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ARTICLE

Aloe Royal Jelly Powder Contributes to Maintain Normal Immunity: a Randomized Clinical Trial

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ABSTRACT

Objective: To study the safety and the function of maintaining normal immunity of product with royal jelly lyophilized powder and whole-leaf aloe drying powder as main raw materials. Methods: Selected 125 subjects qualified for inclusion/exclusion criteria for a trial test. (The trial group lost 9 subjects. The control group lost 6 subjects.54 effective subjects of trial group includes 12 men and 42 women. 56 effective subjects of control group including 9 men and 47 women.) The trial group was evaluated by self-control and inter-group comparison, after 90 days of continuous use of aloe royal jelly. Results: There are significant differences in the overall feeling, physiological feeling, psychological feeling and comprehensive evaluation of the individuals in the trial group after 90 days ($P<0.001$), which are higher than before. The control group has no statistically significant difference in the comprehensive evaluation before and after the trial ($P>0.05$). The ratio of CD4/CD8, IgG, IgA and IgM in the trial group and the placebo control group are above the normal low-limit. There is no obvious abnormality in indicators of blood test, blood biochemistry, liver and kidney function and other clinical tests. Conclusion: Aloe royal jelly powder contributes to maintain normal immune function and has no harmful effect to the health of subjects.

1. Introduction

Royal jelly has very high nutrition and immune value. It also has immune value in its pharmacological actions.[1-4] This paper investigates a cohort study on the health food which uses the royal jelly lyophilized powder and whole-leaf aloe drying powder as main materials, in order to investigate its safety and the function of maintaining the normal immunity.

2 Materials and Methods

2.1 Sample and Placebo

Aloe royal jelly powder used the royal jelly lyophilized powder and whole-leaf aloe drying powder as main materials. It had passed animal toxicology safety assessment and hygienic examination. Placebo's size and appearance were the same as the functional sample.

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2.2 The Subjects

The trial program was approved by the ethics committee of Tianjin Third Hospital. The subject inclusion criteria: the comprehensive evaluation score of the immune-related health score table was less than 80. The ratio of CD4 and CD8 to the peripheral blood T lymphocyte subsets, the ratio of CD4/CD8, the content of serum immunoglobulin IgG, IgA, IgM, IgE and the content of interleukin IL-2 and IL-4 were within the normal range. The subject exclusion criteria:

(1) Those who could not eat orally or who could not take this health food according to the rules.

(2) Those who were over 70 years old, pregnant or lactating women or who were intolerant or allergic to this health food.

(3) Those whose chief complaint was not clear.

(4) Those who had severe occupational disease or other severe diseases.

(5) Those who had serious diseases such as heart, brain, liver, kidney and hematopoietic system diseases or who had psychotic disease.

(6) those whose the ratio of CD4 and CD8 in peripheral blood T lymphocyte subsets, the ratio of CD4/CD8, the content of serum immunoglobulin IgG, IgA, IgM, IgE or the content of serum interleukin IL-2 and IL-4 were higher than the upper limit of normal value or lower than the normal value.

(7) Those who had immune-related diseases such as systemic lupus erythematosus, rheumatoid arthritis, systemic vasculitis, scleroderma, pemphigus, dermatomyositis, mixed connective tissue disease, primary thrombocytopenic purpura, autoimmune hemolytic anemia, Hashimoto's thyroiditis, primary myxedema, hyperthyreosis, ulcerative colitis and so on.

(8) Those who did not take this health food according to the regulations or whose incomplete information affected the efficacy or safety judge.

(9) Those who took food or medicine related to the function of this health food in the short term, affecting the judgment of the result.

2.3 Experiment Design and Grouping

The experiment was designed between groups and self-control. The subjects were randomly divided into trial and control groups according to the immune-related indexes. Reduce the gap between sex, age, diet and other factors as far as possible, and reduce the impact on the results of the experiment. Ensure the comparability between the groups through the balance test.

2.4 Dose and Time

The trial group took the samples 2 times a day per person, 5g each time. Pour cool boiled water to drink. The control group was given placebo. And the same method was taken with the trial group. Samples and placebos were taken continuously for 90 days.

2.5 Observation Indicators

2.5.1 Safety Indicators

General indicators were observed including sleep, diet, mental status, stool and so on. Before the experiment, Chest X-ray, electrocardiogram and abdominal B-ultrasound examination were performed. Blood routine examination, blood biochemical examination, blood pressure, heart rate and liver and kidney function were performed before and after the trial.[5]

2.5.2 Functional Indicators

Criteria: Two or more indicators, including overall feeling, physiological feeling, psychological feeling and comprehensive evaluation, had a statistically significant difference in the trial group ($P<0.05$). Meanwhile, indicators had no statistically significant difference in the control group. If all of indicators in the trial group and control group, including ratio of CD4/CD8, IgG, IgA, IgM, were above the low limit of normal value after the experiment, the health product was judged to have the function of maintaining normal immunity.

2.6 Data Statistics Method

The matched t test was used to compare the self-control data, and the group t test was used to compare the means of two groups. The group t test needed the variance homogeneity test. The data of the non-normal distribution or the inhomogeneous variance were converted properly. After the normal variance was satisfied, the converted data was used for t test. If the converted data could still not satisfy the requirement of homogeneous normal variance, the t' test or rank sum test should be used. But the data with large coefficient of variation (such as $CV>50\%$) should be tested by rank sum test.

2.7 Result Determination Method

Two or more indicators, including overall feeling, physiological feeling, psychological feeling and comprehensive evaluation, had a statistically significant difference in the trial group ($P<0.05$). Meanwhile, indicators had no statistically significant difference in the control group. If all of indicators in the trial group and control group, including ratio of CD4/CD8, IgG, IgA, IgM, were above the low limit of normal value after the experiment, the health product was judged to have the function of maintaining normal immunity.

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3 Results

3.1 General Situation

At the beginning of the experiment, the volunteers who satisfy the criteria are divided into the trial group (63 cases) and the control group (62 cases). Before the experiment, the general conditions of two groups (age, mental state, sleep status and diet) are generally the same. The inspection results of volunteers in two groups shows that there are no obvious abnormalities in inspections of abdominal B-ultrasound, electrocardiogram and chest X-ray. There is no significant difference in CD4, CD4/CD8 and IgG (P>0.05). The number of loss is 15 cases. The final effective statistics numbers are 54 cases in the trial group and 56 cases in the control group. The loss rate is 12%. The basic situation of two groups is shown in Table 1.

Table 1. Comparison of the balance between two groups before the experiment

Items	Trial Group	Control Group
Cases	54	56
Male/Female	12 / 42	9 / 47
Age(Years)	55.04±9.90	55.23±9.66
Immune-related health rating score	68.56±8.47	65.32±12.31
CD4	31.79±5.09	32.38±4.57
CD4/CD8	1.65±0.57	1.84±0.59
IgG	12.97±4.62	12.61±3.71

3.2 Effect of Samples on Safety Indicators

The heart rate and blood pressure of volunteers in two groups are in the normal range. There is no significant difference of volunteers in trial group before and after experiment (P>0.05). There are no obvious abnormalities in two groups' blood, urine and stool routine examination and blood biochemical examination before and after experiment. It indicates that samples have no harmful effect to volunteers' health. See Table 2 for results.

3.3 Effect of Samples on Functional Indicators

3.3.1 Health Scores

There are statistically significant differences in the overall feelings, physiological feelings, psychological feelings and comprehensive evaluation before and after the experimental diet (P<0.001). The score after experiment is higher than it before experiment. The differences in overall feelings, physiological feelings, psychological feelings and comprehensive evaluation are statistically significant between two groups (p<0.01). See Table 3, 4 for results.

3.3.2 Cellular Immunity Indicators

There is no significant difference in cellular immunity indicators of two groups before and after experiment (P > 0.05), as shown in Table 5.

Table 2. Comparison of safety indicators before and after experiment

	Trial Group (n=54)		Control Group (n=56)	
	Before	After	Before	After
Leukocyte ($\times10^9$/L)	6.03±1.27	6.21±1.74	6.01±1.38	5.95±1.43
Erythrocyte ($\times10^{12}$/L)	4.72±0.39	4.66±0.40	4.70±0.39	4.70±0.36
Platelet ($\times10^9$/L)	234.54±43.21	237.72±44.85	251.52±48.11	250.84±48.00
Hemoglobin (g/L)	142.26±10.85	139.94±13.41	141.46±10.55	139.86±9.88
Total Protein (g/L)	74.04±3.66	73.17±4.51	75.55±3.52	74.81±4.16
Albumin (g/L)	47.45±2.22	46.79±2.61	47.39±4.83	46.55±2.47
Glutamic-pyruvic Transaminase (U/L)	21.26±10.97	19.87±10.22	27.93±17.92	24.23±17.26
Glutamic-oxalacetic Transaminase(U/L)	19.81±6.62	19.61±6.24	22.82±9.15	20.82±7.98
Urea (mmol/L)	5.08±1.05	5.25±1.14	4.84±1.18	5.16±1.36
Creatinine (μmol/L)	69.93±14.90	67.78±15.65	65.46±14.79	66.13±18.10
Glucose (mmol/L)	5.49±0.99	5.41±1.02	5.36±0.80	5.24±0.98
Total Bilirubin (μmol/L)	11.52±3.18	10.95±2.72	11.41±3.12	10.57±4.73
Total Cholesterol (mmol/L)	5.18±1.11	5.28±1.02	5.14±0.97	5.25±0.84
Triglyceride (mmol/L)	1.37±0.74	1.54±0.84	1.70±1.08	1.85±1.05
Heart Rate (Times/min)	73.56±10.58	73.24±9.65	74.77±11.59	74.77±10.79
Systolic Pressure (mmHg)	130.07±19.22	129.96±18.60	135.16±19.32	135.48±18.54
Diastolic Pressure (mmHg)	77.26±9.23	77.13±8.40	78.80±14.84	78.61±13.60
Urine Routine	normal	normal	normal	normal
Stool Routine	Normal	normal	normal	normal

Notes: All of volunteers of trial group have no adverse reactions during the experiment, such as nausea, flatulence, diarrhea and allergy and so on.

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Table 3. Comparison of health scores in trial group before and after experiment

	Cases	Before	After
Overall feeling	54	22.17±3.17	23.52±2.63***##
physiological feeling	54	22.76±4.12	24.28±4.07***##
psychological feeling	54	23.63±4.11	25.20±3.72***##
comprehensive evaluation	54	68.56±8.47	73.00±7.65***##

Notes: Self-comparison *** P<0.001; Comparison between two groups ## P<0.01

Table 4. Comparison of health scores in control group before and after experiment

	Cases	Before	After
Comprehensive Evaluation	56	65.32±12.31	64.73±12.19###

Notes: Self-comparison p>0.05; Comparison between two groups ### p<0.001

Table 5. Changes of cellular immune indicators before and after experiment

	Trial Group(n=54)		Control Group(n=56)	
	Before	After	Before	After
CD4/CD8	1.65±0.57	1.78±0.71	1.84±0.59	1.90±0.72
CD4	31.79±5.09	31.36±6.72	32.38±4.57	32.58±7.23
CD8	21.41±7.59	19.93±7.79	19.26±6.10	18.88±5.90

Notes: Self-comparison P>0.05; Comparison between two groups P>0.05

3.3.3 Humoral Immune Indicators

The mean values of two groups are in the normal range before and after experiment. See Table 6 for results.

Table 6. Changes of humoral immune indicators before and after experiment

	Trial Group(n=54)		Control Group(n=56)	
	Before	After	Before	After
IgE	0.04±0.09	0.19±0.21***	0.05±0.11	0.21±0.23***
IgG	12.97±4.62	22.04±5.73***	12.61±3.71	22.02±8.30***
IgA	1.82±0.83	2.01±0.88	2.00±1.00	1.90±0.96
IgM	1.80±1.85	0.90±0.40**#	1.67±1.61	0.73±0.35***
IL-2	33.54±5.91	6.70±3.28***	35.00±7.45	7.97±6.59***
IL-4	13.00±6.16	22.41±51.86	13.76±6.94	25.16±52.93

Notes: Self-comparison *** p<0.001, ** p<0.01; Comparison between two groups # p<0.05

4. Conclusion

The volunteers who are in accordance with the experimental standard are tested for 110 cases (including 54 cases in trial group, 12 men and 42 women, 56 cases in control group: 9 men and 47 women). The control group is given placebo. The control group has no statistically significant difference in their comprehensive evaluation before and after experiment (P > 0.05). And the trial group is given aloe royal jelly mineral powder. After 90 days, there are significant differences in overall feelings, physiological feelings, psychological feelings and comprehensive evaluation (P<0.001). The test is higher than before. The ratio of CD4/CD8, IgG, IgA and IgM in trial group and control group are all above the low-limit of the normal value. According to the revision of "enhanced immunity function evaluation test method", the results show that aloe royal jelly powder has the function of maintaining normal immunity.[6,7]

Before and after experiment, the results of blood, urine, stool routine examination and blood biochemical examinations are in the normal range. They show that the sample has no adverse effect on the volunteers' health. No adverse reactions such as nausea, flatulence, diarrhea and allergic reactions are found during the experiment, indicating that the safety of sample satisfies the requirements.

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