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The Study of the Herbal Product Quality and Effectiveness

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ABSTRACT

Our extensive testing resulted in the following qualitative and quantitative composition for a new biologically active herbal product (the dietary supplement). One mg capsule contains: L-lysine - 200; oxycinnamic acids - 1.5; vitamin C - 35; polysaccharides, not less than 2.1; caffeine, not less than 10; salicin, not less than 6; zinc - 7.5; quercetin - 7.5; rutin - 7.5; vitamin E - 3.5; thiamine - 0.15; folic acid 0.02; cyanocobalamin - 0.00045. These components possess the necessary substances and biochemical characteristics for the new dietary supplement to be used in strengthening the immune system and preventing infectious diseases. A new encapsulation process has been developed that allows several substances, which are usually incompatible due to their differences, to be used in one capsule. To examine the effectiveness, patients with acute respiratory infections were given the dietary supplement and clinical evidence was gathered. The patients administered 1 capsule of the dietary supplement twice a day demonstrated a noticeable reduction in the severity of the symptoms and the shortened acute phase. The new dietary supplement underwent the certification procedure according to ISO 9001:2000, proved to comply with GMP standard, the sanitary-epidemiological certificate was obtained and the mandatory State Registration was completed. The dietary supplement was tested in the scientific research-to-production facilities of Art-Life Scientific Production Association (Tomsk city), to ensure quality.

Key words: *Plant-based food supplement, Composition, Technology, Quality indicators, Efficacy, Functional properties*

INTRODUCTION

Extensive international research has been carried out to analyze the nutrition effectiveness in treating metabolism disorders [1-6]. The diseases discussed in this paper are acute respiratory infections, which are among the most widespread infections that are persistent, have a rapid onset, and can result in serious complications [7-13].
The development of different dietary supplements, including biologically active additives (BAA), is currently particularly relevant, as they are among the fastest and most cost-effective to produce [14-17].

MATERIALS AND METHODS

The study researched the food supplement raw materials and the finished product. To assess the functional properties and efficacy of the dietary supplement, the researchers used standard clinical methods.
Thirty patients diagnosed with acute respiratory infections and experiencing such symptoms as rhinorrhea, headache, fever, muscle, and joint pain were divided into two groups, with the first (main) group of fifteen patients being treated at home and receiving the dietary supplement daily over the study period. While the second group

of 15 patients of similar gender, age, an the severity of disease formed the control group. The participants for both groups were carefully chosen to keep all the variables as similar as possible; the patients were between the ages of 17 and 38 and had no severe somatic symptoms. After having been informed of all the aspects of the dietary supplement trial, all of the patients had to sign an informed consent to participate in the study.

The course of the clinical trial lasted for 28 days. For the first seven days, the participants of the first (main) group were prescribed to take 1 capsule of the dietary supplement twice a day during meals; and for the convalescence period, which was twenty-one-day long and coincided with the seasonal increase in viral infections, they were prescribed 1 capsule a day.

Before and after the clinical trial, participants of both groups underwent compulsory blood tests. Subjective symptoms, immunocompetent cells of different phenotypic classes, and the level of interferon gamma were carefully examined. Blood tests of the participants who received the dietary supplement were taken on the twenty-ninth and thirtieth days of the clinical trial.

RESULTS AND DISCUSSION

The scientifically proven formula for a new biologically active herbal product (the dietary supplement) for mg/1 capsule includes: L-lysine - 200; oxycinnamic acids - 1.5; vitamin C - 35; polysaccharides, not less than 2.1; caffeine, not less than 10; salicin, not less than 6; zinc - 7.5; quercetin - 7.5; rutin - 7.5; vitamin E - 3.5; thiamine - 0.15; folic acid 0.02; cyanocobalamin - 0.00045.

A new innovative technique has been developed to to produce dietary supplements in capsules. The process includes raw materials preparation, encapsulation mixture preparation, encapsulation and dedusting, liquid extraction, thickening of liquid extract, drying the extract with spray drying.

The obvious benefit of the technique developed is the opportunity to combine several substances, which are usually incompatible due to their differences, in one capsule. The gelatine shell of the capsule protects the contents against adverse conditions and helps release the contents gradually and let them be properly absorbed.

A carefully planned and administered manufacturing process and the right formula are of great importance to the functional characteristics of this dietary supplementa.

Based on the findings of organoleptic, physicochemical, and microbiological trials conducted, the following indicators, regulating the quality of the supplement and its nutritional value, were formulated **(Table 1)**.

Table 1. Dietary Supplement Quality Indicators

Quality Indicator	Description
Visual Appearance	gelatine capsules
Capsule Contents Colour	grey with particles
Capsule Contents Smell and taste	specific
Average capsule weight, mg	600 (540-660)
Capsule dissolution, no longer than a minute	60
Biologically active substances, mg per 1 capsule	
Zink	7.5 (6.0-9.0)
Rutin	7.5 (6.0-9.0)
Quercetin	7.5 (6.0-9.0)
Thiamine (B_1) , mcg	150 (120-180)
Cyanocobalamin (B_{12}), mcg	0.45 (0.3-0.6)
Vitamin E	3.5 (2.45-4.55)
Ascorbic Acid (C)	35.0 (28.0-42.0)
Caffeine, not less than	1.5
L-Lysine, not less than	200
Oxycinnamic Acids, not less than	1.5

According to the findings of research, the developed dietary supplement has specific antiviral, anti-inflammatory, and immunostimulating effects, and is effective in the combination therapy of acute viral diseases, exacerbations, and chronic viral infections, including herpetic.

To evaluate both the effectiveness and the health benefits of the new dietary supplement, a clinical trial was conducted.

Thirty patients diagnosed with acute respiratory infections and experiencing such symptoms as rhinorrhea, headache, fever, muscle, and joint pain were divided into two groups, with the first (main) group of fifteen patients being treated at home and receiving the dietary supplement daily over the study period. While the second group of 15 patients of similar gender, age, and the severity of disease formed the control group. The participants for both groups were carefully chosen to keep all the variables as similar as possible; the patients were between the ages of 17 and 38 and had no severe somatic symptoms. After having been informed of all the aspects of the dietary supplement trial, all of the patients had to sign an informed consent to participate in the study.

The course of the clinical trial lasted for 28 days. For the first seven days, the participants of the first (main) group were prescribed to take 1 capsule of the dietary supplement twice a day during meals; and for the convalescence period, which was twenty-one-day long and coincided with the seasonal increase in viral infections, they were prescribed 1 capsule a day.

Before and after the clinical trial, participants of both groups underwent compulsory blood tests. Subjective symptoms, immunocompetent cells of different phenotypic classes, and the level of interferon gamma were carefully examined. Blood tests of the participants who received the dietary supplement were taken on the twenty-ninth and thirtieth days of the clinical trial.

On the second and third days of the clinical trial, the overall health of the fifteen patients who received the dietary supplement demonstrated positive changes. The patients reported they felt much better, experienced less pain and soreness in their muscles and joints, the intensity of their nasal congestion and headaches subsided. Our comparative analysis of the intensity of acute respiratory infections symptoms indicates that the dietary supplement helps to lessen the severity of the symptoms **(Table 2)**. The patients experienced considerable general relief.

Table 2. The Changes in the Clinical Symptoms of the Patients in the Main Group on the Second and Third Days of the Clinical Trial

Acute Respiratory infections symptoms	The main group, n=15		The control group, n=15		Level of changes significance	
	Before taking the dietary supplement	After taking the dietary supplement	Before taking the dietary supplement	After taking the dietary supplement	Before taking the dietary supplement	After taking the dietary supplement
Headache	15	3	15	9	-	0.030
Rhinorrea	15	3	14	7	0.50	0.13
Muscle and joint pain	14	4	13	10	0.50	0.032
Fever	13	4	14	7	0.50	0.22

After taking the dietary supplement for two or three days the number of patients from the first (main) group reporting headache was smaller compared to the number of patients from the second (control) group still experiencing headaches. The dietary supplement helped to relieve muscle and joint pain and reach positive results in subsiding fever and rhinorrhea.

Upon the implementation of the general haematological examination of the patients, we found that some homeostasis parameters demonstrated positive trends which indicated recovery from the destruction, the decrease in the inflammatory response **(Table 3)**. The data obtained demonstrates that specific immunocompetent cells were appropriately stimulated and, thus, initiated the immune response, as can be seen from the changes in blood lymphocytes of the patients from the first (main) group.

Table 3. The Changes in the Homeostasis Parameters of the Patients from the Main Group

Acute Respiratory infections symptoms	The main group, n=15		The control group, n=15		Level of changes significance	
	Before taking the dietary supplement	After taking the dietary supplement	Before taking the dietary supplement	After taking the dietary supplement	Before taking the dietary supplement	After taking the dietary supplement
White blood cell, 10^{12}/l	5.24±0.14	5.24±0.14	6.51±0.21	6.15±0.21	0.88	0.003

Mature neutrophils, %	68.04±1.51	68.04±1.13	64.71±1.38	64.87±1.47	0.95	0.67
Immature neutrophils, %	1.82±0.54	1.88±0.21	0.70±0.19	1.09±0.17	0.08	0.044
Monocytes, %	5.52±0.43	5.92±0.40	7.92±0.44	7.30±0.62	0.48	0.60
Basophils, %	0.44±0.12	0.32±0.10	0.17±0.08	0.30±0.10	0.50	0.27
Eosinophils, %	5.52±0.36	5.23±0.34	4.79±0.26	5.48±0.25	0.35	0.07
Lympocytes, %	20.68±0.87	20.72±0.75	26.33±0.98	21.35±1.39	0.95	0.027
ESR, mm/h	8.8±1.9	8.6±2.5	7.1±1.3	7.4±1.6	0.29	0.24

Note * - $p<0.05$ when changes are compared within one group

Considering the results of the general haematological examination, we can state that after the dietary supplement was administered there was a proven increase ($p<0.05$) in the absolute number of peripheral blood leukocytes. That was due to the increase in the count. The patients from the first (main) group, who were given the dietary supplement, had a decline in the mature neutrophils count which indicates the decrease in the severity of fatigue. One of the benefits of taking the dietary supplement is the decrease in the seromucoid level proven by the careful analysis of the biochemical profile of the patients from the first (main) group. When the dietary supplement was taken, the results of the tests for the first (main) group patients demonstrated a decrease in the seromucoid level from 0.287 ± 0.054 to 0.174 ± 0.096 mol/L, while there was a much slighter decrease from 0.290 ± 0.085 to 0.246 ± 0.073 mmol/L in the second (control) group patients.

To evaluate the effect of the dietary supplement on patients treated for acute respiratory infections, the testing of the phenotypic types of lymphocyte subpopulations was performed **(Table 4)**.

Table 4. Lymphocytes Subpopulations of Peripheral Blood of the Patients from the Main Group

Phenotypic types of lymphocytes	The main group, n=15		The control group, n=15		Level of changes significance	
	Before taking the dietary supplement	After taking the dietary supplement	Before taking the dietary supplement	After taking the dietary supplement	Before taking the dietary supplement	After taking the dietary supplement
$CD3^+$, %	51.68±2.62	50.32±2.61	60.79±2.03	52.65±2.63	0.78	0.048
$CD4^+$, %	31.92±1.26	33.36±1.59	35.71±1.41	32.48±0.49	0.68	0.09
$CD8^+$, %	33.40±1.19	32.72±1.38	26.38±0.39	31.30±1.46	0.17	0.037
$CD4^+$/ $CD8^+$	1.91±0.42	1.65±0.23	1.84±0.16	1.70±0.15	0.62	0.07
$CD72^+$, %	13.52±1.11	13.60±0.73	15.75±1.15	14.09±0.90	0.60	0.51

When compared, there was a significant difference in CD3+ T-lymphocytes percentage count if the patients received the dietary supplement to accompany their main treatment (60.79±2.03 versus 51.68±2.62 %, $p=0.033$). Moreover, there was a noticeable increase in the count of CD4+ T-helper cells from 31.92±1.26 % to 35.71±1.41, $p<0.05$). There was no statistically significant difference for $CD8^+$ or $CD72^+$.

Thus, the changes in cellular immunity of the patients taking the dietary supplement are observed in a statistically significant ($p<0.05$) increase in the percentage of lymphocytes of CD3 + and CD4 + phenotypes, which indicates an increase in the antiviral potential of the body.

The study of the IFN-γ level, which is a cytokine with anti-inflammatory properties, demonstrated that the patients taking the dietary supplement had a significant reduction in the cytokine content in their bodies both during the acute period of the disease and the period of convalescence **(Table 5)**.

Table 5. Serum IFN-γ Level Data Listed as Median (25% - 75%) before and after taking the dietary supplement

Controlled	The main group, n=15	The control group, n=15	Level of changes significance p*
Before taking the dietary supplement	1.23 (0-6.45)	3.05 (0-5.95)	0.64
After taking the dietary supplement	0 (0-3.19)	14.31 (2.13-18.75)	<0.001

Note: * Mann Whitney U Test was applied to compare the findings

Diets enriched with the dietary supplement help reduce the frequency of acute viral diseases, with data indicating that the patients taking the dietary supplement before the start of the seasonal increase in viral infections are on average 1.8-3.0 times less likely to see a doctor for acute respiratory viral infections if compared with their medical history.

Remote patient monitoring enabled us to track health data during the seasonal virus infection outbreak, and it was discovered that 8 out of 15 patients of the second (control) group developed an acute respiratory virus infection and had to apply for medical help when on the other hand, only 1 patient from the first (main) group had to seek medical advice ($p<0.001$).

Therefore, if the dietary supplement becomes a part of the complex therapy for acute respiratory infections, then, the disease duration is shortened due to enhancement of the antiviral response of immunocompetent cells, and the reduction of the pro-inflammatory cytokine IFN-γ.

The multivalent effect of the dietary supplement components reveals a tropism for the anti-inflammatory response, demonstrates a protective effect on the systems involved in the anti-inflammatory response, helps reduce fatigue, and, therefore, can be recommended as complementary therapy for acute respiratory infections.

Taking into account the positive change in the seromucoid composition, we should highlight the opportunity of the prophylactic use of the dietary supplement to prevent the diseases from occurring, to increase the ability of the T cell arm of the immune system to destroy infected cells, particularly when the patient is exposed to any physical or emotional tension or unhealthy environment.

CONCLUSION

The findings of the clinical trial indicate that the dietary supplement tested is effective both in the complex therapy of acute respiratory diseases and in disease prevention during the seasonal increase in viral infections.

The tested dietary supplement produces marked improvement and anti-inflammatory and immunomodulating effects cause no adverse effects and improve health of patients diagnosed with acute respiratory diseases.

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