

**NUTRITIONAL CLINICAL STUDY
ON YOUTH USING HAELAN 851
Ages 6 months - 11 Years Age**

The pharmacological Department of the Provincial Health Council designated three institutions including Fujian Medical College with its Pediatrics Department of Union Hospital, Fuzhou Children's Hospital, and the Convalescent Hospital of the Provincial Coal Mines for the research work on the Haelan 851 concentrated oral fluid nutritional product on 101 cases of child malnutrition. In addition to the 101 cases of malnutrition receiving the Haelan 851 concentrated oral liquid nutritional supplementation, 60 additional children with malnutrition were nutritionally supplemented with the Hospital Standard "Child Health Protecting Oral Fluid". This was the control group. The work was done between March and August, 1992. The results of this clinical nutritional study is summarized below.

The objectives and Methods:

1. Selection of Patients:

Cases were selected according to the standards written in the college textbook "Practical Pediatrics", written by Prof. Tsu Fu-tang, and other related standards. Children of 2-7 years old with light malnutrition were especially selected; they were found to have gastro-splenic weakness or blood respiratory deficiency according to Chinese Traditional Medical practice.

2. Amount of Nutritional Supplementation:

Test group: 10 cc of Haelan 851 Oral Fluid was given three times daily for a period of 4-8 weeks. Control group: 10 cc per day total of the Child Health Protecting Oral Fluid was given to those in this group. This was given for 4-8 weeks also. In both groups, cases were unselected for better comparison and during the test periods no Chinese or Western medicine or supplements of nutritional value was given simultaneously.

3. Method of Observation and Test Standards:

Cases for observation were given complete physical examinations before given the Oral Fluids, this included body height, body weight, subcutaneous fat, arm circumference (right), blood and urine routines, liver functions, electro-cardiograms, blood trace elements of iron and zinc. All measurements were done by the same personnel responsible for this special kind of work, and under similar conditions, such as the amount of dress, the time for observations, etc.

4. General Information:

The test group is made up of 101 cases, 46 males and 55 females, at the age of 6 months to 11 years. The age distribution was 1 year old: 1 case, more than 1 year old: 16 cases, more than 3 years old: 69 cases, 7-11 years old: 15 cases. The degree of malnutrition according to Western medicine was 1st degree: 94 cases, 2nd degree: 1 case, and 3rd degree: 3 cases. According to Chinese Traditional Medicine: gastro-splenic weakness: 83 cases, blood and respiratory deficiency: 18 cases. The test group using Haelan 851 and the control group using "Child Health Protecting Fluid" are tabulated below:

3. The changes in body weight (BW), arm circumference (AC), subcutaneous fat (SF) before and after nutritional supplementation with Haelan 851 Oral Liquid. (see table 1)

Table 1

Body weight, arm circumference and subcutaneous fat changes before and after nutritional supplementation testing

	<u>N</u>	<u>BW</u>	<u>N</u>	<u>AC</u>	<u>N</u>	<u>SF</u>
Before Nutrition	97	14.67 +/- 4.36	97	14.89 +/- 1.12	97	0.411 +/- 0.184
After Nutrition:	97	16.07 +/- 4.46	97	15.61 +/- 1.18	97	0.463 +/- 0.12

Table 1 shows the changes before and after treatment; there is an increase in BW, AC, and SF ; the change are very obvious (P < 0.001)

4. Haelan 851 oral fluid was given to some malnourished children, whose blood hemoglobin (Hb) and trace elements of iron (M-Fe) and Zinc (M-Zn) were below normal.

Table 2.

Changes in Hb, M-Fe, M-Zn before and after nutrition supplementation

	<u>N</u>	<u>Hb</u>	<u>N</u>	<u>M-Fe</u>	<u>N</u>	<u>M-Zn</u>
Before Nutrition	18	106.94 +/- 9.62	17	70.89 +/- 12.06	39	59.32 +/- 12.18
After Nutrition	18	113.77 +/- 7.58 P < 0.05	17	94.92 +/- 23.58 P < 1.05	39	68.01 +/- 14.15 P < 0.01

Table 2 shows the trace elements iron and zinc go up after the nutritional supplementation: the difference between "before" and "after" is remarkable or very obvious. The rise in hemoglobin after nutritional supplementation is not as remarkable.

5. Table 3 shows the change in appetite after giving Haelan 851 concentrated nutritional oral liquid to the children.

Table 5 shows that the Haelan 851 nutritionally supplemented group is better than the control group that received nutritional supplementation with the Child Health Protecting Oral Fluid in increasing the children's arm circumference and subcutaneous fat ($P < 0.05-0.005$), but in increasing the body weight both oral fluids have about the same effect.

8. The relationship between the benefits of nutritional supplementation for those classified as Chinese Traditional Medical types is shown in Table 6.

Table 6

<u>Type :</u>	<u>No. of Cases</u>	<u>Obviously Effective</u>	<u>Effective</u>	<u>No Effect</u>
Gastro-splenic weakness	79	40	29	10
Blood-respiratory deficiency	17	10	6	1

Rigid analysis indicates that both groups have similar beneficial effects ($P > 0.05$). This shows the Haelan 851 nutritionally supplemented diet has quite a broad sphere of usefulness and adaptation for those with malnutrition in both classification types.

9. Observations for Side Effects

In this group of 101 cases, taking nutritional supplementation oral fluid for 4-8 weeks, there was no bad side effects observed. The nutritional supplementation used in this study is a concentrated oral fluid taken in a small volume that is easily taken by children. Through blood and urine routine examinations, liver function tests, Ekg. examinations (before and after the nutritional testing), no obvious abnormal findings were observed.

At present, it may be considered quite safe to use the Haelan 851 concentrated nutritional oral fluid for nutrition in clinical use.

DISCUSSIONS

1. Malnutrition in children is listed among one of the four most important preventative conditions. According to Chinese traditional medicine it belongs to a digestive disturbance of childhood being caused by many different etiological agents, resulting in chronic deficiency in nutrition. Haelan 851 oral fluid is made from soybeans a raw material, through fermentation by biological technology, with fine mineral spring water as a component. Besides amino acids and vitamins, it also contains some mineral trace elements which are very necessary for the human

body's health. It therefore, is beneficial to the stomach, spleen and kidneys and may be used for diuretic as well as for combating dehydration purposes.

2. Through clinical applications in 101 cases of malnutrition in children, it was found to have a total effective rate of 89.11% with an obvious effective rate of 49.51%. Through 4-8 weeks of testing we may expect evident increases in the patients body weight, arm circumference and subcutaneous fat. The difference between the "before" and "after" nutrition supplementation is quite obvious. ($P < 0.001$)
3. For mild anemic patients ($Hb < 110g/L$) or low trace elements of iron ($< 87 \mu g/dl$) and zinc ($< 76 \mu g/dl$) cases, there is marked rise in iron and zinc among the Haelan 851 nutritionally supplemented cases. As to the amount of hemoglobin, there is a tendency to rise. Both iron and zinc are necessary for human health. The former is the oxygen carrier in the hemoglobin and also the active constituent of enzymes. The latter participates in the synthesis of many kinds of enzymes in the body and has the ability of promoting the growth and development as well as improving the appetite. Therefore Haelan 851 oral fluid has important nutritional components to promote growth and development as well as correcting anemia in the children.
4. Under comparable conditions, we observed the therapeutic value of Haelan 851 concentrated nutritional oral fluid and the Child Health Protecting Oral Fluid in the diet of malnourished children. The results show that the Haelan 851 concentrated nutritional oral liquid is better than the Child Health Protecting Fluid in increasing the arm circumference and subcutaneous fat, but in increasing the body weight, both have similar effects.
5. Haelan 851 concentrated nutritional oral liquid has similar positive benefits for those with malnutrition of the two following types: in gastro-splenic weakness type and in blood-respiratory deficiency types. This explains the broad sphere of utility of the nutritional benefits of Haelan 851 concentrated nutritional oral liquid.
6. Haelan 851 concentrated nutritional oral liquid has no obvious bad side effects. The nutritional supplementation amount is small and quite acceptable to children. There is no visible bad reaction for the heart, liver and kidney functions. It is safe in the clinical dosage.

In summary, Haelan 851 concentrated nutritional oral fluid is a new and safe nutritional product which may be used by malnourished children, with the results of a fair increase in body weight, arm circumference, subcutaneous fat, correction of deficiency in the trace elements of iron and zinc, improvement of appetite and promotion of development and growth.

Table 3

The improvement of appetite before and after nutrition

Total No. of Cases 90	<u>Normal</u>	<u>Slightly Decreased</u>	<u>Not so good on appetite</u>	<u>Poor Appetite</u>
Before Nutrition	9	30	47	4
After Nutrition	40	42	8	0

6. Table 4 shows the improvement values between the two groups receiving either the Haelan 851 or the Child Health Protecting Oral Fluid nutritional supplementation.

Table 4

Comparison between the Haelan 851 group and the control Group

	<u>Cases</u>	<u>Obviously Effective</u>	<u>Effective</u>	<u>No Effect</u>
Haelan 851 Group	60	30	25	5
Child Health Protecting Oral Fluid Group	60	20	20	20

Through rigid analysis, it is evident that the Haelan 851 nutritionally fed group is better than the group fed the Child Health Protecting Fluid (P < 0.01)

7. A comparison is made between the two groups on the changes in body weight, arm circumference and subcutaneous fat. (see table 5)

Table 5

**Comparison of the two groups on changes in body weight,
 arm circumference and subcutaneous fat. (kg, cm, x s)**

No. of cases - 60

Haelan 851 Nutrition Group	1.445 ^x	0.769 ^{xxx}	0.128
Child Health Protecting Group	1.051	0.326	0.078
	x P 0.05	xx P 0.05	xxx P 0.005

	<u>Haelan 851 Test Group</u>	<u>Child Health Protecting Fluid (Control Group)</u>
Number of Cases:	60	60
Sex: Male	33	32
Female	27	28
Age/Years		
1<	1	1
1>	15	18
3>	31	32
7>	13	9
Degree of Malnutrition		
1st	53	51
2nd	4	9
3rd	3	0
Gastro Splenic Weakness	44	37
Blood Respiratory Deficiency	16	23

According to the statistical method, the results of the above mentioned two groups were compared and found that no marked conditional difference existed (P value all > 0.05). Thus the two groups have good comparability in regards to age, sex, or the clinical type division according to Western medicine and Chinese Traditional medicine.

RESULTS

1. The standard of estimation of the value of the nutritional supplementation:

Obviously effective: Marked improvement in spirit and appetite, disappearance of symptoms, increase of body weight more than 1 kilogram in one month.

Effective: Improvement in spirit and appetite, decrease in symptoms, increase of body weight within 0.5-1 kilogram.

No Value: No improvement in spirit and appetite, no increase in body weight or the increase is less than .05 kilogram.

2. The overall therapeutic value of using Haelan 851 concentrated oral nutritional fluid for children who suffer from malnutrition.

This series has 101 cases including 50 cases obviously effective (49.51 %), 35 cases effective (39.6 %) and 11 cases no value (10.89 %). The total effective rate is 84.11%.