# METHODOLOGICAL ASPECTS AND OPERATIONAL EXPERIENCE OF THE NEW BAA WITH TARGETED FUNCTIONAL PROPERTIES

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Received February 11, 2016; Accepted in revised form June 30, 2016; Published December 30, 2016

**Abstract**: Specialized food products development, including biologically active additives (BAA), is one of the priority areas in the realization of the healthy eating program and the food and pharmaceutical industries development in the Russian Federation. A lot of attention is paid to the proof of effectiveness and functional orientation of the concerned foodstuff. Dietetic therapy with the use of BAA is considered to be the most available way to improve the modern man's nutrition and health. The aim of this work was to develop and confirm specialized food products' practical application through clinical trials and mass production organization. Specialized products for dietetic nutrition and protective diet such as BAA ("Energopan", "Cleopanta", "Green Star") and the "Light mood" bar were developed. Methodological aspects of the new types of the specialized products' creation were described. Prescription formulas with account taken of pharmacological characteristics of their active principles were scientifically proven. Regulated indices of nutrition value including recommended amount of consumption of the developed product and safety criteria that allowed establishing duration of realization were identified. Clinical trials of the specialized products were conducted: "Light mood" bar and the BAA "Green Star" were included in study groups' ration and their biomedical measurements characterizing metabolic care were analyzed. Observational results allowed to recommend the "Light mood" bar for prophylaxis and treatment of the constipation in combination with other somatic diseases and the BAA "Green Star" for digestion health improvement in the function of energy absorbent and improvement of the overall level of metabolism. Developed products' formulation and technology were tested under production conditions in the SPA "Yug" and the "Art-Life" company (Russia).

**Keywords**: prescription ingredients, biologically active additives, functional properties, effectiveness, clinical trials

**DOI:** 10.21179/2308-4057-2016-2-66-74 *Foods and Raw Materials*, 2016, vol. 4, no. 2, pp. 66–74.

## INTRODUCTION

Nutrition is one of the most important factors determining the health of the population. Healthy eating helps to prevent diseases, to prolong life, to improve working capacity, to enable adaption to environmental conditions. At the same time there are negative trends in the health status of the population. The majority has nutrition disorders due to both poor nutrient materials intake, especially vitamins, macro- and micronutrients, and complete proteins, as well as their irrational ratio. There is every reason to believe that the most rapid, economical and scientifically grounded way to solve the nutrition rationalization problem is the widespread use of specialized products, including BAA [12, 14].

The RAND Corporation presented the results of the evaluation of the world community science and technology and social and economic development prospects for the period until 2020, including "challenge-response" mechanism. The driving forces of the modern innovation process and obstacles on its way and various scientific and technological development priorities were analyzed. Among the latter the main attention is given to healthy lifestyle and ultimate nutrition ensuring and prevention of common conditions of the infectious and nutritional (non-infectious) nature. In relation to this trend the great importance have development issues of specialized products, including BAA, study of the composition, pharmacologic orientation and functional properties of starting materials. They are determined by science and technology priorities of the modern nutritiology. Also the importance is given to the efficiency evidence and functional orientation of the concerned food products by conducting clinical trials. In such case dietetic therapy is considered to be the most available way to improve the modern man's nutrition and health [13, 15, 20].

## OBJECTS AND METHODS OF STUDY

The objects of research were starting materials used in development of prescription formulae for the new BAA types such as “Energopan”, ‘Cleopanta”, “Green Star”, “Light mood” bar, and their laboratory and industrial samples.

Standard and special methods of quality and safety research of the developed products were used with the help of spectophotometery, stripping voltammetry, and liquid chromatography. Tests were carried out on the basis of accredited laboratories of the SPA “Yug” (Biysk, Russia) and “Art-life” company (Tomsk, Russia).

For the “Cleopanta” identification the panto-hematogen authenticity was conducted according to the developed technique. 10 ml of Feling reagent are added to a solution of 0.2 g of the capsule contents in 5 ml of the water and brought to boil. Glucose flocculates in russet. The resulting solution is put to test according to GOST (All Union State Standars) 30418-96 to isolate triglycerides’ fatty acid composition that occurs in plasma lipoproteins.

The content of pantohematogen is determined spectrophotometrically by the level of hemoglobin at a wavelength of 540 nm. About 0.8 g of the capsule contents is placed in a mortar, then 5 ml of 0.5% aqueous ammonia solution are added and everything is pestled until dissolved. The solution is quantitatively transferred to a 50 ml volumetric flask with wash of 0.5% ammonia solution (10 ml three times). The resulting solution is kept at room temperature in a shadowed place with intermittent mixing for an hour and filtered through cheesecloth or cotton plug, the filter is washed with 0.5% ammonia solution to bring the total filtrate volume to 50 ml. The optical density of the solution is measured on a spectrophotometer at a wavelength of 540 nm in a cuvette with 10 mm layer thickness by using the 0.5% ammonia solution as a blank solution. The optical density should be at least 0.4.

The data obtained from examination and monitoring of 30 patients with functional constipation of the 1-2 type was used when clinical trials of the “Light mood” bar were conducted. The diagnosis of functional constipation was made by a gastroenterologist after patients’ cohort study on the basis of historical studies, results of physical examination, laboratory and instrumental methods of research as well as test results of diagnosing the quality of life over time during treatment. Patients with FC were given 1-2 “Light mood” bars for 15 days before bedtime. Differences between parameters of comparison were considered statistically dissimilar at $P<0.05$. The study was conducted in accordance with the principles of the World Medical Association's Declaration of Helsinki (as revised in 2000 with the explanations given at the WMA’s General Assembly in Tokyo, 2004), the rules of International Conference on Harmonisation Good Clinical Practice (ICHGCP), the ethical principles stated in the EU directive 2001/20/EU and with the requirements of the Russian Federation legislation. Each patient signed the "Informed consent" to participate in the trials. The research was carried out at the central research laboratory of the Kemerovo State Medical Academy and at the “Medical practice” clinic (Kemerovo, Russia).

The average age of patients was $38.5 \pm 8.3$ years. The initial state analysis of the patients with FC was carried out according to objective research, on the basis of subjective complaints registration and gastrointestinal status in accordance with the Rome III criteria, 2006. The diagnosis of FC was made based on the exclusion of organic pathology of the abdominal cavity organs after laboratory, endoscopic, radiological and morphological diagnostic. All patients were offered the Nottingham Health Profile. Full-scale tests on effectiveness and functional orientation of the BAA “Green Star” were conducted on 25 volunteers. The study was carried out at the Siberian State Medical University’s Department of Internal Medicine, Faculty of Professional Development and Retraining.

The main group was made up of 25 volunteers without symptoms whose professional life related with vigorous physical activities as well as neuropsychic activities wasn’t interrupted: 11 drivers of public transport at the age from 36 to 47 and 14 managers at the age from 28 to 44 (4 men and 10 women). The control group consisted of 15 healthy volunteers of similar occupation, randomized by gender and age. The active treatment group took the “Green Star” bioactive complex outpatiently and the control group took multivitamin preparations.

## RESULTS AND DISCUSSION

A series of specialized products of different functional orientation was developed. Regulated quality parameters and shelf life and storage conditions were developed; their efficiency and functional orientation evidences were proven.

Observance of the following methodological principles is required for specialized products (such as BAA) development:

– Prescription formula (its qualitative and quantitative composition) must be designed with consideration for macro- and micronutrients of certain groups and minor food items needs, as well as their synergistic effect on the metabolism of healthy and diseased organisms;

– Used ingredients and the product itself must meet the requirements in terms of safety and consumer preferences;

– Regulated nutritional value indicators must provide at least 10% of the daily nutrient requirement, providing the application of the recommended product amount;

– Developed products should be affordable for different groups of the population.

The prescription formula of the specialized products with account of active principles influence on healthy and sick person’s metabolic processes was scientifically grounded. In this context there is a good reason to consider the basic prescription ingredients which functional properties are presented in the existing literature and the results of their own research [2–10, 17, 18].

The description of the tested products’ basic prescription ingredients is given below.

The BAA "Cleopanta": glucose, licorice root (*Radices Glycyrrhizae*), dry pantohematogen (red deer, Manchurian deer or dappled deer blood dried up with a method of deep vacuum dehydration) and ascorbic acid.

The licorice roots (*Radices Glycyrrhizae*) have antioxidant properties, protect the body from free radicals, contain flavonoids – liquiritin, liquiritoside, isoliquiritin, neolikviritin, ramnolikviritin, uralozid, ramnoizolikviritin, which slow down body aging processes, prevent the development of atherosclerosis and cardiovascular disease. Glucose and ascorbic acid have synergistic properties in relation to the described metabolic processes.

Pantohematogen is a red dear's blood, taken in the final period of antlers growth (before ossification). Pantohematogen contains: essential and nonessential amino acids (lysine, arginine, histidine, 4-hydroxyproline, threonine, tryptophan, glutamic acid, proline, serine, glycine, alanine, valine, cystine, isoleucine), peptides, nucleic acid bases, lipids (phospholipids, triglycerides, sphingomyelin, lecithin), hormones, vitamins A and E, and a complex of various macro- and micronutrients (potassium, sodium, magnesium, ferrum etc.). Pantohematogen greatly contributes to the organism resistance to negative effects of various adverse environmental factors, improves metabolic processes, slows body aging processes, improves immunity, and increases the body's resistance to bacterial and viral infections. It also reduces fatigability, improves mental capacity and central nervous function.

The BAA "Energopan": pantohematogen, rhizomes and roots of *Rhizoma et radices Rhodiolae roseae*, glucose and ascorbic acid.

*Rhodiola rosea* is a perennial flowering plant in the family Crassulaceae. It grows in cold regions of the world, including mountainous areas in Eastern Siberia and Altai. Rhodiola roots contain phenols, aromatic compounds, carbohydrates (glucose, fructose), organic acids (malic, oxalic, citric, succinic), essential oil, terpenoids, and flavonoids (total of about 86 components). Rhodiola rosea has anti-viral, tonic, antitumor, antibacterial, antimicrobial, antipyretic, anti-inflammatory and antitoxic effect.

The BAA "Green Star": spirulina, chlorella, apple pectin, kelp thallus, wheatgrass, farina, catalase, rosehips, Echinacea Purpurea, lactobacterium complex, tocopheryl acetate (vitamin E), ginkgo biloba extract, blueberry, green tea, superoxide dismutase, gelee royale and coenzyme Q10.

The basis of the complex is a balanced combination of spirulina and chlorella. Spirulina is a complete protein and it contains essential amino acids which constitute up to 65–75% of its weight. Spirulina's mineral composition distinctive feature is that it contains digestible chelated microelememts. Chlorella is rich in chlorophyll which is an effective disinfectant of natural origin; it strengthens cell membranes, stimulates the connective tissues formation, and accelerates the healing of erosions, ulcers and open wounds. Seaweed cell walls contain polysaccharides which together with wheat fiber and pectin improve the functioning of the gastrointestinal tract and intestinal peristalsis. Active substances in Echinacea have immunostimulatory effects and ginkgo biloba extract has beneficial effects on blood flow. The "Green Star" complex has antioxidant activity due to the active substances of rosehips, blueberry, green tea, enzymes and vitamin E.

The specialized product "Light mood": prunes, raisins, apple, fructose, senna extract, oat flakes (milled), gum-arabic, wheat bran, caraway (milled seed), potassium sorbate, citric acid.

Prunes contain fructose, glucose, saccharose, malic acid, oxalic acid, citric acid, salicylic acid, pectin, polyphenolic and nitrogenous matters, vitamins A, C, $B_1$, $B_2$, P, significant amount of significant amounts of potassium and phosphorus, less sodium, calcium, magnesium and ferrum.

Prunes have a beneficial effect on the gastrointestinal tract, helps to get rid of constipation and to normalize of the digestive system; it is useful for heart problems and high blood pressure's solutions, kidney diseases, rheumatism, liver diseases and atherosclerosis. It improves eyesight due to the high concentration of vitamin A.

Raisins contain beneficial carbohydrates, organic acids, dietary fibers, proteins, some fat, vitamins A, C, E, H, B-group, beta carotene, trace elements – zinc, selenium, iron, manganese, copper. They are especially rich in potassium, necessary for kidneys and the heart muscle, metabolism in the skin and neurotransmission, and maintenance of normal blood composition. Because of nicotinic acid they have a calming effect and regulate the nervous system. They help to eliminate toxins and fluid due to diuretic action. Organic acids contained in raisins are characterized by antioxidant and antibacterial properties.

Apples. Their nutrient composition explains their useful properties. Apples contain vitamins C, $B_1$, $B_2$, $B_6$, P, E, carotene, potassium, iron, magnesium, calcium, pectins, sugar, and organic acids. They also contain the following trace elements: phosphorus, manganese, sodium, sulfur, aluminum, boron, vanadium, iodine, copper, molybdenum, nickel, fluorine, chromium and zinc. They contribute to the normalization of the gastrointestinal tract and the digestive system, and they are used to prevent constipation and to increase appetite. Apples contain chlorogenic acid which contributes to the oxalic acid elimination and normal liver functioning.

Apple pectin plays a pivotal role in the formation of dejection. This circumstance, as well as evident irritant effect on the mechanoreceptors of the intestinal mucosa, plays a key role in the stimulation of peristalsis and the regulation of the motor function of entodermal canal. The lack of pectin in nutrition leads to gallbladder and colon dyskinesia.

Pectin substances adsorb exo- and endotoxins, salts of heavy-metal and radionuclides. Pectins, reacting with bile acids, reduce fat absorption and cholesterol. They suspend gastric emptying and thus slow down the absorption of sugar by coating the mucosa of the gastrointestinal tract. They have a cidal effect on opportunistic pathogens and the causative agents of acute intestinal infections without disrupting the balance of microflora. Pectins help to improve parietal

digestion and to normalize intestinal microbiocenosis with positive effect on skin condition.

Senna extract (*Cassia acutifolia Del*.). It contains anthraglycosides (sennosides A and B, rhein, aloe-emodin), flavonoid glycosides (isorhamnetin, kaempferol, kaempferide), organic acids (stearic acid, palmic acid, etc.), and phytosterol. Senna extract has laxative properties, improves motor function of the colon, and contains no bitter or tanning principles, that is why it doesn't increase appetite and doesn't cause constipation after laxative action.

The main active substances are anthraglycosides which under the influence of digestive enzymes and bacterial processes cleave into sugar and aglycone. The latter irritate receptors of the mucosa of the gastrointestinal tract increasing motion activity but not the secretions.

Field caraway (*Carum carvi*). The substances contained in the caraway fruits have beneficial effects on various body systems. They can relieve spasms of the smooth stomach muscles, biliary ducts, and gastrointestinal tract reduce the activity of enzymes in pathological processes in the stomach and intestine, which is beneficial for health because it reduces the processes of fermentation and putrefaction.

Cummin seeds can exert diuretic and expectorant action and have galactogogue effect. Their bactericidal action is proven. Caraway fruits improve the separation of bile and similarly affect the secretion of gastric juice and pancreatic enzymes; they increase appetite and have a calming effect.

Oat (*Avéna satíva*). It contains mucus and has a coating effect on gastrointestinal tract. Oat is the source of soluble and insoluble dietary fiber, which is able to absorb and remove toxins and to exert a prebiotic effect. Oat is rich in substances that are necessary to cleanse the blood vessels from atherosclerotic plaques, maintain normal cholesterol and blood sugar, and help to normalize weight (zinc, chromium, vitamins B and F).

Oat is made up of 60% of starch, 14% of protein, enzymes, vitamins A, B, E, choline, tyrosine, silicium, copper, trigonelline, sugar, calcium and phosphorus mineral salts. The amino acid composition is the closest to the animal protein, and a unique set of organic compounds is necessary for treatment of various hepatic diseases. Oat contains an enzyme which (like the pancreatic enzyme - amylase) helps in the absorption of carbohydrates.

Gum-arabic is an air-dried exudate from the trunks and branches of the Acacia Senegal Acacia Seyal. It is a polysaccharide with prebiotic properties. Natural water-soluble fiber which is not absorbed by the upper gastrointestinal tract, in the colon is completely fermented by bacteria to the formation of carbon dioxide and organic acids. The latter, lowering the pH of the intestinal environment, prevents the development of harmful microorganisms and contributes to their removal. Gum-arabic is a substrate for probiotic microorganisms that helps to develop their own colonization resistance of microflora.

Dietary wheat bran contains fiber helps to cleanse the gastrointestinal tract and improves its activity. Fiber is recycled by intestinal bacteria into substances that prevent colon cancer, displays the body of carcinogens and other toxic substances contained in food, and helps to control sugar and cholesterol in the blood by reducing their absorption in the intestine.

The present analysis of the functional properties of the prescription ingredients and their synergistic effects on metabolic processes led to the development of specialized products' prescription formula.

According to the results of the organoleptic and physico-chemical studies in the process of production and storage, specialized products' regulated indicators of nutritional value were defined on the basis of the recommended amount of their consumption.

Hygienic well-being, terms and modes of implementation of the developed products were established through the study of sanitary-hygienic and sanitary-toxicological parameters.

Examples are the studies on the safety of the BAA "Energopan" (Table 1) which meet the requirements [16].

**Table 1**. BAA "Energopan" safety analysis

| Definable parameter | Permissible levels in normative documents | Results | Error |
|---|---|---|---|
| Microbiological attributes | | | |
| Coliforms in 0.1 g | Not allowed | Not found | – |
| *E.Coli* in 1.0 g | Not allowed | Not found | – |
| Pathogens including salmonella in 10 g | Not allowed | Not found | – |
| QMA&OAMO | Up to 10 000 CFU/gm | < 100 | – |
| Staphylococcus aureus | Not allowed | Not found | – |
| Pesticides | | | |
| Aldrin | ≤ 0.002 mg/kg | < 0.002 | – |
| Heptachlor | ≤ 0.002 mg/kg | < 0.002 | – |
| HCH (sum of isomers) | ≤ 0.1 mg/kg | < 0.005 | – |
| DDT (sum of isomers) | ≤ 0.1 mg/kg | < 0.005 | – |
| Toxic metals | | | |
| Cadmium | ≤ 1.0 mg/kg | 0.031 | 0.012 |
| Lead | ≤ 1.0 mg/kg | 0.32 | 0.13 |
| Arsenicum | ≤ 1.5 mg/kg | < 0.02 | – |
| Mercury | ≤ 0.2 mg/kg | < 0.02 | – |
| Physical and chemical parameters | | | |
| Iron, in 100 g | 40–60 mg | 57.9 | 5.8 |

Encapsulated formulation of the BAA "Green Star" (mass 0.6 g) contains (mg in 1 capsule): spirulina – 150, chlorella – 50, apple pectin – 50, kelp thallus – 50, wheatgrass – 50, farina – 20, catalase – 20, rosehips – 15, Echinacea Purpurea – 10, lactobacterium comp-lex – 10, tocopheryl acetate (vitamin E) – 5, ginkgo biloba extract – 4, blueberry – 3, green tea – 3, superoxide dismutase – 3, gelee royale – 2 and coenzyme Q10 – 1.

Take 2 capsules 2 times per day with food to get regulated ingredients (Table 2).

BAA have following competitive advantages:
– They contain protein-bound iodine. This iodine is much better absorbed by the body, and the protein serves as an additional source of amino acids;
– Minerals included in the BAA are in chelate state, i.e. in conjunction with organic molecules that help to improve the absorption of the micronutrients;
– The complex provides soft enterosorption without causing the acceleration of intestinal peristalsis.

According to the expert's opinion the bioactive complex "Green Star" is recommended when there is/are:
– Intoxication of any origin;
– Infectious and parasitic diseases;
– Diseases of the digestive system;
– Allergies, immune system dysfunction;
– Prevention and correction of dysbacteriosis;
– Chronic non-communicable inflammatory diseases;
– The prevention and treatment of thyroid diseases related to iodine deficiency;
– Preventing hypoxia at high altitudes, low temperatures, heavy physical activities, extreme sports [1].

Period of validity is 3 years at temperature not above 18 ± 0.3°C and relative humidity not more than 75 % (with a margin of "strength" – 3 months).

The specialized product "Light mood" contains, mg/1 bar (15 mg): prunes – 8259.5, raisins – 3300, apple – 2700, fructose – 1600, senna extract – 900, oat flakes (milled) – 500, gum-arabic – 400, wheat bran – 300, caraway (milled seed) – 35, potassium sorbate – 4, citric acid – 1.5.

Take 1 bar per day before sleep (Table 3).

The product is marketed as dietetic (therapeutic and preventive) nutrition; it is a source of Senna anthraquinones and dietary fiber. The bar helps in purgation, the normalization of microflora and vermicular movement of the gastrointestinal tract. It has a relaxing effect, mild laxative, coating, anti-inflammatory and antiseptic effect, helps to eliminate toxins, toxic metals and radionuclides from the body [1].

Period of validity is 12 months at temperature not above 18 ± 0.3°C and relative humidity not more than 75% (with a margin of "strength" – 3 months).

The BAA "Cleopanta" formula: dry pantohe-matogen, licorice root (Radices Glycyrrhizae), glucose and ascorbic acid in proportion, g/1 capsule: 0.025, 0.060 and 0.005. Adults take 3 capsules daily with food (1.8 g) 3 times a day that provides intake of the regulated amount of micronutrients (Table 4).

**Table 2**. Indicators of the nutritional value of the recommended amount of the BAA "Green Star"

| Parameter name | Content | Daily value | | Satisfaction of the daily requirement in Russia/abroad |
|---|---|---|---|---|
| | | In Russia (men and women, 18–59 y.o.), [11] | Abroad (men and women, 19–50 y.o.), [19] | |
| Vitamin E, mg | 20 | 15 | 15 | 133/133 |
| Iodine, mg | 0.115 | 0.150 | 0.150 | 77/77 |
| Coenzyme Q10, mg | 4 | 30 | no data | 13/- |
| Dietary fiber, g | 1.04 | 20 | 20 | 5/5 |
| Lactic bacteria | $2*10^5$ CFU | – | – | – |

**Table 3**. Indicators of the nutritional value of the recommended amount of the specialized product "Light mood"

| Parameter name | 1 bar (15 g) content | Daily value | | Satisfaction of the daily requirement in Russia/abroad |
|---|---|---|---|---|
| | | In Russia (men and women, 18–59 y.o.), [11] | Abroad (men and women, 19–50 y.o.), [19] | |
| Soluble dietary fiber, g | 1.8 | 20 | 20 | 9/9 |
| The content of total aglycones of anthracene series, in terms of methyl chrysazin, mg | 9.0 | 10 | No data | 90/- |

**Table 4**. Indicators of the nutritional value of the recommended amount of the BAA "Cleopamta"

| Parameter name | Content in the recommended product's amount | Daily value (averaage) | | Satisfaction of the daily requirement in Russia/abroad |
|---|---|---|---|---|
| | | In Russia (men and women, 18–59 y.o.), [11] | Abroad (men and women, 19–50 y.o.), [19] | |
| Glycyrrhizic acid, mg | 49 | no data | no data | – |
| Iron, mg | 2.7 | 10 (men)<br>18 (women) | 8 (men)<br>18 (women) | 27/34<br>15/15 |
| Ascorbic acid, mg | 135 | 90 | 82 | 150/165 |

The BAA is used as a source of flavonoids, vitamin C and iron. The pharmacological focus of the active principles of the biologically active components defines the functional orientation of the specialized product. Its use in the correction of metabolic disorders:

– Restores the hormonal balance in woman's body;
– Prevents premature menopause, slows the aging process;
– Increases the body's resistance in diseases of the female reproductive organs;
– Helps to normalize the process of puberty for young girls;
– Improves the functional state of the female reproductive system;
– Normalizes the metabolism of estrogen;
– Reduces the risk of hormone-dependent diseases of the female reproductive system;
– Helps to restore the menstrual function of the body [5].

The test results should contain the following data with acceptable deviations of each indicator ±10% when compared with samples obtained from the blood of cattle (Table 5).

Period of validity is 2 years in a dry shadowed place or household refrigerator (with a margin of "strength" – 3 months).

The BAA "Energopan" contains, g/1 capsule (0.8 g): rhizomes and roots of *Rhizoma et radices Rhodiolae* roseae – 0.150, pantohematogen – 0.025, glucose – 0.020, ascorbic acid – 0.005 (Table 6).

Take 3 capsules 2 times daily.

The pharmacological focus of the active principles of the biologically active components defines the functional orientation of the specialized product and its use in the correction of metabolic disorders:

– Performance incoordination;
– Contributes to a comprehensive correction of chronic fatigue syndrome;
– Helps to prevent fatigue;
– Normalizes the immune system activity;
– Reduces the level of anxiety;
– Improves cerebral circulation
– Improves concentration and memory;
– Normalizes and improves sexual function;
– Has a normalising effect in the treatment of sexual neurosis and functional impotence;
– Optimizes the central nervous system [5].

Period of validity is 2 years in a dry shadowed place or household refrigerator (with a margin of "strength" - 3 months).

The studies to confirm the effectiveness and functional orientation of the developed products were carried out on representative population.

Clinical trials of the specialized product, "Light mood" bar, were carried out.

Positive dynamics of patients' objective and subjective state was shown as a result of diet therapy. Good acceptability of the product was proven; the side effects of the internal organs, nervous and cardiovascular systems, and the skin were not revealed.

The table 7 shows that a positive dynamics of FC clinical implications was noted as a result of the specialized product taking.

General well-being of the majority of patients (87%) improved; defecation became more frequent (85% of patients had it daily in the morning). Others had defecation 1 time in 2–3 days, and only one patient had to add lactose.

**Table 5**. The authenticity of pantohematogen on comparative fatty acid composition of plasma lipoprotein triglycerides

| Parameter name, % from FA sum | Original composition | The composition, obtained from the cattle blood |
|---|---|---|
| Lauric acid (12 : 0) | < 0.1 | < 0.1 |
| Myristic acid (14 : 0) | 1.0 | 1.1 |
| Palmitoleic acid (16 : 1) | 2.6 | 1.1 |
| Palmic acid (16 : 0) | 20.6 | 18.5 |
| Stearic acid (18 : 0) | 17.5 | 20.0 |
| Oleic acid (18 : 1) | 28.6 | 21.3 |
| Linoleic acid (18 : 2) | 15.8 | 24.9 |
| Linolenoic acid (18 : 3) | 2.7 | 6.4 |
| Arachidonic acid | 6.6 | 3.3 |

**Table 6**. Indicators of the nutritional value of the recommended amount of the BAA "Energopan"

| Parameter name | Content in the recommended product's amount | Daily value | | Satisfaction of the daily requirement in Russia/abroad |
|---|---|---|---|---|
| | | In Russia (men and women, 18–59 y.o.), [11] | Abroad (men and women, 19–50 y.o.), [19] | |
| Ascorbic acid, mg | 120 | 90 | 82 | 133/146 |
| Polyphenol (salidroside), mg | 36 | no data | no data | – |
| Iron, mg | 2.4 | 10 (men)<br>18 (women) | 8 (men)<br>18 (women) | 24/30<br>13/13 |

**Table 7**. Dynamics of clinical symptoms in patients with PC after specialized product taking

| Clinical implications | Before treatment n = 30 | After treatment n = 30 |
|---|---|---|
| General well-being improvement | 100% | 21%* |
| Defecation 1 time per day | 0% | 85%* |
| Defecation rarer than 1 time per day | 25% | 10%* |
| Defecation rarer than 1 time in 3 days | 60% | 5%* |
| Defecation rarer than 1 time in 5 days | 15% | 0%* |

*Note*. * – difference is significant in comparison with results before treatment at $P < 0.05$.

The studies were carried out with the help of the Nottingham Health Profile which is one of the methods of the quality of life assessment.

The World Health Organization defines the quality of life as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns".

The study of quality of life allows to identify factors that contribute to life improvement and finding its meaning.

Respondents were asked to reflect the impact of their health state on the activity in seven areas of everyday activities, reflecting the quality of life.

Energy level: "I quickly get tired" (24.00); "I do everything by forcing myself" (36.80); "I feel tired all the time" (39.20).

Sensation of pain: "I feel pain when I go up and down the stairs and walk" (5.83), "I feel pain when I stand" (8.96), "I feel pain when I change body position" (9.99), "I feel pain when I sit" (10.49), "I feel pain when I walk" (11.22), "I feel pain at night" (12.91), "I feel unbearable pain" (19.74), "I always feel pain" (20.86).

Emotional state: "The days are like a heavy burden" (7.08), "I often feel my critical state" (7.22), "I forgot when I was happy" (9.31), "I am often in a bad mood" (9.76), "Everything disappoints me" (10.47), "I wake up depressed" (12.01), "Anxiety wakes me up at night" (13.95), "I think I can't control myself" (13.99), "I don't want to live" (16.21).

Sleep: "I wake up too early" (12.45), "I can't sleep" (15.94), "My sleep is bad" (21.48), "I take pills to sleep" (23.14), "Most of the night I lie awake" (26.99).

Social isolation: "I think that it is hard to get along with people" (15.97), "I think it is hard to communicate with people" (19.36), "I think I don't have me loved ones" (20.13), "I feel lonely" (22.01), "I feel that I am a burden to people" (22.53).

Physical activity: "I find it difficult to reach out to others" (9.30), "I find it difficult to bend down" (10.57), "I find it difficult to go up and down the stairs" (10.79), "I find it difficult to stand for a long period of time" (11.20), "I can only move around the house" (11.54), "I find it difficult to dress myself (12.61), "I need help to go outside" (12.69), "I can't go outside" (21.30).

Respondents answer "yes" and put points if they have these restrictions and answer "no" and don't put points if they don't.

The test results are shown in the Table 8. In general the dynamics is positive.

On the basis of these data the following conclusions were made:

1. The taking of the specialized product, "Light mood" bar, by the patients with PC 1–2 type has a positive effect on clinical implications.
2. The patients with PC 1–2 type noted the improvement of mood and well-being, and therefore quality of life.
3. Dietetic therapy helps to normalize defecation, improve the quality of life of this group of patients.
4. The product has good acceptability and does not cause any side effects.

The obtained data give reason to recommend the product for a dietetic therapy to improve the body's resistance to adverse environmental influences, stressful situations, emotional and physical stress, and restoring normal defecation. This specialized product can be recommended in complex treatment and for prevention of constipation in combination with other somatic diseases in the compensation stage.

The clinical trials on the BAA "Green Star" were carried out. Despite the lack of evidence of any acute or chronic disease all patients at the beginning of the observation noted fatigue; in some cases there were complaints of somatic and vegetal character. There were certain signs of dysfunction of the digestive system, which included complaints about irregular bowel movements, belching or episodic nausea. The taking of specialized products allowed to change the pattern in the direction of decreasing of the presented complaints frequency, and in some cases "Green Star" had a more positive effect than a multivitamin complex, in particular, fatigue as one of the symptoms of intoxication significantly reduced (Fig. 1).

After taking the "Green star" volunteers from the experimental group noted restoration of normal levels of hemoglobin. A positive effect was observed in the form of improved pigment metabolism and functioning of hepatic cells in the main group of patients taking the "Green Star", according to terms of the content of bilirubin in the blood (Fig. 2).

**Table 8**. Dynamics of clinical symptoms in patients with PC after taking of "Light mood" bar

| Parameter | Before treatment, points n = 30 | After treatment, points n = 30 |
|---|---|---|
| Energy level | 45.3 ± 1.5 | 34.2 ± 1.3 |
| Sensation of pain | 23.5 ± 1.7 | 21.5 ± 2.4 |
| Emotional state | 74.2 ± 1.8 | 34.6 ± 1.5* |
| Sleep | 34.3 ± 1.8 | 35.1 ± 1.3 |
| Social isolation | 24.2 ± 1.5 | 26.4 ± 1.7 |
| Physical activity | 32.1 ± 1.6 | 24.3 ± 1.3 |
| Total | 233.6 ± 4.1 | 176.1 ± 3.4 |

*Note*. * – difference is significant in comparison with results before treatment $P < 0.05$.

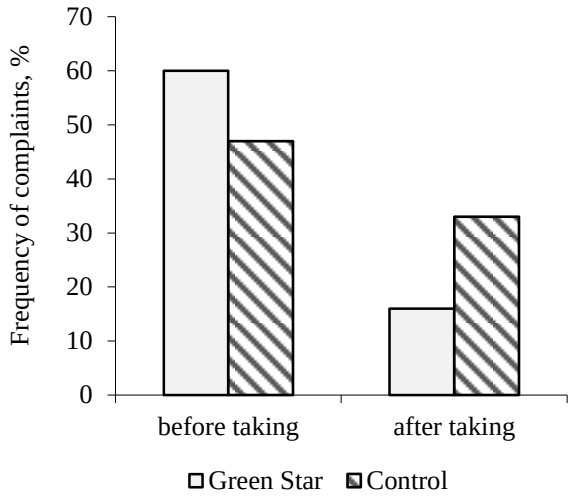


**Fig. 1.** Patients' fatigue frequency.

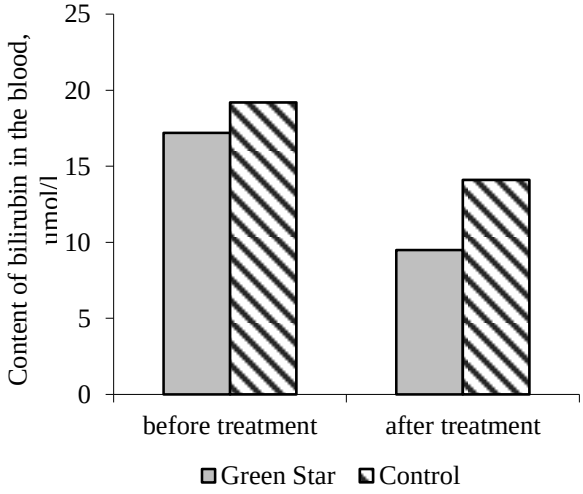


**Fig. 2.** The content of bilirubin in the blood.

After the coprological survey the following conclusions were made: the "Green Star" taking helps to restore digestion health and reduces the frequency of registration of undigested muscle fibers in the test material samples in 1.6 times in comparison with the benchmarks, and mucus in 2.2 times.

It was concluded that the BAA has the ability to improve digestive health, reduces overall toxicity, has a positive effect on metabolic processes. It can be taken as enterosorbent and to improve metabolic indicators.

Technical documents are developed and approved, the expert opinion of the Institute of Nutrition RAMS and Rospotrebandzor is received.

Developed products' formulation and technology were tested under production conditions in the SPA "Yug" and the "Art-Life" company (Russia), certified under the international standards ISO 9001, 22000 and GMP requirements, which allows, in addition to novelty and demand on the market , to present the products as innovative.

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**Please cite this article in press as:** Lobach E.Yu. and Poznyakovskiy V.M. Methodological aspects and operational experience of the new baa with targeted functional properties. *Foods and Raw Materials*, 2016, vol. 4, no. 2, pp. 66–74. DOI: 10.21179/2308-4057-2016-2-66-74.