

# **Therapeutic effect of adjuvant treatment for cancer with ZhenHua 851 fermented soy in 170 cases**

851 Clinical Testing Collaborative Group

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## **ABSTRACT**

When the main outcome measures of treating cancer with both chemotherapy and the ZhenHua 851 fermented soy in this study (136 cases) were compared with those of treating cancer purely with chemotherapy (131 cases), statistical significance was found in the therapeutic effect of treating deficiency syndrome, for the ZhenHua 851 fermented soy improving living quality, enhancing appetite, relieving hypodynamia, improving immunity, alleviating the degree of decrease in hemogram caused by chemotherapy. It also has some therapeutic effect for the patients whose leukocyte and hemoglobin level were under normal before therapy and can give some protection for liver and kidney. When the main outcome measures of treating cancer with both radiotherapy and the ZhenHua 851 fermented soy (34 cases) were compared with those of treating cancer purely with radiotherapy (32 cases) , statistical significance was shown in the therapeutic effect of treating deficiency syndrome and in raising the IgG level. No toxic reaction was seen in blood, heart, liver and kidney when using the fermented soy. ZhenHua 851fermented soy can be used as accessory administration for cancer.

From March 1992 to October 1992, ZhenHua 851 fermented soy was applied with chemotherapy or radiotherapy for cancer in 170 cases (in 136 cases with chemotherapy, in 34 cases with radiotherapy). The control group had 163 cases (of which 131 cases were treated by chemotherapy only and 32 by radiotherapy only). A comparative observation was made between the two groups, and the results are listed as below.

## Subjects and Methods

### Subjects

1. **Group:** All cases were randomly divided into two main groups. In the chemotherapy group, 136 cases (the treatment group) were treated with both chemotherapy and ZhenHua 851 fermented soy, while 131 cases (the control group) were treated with chemotherapy only; in the radiotherapy group, 34 cases (the treatment group) were treated with both radiotherapy and the liquid, while 32 cases (the control group) were treated with radiotherapy only.
2. **Diseases:** the chemotherapy group mainly consists of those with cancer of the stomach, liver, esophagus, large intestine, lung and breast. Within it, the two groups are comparable ( $P>0.1$ ); the radiotherapy group mainly consists of nasopharyngeal cancer and laryngo-carcinoma. Within it, the type and the stage of the diseases between the two groups are comparable ( $P>0.1$ ).
3. **Sexes:** In the treatment group of chemotherapy, 94 cases are male and 42 cases are female, while in the control group, 84 cases are male, and 47 cases are female; in the treatment group of radiotherapy, 25 cases are male and 9 cases are female, while in the control group 26 cases are male and 6 cases are female. Both are comparable ( $P>0.1$ ).
4. **Ages:** The age in the treatment group of chemotherapy is between 17 and 83 years old, and the average is 53.10; the age in the control group varies from 16 to 80 years old, and the average is 53.23. The age in the treatment group of radiotherapy is between 30 to 73 years old and the average is 49.74; the age in the control group varies from 31 to 72 years old, and the average is 50.06. Both are comparable ( $P>0.1$ ).
5. **Types of deficiency syndromes in TCM** the deficiency syndromes between the two groups are comparable ( $P>0.1$ ). See table 1 & 2.

### Treating Methods

1. **Chemotherapy group:** the chemotherapy plan of the treatment group is similar to that of the control group. The chemotherapy plans for varied kinds of cancers are based on the STANDARD. In the treatment group, Yang Zhenhua 851 fermented soy was applied in addition, 80ml per time, twice per day, for 2 months. In the control group, for 70 cases, Leucogenum was used in addition 20mg per time, three times per day, and batyl alcohol was also given 0.1 per time, three times per day; Leukogenic was not used in 30 cases; The herbal medicine for invigorating spleen and tonifying kidney was given in addition for 31 cases (the effect on peripheral hemogram is not taken into account statistically).
2. **Radiotherapy group:** conventional radiotherapy was used in both the treatment group and the control group, Total tumor volume was 70~80gr.  $^{60}\text{Co}$ , acceleration or deep X-ray was used for therapy. In the 34 cases of treatment group, leukogenic drugs (Leucogenum or Berbamine, the effect on peripheral hemogram is not taken into account statistically) was given in addition for 12 cases, while in the other 22 cases leukogenic was not taken. 9 cases took ZhenHua 851 fermented soy 160ml per day, and the other 13 cases took the liquid 100ml per day. In the 32 cases of control group, leukogenic was

given in addition for 15 cases, while in the other 17 cases leukogenic was not taken.

### **Observation Methods and Main Outcome Measures**

Clinical observation and recording were scheduled every day. The uniform observation sheets were filled in accordingly. The following items were recorded every week: variation of deficiency syndrome, symptoms, Blood tests plus blood platelet, toxic reaction of radiotherapy or chemotherapy, and side effects of ZhenHua 851 fermented soy. Every month, the function of heart, liver, and kidney were tested, living quality was assessed, and variation of mass size was recorded. Total protein, albumin, globulin, cell immunity (Lymphocyte transformation test), NK cell and humoral immunity were tested before therapy and after therapy separately.

### **Evaluation Criterion of Therapeutic Effect**

#### 1. Deficiency Syndrome:

Conspicuous: after therapy, deficiency syndrome disappears or takes a favorable turn remarkably.

Effective: after therapy, deficiency syndrome changes for the better

Stabilizing: after therapy, deficiency syndrome remains the same

Inert: after therapy, deficiency syndrome deteriorates.

#### 2. Living quality: adopt Karnofsky performance scale, KPS

3. Grade standard of short-term therapeutic effect on Solid tumor: complete remission (CR), partial remission (PR), moderate remission (MR), stable disease (SD), and progression disease (PD)

4. The symptoms of the acute and sub-acute toxic reaction of radiotherapy or chemotherapy and the indexing standard: degree 0, 1, 2, 3, and 4.

### **Statistical Methods**

The measurement material uses the t test, counting material uses chi-square test, the rank material uses the Ridit analysis.

## Results

### I The therapeutic effect of ZhenHua 851 fermented soy on deficiency syndrome

1. In the chemotherapy group: the total effective rate (the conspicuous cases plus the effective cases) on deficiency syndrome is 67.46% (85/126) in the treatment group, which is remarkably higher than 40.60% (41/101) in the control group ( $P < 0.01$ ). The effective rate on Qi-deficiency syndrome or Yin-deficiency syndrome in the treatment group is remarkably higher than that in the control group ( $P < 0.01$  /  $P < 0.05$ ). However, there appears no significant difference when the effective rate on deficiency of blood or on mixed deficiency is considered between the two groups ( $P > 0.05$ ). See table 1

Table 1 The therapeutic effect of ZhenHua 851 fermented soy on deficiency syndrome in the chemotherapy group

Deficiency type	Group	Case	Marked effect (%)	Effect (%)	Stability (%)	No effect (%)	P
Qi deficiency	Treatment	41	2 (4.88)	33 (80.49)	2 (4.88)	4 (9.75)	<0.01
	Control	34	2 (5.88)	12 (35.29)	8 (23.53)	12 (35.29)	
Blood deficiency	Treatment	13	1 (7.69)	8 (61.54)	1 (7.69)	3 (23.08)	>0.05
	Control	9	1 (11.11)	0	5 (55.56)	3 (33.33)	
Yang deficiency	Treatment	2	0	1 (50.00)	0	1 (50.00)	
	Control	1	0	0	0	1 (100.00)	
Yin deficiency	Treatment	18	2 (11.11)	12 (66.67)	1 (5.55)	3 (16.67)	<0.05
	Control	9	0	1 (11.11)	5 (55.56)	3 (33.33)	
Mixed deficiency	Treatment	52	0	26 (50.00)	21 (40.38)	5 (9.62)	>0.05
	Control	48	1 (2.08)	24 (50.00)	9 (18.75)	14 (29.17)	
Total	Treatment	126	5 (3.97)	80 (63.49)	25 (19.84)	16 (12.70)	<0.01
	Control	101	4 (3.96)	37 (36.64)	27 (26.73)	33 (32.67)	

2. In the radiotherapy group: the total effective rate on deficiency syndrome in the treatment group is higher than that in the control group,  $P < 0.05$ , calculated by Ridit analysis. See table 2.

Table 2 The therapeutic effect of ZhenHua 851 fermented soy on deficiency syndrome in the radiotherapy group

Deficiency type	Group	Case	Marked effect (%)	Effect (%)	Stability (%)	No effect (%)	P
Qi deficiency	Treatment	5	1	3	1	0	
	Control	3	0	0	0	3	
Blood deficiency	Treatment	1	0	1	0	0	
	Control	0					
Yang deficiency	Treatment	0					
	Control	0					

Yin deficiency	Treatment	6	4	1	1	0	
	Control	9	4	0	0	5	
Mixed deficiency	Treatment	2	1	1	0	0	
	Control	0					
Total	Treatment	14	6	6	2	0	<0.05
	Control	12	4	0	0	8	

## II The short term curative effect of ZhenHua 851 fermented soy on solid tumor

1. In the chemotherapy group: there is no significant difference in the short term curative effect of ZhenHua 851 fermented soy on solid tumor between the two groups.  $P>0.05$ . See table 3.

Table 3 Effect of ZhenHua 851 fermented soy on the short term curative effect upon solid tumor in the chemotherapy group

Group	Case	CR (%)	PR (%)	MR (%)	SD (%)	PD (%)	P
Treatment	62	5 (8.06)	10 (16.13)	6 (9.68)	33 (53.23)	8 (12.90)	>0.05
Control	59	1 (1.70)	17 (28.81)	8 (13.56)	25 (42.37)	8 (13.56)	

2. In the radiotherapy group: there is no significant difference in the short term curative effect of ZhenHua 851 fermented soy on solid tumor between the two groups.  $P>0.05$ . See table 4.

Table 4 Effect of ZhenHua 851 fermented soy on the short term curative effect upon solid tumor in the radiotherapy group

Group	Case	CR (%)	PR (%)	MR (%)	SD (%)	PD (%)	P
Treatment	34	24 (70.59)	8 (23.53)	0	1 (2.94)	1 (2.94)	>0.05
Control	32	18 (56.25)	13 (40.63)	0	0	1 (3.12)	

## III The effect of ZhenHua 851 fermented soy on living quality

1. In the chemotherapy group: the living quality improved remarkably in the treatment group while the quality of life decreased remarkably in the control group. There existed significant difference between the two groups. See table 5

Table 5 Effect of ZhenHua 851 fermented soy on living quality in the chemotherapy group

Group	Case	Pre-treatment ( $\bar{X} \pm SD$ )	Post-treatment ( $\bar{X} \pm SD$ )	P	
				Within Group	Between Group
Treatment	136	76.32±14.69	83.90±55.26	<0.01	<0.01
Control	131	79.96±10.96	76.22±12.80	<0.01	

2. In the radiotherapy group: as far as the living quality was concerned, there was no significant difference between the two groups,  $P>0.05$ . See table 6.

Table 6 Effect of ZhenHua 851 fermented soy on living quality in the radiotherapy group

Group	Case	Pre-treatment ( $\bar{X} \pm SD$ )	Post-treatment ( $\bar{X} \pm SD$ )	P	
				Within Group	Between Group
Treatment	34	84.12±8.48	86.24±7.57	>0.05	>0.05
Control	32	84.06±7.98	85.60±7.01	>0.05	

#### IV The effect of ZhenHua 851 fermented soy on symptoms

1. Variation of symptoms in the chemotherapy group: in the aspect of improving appetite and alleviating fatigue, the effect in the treatment group was better than that in the control group ( $P < 0.01$ ). See table 7.

Table 7 Changes of symptoms in the chemotherapy group

Symptom	Group	Case	Mitigation (%)	Stability (%)	Aggravation Case (%)	P
Decrease appetite	Treatment	72	49 (68.06)	18 (25.00)	5 (6.94)	<0.01
	Control	81	18 (22.22)	33 (40.74)	30 (37.04)	
Weakness	Treatment	90	56 (62.22)	28 (31.11)	6 (16.67)	<0.01
	Control	70	13 (18.57)	29 (41.43)	28 (40.00)	
Insomnia	Treatment	18	11 (61.11)	7 (38.89)	0	>0.05
	Control	18	5 (27.78)	12 (66.67)	1 (5.55)	

2. Variation of symptoms in the radiotherapy group: there was no significant difference in symptoms between the two groups. See table 8

Table 8 Changes of symptoms in the radiotherapy group

Symptom	Group	Case	Mitigation (%)	Stability (%)	Aggravation Case (%)	P
Decrease appetite	Treatment	34	4 (11.77)	21 (61.76)	9 (26.47)	>0.05
	Control	32	0	19 (59.38)	13 (40.62)	
Weakness	Treatment	34	6 (17.65)	24 (70.59)	4 (11.76)	>0.05
	Control	32	2 (6.25)	30 (93.75)	0	
Insomnia	Treatment	34	3 (8.82)	31 (91.18)	0	>0.05
	Control	32	0	32 (100.00)	0	

#### V The effect of ZhenHua 851 fermented soy on weight

1. Variation of weight in the chemotherapy group: if the patient gain an average weight by 0.5kg or more after therapy, that is taken for an increase of weight. If the patient lose an average weight by more than 0.5kg after therapy, that is taken for a decrease of weight. The rest are taken for a stable state of weight. There was significant difference in variation of weight between the two groups ( $P < 0.01$ ). See table 9.

Table 9 Changes of weight in the chemotherapy group

Group	Case	Increase (%)	Stability (%)	Decrease (%)	P
Treatment	136	63 (46.32)	33 (24.27)	40 (29.41)	<0.01
Control	131	20 (15.27)	35 (26.72)	76 (58.01)	

2. Variation of weight in the radiotherapy group: there was no significant difference in variation of weight between the two groups. See table 10.

Table 10 Changes of weight in the radiotherapy group

Group	Case	Increase (%)	Stability (%)	Decrease (%)	P
Treatment	34	6 (17.65)	3 (8.82)	25 (73.53)	>0.05
Control	32	2 (6.25)	0	30 (93.75)	

## VI The effect of ZhenHua 851 fermented soy on immunity

1. In the chemotherapy group: the cell immunity and humoral immunity were enhanced in the treatment group. There was significant difference in variation of weight between the two groups (P<0.01). See table 11 & 12.

Table 11 Changes of cell immunity function in the chemotherapy group

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ ) %	Post-treatment ( $\bar{x} \pm SD$ ) %	P	
					Within Group	Between Group
LTT*	Treatment	65	55.95±8.02	56.28±8.55	>0.05	<0.01
	Control	75	55.85±8.87	49.41±12.21	<0.01	
CD3	Treatment	30	43.53±4.55	43.47±5.10	>0.05	<0.01
	Control	30	45.47±3.56	38.57±4.50	<0.01	
CD4	Treatment	30	44.07±4.60	43.10±5.13	>0.05	<0.01
	Control	30	42.60±5.20	38.27±5.62	<0.01	
NK cell	Treatment	15	9.60±5.11	12.00±4.23	<0.05	<0.01
	Control	14	12.96±4.31	10.80±4.00	<0.05	

\* LTT : Lymphocyte Transformation Test

Table 12 Changes of humoral immunity function in the chemotherapy group

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ ) g/L	Post-treatment ( $\bar{x} \pm SD$ ) g/L	P	
					Within Group	Between Group
IgG	Treatment	71	10.90±4.69	11.92±5.06	<0.05	<0.01
	Control	75	11.90±4.38	11.05±4.99	<0.05	
IgA	Treatment	72	1.63±0.67	1.73±1.32	>0.05	<0.01
	Control	75	1.65±0.76	1.38±0.76	<0.01	

IgM	Treatment	71	1.24±0.59	1.55±1.05	<0.05	<0.01
	Control	75	1.53±0.78	1.30±0.73	<0.01	

2. In the radiotherapy group: IgA was raised in the treatment group, and there was significant difference compared to the control group (P<0.01). See table 13.

Table 13 Changes of immunity function in the radiotherapy group

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
					Within Group	Between Group
LTT (%)	Treatment	31	59.77±12.68	57.03±11.25	>0.05	>0.05
	Control	30	59.83±17.67	56.03±10.16	>0.05	
IgG (g/L)	Treatment	34	10.55±4.11	11.80±3.84	>0.05	>0.05
	Control	31	13.24±5.50	3.85±5.50	>0.05	
IgA (g/L)	Treatment	34	1.74±1.31	2.39±2.18	<0.05	<0.01
	Control	31	2.07±1.03	1.88±0.80	>0.05	
IgM (g/L)	Treatment	34	1.28±0.70	1.73±1.39	>0.05	>0.05
	Control	31	1.66±0.90	1.84±0.80	>0.05	

\* LTT : Lymphocyte Transformation Test

## VII The effect of ZhenHua 851 fermented soy on toxic reaction caused by chemotherapy or radiotherapy

1. The effect on toxic reaction of chemotherapy in blood system

(1) The effect of ZhenHua 851 fermented soy and leukogenic drug on toxic reaction of chemotherapy in blood system were studied separately. There was no significant difference between them in the effect on WBC, absolute value of granulocyte, Hb and blood platelet (P>0.05). See table 14.

Table 14. Effect of ZhenHua 851 fermented soy and leukogenic drug respectively on toxic reaction of chemotherapy group in blood system

Item	Group	Case	Post-treatment Indexing (%)					Ridit	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
			Degree 0	Degree 1	Degree 2	Degree 3	Degree 4				Within Group	Between Group
WBC ( $\times 10^9/L$ )	Treatment	75	50 (66.67)	17 (22.67)	0	0	0	>0.05	5.557±2.088	4.933±1.797	<0.01	>0.05
	Control	70	43 (61.43)	24 (34.29)	3 (4.28)	0	0		5.750±1.850	4.602±1.308	<0.01	
Granulocyte ( $\times 10^9/L$ )	Treatment	73	60 (82.19)	8 (10.96)	4 (5.48)	1 (1.37)	0	>0.05	3.554±1.578	3.135±1.398	<0.01	>0.05
	Control	70	59 (84.28)	11 (15.71)	0	0	0		3.913±1.369	3.040±1.036	<0.01	



Hb (g/L)	Treatment	75	20 (26.67)	30 (40.00)	19 (25.33)	4 (5.33)	2 (2.67)	>0.05	102.200±19.946	98.924±14.632	>0.05	>0.05
	Control	70	20 (28.57)	31 (44.29)	12 (17.14)	7 (10.00)	0		102.442±17.43	100.411±13.273	>0.05	
Platelet (×10 <sup>9</sup> /L)	Treatment	47	75 (100.00)	0	0	0	0	>0.05	220.298±81.957	194.766±62.043	<0.05	>0.05
	Control	45	70 (100.00)	0	0	0	0		218.244±77.105	196.531±49.750	<0.01	
Hemorrhage	Treatment	75	75 (100.00)	0	0	0	0	>0.05				
	Control	70	69 (98.57)	0	1 (1.43)	0	0					

Control : leukogenic drug

- (2) The effect of ZhenHua 851 fermented soy taken at varied dosage and leukogenic drug on toxic reaction of chemotherapy in blood system were studied separately. ZhenHua 851 fermented soy was taken at the dosage of 160ml or 100ml per day, and compared to the control group in turn below. There was no significant difference ( $P>0.05$ ). See table 15.

Table 15 Chemotherapy combined with varied dosage of ZhenHua 851 fermented soy or leukogenic drug and comparison of their effect on toxic reaction of chemotherapy in blood system

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
					Within Group	With Control
WBC (×10 <sup>9</sup> /L)	Treatment 160ml/day	49	5.727±2.294	5.021±1.935	<0.01	>0.05
	100ml/day	26	5.223±1.658	4.736±1.534	>0.05	>0.05
	Control	70	5.757±1.860	4.602±1.308	<0.01	
Granulocyte (×10 <sup>9</sup> /L)	Treatment 160ml/day	47	3.582±1.734	3.225±1.458	>0.05	>0.05
	100ml/day	26	3.426±1.560	3.016±1.233	<0.05	>0.05
	Control	70	3.913±1.369	3.040±1.036	<0.01	
Hb (g/L)	Treatment 160ml/日	49	98.633±23.140	96.739±17.780	>0.05	>0.05
	100ml/日	26	105.846±20.023	104.019±15.553	>0.05	>0.05
	Control	70	102.492±17.430	100.411±13.273	>0.05	
Platelet (×10 <sup>9</sup> /L)	Treatment 160ml/日	21	225.048±72.162	212.333±65.534	<0.05	>0.05
	100ml/日	23	216.462±91.803	180.808±59.582	<0.05	>0.05
	Control	45	218.24±77.105	196.531±49.750	<0.01	

Control : leukogenic drug

- (3) The effect of ZhenHua 851 fermented soy taken in advance or not and leukogenic drug on toxic reaction of chemotherapy in blood system: ZhenHua 851 fermented soy was taken in advance or not, and compared to the control group taking leukogenic drug in turn below. There was no significant difference ( $P>0.05$ ). See

table 16.

Table 16 Chemotherapy combined with ZhenHua 851 fermented soy taken in advance or not or combined with leukogenic drug and comparison of their effect on toxic reaction of chemotherapy in blood system

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P		
					Within Group	Whether Advance	With Control
WBC ( $\times 10^9/L$ )	Treatment (Advance)	25	5.248 $\pm$ 2.155	4.318 $\pm$ 1.462	<0.05		>0.05
	(No advance)	37	5.605 $\pm$ 1.952	5.187 $\pm$ 1.584	>0.05	>0.05	>0.05
	Control	70	5.750 $\pm$ 1.850	4.602 $\pm$ 1.308	<0.01		
Granulocyte ( $\times 10^9/L$ )	Treatment (Advance)	23	3.414 $\pm$ 1.731	2.765 $\pm$ 1.215	>0.05		>0.05
	(No advance)	37	3.710 $\pm$ 1.572	3.239 $\pm$ 1.290	<0.05	>0.05	>0.05
	Control	70	3.913 $\pm$ 1.369	3.040 $\pm$ 1.036	<0.01		
Hb (g/L)	Treatment (Advance)	25	102.600 $\pm$ 18.018	100.484 $\pm$ 13.649	>0.05		>0.05
	(No advance)	37	106.946 $\pm$ 18.474	103.273 $\pm$ 16.131	<0.05	>0.05	>0.05
	Control	70	102.442 $\pm$ 17.430	100.411 $\pm$ 13.273	>0.05		
Platelet ( $\times 10^9/L$ )	Treatment (Advance)	15	356.933 $\pm$ 84.167	304.733 $\pm$ 42.323	<0.05		>0.05
	(No advance)	28	188.393 $\pm$ 82.327	196.531 $\pm$ 49.750	<0.01	>0.05	>0.05
	Control	45	218.244 $\pm$ 77.105	196.531 $\pm$ 49.750	<0.01		

(4) The effect of combined usage of chemotherapy with ZhenHua 851 fermented soy or leukogenic drug on WBC and Hb that is below normal before therapy: the average value of WBC rose after therapy in both the two groups, and there was no significant difference, which indicates that ZhenHua 851 fermented soy has some leukogenic effect. See table 17. There were which granulocyte level was below normal, 10 in the treatment group and 1 in the control group respectively; there was none and 1 case which blood platelet level was below normal, going to the treatment group and control group respectively. The cases are not enough to do statistical analysis.

Table 17 Effect of combined usage of chemotherapy with ZhenHua 851 fermented soy or leukogenic drug on WBC and Hb that is below normal before therapy

Item	Group	Case	Increase Case (%)	Decrease Case (%)	P	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
								Within Group	Between Group
WBC	Treatment	17	8(47.06)	9(52.94)	>0.05	3.235 $\pm$ 0.455	3.751 $\pm$ 1.182	>0.05	>0.05
	Control	9	4(44.44)	5(55.56)		3.589 $\pm$ 0.262	3.661 $\pm$ 0.554	>0.05	
Hb	Treatment	49	23(46.94)	26(53.06)	>0.05	92.265 $\pm$ 16.469	94.458 $\pm$ 15.284	>0.05	>0.05
	Control	42	27(64.29)	15(35.71)		91.286 $\pm$ 12.657	96.045 $\pm$ 13.709	>0.05	

Control : Leukogenic drug

(5) The effect of combined usage of chemotherapy with ZhenHua 851 or herbal

medicine (invigorating spleen and tonifying kidney) on toxic reaction in blood system: there was no significant difference. See table 18.

Table 18 Effect of combined usage of chemotherapy with ZhenHua 851 fermented soy or herbal medicine on toxic reaction in blood

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
					Within Group	Between Group
WBC ( $\times 10^9/L$ )	Treatment	31	5.832 $\pm$ 3.183	5.450 $\pm$ 1.380	>0.05	P>0.05
	Control	31	5.242 $\pm$ 1.291	4.771 $\pm$ 1.753	>0.05	
Granulocyte ( $\times 10^9/L$ )	Treatment	31	3.918 $\pm$ 2.703	5.527 $\pm$ 1.139	>0.05	P>0.05
	Control	31	3.392 $\pm$ 0.966	3.097 $\pm$ 0.744	>0.05	
Platelet ( $\times 10^9/L$ )	Treatment	31	110.709 $\pm$ 17.440	114.403 $\pm$ 12.450	>0.05	P>0.05
	Control	31	108.710 $\pm$ 18.218	111.435 $\pm$ 19.921	>0.05	
Hb (g/L)	Treatment	31	98.871 $\pm$ 16.883	97.813 $\pm$ 20.075	>0.05	P>0.05
	Control	31	105.548 $\pm$ 17.555	102.729 $\pm$ 16.654	>0.05	

(6) The effect of combined usage of chemotherapy with ZhenHua 851 or chemotherapy only (not using leukogenic drug, negative control) on toxic reaction in blood system: ZhenHua 851 fermented soy prescribed for cancer patients having chemotherapy can prevent decline of CBC and blood platelet, which had significant difference compared to negative control. See table 19

Table 19 Effect of combined usage of chemotherapy with ZhenHua 851 fermented soy or chemotherapy only (not using leukogenic drug) on toxic reaction in blood

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
					Within Group	Between Group
WBC ( $\times 10^9/L$ )	Treatment	30	4.743 $\pm$ 1.208	5.451 $\pm$ 0.857	<0.01	P<0.01
	Control	30	5.290 $\pm$ 0.850	4.450 $\pm$ 0.800	<0.01	
Granulocyte ( $\times 10^9/L$ )	Treatment	30	3.200 $\pm$ 0.820	3.660 $\pm$ 0.690	<0.01	P<0.01
	Control	30	3.720 $\pm$ 0.580	3.090 $\pm$ 0.450	<0.01	
Hb (g/L)	Treatment	30	94.630 $\pm$ 18.000	96.890 $\pm$ 16.080	>0.05	P<0.01
	Control	30	103.670 $\pm$ 13.240	99.200 $\pm$ 11.630	<0.01	
Platelet ( $\times 10^9/L$ )	Treatment	30	140.300 $\pm$ 4.880	160.030 $\pm$ 4.360	<0.01	P<0.01
	Control	30	157.330 $\pm$ 3.520	145.530 $\pm$ 5.330	<0.01	

## 2. The effect on toxic reaction of radiotherapy in blood system

(1) There was no significant difference (P>0.05) between the effect of combined usage of radiotherapy with ZhenHua 851 fermented soy and that with leukogenic drug on toxic reaction of radiotherapy in blood system. See table 20

Table 20 Effect of combined usage of radiotherapy with ZhenHua 851 fermented soy or leukogenic drug on toxic reaction of radiotherapy in blood system

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Average rate of decline (%)	P	
						Within Group	Between Group
WBC ( $\times 10^9/L$ )	Treatment	22	6.85 $\pm$ 2.45	5.71 $\pm$ 1.05	16.5	<0.05	>0.4
	Control	15	6.95 $\pm$ 2.25	5.71 $\pm$ 1.05	10.4	>0.05	
Granulocyte ( $\times 10^9/L$ )	Treatment	22	4.74 $\pm$ 1.82	4.21 $\pm$ 0.89	11.0	>0.1	>0.4
	Control	15	3.96 $\pm$ 1.14	3.90 $\pm$ 1.10	1.5	>0.5	
Hb (g/L)	Treatment	22	117.50 $\pm$ 7.10	115.03 $\pm$ 8.73	2.1	>0.5	>0.5
	Control	15	119.00 $\pm$ 8.31	118.03 $\pm$ 7.964	0.8	>0.5	
Platelet ( $\times 10^9/L$ )	Treatment	22	273.41 $\pm$ 87.68	251.36 $\pm$ 60.30	8.1	>0.1	>0.2
	Control	15	119.00 $\pm$ 8.31	118.03 $\pm$ 7.96	0.8	>0.5	

(2) There was no significant difference ( $P>0.05$ ) between the effect of combined usage of radiotherapy with ZhenHua 851 fermented soy and that of radiotherapy without leukogenic drug on toxic reaction in blood system. See table 21

Table 21 Effect of combined usage of radiotherapy with ZhenHua 851 fermented soy and that of radiotherapy without leukogenic drug on toxic reaction in blood system

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Average rate of decline (%)	P	
						Within Group	Between Group
WBC ( $\times 10^9/L$ )	Treatment	22	6.85 $\pm$ 2.45	5.71 $\pm$ 1.05	16.5	<0.05	>0.05
	Control	17	7.32 $\pm$ 2.47	5.82 $\pm$ 1.75	20.6	<0.01	
Granulocyte ( $\times 10^9/L$ )	Treatment	22	4.74 $\pm$ 1.82	4.21 $\pm$ 0.89	11.0	>0.1	>0.05
	Control	17	5.63 $\pm$ 3.43	4.17 $\pm$ 1.32	25.9	>0.1	
Hb (g/L)	Treatment	22	117.50 $\pm$ 7.10	115.03 $\pm$ 8.73	2.1	>0.5	>0.05
	Control	17	117.00 $\pm$ 9.98	112.14 $\pm$ 6.91	4.2	<0.02	
Platelet ( $\times 10^9/L$ )	Treatment	22	273.41 $\pm$ 87.68	251.36 $\pm$ 60.30	8.1	>0.1	>0.05
	Control	17	295.94 $\pm$ 93.57	245.45 $\pm$ 54.49	17.0	>0.05	

### 3. The effect on toxic reaction of chemotherapy in the digestive system

(1) There was no significant difference in the effect of ZhenHua 851 fermented soy on toxic reaction in the digestive system, compared to the control. See table 22

Table 22 Effect of 851(Y) fermented soy on toxic reaction of chemotherapy in the digestive system

Item	Group	Case	Indexing (%)				P
			degree 0	degree 1	degree 2	degree 3	
Nausea and vomiting	Treatment	136	71(52.21)	35(21.74)	18(13.23)	12(8.82)	>0.05
	Control	131	47(35.88)	51(38.93)	24(18.32)	9(6.87)	
Diarrhea	Treatment	136	127(93.38)	5(3.68)	3(2.21)	1(0.73)	>0.05

	Control	131	119(90.84)	7(5.34)	3(2.29)	2(1.57)	
Constipation	Treatment	136	128(94.12)	6(4.41)	2(1.47)	0	>0.05
	Control	131	125(95.42)	5(3.82)	1(0.76)	0	
Oral mucosa damage	Treatment	136	130(95.59)	3(2.21)	2(1.47)	1(0.73)	>0.05
	Control	131	120(91.60)	9(6.87)	2(1.52)	0	

(2) The effect on liver function: there were 8 abnormal SGPT cases in the treatment group, 2 out of which recovered after therapy, and the value of SGPT decreased obviously in 6 cases; there were 7 abnormal SGPT cases in the control group, 2 out of which recovered, 2 rose, 2 decreased, and 1 unchanged. There were 11 ALP-increasing cases in the treatment group, 8 recovered, 1 decreased, 2 increased after therapy; there were 4 ALP-increasing cases in the control, 3 increased, 1 decreased after therapy. The value of SGPT and ALP had decreased to some extent in the treatment group after therapy, while the value did opposite in the control. There was significant difference in the SGPT value between the two groups, which indicate that the fermented soy has some effect of protecting liver function. See table 23.

Table 23 Effect of ZhenHua 851 fermented soy on liver function in the chemotherapy group

Group	Case	SGPT (mmol/L)		P		Case	ALP (U/L)		P	
		Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Within Group	Between Group		Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Within Group	Between Group
Treatment	89	460.06±25.34	330.11±245.01	>0.05	<0.05	88	72.34±51.81	70.42±48.71	>0.05	>0.05
Control	84	261.47±191.23	284.00±217.30	>0.05		83	65.26±37.32	77.64±64.03	<0.05	

4. The effect on toxic reaction of radiotherapy in the digestive system: there was no significant difference in the effect on toxic reaction in the digestive system between the two groups ( $P>0.05$ ). See table 24 & 25.

Table 24 Effect of ZhenHua 851 fermented soy on toxic reaction of radiotherapy in the digestive system

Item	Group	Case	Indexing (%)					P
			degree 0	degree 1	degree 2	degree 3	degree 4	
Nausea and vomiting	Treatment	34	27(79.41)	5(14.71)	1(2.94)	1(2.94)	0	>0.05
	Control	32	24(75.00)	8(25.00)	0	0	0	
Diarrhea	Treatment	34	34(100.00)	0	0	0	0	>0.05
	Control	32	31(96.88)	1(3.17)	0	0	0	
Constipation	Treatment	34	34(100.00)	0	0	0	0	>0.05
	Control	32	32(100.00)	0	0	0	0	
Oral mucosa damage	Treatment	34	13(38.23)	5(14.71)	10(29.41)	5(14.71)	1(2.94)	>0.05
	Control	32	16(50.00)	5(15.63)	6(18.74)	5(15.63)	0	

Table 25 Effect of ZhenHua 851 fermented soy on liver function in the radiotherapy group

Group	Case	ALP (U/L)		P	
		Pretreatment	Post-treatment	Within Group	Between Group
Treatment	34	97.03±58.37	80.27±27.06	>0.05	>0.05
Control	32	87.12±45.33	86.69±32.81	>0.05	

\* SGPT were normal in both Pretreatment and Post-treatment groups

5. The effect on toxic reaction of chemotherapy in the urinary system: there were 2 low degree haemoglobinuria cases after therapy in the two groups separately, but no haematuria occurred. BUN average decreased to some extent in the treatment group after therapy, Cr average after therapy was close to that before therapy, while they both increased significantly in the control (P<0.01), Between groups were significantly different, which indicates that ZhenHua 851 fermented soy has some effect of protecting renal damage caused by chemotherapy drug. See table 26 & 27.

Table 26 Effect of ZhenHua 851 fermented soy on toxic reaction of chemotherapy in the urinary system

Item	Group	Case	Indexing (%)				
			degree 0	degree 1	degree 2	degree 3	degree 4
Proteinuria	Treatment	136	134(98.53)	2(1.47)	0	0	0
	Control	131	129(98.47)	2(1.53)	0	0	0
Hematuria	Treatment	136	136(100.00)	0	0	0	0
	Control	131	131(100.00)	0	0	0	0

Table 27 Effect of ZhenHua 851 fermented soy on renal function in the chemotherapy group

Group	Case	Blood urea nitrogen (mmol/L)		P		Case	Blood creatinine (μmmol/L)		P	
		Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Within Group	Between Group		Pretreatment ( $\bar{x} \pm SD$ )	Pos-treatment ( $\bar{x} \pm SD$ )	Within Group	Between Group
Treatment	111	5.13±2.95	4.95±1.33	>0.05	<0.01	110	97.15±30.64	97.99±23.46	>0.05	<0.01
Control	100	4.26±1.03	5.04±1.42	<0.01		90	89.28±22.13	107.08±41.27	<0.01	

6. The effect on toxic reaction of radiotherapy in the urinary system: routine urine test and kidney function test showed no abnormality. See table 28 & 29.

Table 28 Effect of ZhenHua 851 fermented soy on toxic reaction of radiotherapy in the urinary system

Item	Group	Case	Indexing (%)				
			degree 0	degree 1	degree 2	degree 3	degree 4
Proteinuria	Treatment	34	34(100.00)	0	0	0	0
	Control	32	32(100.00)	0	0	0	0
Hematuria	Treatment	34	34(100.00)	0	0	0	0
	Control	32	32(100.00)	0	0	0	0

Table 29 Effect of ZhenHua 851 fermented soy on renal function in radiotherapy group

Group	Case	Blood urea nitrogen (mmol/L)	P	Case	Blood creatinine (μmmol/L)	P
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		Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Within Group	Between Group		Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	Within Group	Between Group
Treatment	34	4.97±1.03	4.60±1.05	>0.05	>0.05	34	82.35±26.27	71.41±24.21	<0.05	>0.05
Control	31	5.12±1.12	4.60±0.90	<0.05		31	83.34±24.26	79.86±17.51	<0.05	

7. The effect on toxic reaction of chemotherapy or radiotherapy in cardiovascular system

(1) The effect on ECG: There were a few myocardial injury cases in both groups, but there was no significant difference ( $P>0.05$ ). See table 30.

Table 30 Effect of ZhenHua 851 fermented soy on ECG in the chemotherapy & radiotherapy group

Method	Group	Case	Indexing (%)					P
			degree 0	degree 1	degree 2	degree 3	degree 4	
Chemotherapy	Treatment	136	132(97.06)	0	0	1(0.74)	3(2.20)	>0.05
	Control	108	104(96.29)	1(0.93)	1(0.93)	0	2(1.85)	
Radiotherapy	Treatment	34	32(94.12)	0	0	0	2(5.88)	>0.05
	Control	32	26(81.25)	0	2(6.25)	3(9.38)	1(3.12)	

(2) The effect on blood pressure: in chemotherapy group: 132 cases in the treatment group and 131 in the control group had blood pressure test, their blood pressure was within normal range. In radiotherapy group: 34 cases in the treatment group and 32 in the control group had blood pressure test, normal as well.

8. The effect on hair loss in the chemotherapy & radiotherapy group: there was no significant difference ( $P>0.05$ ). See table 31.

Table 31 Effect of ZhenHua 851 fermented soy on hair loss in the chemotherapy & radiotherapy group

Item	Group	Case	Indexing (%)				P
			degree 0	degree 1	degree 2	degree 3	
Chemotherapy	Treatment	136	110(80.88)	8(5.88)	15(4.03)	3(2.21)	>0.05
	Control	131	104(79.39)	18(3.74)	7(5.34)	2(1.53)	
Radiotherapy	Treatment	34	18(52.94)	16(47.06)	0	0	>0.05
	Control	32	10(31.25)	22(68.75)	0	0	

9. The effect on chemotherapy and radiotherapy interruptions: the treatment interruptions (TI) rate in the treatment groups of chemotherapy and radiotherapy were slightly lower than that in the control groups, but there was no significant difference ( $P>0.05$ ). See table 32.

Table 32 Effect of ZhenHua 851 fermented soy on chemotherapy and radiotherapy interruptions

Method	Group	Case	No interruption (%)	Interruption (%)	P
Chemotherapy	Treatment	130	95(73.08)	35(26.92)	>0.05

	Control	127	85(66.93)	42(33.07)	
Radiotherapy	Treatment	34	32(94.12)	2(5.88)	>0.05
	Control	32	29(90.63)	3(9.37)	

10. The effect on serum protein in the chemotherapy group: the average values of total protein and albumin in the treatment group increased slightly after therapy, while those in the control group decreased obviously ( $P < 0.05$ ), and there was significant difference between groups ( $P < 0.01$  or  $P < 0.05$  separately), which indicates that ZhenHua 851 fermented soy can promote Protein Synthesis. See table 33.

Table 33 Effect of ZhenHua 851 fermented soy on serum protein in the chemotherapy group

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
					Within Group	Between Group
Total protein (g/L)	Treatment	101	65.31±10.01	67.47±5.99	>0.05	<0.01
	Control	103	65.64±6.53	64.20±6.07	<0.05	
Albumin (g/L)	Treatment	107	38.78±5.65	39.13±5.26	>0.05	<0.05
	Control	102	39.44±4.74	38.18±5.24	<0.05	
Glubulin (g/L)	Treatment	101	27.55±5.59	28.02±5.57	>0.05	>0.05
	Control	102	26.04±5.41	26.00±5.67	>0.05	

11. The effect on serum protein in the radiotherapy group: there was no significant difference ( $P > 0.05$ ). See table 34

Table 34 Effect of ZhenHua 851 fermented soy on serum protein in the radiotherapy group

Item	Group	Case	Pretreatment ( $\bar{x} \pm SD$ )	Post-treatment ( $\bar{x} \pm SD$ )	P	
					Within Group	Between Group
Total protein (g/L)	Treatment	34	71.00±6.38	71.04±4.60	>0.05	>0.05
	Control	32	70.06±3.37	70.06±5.38	>0.05	
Albumin (g/L)	Treatment	34	41.22±4.00	39.97±3.24	>0.05	>0.05
	Control	32	39.63±3.52	39.23±2.64	>0.05	
Glubulin (g/L)	Treatment	34	30.78±6.34	31.62±4.64	>0.05	>0.05
	Control	32	31.125±6.14	31.39±4.08	>0.05	

12. Side effect: ZhenHua 851 fermented soy had no toxic reaction upon heart, liver and kidney. In 7.35% (10/136) cases nausea and vomiting symptoms occurred when ZhenHua 851 fermented soy used during chemotherapy; no toxic or side effect occurred when ZhenHua 851 fermented soy used during radiotherapy.



## Typical Cases

**Sample 1** The patient a Mr. Huang, whose hospitalized number was 12750, was a peasant, male, 59 years old. He entered the Department of Radiotherapy in Fujian Province Oncology Hospital on March 3, 1992 with the diagnosis low grade differentiated nasopharyngeal carcinoma T<sub>4</sub>N<sub>2</sub>M<sub>0</sub> (IV). He had Qi-deficiency syndrome, poor appetite, 70 score for living quality, WBC 11.5×10<sup>9</sup>/L, Hb 126g/L, blood platelet 126×10<sup>9</sup>/L, Lymphocyte transformation test 51%, IgG 5.8g/L, IgM 0.5g/L, and the rest items tested were normal. Radical radiotherapy was carried on, and ZhenHua 851 fermented soy was taken at the meantime 180ml tid. WBC was 4×10<sup>9</sup>/L at the lowest during radiotherapy, and Hb 99g/L. Hemogram had stabilized at normal range after radiotherapy, with the results that WBC were mostly above 6×10<sup>9</sup>/L, Lymphocyte transformation ratio rising from 51% to 63%, IgG from 5.8g/L to 9.3g/L, IgM from 0.5g/L to 1.2g/L. The primary lesion disappeared and the deficiency syndrome was cured. The nausea symptom seen at the beginning of radiotherapy appeared no more later on. The appetite became good, hypodynamia improved, and the score of living quality rose to 95 from 70.

**Sample 2** The patient a Mr. Yang, whose hospitalized number was 15348, was male, 57 years old. He entered the Department of Internal Medicine in Fujian Province Oncology Hospital for Hodgkin's disease (IA) on March 2, 1992. The chemotherapy CTD+VCR+ADR+Prod was carried on for two periods, and then radiotherapy with linear accelerator 4000cGy/20 times/28 days. ZhenHua 851 fermented soy was given at the meantime 80ml bid, up to 8.5L total amount. Before therapy the patient had deficiency of blood, which got improved after therapy. Lymphocyte transformation ratio rose (40% to 75%), IgG from 8.3g/L to 10.1g/L, IgM from 0.9g/L to 1.61g/L, IgA decreasing from 1.9g/L to 1.79g/L. Hemogram stabilized at normal range basically to make the therapy go smoothly. Enlarged lymph nodes disappeared at the examination after therapy, the results of other items were normal. The patient was discharged from hospital after CR.

**Sample 3** The patient a Ms. Hong was female, 56 years old, who had surgery for rectal ulcerative medium grade differentiated adenocarcinoma (T<sub>2</sub>N<sub>1</sub>M<sub>1</sub> liver metastaticum). The patient had chemotherapy with 5-Fu0.5gi.v.gtt.q.w for four times at other hospital, and was forced to stop because WBC decreased to under 2.0×10<sup>9</sup>/L. Then she was transferred to Fuzhou First Hospital on March 2, 1992. At the time of admission, the patient felt fatigue, had poor appetite, and weighed 48kg. After a month treatment in hospital, WBC rose to 4.7×10<sup>9</sup>/L, and chemotherapy with 5-Fu0.75gi.v.gtt.q.w began to be performed 8 times per month from March 28, 1992. At the meantime ZhenHua 851 fermented soy was given 80ml, bid. WBC remained above 3.6×10<sup>9</sup>/L (the average 4.6×10<sup>9</sup>/L). The patient reported that her appetite was remarkably improved and she did not feel fatigue any more. Her weight increased from 48kg to 54kg. Hepatic metastatic lesion did not develop according to B-ultrasound detection. Stop using the liquid after two months, and carry on the chemotherapy as originally designed.

## Summary

### **1. The therapeutic effect of ZhenHua 851 fermented soy on deficiency syndrome of cancer:**

92.7% (126/136) patients in chemotherapy group had deficiency syndrome. The combined usage of the liquid and chemotherapy can improve deficiency syndrome, especially for those with Qi-deficiency ( $P<0.01$ ) and Yin-deficiency ( $P<0.05$ ). The same result ( $P<0.05$ ) repeated in radiotherapy group, in which the patients with deficiency syndrome were 41.2% (14/34).

2. The effect of ZhenHua 851 fermented soy on immunity: the combined usage of the liquid and chemotherapy can enhance cell immunity (Lymphocyte transformation test, T lymphocyte group, NK cell) and Humoral immunity (IgG, IgA, IgM). There is significant difference ( $P<0.01$ ) when compared with the control group. the combined usage of the liquid and radiotherapy can increase IgA, and there is significant difference ( $P<0.01$ ) when compared with the control group.

3. The effect of ZhenHua 851 fermented soy on clinical symptoms: the combined usage of the liquid and chemotherapy has a better therapeutic effect than that of the control group on relieving fatigue, enhancing appetite, increasing weight, and improving living quality ( $P<0.01$ ).

### 4. The effect on toxic reaction of chemotherapy and radiotherapy:

- (1) The effect on peripheral hemogram: the average value of blood tests or blood platelet in the treatment group of chemotherapy declined less than that in the control group ( $P<0.01$ ), which is in agreement with the results of pharmacology experiments. It also has therapeutic effect for those whose Leukocyte and Hb level are below normal before therapy. When the effect of using chemotherapy with the liquid was compared to that of using chemotherapy with herbal medicine that invigorating spleen and tonifying kidney, there is no significant difference in hemogram. Whether having the liquid beforehand or not, there is no significant difference in hemogram. The above information shows that using the liquid with chemotherapy can prevent decline in hemogram and has therapeutic effect for those whose Leukocyte and Hb level are below normal before therapy.
- (2) The effect on liver function: using the liquid with chemotherapy can not only alleviate the damage to live function, but also decrease SGPT and increase total protein and albumin ( $P<0.01$ ).
- (3) The effect on toxic reaction in gastrointestinal tract: anorexia was less ( $P<0.01$ ) in the treatment group of chemotherapy than that in the control group, though diarrhea, constipation, Oral mucosa damage showed no significant sign of improving ( $P>0.05$ ); the toxic reaction in gastrointestinal tract between the treatment group of radiotherapy and that the control group showed no significant difference ( $P>0.05$ ).
- (4) The effect on toxic reaction in urinary system: using the fermented soy with chemotherapy can decrease blood creatinine (Cr), blood urea nitrogen(BUN) and had

a significant difference when compared with the control group.

(5) The effect on toxic reaction in cardiovascular system: In both groups the variation of blood pressure and electrocardiogram showed no significant difference ( $P>0.05$ ).

5. The Short-term Curative Effect on solid tumor: there was no significant difference in both treatment group ( $P>0.05$ ), which indicate that the liquid has no notable positive effect of anti-tumor for chemotherapy or radiotherapy in short term. However, the long-term effect are left for further inquiry .

Side effects: No toxic reaction was seen in blood, heart, liver and kidney when using the fermented soy with chemotherapy or radiotherapy. Nausea and vomiting occurred in 7.35% (10/136) patients. It may be relevant to the unaccustomed taste or the chemotherapy itself. However, No such side effects showed in radiotherapy group.

Stated thus, ZhenHua 851 fermented soy can be used as adjuvant administration for cancer.

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3. See above, P13
4. See above, P10-11

**Collation:** Chen Limin & Li Pintu from Fuzhou Institute of Medical Sciences  
Department of Radiotherapy and Department of Internal Medicine in Fujian Oncology  
Hospital  
Fuzhou First Hospital(Fuzhou Oncology Institute of TCM combined with Modern  
Medicine)  
Division of Oncology Surgery, Fuzhou Hospital of TCM combined with Modern  
Medicine  
The Affiliated Hospital of Fujian College of TCM  
Fujian Institute of TCM  
Department of Oncology, Fujian Provincial Hospital