 12,1 %, а также уменьшение жировой массы на 1,5 % при сохранении мышечной ткани. Отмечено существенное улучшение метаболических показателей: снижение уровня гомоцистеина на 13,0 %, уменьшение окислительного стресса (малоновый альдегид снизился на 31,9 %) и повышение уровня витамина B_{12} на 58,3 %. Применение данной диетотерапии не сопровождалось развитием побочных реакций.

Специализированный для диетического профилактического питания продукт, изготовленный по технологии сыра, может быть рекомендован для использования в диетическом профилактическом питании путем включения в состав рациона для снижения кардиоваскулярных рисков.

Ключевые слова. Заменители молочного жира, дислипидемия, биоимпедансометрия, кардиопротекция, антиатерогенный

Финансирование. Работа по подготовке рукописи проведена за счет средств субсидии на выполнение государственного задания по направлению FGMF-2025-0007 «Разработка состава, рецептур, технологий продуктов детского и геродиетического питания для оптимизации пищевых рационов детей различных возрастных групп и лиц пожилого возраста, а также разработка способов профилактики и коррекции нарушений пищевого статуса у детей и подростков с применением инновационных продуктов детского питания».

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Introduction

Cardiovascular diseases (CVDs) are the leading cause of death both in Russia and worldwide. According to the World Health Organization (WHO), they account for about one-third of all deaths, with a significant proportion of premature deaths among people under 70 years of age [1, 2]. Cardiovascular diseases include ischemic heart disease, cerebrovascular disease, peripheral arterial

¹ Научно-исследовательский институт детского питания – филиал Федерального государственного бюджетного учреждения науки «Федеральный исследовательский центр питания, биотехнологии и безопасности пищи», Истра, Россия

 $^{^{2}}$ Федеральный исследовательский центр питания, биотехнологии и безопасности пищи, Москва, Россия

³ ООО Научное производственное объединение «Биомедицинские инновационные технологии», Медное, Россия

disease, rheumatic heart disease, congenital defects, deep vein thrombosis, and pulmonary embolism. Myocardial infarction and stroke are among the most common and dangerous complications of CVDs. They are caused by atherosclerotic changes in the vascular wall, namely fatty and cholesterol plaques that narrow the lumen of the artery [3, 4].

The main risk factors for CVDs are behavioral in nature and include an unhealthy diet, low physical activity, smoking, alcohol abuse, as well as overweight and obesity. Other contributing factors are hypercholesterolemia, hypertension, and diabetes mellitus [5]. High cholesterol is a common condition in Russia. According to the All-Russian Epidemiological Study of Cardiovascular Diseases and their Risk Factors (ESSE-RF), 8.1% of men and 57.9% of women have high cholesterol levels, with their average values approaching the threshold for the norm. Obesity, especially abdominal obesity, has also reached epidemic proportions afflicting 30% of the adult population according to the ESSE-RF. Diabetes mellitus, especially type 2, is an independent risk factor for CVDs that significantly increases the risk of developing atherosclerosis. According to various sources, the incidence of diabetes in Russia ranges from 3.1 to 8.2%, with almost 90% of all cases being type 2 diabetes [6–8]. Its dietary risk factors include excessive consumption of salt, saturated and trans fats, as well as inadequate consumption of fiber, vegetables, and fruits. On average, Russians consume more than 11 g salt per day, while the WHO recommends limiting its consumption to 5 g. Lower sodium intake has been shown to reduce blood pressure and the risk of stroke [9]. Trans fats are the most atherogenic components of the diet. Their increase by only 2% leads to a 23% increase in the risk of coronary heart disease [10, 11].

Although the risk factors for CVDs have long been known, large-scale studies such as the REACH registry and EUROASPIRE demonstrate their high prevalence and inadequate control. This highlights the clinical importance of their prevention, monitoring, and correction [12]. The cornerstone of prevention is a healthy diet, with abstinence from smoking and alcohol, as well as increased physical activity and controlled body weight, blood pressure, cholesterol, and blood sugar levels [3]. This calls for creating specialized food products with proven therapeutic and preventative efficacy to restore reduced or lost bodily functions and enhance the body's adaptive capacity. These products should contain ingredients that can correct metabolic and antioxidant status disorders from an evidence-based medicine perspective [13].

Diet therapy is one of the main non-drug methods for preventing and treating CVDs. Modern dietary approaches aim not only to reduce caloric intake but also to optimize the diet by incorporating macro- and micronutrients, as well as specialized products fortified with vitamins and antioxidants [14, 15]. Another risk factor for cardiovascular health is dyslipidemia, which is characterized by elevated levels of low-density lipoproteins [16]. Numerous studies demonstrate that excessive consumption of saturated fatty acids leads to a significant increase in LDL cholesterol levels in the blood plasma. Doctors are particularly concerned about traditional dairy products that are high in saturated fats. These products are associated with an increased risk of atherosclerosis, a pathological change in large arteries that underlies most cardiovascular pathologies [17, 18].

Modern approaches to addressing dyslipidemia include the development of low-fat products [19]. However, fats affect the sensory properties of food, so their complete elimination can reduce its consumer appeal [20]. Therefore, fat substitutes are used to preserve the taste and texture of foods while reducing their caloric content [21].

Clinical guidelines from the American Heart Association and the European Society of Cardiology emphasize the importance of non-pharmacological approaches to reducing cardiovascular risk, including the modification of the fat composition of food. For the primary prevention of CVDs, they recommend using vegetable oils to replace saturated fatty acids with mono- and polyunsaturated fatty acids. Furthermore, the guidelines highlight the benefits of a plant-based diet, which is associated with lower mortality compared to a diet based on animal products [22, 23].

Therefore, modern strategies for preventing cardiovascular disease should be comprehensive and involve limiting saturated fatty acids in foods while preserving their sensory and nutritional properties; replacing saturated fatty acids with biologically complete alternatives while monitoring their lipid profile and the origin of their fat components; and personalizing diet therapy based on the patient's metabolic status. These approaches can simultaneously improve the lipid profile and nutritional appeal of diet foods, as well as ensure better weight control.

Milk fat replacers are products designed to replace, partially or completely, natural milk fat in foods. Their use benefits both consumers and food manufacturers. In particular, milk fat replacers:

- promote cardiovascular health by reducing low-density lipoproteins, aid weight management due to reduced caloric content [24, 25], and make dairy products more available in the regions where natural milk fat production is limited for climatic or economic reasons [26];
- are a cost-effective ingredient (compared to natural milk fat) that can be used to create products with a longer shelf life and therefore lower product loss and higher market availability [27]; and
- have certain technological properties that can improve the texture, structure, and stability of various food products such as ice cream, cream, cheese, and baked goods [28].

In this study, we aimed to evaluate the effectiveness of a diet fortified with a specialized preventative product manufactured according to the cheese technology in comparison with an unfortified diet in adults.

Study objects and methods

Forty patients from the Personalized Diet Therapy Department were recruited for the study according to the inclusion and exclusion criteria (see below). The study was approved by the local ethics committee of the Federal Research Center of Nutrition and Biotechnology (Protocol No. 3, March 15, 2023).

Inclusion criteria:

- age of 18 to 60 years old;
- a signed informed consent;
- obesity (BMI over 3 kg/m²);
- arterial hypertension for at least 5 years (including drug-controlled hypertension); and
- lipoprotein metabolism disorders: pure hypercholesterolemia, mixed hyperlipidemia (including drug-controlled disorders) for at least 5 years.

Exclusion criteria:

- pregnancy and/or breastfeeding;
- patient's reluctance;
- intolerance to ingredients in the study product;
- history of food allergies;
- acute myocardial infarction, acute cerebrovascular disorder, major surgery, or injury sustained over the last 6 months;
- cancer; and
- gastrointestinal pathology requiring medical correction.

The patients were randomized into two groups: a study group of 20 patients and a control of 20 patients. The groups were matched and controlled for age, gender, symptoms, disease duration, and medication use. No statistically significant differences were found between the groups for any of these parameters.

The control group received a low-calorie standard diet for two weeks, with moderate energy restriction (up to 1300–1600 kcal/day) mainly at the expense of fats and carbohydrates. Simple sugars were excluded, animal fats were reduced, and table salt was limited to 3–5 g/day.

The study group had a modified diet therapy for two weeks, which was a low-calorie standard diet fortified with a specialized preventative product (100 g) made according to the cheese technology.

The specialized preventative diet product was manufactured according to the technological guidelines and food production requirements established by the Technical Regulations of the Customs Union.

The nutritional and energy value of 100 g of the product is provided in Table 1.

The average daily nutrient content and energy value of the diets are presented in Table 2.

The diets had limited amounts of table salt (5 g/day), as well as chemical and mechanical irritants to the stom-

Table 1. Nutritional value of the specialized product (per 100 g)

Таблица 1. Пищевая ценность специализированного продукта (содержание в 100 г продукта)

Component	Value
Fat, g	25.0
Protein, g	14.0
Carbohydrates, g	5.0
Vitamin E (tocopherol), mg	15.0
Vitamin B ₁₂ (cyanocobalamin), mcg	3.0
Energy value, kcal/kJ	301.0/1260.0

Table 2. Average daily nutrient content and energy value of the diets

Таблица 2. Среднесуточное содержание пищевых веществ и энергетическая ценность диет

Туре	Protein, g	Fat, g	Carbo-	Energy
of diet			hydrates, g	value, kcal
Low-	70–80	60–70	130–150	1340–1550
calorie diet				
Modified	84–94	85–95	135–155	1640–1850
diet	04-94	05-95	133-133	10-10-1030

ach and bile ducts. The meals were boiled, stewed, baked, pureed, or steamed. The food temperature ranged from 15 to 60–65°C. Free liquid intake was 1.5–2.0 liters. The patients had six meals a day.

Medication therapy was administered according to the standard regimens for medical conditions and was not adjusted during the study.

General clinical methods. Clinical and functional research methods included collecting complaints, taking a medical history, and performing a physical examination.

All the patients had their height and weight measured, with their BMI calculated using the Quetelet's index (kg/m^2) = weight/height.

They had their blood pressure measured with a mechanical tonometer, as well as their heart rate.

Biochemical analyses were performed using an AU 680 automated analyzer (Beckman Coulter, USA). Serum venous blood was analyzed for total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, glucose, creatinine with a calculated glomerular filtration rate, urea, uric acid, total bilirubin, alanine aminotransferase, aspartate aminotransferase, and potassium.

Complete blood panel parameters were assessed using an LH 750 analyzer (Beckman Coulter, USA). They included red blood cell and white blood cell counts, hemoglobin, platelet, and an erythrocyte sedimentation rate.

Insulin levels were measured using an Immulite Xp 2000i automated analyzer (Siemens Healthcare Diagnostics, Germany).

The vitamin status (vitamins E, B₁₂, homocysteine) was assessed using an AU 680 automated analyzer (Beckman Coulter, USA).

The antioxidant defense indicators (plasma antioxidant activity, superoxide dismutase, malondialdehyde) were determined using an ELISA reader (Tecan, USA).

The nutritional intake (dietary energy, macro- and micronutrients) was assessed by frequency analysis using the Nutrilogic service (Nutrilogic, Russia, state registration certificate No. 2018614588 dated February 19, 2018).

Body composition measurements were analyzed by bioimpedance analysis using the LookinBody software and the InBody 720 analyzer (Biospace, South Korea). They included fat mass, lean mass, skeletal muscle mass, and total body water. For the measurements, the patients had to be in the fasting state, stand barefoot on a scale, and hold the analyzer handles with both hands.

Basal metabolic expenditure was measured by indirect calorimetry using a Quark RMR stationary metabolograph (COSMED, Italy) with a dome. The respiratory quotient was calculated from noninvasive measurements of oxygen consumption and carbon dioxide production, as well as ventilation parameters.

Daily protein losses were calculated based on the concentration of urea in a 24-hour urine sample using the formula:

$$POR = (U \times 0.446 + 4) \times 6.25$$

where POR is the protein oxidation rate, g/day; U is the urea, g/day. The resulting residual nitrogen value was used to further calculate daily protein losses. The fat oxidation rate and the carbohydrate oxidation rate were also determined by using the software (COSMED, Italy).

The course of treatment was recorded in the patients' medical records. The measured parameter values were entered in the individual patient registration cards according to the research protocol.

The dishes were evaluated on a 5-point scale for their sensory properties such as taste, smell, color, consistency, and appearance.

Statistical research methods. Quantitative variables were assessed for normal distribution using the Shapiro-Wilk test (for fewer than 50 subjects) or the Kolmogorov-Smirnov test (for more than 50 subjects).

Normally distributed quantitative variables were described using mean values (M) and standard deviations (SD), along with 95% confidence intervals (95% CI).

If not normally distributed, quantitative data were described using the median (Me) and lower and upper quartiles (Q1–Q3).

Categorical data were described in absolute values and percentages.

The Student's *t*-test was performed to compare two groups for a normally distributed quantitative variable, assuming equal variances.

The Mann-Whitney *U*-test was performed to compare two groups for a non-normally distributed quantitative

variable. The paired Student's *t*-test was performed to compare normally distributed quantitative variables in two related samples.

The Wilcoxon *t*-test was performed to compare nonnormally distributed quantitative variables in two related groups. The software StatTech v. 3.0.4 (StatTech, Russia) was used for statistical analysis.

Results and discussion

Nutritional value of the actual diet. The most common indicators of dysnutrition in the patients were: excessive intake of total fat (+82.5%), saturated fatty acids (+91.1%), and cholesterol (+110.4%), as well as a deficiency of dietary fiber (-33.5%), omega-3 PUFAs (-21.0%), potassium (-19.6%), magnesium (-22.2%), phosphorus (-15.5%), iron (-17.0%), and vitamins A (-12.4%), E (-33.7%), B₂ (-12.1%), and D (-60.7%).

Anthropometric parameters. Almost all the patients, regardless of the diet therapy administered, had statistically significant positive changes in their body weight and body mass index (BMI). The comparative analysis of their anthropometric parameters over time between the groups is presented in Table 3.

As can be seen, only the study group demonstrated a statistically significant reduction in fat mass. In contrast to the study group, the control group showed a statistically significant reduction in lean mass and skeletal muscle mass, suggesting a negative impact of the chosen diet therapy. It should be noted that the study group received a higher-calorie version of the standard diet and its patients had lower body weight. However, they demonstrated significantly better changes in fat and lean mass in addition to weight loss.

Resting energy expenditure. Resting energy expenditure values remained unchanged in both the study and the control groups (Table 4). However, the control group demonstrated a statistically significant increase in the carbohydrate oxidation rate, with a decrease in the fat oxidation rate. This might explain the less efficient loss of fat mass in this group. The protein oxidation rates did not change significantly in both groups.

The data revealed that the modified diet, along with the traditional diet therapy, did not decrease the activity of the body's energy processes or cause changes in the macronutrient oxidation rates.

Blood test parameters. Changes in blood glucose levels are presented in Fig. 1. Initially, the glucose levels did not differ statistically between the groups, with 6.4 (5.8–6.7) mmol/L in the control group and 6.0 (5.4–6.4) mmol/L in the study group. The treatment (diet therapy) caused no increase in this parameter, with no hypoglycemic therapy administered. Furthermore, there was a significant decrease within the reference range in the control group. Thus, the modified diet produced no effect on the patients' glycemic profile.

Changes in the lipid profile during the diet therapy are presented in Table 5.

Comparable statistically significant changes were observed in both groups during the treatment, namely a decrease in total cholesterol and low-density lipoprotein cholesterol. This indicated an anti-atherogenic effect of the modified diet, comparable to the standard diet therapy. A relatively negative effect of the diet therapy was a significant decrease in high-density lipoprotein cholesterol, from 1.5 ± 0.3 to 1.4 ± 0.3 mmol/L in the study group and from 1.1 ± 0.2 to 1.0 ± 0.2 mmol/L in the control group.

Blood vitamin analysis (Table 6) revealed an increase in vitamin B₁₂ levels from 252 (228–325) to 399 (270–462) pg/mL in the study group, with no changes in the control group. Vitamin E levels decreased in the study group, while remaining unchanged in the control group.

Homocysteine levels decreased from 11.5 ± 1.2 to 10.0 ± 1.0 µmol/L (p < 0.001) in the study group and from 12.3 ± 0.9 to 10.6 ± 0.6 µmol/L (p < 0.001) in the control group (Fig. 2), demonstrating the anti-atherogenic effect of the modified diet.

Table 3. Body composition changes during diet therapy

Таблица 3. Анализ динамики показателей состава тела на фоне проводимой диетотерапии

Parameter	Stage	Control group	Study group
Body weight	1	111.6 (89.3–117.6)	88.7 (78.2–92.8)
$Me(Q_1-Q_3), kg$	2	106.0 (88.3–115.0)	86.8 (77.1–91.8)
	p	0.002*	< 0.001*
Body mass index	1	38.7 ± 7.7	33.5 ± 7.0
$M \pm SD, kg/m^2$	2	38.1 ± 7.4	33.1 ± 6.8
	p	0.001*	< 0.001*
Fat mass	1	47.0 ± 15.9	39.7 ± 12.6
$M \pm SD, kg$	2	46.6 ± 15.3	39.1 ± 12.2
	p	0.293	0.015*
Lean mass	1	57.2 (52.9–64.5)	46.7 (41.2–48.2)
Me (Q ₁ –Q ₃), kg	2	56.3 (52.7–63.4)	45.4 (40.9–49.1)
	p	0.001*	0.078
Skeletal muscle mass	1	33.6 (31.1–39.8)	27.1 (23.9–27.9)
Me (Q ₁ –Q ₃), kg	2	33.2 (31.0–38.1)	26.4 (23.7–28.6)
	p	0.004*	0.092
Total body water	1	44.6 (41.2–49.9)	36.4 (32.0–37.7)
Me (Q ₁ –Q ₃), kg	2	44.2 (41.1–49.0)	35.3 (31.8–38.5)
	p	0.021*	0.078

Note: * – statistically significant differences (p < 0.05).

Примечание: * — различия показателей статистически значимы (p < 0.05).

Table 4. Changes in resting energy expenditure during diet therapy

Таблица 4. Анализ динамики показателей энерготрат покоя на фоне проводимой диетотерапии

Parameter	Stage	Control group	Study group
Carbohydrate oxidation	1	21 (15–26)	75 (10–320)
Me (Q_1 – Q_3), g /day	2	47 (41–73)	108 (16–289)
	p	< 0.001*	0.640
Fat oxidation	1	200 (186–234)	131 (35–154)
Me (Q ₁ –Q ₃), g/day	2	182 (152–218)	132 (87–183)
	p	0.049*	0.284
Protein oxidation	1	77 (71–85)	58 (51–62)
Me (Q_1-Q_3) , g/day	2	76 (70–86)	65 (50–73)
	p	0.670	0.212
Resting energy expenditure	1	2042 (1882–2260)	1564 (1384–1694)
Me (Q1-Q3), kcal/day	2	2037 (1859–2281)	1726 (1328–1950)
	p	0.670	0.495

Note: * – statistically significant differences (p < 0.05).

Примечание: * — различия показателей статистически значимы (p < 0.05).

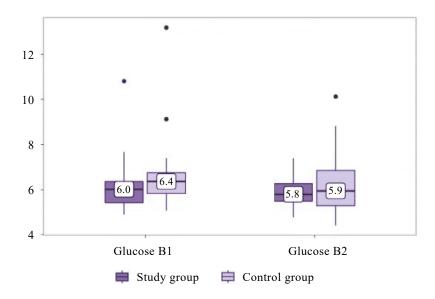


Figure 1. Changes in blood glucose levels during diet therapy Рисунок1. Анализ динамики глюкозы крови на фоне проводимой диетотерапии

Table 5. Changes in lipid profile during diet therapy

Таблица 5. Анализ динамики липидного профиля на фоне проводимой диетотерапии

Parameter	Stage	Control group	Study group
Total cholesterol	1	4.7 ± 1.2	5.2 ± 1.3
$M \pm SD$, mmol/L	2	3.9 ± 1.0	4.5 ± 1.2
	p	0.001*	0.019*
Triglycerides	1	1.5 (1.1–2.1)	0.9 (0.8–1.2)
Me (Q ₁ –Q ₃), mmol/L	2	1.1 (0.9–1.3)	0.8 (0.6–1.1)
	p	0.005*	0.097
High-density lipoprotein	1	1.1 ± 0.2	1.5 ± 0.3
cholesterol M ± SD, mmol/L	2	1.0 ± 0.2	1.4 ± 0.3
	p	0.015*	0.016*
Low-density lipoprotein cholesterol $M \pm SD$, mmol/L	1	3.1 ± 1.0	3.3 ± 1.0
	2	2.5 ± 0.8	2.9 ± 1.0
	p	< 0.001*	0.035*

Note: * – statistically significant differences (p < 0.05).

Примечание: * — различия показателей статистически значимы (p < 0.05).

Table 6. Changes in vitamin levels during diet therapy

Таблица 6. Анализ динамики витаминов на фоне проводимой диетотерапии

Parameter	Stage	Control group	Study group
Vitamin E	1	1.2 (1.1–1.4)	1.4 (1.2–1.6)
Me (Q ₁ –Q ₃), mcg/mL	2	1.2 (1.0–1.3)	1.2 (1.0–1.5)
	p	0.258	0.009*
Vitamin B ₁₂	1	248 (127–320)	252 (228–325)
Me (Q_1-Q_3) , pg/mL	2	265 (143–440)	399 (270–462)
	р	0.927	< 0.001*

Note: * – statistically significant differences (p < 0.05).

Примечание: * — различия показателей статистически значимы (p < 0.05).

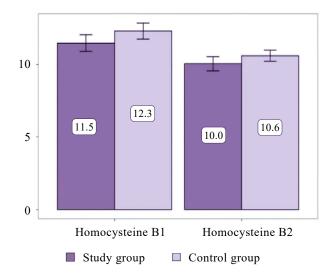


Figure 2. Changes in homocysteine levels during diet therapy
Рисунок 2. Анализ динамики гомоцистеина на фоне проводимой диетотерапии

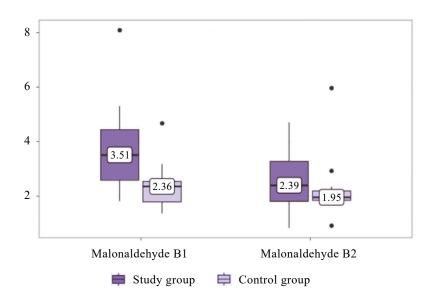


Figure 3. Changes in malonaldehyde levels during diet therapy

Рисунок 3. Анализ динамики малонового альдегида на фоне проводимой диетотерапии

Superoxide dismutase levels did not change significantly in either group during the diet therapy. In particular, they slightly increased from 184.62 ± 44.19 to 206.17 ± 49.08 (p = 0.079) in the study group and from 161.22 ± 66.02 to 169.40 ± 25.24 (p = 0.700) in the control group.

As can be seen from Fig. 3, the concentration of malonaldehyde significantly decreased from 3.51 (2.58–4.44) to 2.39 (1.80–3.27) in the study group (p = 0.002), but remained unchanged in the control group (p = 0.497). Our results indicated a decrease in the intensity of lipid peroxidation during the diet therapy. No changes in blood insulin levels were observed in either of the groups.

Other biochemical blood parameters showed similar trends in both groups and were characterized by mod-

erate changes within the reference values (Table 7). A statistically significant decrease was observed in aspartate aminotransferase levels in the study group, namely from 22.5 (19.3–29.8) to 22.1 (18.2–26.4) U/L. Total bilirubin levels also significantly decreased, from 12.3 (10.0–15.7) to 10.0 (7.4–12.1) µmol/L in the study group and from 14.5 (11.1–18.5) to 12.9 (10.4–14.1) µmol/L in the control group. However, these values remained within the reference ranges.

Tolerability of the diet therapy. The modified diet showed good tolerability and safety, with no side effects or signs of intolerance observed during the study period in either the control or study groups (dyspepsia: regurgitation, nausea, heartburn, bitter taste in the mouth; stomach ache; allergic reactions).

Table 7. Changes in biochemical blood parameters during diet therapy

Таблица 7. Анализ динамики биохимических показателей крови на фоне проводимой диетотерапии

Parameter	Stage	Control group	Study group
Aspartate aminotransferase	1	22.2 (19.9–26.2)	22.5 (19.3–29.8)
Me (Q ₁ –Q ₃), U/L	2	25.1 (22.7–29.5)	22.1 (18.2–26.4)
	р	0.060	0.036*
Alanine aminotransferase	1	24.7 (18.7–33.0)	19.9 (15.5–32.2)
Me (Q ₁ –Q ₃), U/L	2	31.1 (21.3–35.5)	17.0 (14.2–25.0)
	p	0.580	0.165
Total bilirubin	1	14.5 (11.1–18.5)	12.3 (10.0–15.7)
Me (Q1–Q3), μmol/L	2	12.9 (10.4–14.1)	10.0 (7.4–12.1)
	р	0.048*	0.014*
Creatinine	1	86.3 (72.6–99.4)	80.2 (72.0–89.5)
Me (Q1–Q3), μmol/L	2	93.5 (74.9–102.6)	82.5 (77.5–87.5)
	p	0.368	0.143
Glomerular filtration rate	1	74 ± 21	73 ± 16
$M \pm SD$	2	72 ± 19	70 ± 15
	p	0.280	0.188
Urea	1	5.1 (4.3–6.7)	5.7 (5.1–6.8)
Me (Q ₁ –Q ₃), mmol/L	2	5.3 (4.8–7.5)	6.5 (5.5–6.8)
	p	0.464	0.097
Uric acid	1	375.4 ± 109.7	313.3 ± 100.2
$M \pm SD$, $\mu mol/L$	2	393.9 ± 111.8	313.8 ± 86.1
	p	0.162	0.952
Potassium	1	4.3 (4.1–4.4)	4.4 (4.0–4.5)
Me (Q ₁ –Q ₃), mmol/L	2	4.4 (4.0–4.7)	4.4 (4.2–4.6)
	р	0.246	0.064

Note: * – statistically significant differences (p < 0.05).

Примечание: * — различия показателей статистически значимы (p < 0.05).

Table 8. Sensory evaluation of diet therapy Таблица 8. Органолептическая оценка диетотерапии

Parameter	Control group	Study group	
	Average scores on a 5-point scale		
Taste	4.25	4.85	
Smell	4.15	4.80	
Color	4.50	4.95	
Consistency	4.35	4.85	
Appearance	4.50	4.95	

The sensory evaluation of the diet products included the following parameters: taste, smell, color, consistency, and appearance (Table 8). According to the results, the modified diet was evaluated positively, with scores averaging 24 out of 25 in the study group, compared to 22 out of 25 in the control group.

Conclusion

The modified diet (fortified with a specialized preventative product manufactured using cheese technology) demonstrated a number of clinically significant effects compared to the standard diet therapy. In particular, we found a statistically significant reduction in total cholesterol and low-density lipoprotein cholesterol levels, indicating the antiatherogenic effect of the diet therapy and a reduced risk of cardiovascular complications. We also observed a statistically significant decrease in homocysteine levels, a risk factor for vascular pathologies, including peripheral arterial disease, nephropathy, and retinopathy. Further, the modified diet helped replenish vitamin B₁₂ deficiency and reduce malonaldehyde levels, lessening the intensity of lipid peroxidation. Among its other positive effects was the ability to maintain resting energy expenditure while reducing body weight. Despite its higher caloric content, the modified diet significantly reduced fat mass in obese patients while maintaining their lean mass. In addition, we observed a reduction in clinical symptoms among the patients. Finally, the specialized product received a good sensory evaluation and showed excellent tolerability.

Thus, our specialized preventative diet product can be incorporated into preventative dietary regimens to maintain cardiovascular health.

We plan to expand the range of specialized preventative products by formulating products with bioactive ingredients that have proven cardioprotective effects. Algae, for example, have great potential due to their complex of bioactive compounds with a pronounced positive effect on the cardiovascular system.

Algae components such as omega-3 polyunsaturated fatty acids, antioxidants, peptides, and polysaccharides help reduce the risk of cardiovascular disease by improving lipid profiles, lowering blood pressure, and reducing inflammation and oxidative stress. Algae are a rich source of omega-3 fatty acids, such as eicosapentaenoic and docosahexaenoic acids. These acids have hypolipidemic and antihypertensive effects, improving the endothelial function and reducing the risk of arrhythmia. Studies have shown that these acids obtained from the microalgae Schizochytrium and Crypthecodinium can reduce plasma triglyceride levels and systolic blood pressure in both animals and humans. Algae also contain high levels of antioxidants, such as carotenoids (e.g., astaxanthin), polyphenols, and vitamin C. These compounds reduce oxidative stress, which plays a key role in the development of atherosclerosis and other cardiovascular diseases. Astaxanthin, in particular, has potent antiinflammatory and antioxidant properties, protecting endothelial cells from damage. Furthermore, bioactive peptides isolated from algae such as Laminaria and Ascophyllum can inhibit angiotensin-converting enzyme, lowering blood pressure. Algae polysaccharides, particularly sulfated ones, have a hypocholesterolemic effect, reducing low-density lipoprotein cholesterol and triglyceride levels and stimulating the excretion of bile acids [29–31]. Thus, considering the promising cardioprotective potential of the bioactive compounds derived from algae, our subsequent research will focus on the development

of novel specialized formulations based on these constituents, aimed at comprehensive prevention of cardiovascular diseases.

Contribution

E.S. Simonenko consolidated the material and described the results and discussion; S.V. Simonenko supervised the research and wrote the conclusion; A.A. Khitrov and T.S. Zaletova revised the manuscript; E.S. Semenova and A.V. Begunova described the study objects and methods; I.S. Samsonova collected and consolidated the material, as well as wrote the introduction.

Conflict of interest

The authors declare no conflict of interest.

Критерии авторства

Е. С. Симоненко — обобщение материала, написание раздела статьи по результатам исследования; С. В. Симоненко — руководство проектом, написание заключения; А. А. Хитров, Т. С. Залетова — доработка рукописи; Е. С. Семенова, А. В. Бегунова — написание раздела статьи по методам исследования; И. С. Самсонова — сбор и обобщение материала, написание введения.

Конфликт интересов

Авторы заявляют об отсутствии конфликта интересов.

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Additional information about the authors / Дополнительная информация об авторах

- Elena S. Simonenko / Симоненко Елена Сергеевна ORCID 0000-0002-2878-8069; eLIBRARY SPIN 8486-6017
- Sergey V. Simonenko / Симоненко Сергей Владимирович ORCID 0000-0002-6999-5048; eLIBRARY SPIN 4079-3763
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