

SUMMARY OF STUDY

INTRODUCTION

Coronary heart disease and stroke have contributed significantly to the mortality of both men and women in the developed and developing world. High-density cholesterol-lipoprotein (HDL-C) has been shown to be an “anti-atherogenic lipoprotein”. On the other hand, low-density-cholesterol-lipoprotein (LDL-C) is a contributing factor for developing arteriosclerosis. Functional food has taken an important role in preventing diseases and improving human health. Therefore, we have chosen Alpha-PSP, a form of cereal powder supplement formulated from a proprietary process, with aims to give new dimensions (innovation), for preventing coronary heart disease.

OBJECTIVES

- To obtain information on the efficacy of Alpha-PSP, as an individual component, in increasing HDL-Cholesterol in obese Cho Ray medical and hospital staff with low HDL-C (≤ 45 mg/dl).
- To obtain further information on changes in other lipid profiles (Total Cholesterol, LDL-C, Apolipoprotein A1)
- To evaluate subjectively the tolerability of Alpha-PSP by a questionnaire, on changes in appetite, sleep, feces, other disorders and overall health.

STUDY SUBJECTS

Subjects chosen were staff between the age of 18 and 65 who were official officers, or who were researchers at the Cho Ray hospital. A total of 106 subjects who were obese and have HDL ≤ 45 mg/dl finished the study successfully.

CONDUCT OF THE STUDY

This study was conducted in Cho Ray Hospital, Ho Chi Minh City, Vietnam. Study subjects took 20 g of Alpha-PSP, which is produced by Macro Food Tech – Thailand, every morning for a period of 3 months. Physical measurements (BMI, % body fat, waist/hip ratio) and lipid profile (Total Cholesterol, HDL Cholesterol, Apolipoprotein A1, LDL Cholesterol) were conducted at the beginning of the study and after 3 months. During the study, the use of diets or drugs for managing lipidemia disorder was prohibited.

RESULTS AND DISCUSSION

Significant improvement was observed in the concentration of HDL-C ($p < 0.01$) and Apolipoprotein A-1 ($p < 0.05$) and a reduction in LDL-C ($p < 0.01$). All results gathered demonstrated the expected aim, which was to increase the concentration of HDL-C and Apolipoprotein A-1, while decreasing LDL-C.

CONCLUSIONS

The use of this “Alpha-PSP” natural food supplement powder, as part of an overall diet, proved to be highly successful in lowering the overall risk factors associated with Coronary Heart Disease (CHD) through a significant increase in HDL-C, Apolipoprotein A-1, while concurrently obtaining reduction in LDL-C.



VIETNAMESE MINISTRY OF HEALTH

CHO RAY HOSPITAL - HO CHI MINH CITY

The Efficacy of Alpha-PSP
on
Coronary Heart Disease
in
the Staff of Cho Ray Hospital
with
HDL-Cholesterol
and
Lipidemia Disorders

2001



Cho Ray Hospital

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Ho Chi Minh City - Viet Nam.

**An Open-label, Non-comparative study
to evaluate the efficacy of Alpha-PSP as monotherapy
on HDL-Cholesterol and
Lipidemia Disorders**

Cho Ray Medical and Hospital staff

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Study commencement date: 10 January 2001

Study completion date: 10 August 2001



ENDORSEMENTS

**We would like to thank all our colleagues in Cho Ray Hospital
for helping us to finish the study successfully.**

**Sponsors: Tan Hoan Cau Company - Viet
 Nam(Investigation Fund)
 Macro Food Tech Co. Ltd. – Thailand
 (Alpha-PSP-Food)**

**Studied Food: Alpha-PSP, a mechanically hydrolyzed
 polysaccharidepeptide powder supplement**

**Study Title: An Open-label, Non-comparative study to evaluate
 the efficacy of Alpha-PSP as monotherapy on
 administering HDL-Cholesterol for Cho Ray
 medical and hospital staff with lipidemia disorders**

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CHO RAY HOSPITAL AND DEPARTMENT OF DIETETICS OVERVIEW

Cho Ray hospital has been established since 1900. Cho Ray hospital is a general hospital including the following departments: 28 clinical departments as internal medicine, surgery... 13 sub-clinical departments as diagnostic imaging, clinical biochemistry, pathology, clinical nutrition; and 7 functional as personnel, administration, and accounting. It is a national hospital having about 1,500 beds with over 40,000 in-patients and about 300,000 out-patients per year. Cho Ray hospital is the top referral hospital of the South, which is under the direct supervision of the Ministry of Health. Cho Ray covers the medical treatment of 37 Southern provinces including Ho Chi Minh City, with a total population of over 6 million.

The Department of Dietetics is responsible for doing nutrition support for the in-patients, consulting the clinical nutrition for the physicians in other clinical departments and out-patients, controlling professionally the safety and hygiene of food for the Germany standardized dietetics kitchen providing over 1,000 meals for in-patients every day, doing scientific research, issuing nutritional information and compiling pamphlets for nutrition therapy.

I. INTRODUCTION

Cardiovascular disease has been a fearful killer of human beings for a long time. According to the latest report in 2002 of the World Health Organization (WHO), there are 32 million more people suffering from cardiovascular disease annually. 12 million die annually from this disease, and among them 2/3 are living in the developing countries. WHO has predicted for health and disease for the 21st century that the coronary heart disease (CHD) will continue to be the number one life-claimer among all diseases, because CHD and stroke have contributed significantly to the mortality rates in both men and women not just in most of the industrial countries, but has also been increasing in the developing countries.

In Vietnam, there were 1,006 acute myocardial infarction patients with 122 mortalities and 3,322 partial myocardial ischemic patients with 18 mortalities in 2000, reported by the Office of Health in Ho Chi Minh City, Vietnam.

In the first 6 months in 2001, there were 449 acute myocardial infarction patients with 139 mortalities, 1725 partial myocardial ischemic patients with 513 mortalities.

The epidemiological studies in 7 countries (PROCAM study and Framingham), and the clinical studies (WOSCOP, 4S, AFCAPS, Tex CAPS, CARE and LIPID) have shown the role of the disorders and the therapy efficacy on reducing lipidemia in CHD.

The significant role of an “anti-atherogenic lipoprotein”, a high-density cholesterol-lipoprotein (HDL-C) has been shown much concern. **If the concentration of HDL-C only raises 1 mg/dl, the risk of that disease will reduce 2% for men and 3% for women.** On the one hand, although the low-density-cholesterol-lipoprotein (LDL-C) is an extensively contributing factor for developing arteriosclerosis, 69% of men who have coronary heart disease have a normal or a moderately high LDL-C concentration, while 1/3 of the patients

have a low HDL-C concentration. Therefore, if the HDL-C concentration increases, without necessarily reducing the LDL-C concentration, it will benefit quite a great numbers of patients with coronary heart disease.

There are available some drugs for increasing the HDL-C concentration and decreasing the LDL-C concentration. They work more effectively in patients with low HDL-C and moderately high LDL-C concentration. However, they can worsen the Insulin resistance status (Niacin), and/or cannot reach expected HDL-C concentrations (Statin), reduce the LDL-C and Triglycerides concentration significantly, and their serious side effects are worth considering.

Since the 1980's functional food has been considered. It has taken an important role in preventing diseases and improving human health with its functional ingredients. These can include: oligosaccharides, fiber, fat and fatty acids, antioxidants, phytochemicals, polysaccharides, sugar alcohols, polyphenols, probiotic, amino acids, peptides, and polysaccharidepeptides (PSP).

In our opinion, the use of any functional food to raise HDL-C concentration intentionally can only benefit the patients in that they do not have to suffer from the side effects and it is a pleasure to use a natural food. Therefore, we have chosen Alpha-PSP, a form of cereal powder supplement formulated from a proprietary process, with aims to give new dimensions (innovation), for preventing one of the non-contagious chronic diseases which has an obvious alarmingly increased number of mortalities in this century.

II. OBJECTIVES

2.1 Primary

- To obtain information on the efficacy of Alpha-PSP, as first line monotherapy, in administering HDL-Cholesterol in obese Cho Ray medical and hospital staff with low HDL-C ($\leq 45\text{mg/dl}$).

2.2 Secondary

- To obtain further information on changes in other lipid profiles (Total Cholesterol, LDL-C, Apolipoprotein A1)
- To evaluate subjectively the tolerability of Alpha-PSP by the questionnaire on changes in appetite, sleep, feces, other disorders and overall health.

III. STUDY DESIGN OVERVIEW

This is open-label, non-comparative study conducted in Cho Ray Hospital, the largest hospital in Southern Viet Nam.

1,181 Cho Ray staff were evaluated by BMI, % body fat, and ratio of W/H. Among them, 368 staff identified as obese were accepted for the study and calculated by clinical laboratory tests including fasting lipid profiles (Total cholesterol, HDL-C, LDL-C, Apolipoprotein A1) at Visit 1.

170 subjects who were obese and have HDL $\leq 45\text{ mg/dl}$ were eligible to drink Alpha-PSP 20 g (mixed with 200 – 250 cc of hot water) every morning for a period of 3 months. Of this number, 130 subjects volunteered to participate in the study. After 3 months, they were identified at Visit 2.

This study involved 2 scheduled visits over a period of 3 months.

IV. STUDY POPULATION

4.1 Number of subjects

Included 1,181 Cho Ray medical and hospital staff that have been working in Cho Ray hospital from January 10/2001 to August 10/2001.

Among 368 obese staffs there were approximately 170 with HDL-C \leq 45 mg/dl, but there were 130 who volunteered to drink Alpha-PSP for the 3-month study. 106 subjects remained eligible at the end.

This study was conducted in Cho Ray Hospital.

4.2 Selection Criteria

4.2.1 Inclusion Criteria

Staff must meet ALL of the following criteria to be eligible for inclusion in the study:

1. Staff who are official officers, or who are working for Cho Ray hospital in research.
2. Males and females aged from 18 to 65.

4.2.2 Exclusion Criteria

Staffs are excluded from the study if ANY of the following apply:

1. Staffs aged under 18 or over 65
2. Women who are pregnant
3. Officers with diabetes
4. Staff who are using diets and/or drugs for treating lipidemia disorder.

V. CONDUCT OF THE STUDY

5.1. General Instructions

5.1.1. Concomitant treatment

The use of diets or drugs for managing lipidemia disorder was prohibited during the study. However, there were no cases in this study.

There were 24 subjects who had missed drinking the Alpha-PSP over 5% of total study days (92 days), and have not been included as part of the study.

5.2. Outline of Study Procedures & Detailed Description of Study Visits

5.2.1. General considerations applying to all study visits

Investigators must encourage their subjects to comply with the visit schedules.

Laboratory samples must be collected from subjects in the fasting state. If at any visit the subject has not fasted, specimens for laboratory testing should not be collected. In such cases, the subjects should return to the visit on the following day, or as soon as possible thereafter, in a fasting condition so that specimens could be collected.

5.2.2. Screening Visits

	Visit 1 (Start)	Visit 2 (After 3 months)
(Physical examination ^a (including BMI, % body fat, W/H)		
Lipid profiles ^b (Total Cholesterol, HDL Cholesterol, Apolipoprotein A1, LDL Cholesterol)		

a (see Appendix A)

b (see Appendix B)

VI. STUDY MEDICATION

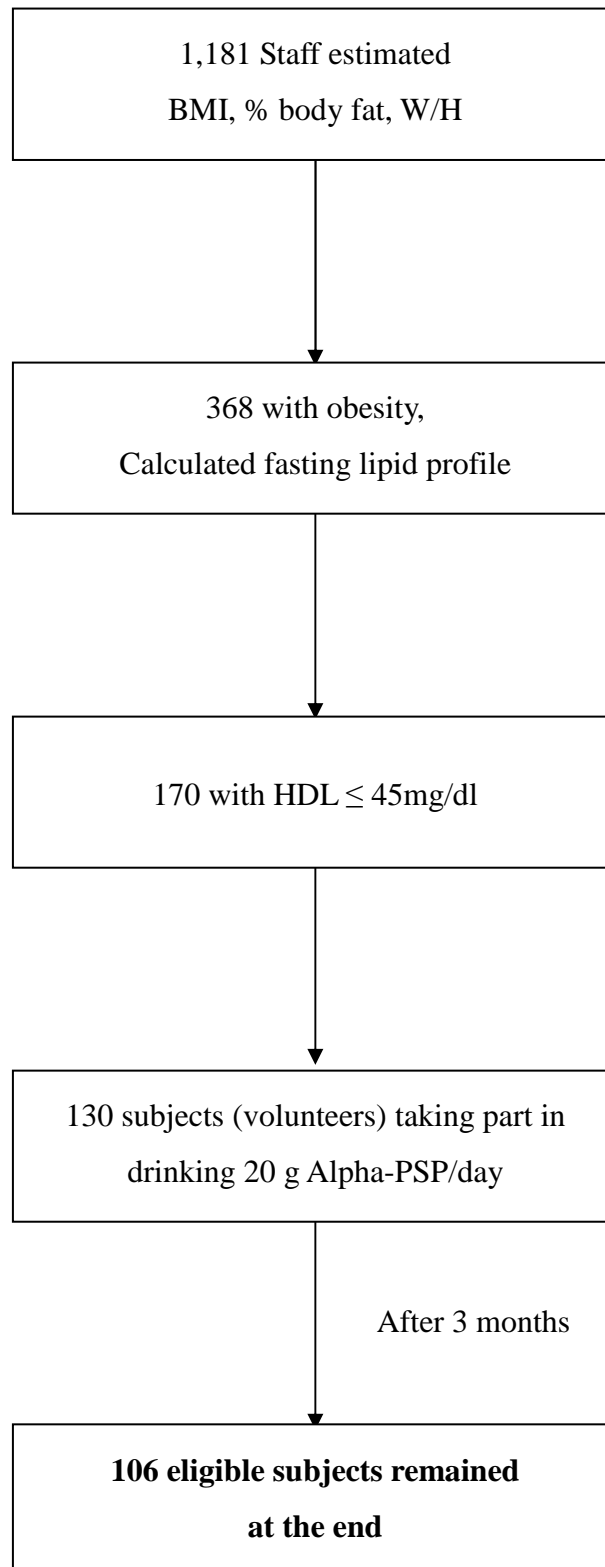
6.1. Dosage

Alpha-PSP, which is produced by Macro Food Tech - Thailand, has been supplied by Tan Hoan Cau Company - Vietnam.

All eligible subjects have been given a dose of 20 g Alpha-PSP per day for 3 months.

6.2. Concomitant Treatment

The use of any diets or drugs other than Alpha-PSP is prohibited during 3 months (92 days).



VII. RESULTS

VIIa. At the beginning

7.1 Job- Age- Sex

Count

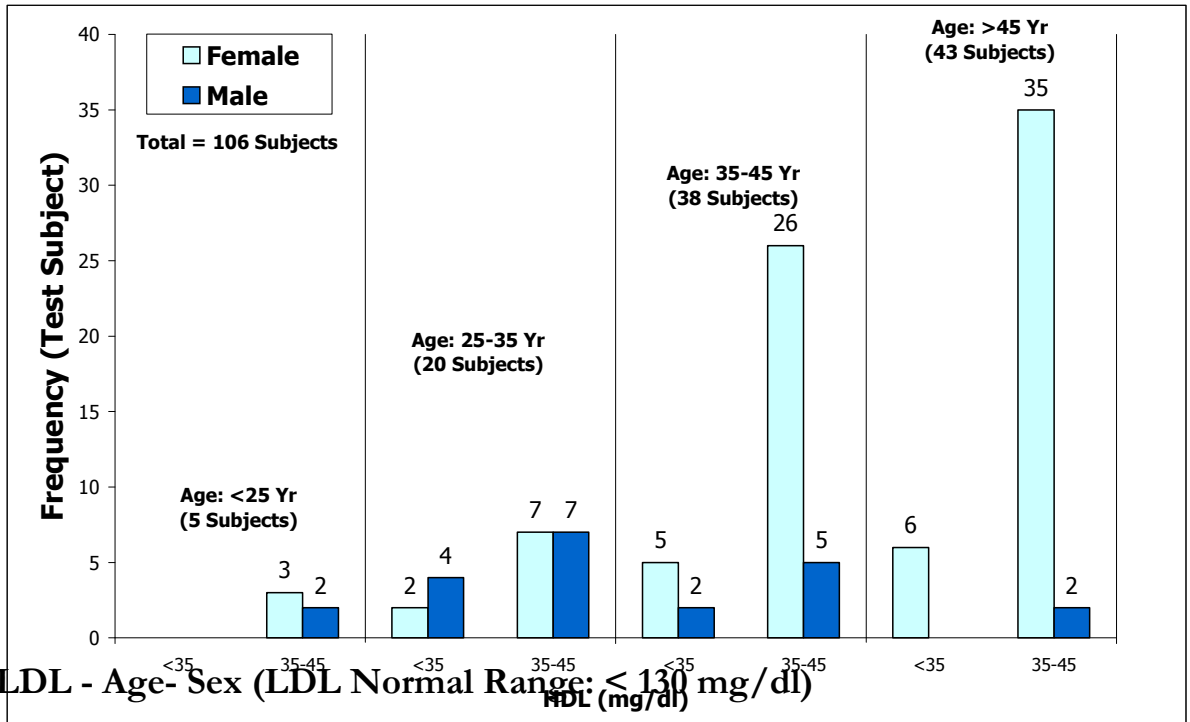
Job	Age	Sex		Total
		F	M	
Medical Executives (Doctors, Administrators, etc.)	25-35		5	5
	35-45	3	1	4
	>45	5	2	7
	Total	8	8	16
Nurse, technician	<25	3	2	5
	25-35	4	4	8
	35-45	13	3	16
	>45	26		26
	Total	46	9	55
Nurse helper and other staff	25-35	5	2	7
	35-45	15	3	18
	>45	10		10
	Total	30	5	35
Grand Total		84	22	106

7.2 Total Cholesterol - Age - Sex

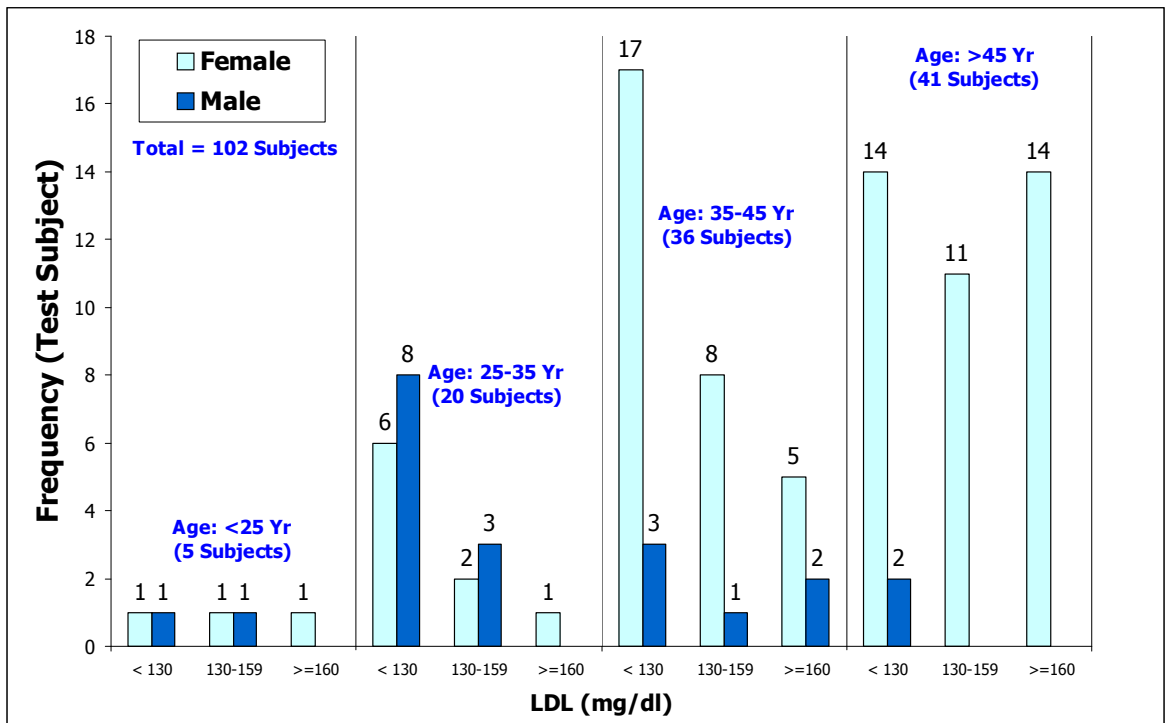
Count

Age	Total Cholesterol	Sex		Total
		F	M	
< 25	100-199	1	1	2
	200-239	1	1	2
	≥ 240	1		1
	Total	3	2	5
25-35	100-199	6	3	9
	200-239	2	8	10
	≥ 240	1		1
	Total	9	11	20
35-45	100-199	16	3	19
	200-239	12	2	14
	≥ 240	3	2	5
	Total	31	7	38
> 45	100-199	9	1	10
	200-239	19	1	20
	≥ 240	13		13
	Total	41	2	43
Grand Total		84	22	106

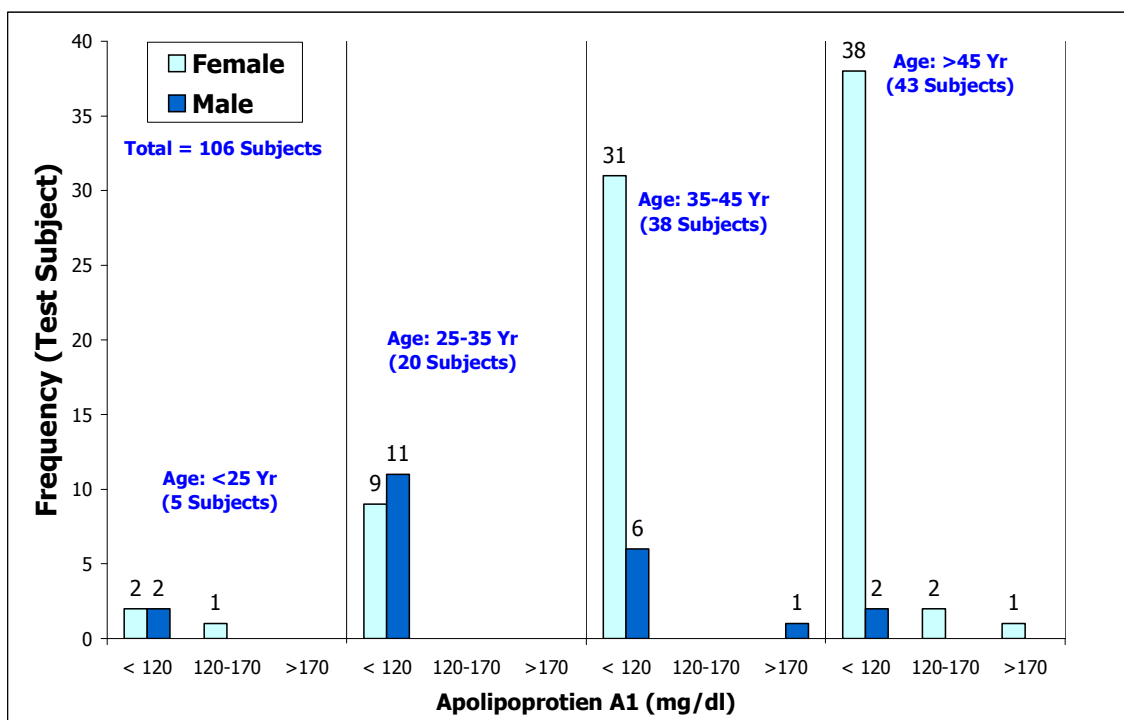
7.3 HDL - Age - Sex (HDL Normal Range: > 45 mg/dl)



7.4 LDL - Age- Sex (LDL Normal Range: ≤ 130 mg/dl)



7.5 Apolipoprotein A1 - Age- Sex (Apolipoprotein A1 Normal Range: 120 - 170 mg/dl)



VIIb. After 3 months

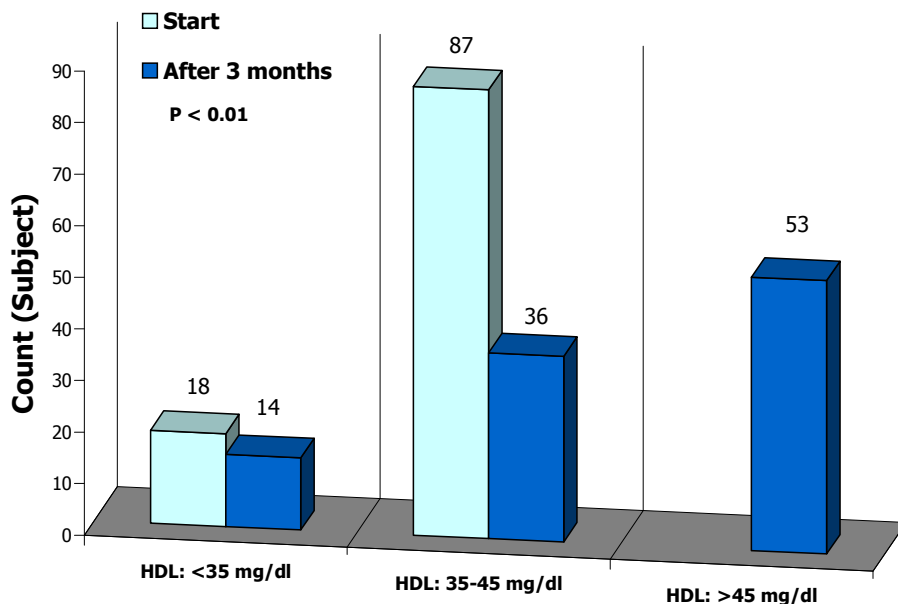
7.6 Total Cholesterol

Paired Samples Test

	Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
				Lower	Upper			
Start-After*	9.434E-02	.8226	7.990E-02	-6.4090E-02	.2528	1.181	105	.240

* After 3 months of drinking Alpha-PSP

7.7 HDL-C (HDL-C Normal Range: > 45 mg/dl)

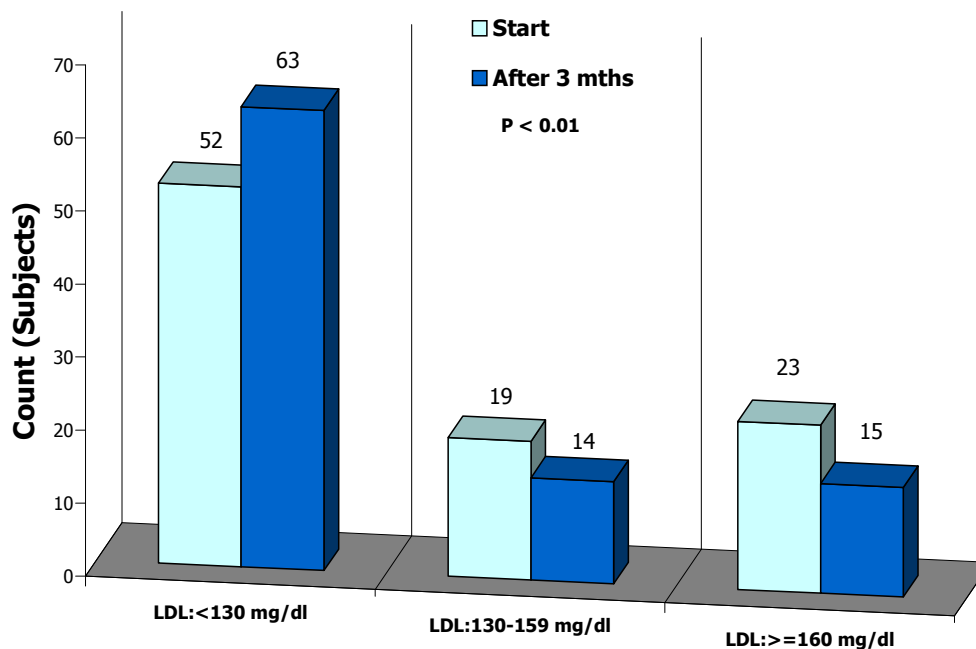


		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HDL	39.14	105	4.13	.40
	HDL*	46.86		10.87	1.06

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 1	HDL - HDL*	-7.71	11.10	1.08	-9.86	-5.57	-7.124	104	.000

* After 3 months of drinking Alpha-PSP

7.8 LDL-C (LDL-C Normal Range: < 130 mg/dl)

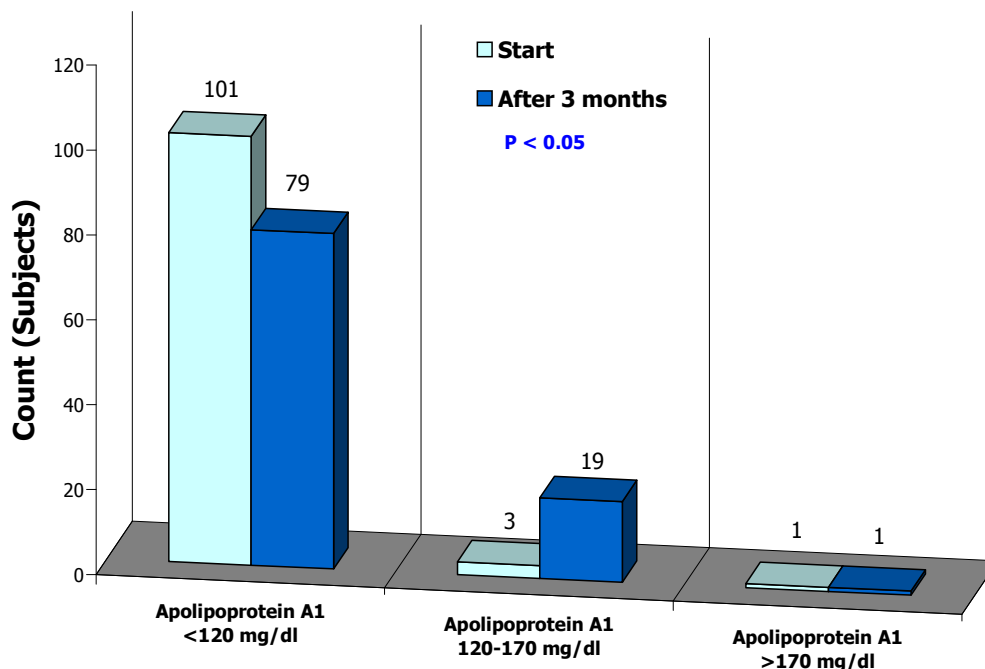


		Mean	N	Std. Deviation	Std. Error Mean
Pair 3	LDL	133.45	95	37.13	3.81
	LDL*	123.17		33.85	3.47

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 3	LDL - LDL*	10.28	36.89	3.79	2.77	17.80	2.717	94	.008

* After 3 months of drinking Alpha-PSP

7.9 Apolipoprotein A1 (Apolipoprotein A1 Normal Range: 120 - 170 mg/dl)



		Mean	N	Std. Deviation	Std. Error Mean
Pair 2	APOA1	103.15	104	17.60	1.73
	APOA1*	108.37		19.01	1.86

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 1	APOA1 – APOA1*	-5.21	23.31	2.29	-9.74	-.68	-2.280	103	.025

* After 3 months of drinking Alpha-PSP

The efficacy of Alpha-PSP on HDL, LDL, Apolipoprotein A1 at each age

A.) Under 25 years of age

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HDL	42.40	5	2.07	.93
	HDL*	48.00	5	8.34	3.73
Pair 2	APOA1	113.40	5	13.22	5.91
	APOA1*	102.40	5	8.88	3.97
Pair 3	LDL	122.75	4	47.97	23.98
	LDL*	121.00	4	12.41	6.20

Paired Samples Test

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 1	HDL - HDL*	-5.60	6.62	2.96	-13.82	2.62	-1.892	4	.131
Pair 2	APOA1 - APOA1*	11.00	20.20	9.03	-14.08	36.08	1.218	4	.290
Pair 3	LDL - LDL*	1.75	36.67	18.34	-56.61	60.11	.095	3	.930

B.) From 25 to 35 years of age

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HDL	37.90	20	4.94	1.10
	HDL*	43.65	20	9.75	2.18
Pair 2	APOA1	97.90	20	14.56	3.26
	APOA1*	100.90	20	18.44	4.12
Pair 3	LDL	122.94	18	30.97	7.30
	LDL*	107.94	18	26.61	6.27

Paired Samples Test

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 1	HDL - HDL*	-5.75	10.70	2.39	-10.76	-7.74	-2.403	19	.027
Pair 2	APOA1 - APOA1*	-3.00	24.94	5.58	-14.67	8.67	-.538	19	.597
Pair 3	LDL - LDL*	15.00	34.16	8.05	-1.99	31.99	1.863	17	.080

*** After 3 months of drinking Alpha-PSP**

C.) From 35 to 45 years of age

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HDL	39.13	38	4.10	.67
	HDL*	46.11	38	12.15	1.97
Pair 2	APOA1	101.18	38	17.61	2.86
	APOA1*	108.66	38	22.97	3.73
Pair 3	LDL	125.57	35	36.15	6.11
	LDL*	120.71	35	32.81	5.55

Paired Samples Test

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 1	HDL - HDL*	-6.97	12.80	2.08	-11.18	-2.77	-3.358	37	.002
Pair 2	APOA1 - APOA1*	-7.47	24.69	4.01	-15.59	.64	-1.866	37	.070
Pair 3	LDL - LDL*	4.86	39.42	6.66	-8.68	18.40	.729	34	.471

D.) Over 45 years of age

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HDL	39.36	42	3.77	.58
	HDL*	48.93	42	10.28	1.59
Pair 2	APOA1	106.29	41	18.75	2.93
	APOA1*	112.46	41	14.97	2.34
Pair 3	LDL	146.82	38	36.97	6.00
	LDL*	132.87	38	36.99	6.00

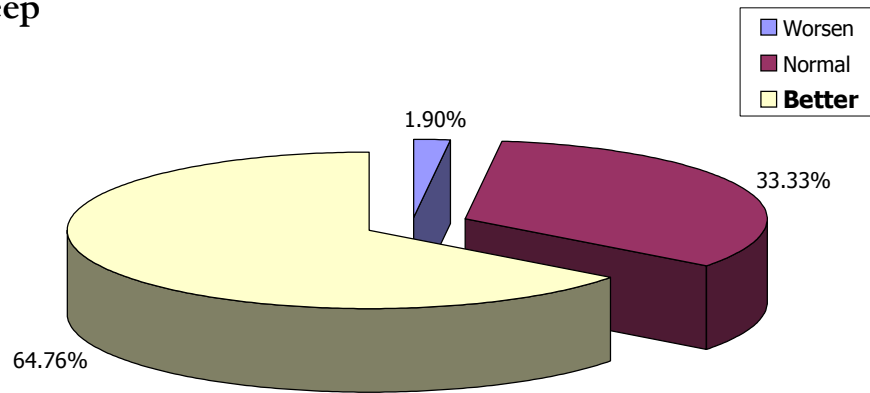
Paired Samples Test

		Paired Differences Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig (2-tailed)
					Lower	Upper			
Pair 1	HDL - HDL*	-9.57	10.03	1.55	-12.70	-6.45	-6.186	41	.000
Pair 2	APOA1 - APOA1*	-6.17	21.38	3.34	-12.92	.58	-1.848	40	.072
Pair 3	LDL - LDL*	13.95	36.39	5.90	1.99	25.91	2.362	37	.024

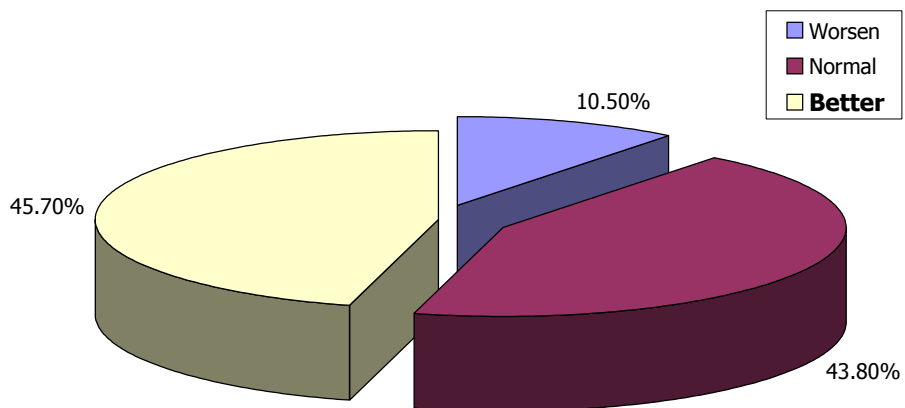
* After 3 months of drinking Alpha-PSP

VIIc. Tolerability of Alpha-PSP

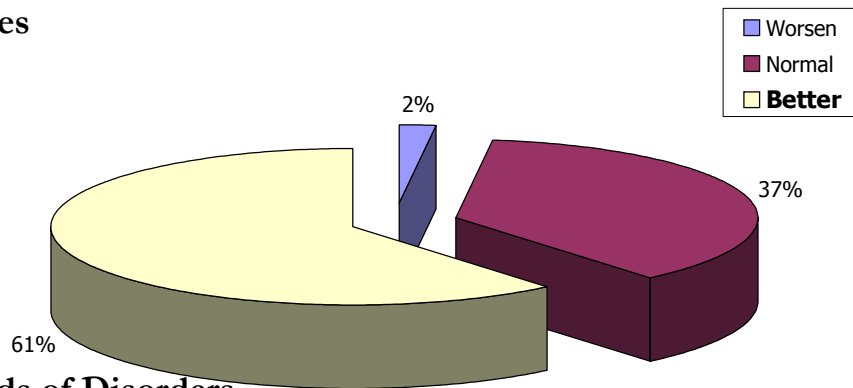
7.10 Sleep



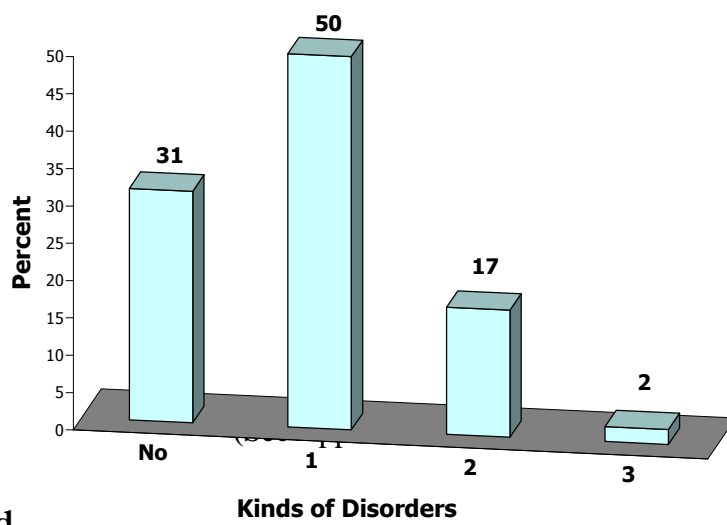
7.11 Appetite



7.12 Feces



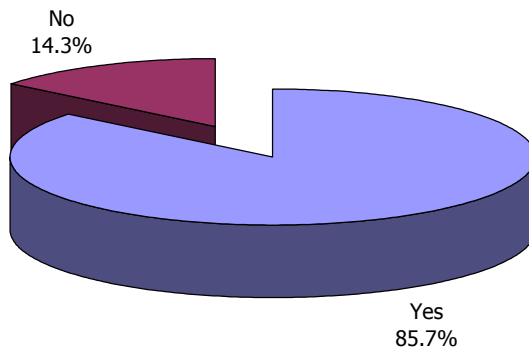
7.13 Kinds of Disorders



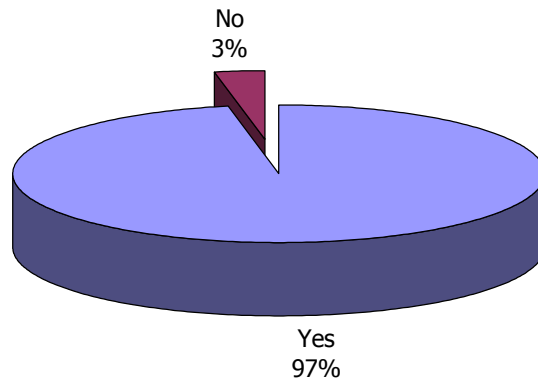
7.14 Improved

	Valid	Percentage
Yes	45	61
No	28	39
Total	73	100

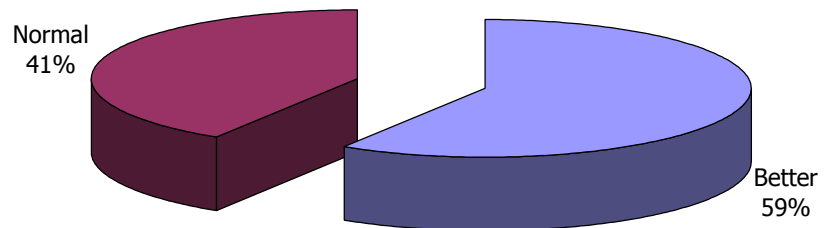
7.15 Continue to drink Alpha-PSP



7.16 Interesting



7.17 Health



VIII DISCUSSION

The purpose of this clinical study is to determine the effect of Alpha-PSP towards cholesterol concentration including Total Cholesterol, LDL-C, HDL-C, and Apolipoprotein A-1 of the Cho Ray Hospital's officials that have index as above that exceeded normal limits. It was an opportunity to establish a treatment group, where we required the test subjects to drink Alpha-PSP everyday without any other changes or influences that may interfere with the results such as customary life style, eating and drinking habits, and (exercise) activities. The intention was to observe and evaluate the above results with the assurance that it was the complete influence of Alpha-PSP.

Before drinking (using) Alpha-PSP, approximately half of the hospital officials, in the age over 35 years, who had high total cholesterol concentration (48.1% for both sexes, in which female was 55% and male 22.7%); LDL-C increased highly 20.6% in total subjects (25% female and 10% male); HDL-C <35 mg/dl in 12.2% of subjects (13% female, 9% male); and HDL-C with 35-45 mg/dl in 77.3% subjects (81% female, 64% male); Apolipoprotein A-1 reduced 75% female (65% in the total) and 7.5% male in which female occupy 82% male – 36%.

After 3 months of drinking regularly 20-gram Alpha-PSP everyday, all of the above parameters changed. Especially significant was the improvement demonstrated in the statistics in the increment of the concentration of HDL-C ($p < 0.01$) and Apolipoprotein A-1 ($p < 0.05$) and decrease in the concentration of LDL-C ($p < 0.01$).

All the results gathered demonstrated the expected aim, which was to increase the concentration of HDL-C and Apolipoprotein A-1, while decreasing LDL-C.

High levels of serum cholesterol LDL-Cholesterol (LDL-C) and low levels of HDL-Cholesterol (HDL-C) and Lipoprotein A-1 are important independent risk factors for coronary heart disease (CHD).

The current study was designed to investigate the serum cholesterol, lowering LDL-C and elevating HDL-C and Apolipoprotein A-1 through the effects of an innovative food powder supplement. This powder supplement is manufactured by Macro Food Tech – Thailand** and its associates and carries a generic name of “Alpha-PSP”. Subjects (n-106) were taken from a random blinded pool of patients currently at risk for CHD. Patients were monitored for total cholesterol (TC), low-density lipoprotein (LDL-C), high-density lipoprotein (HDL-C) and Apolipoprotein A-1 (Apo A-1).

Fasting blood samples were obtained at the beginning of the study and then after three months. The results indicate that the highest significant elevation in serum HDL-C and serum Apo A-1 were achieved after 90 days of using the powdered supplement. LDL-C also decreased significantly. This variability is consistent with blood sampling and without diet restriction or exercise monitoring.

IX. CONCLUSION

The use of this “Alpha-PSP” natural food supplement powder, as part of an overall diet, proved to be highly successful in lowering the overall risk factors associated with Coronary Heart Disease (CHD) through a significant increase in HDL-C, Apo A-1, while concurrently obtaining reduction in LDL-C.

**Macro Food Tech – Thailand, in 2003, was recognized by Thailand’s Department of Science and Technology as one of the top innovative companies in Thailand advancing in Science and Technology. Alpha-PSP supplied by Macro Food Tech – Thailand is being researched and studied (in-vitro) by the Royal Thai Army Hospital and Medical Center. Alpha-PSP from Macro Food Tech – Thailand is also approved for display in the Thai Government Pharmaceutical Organization’s product showcase in Bangkok, Thailand.

APPENDIX A

Standardized Conditions for Body Weight and Height Measurements; % Body Fat, and Waist and Hip Circumferences.

1. Body weight, Height, % Body Fat:

Body weight, height and % body fat are measured at the first visit.

Weight:

Weighing scale must be set on a hard, level and even surface. Scale is accurate, sensitive and robust. Weighing is measured to the nearest 0.1kg.

Height:

Subjects should stand straight, arms hanging loosely to the side, feet together and with heels, buttocks and shoulder blades in contact with the vertical surface of the stadiometer. Height is measured to the nearest 0.1cm.

Body Mass Index:

Body mass index relates weight (kg) with height (m) by a simple calculation to indicate body composition ($BMI = \text{weight}/\text{height}^2$). BMI classifies adults as underweight, normal, overweight or obese.

Western Reference

Body Mass Index (BMI)	Nutritional status
>30	Obese
25-29.9	Overweight
18.5 –24.9	Normal
<18.5	Underweight

Asian Reference

Body Mass Index (BMI)	Nutritional status
>30	Obese
22.9-29.9	Overweight
18.5 –22.9	Normal
<18.5	Underweight

Total body fat:

Total body fat is estimated as a percentage of body fat. Percentage of body fat is calculated by the Tanita Body Fat Scales.

<http://www.tanita.com/world-index.html>

	Normal		Obesity
	<30 age	>30 age	
Male	14-20%	17-23%	≥25%
Female	17-24%	20-27%	≥30%

Record weight, height and % body fat of staff in normal clothing, after removal of shoes, socks and jacket or coat or blouse (Weight: Kg; Height: m)

2. Waist and Hip circumferences

Waist and Hip circumferences are measured at the first visit.

Waist and hip circumferences are measured to the nearest 0.1 cm using a flexible narrow non-stretch tape in adults wearing minimal clothing, standing straight but not pulling in their stomachs. Waist circumference is measured halfway between the lower ribs and the iliac crest, while hip circumference is measured at the largest circumference around the buttocks. Measurement error occurs if the tape is pulled too tight or loose, or is not parallel to the floor or if subjects wear clothes with belts and/or full pockets.

Waist to hip ratio.

The waist to hip ratio (WHR) in adults discriminates between those with upper body or intra-abdominal obesity (WHR ≥ 0.95 in men and ≥ 0.85 in women) and those with lower body or peripheral obesity.

APPENDIX B

(Standardized parameters for laboratory tests including fasting lipid profile)

	Lipid profile	
Total Cholesterol	Normal	100 – 199 mg/dl
	Increase	200 – 239 mg/ dl
		≥ 240 mg/dl
HDL-Cholesterol	Normal	> 45 mg/dl
	Decrease	35 – 45 mg/dl
		< 35 mg/dl
Apolipoprotein A1	Normal	120 – 170 mg/dl
	Decrease	< 120 mg/dl
	Increase	> 170 mg/dl
LDL-Cholesterol	Normal	< 130 mg/dl
	Increase	130 – 159 mg/dl
		≥ 160 mg/dl

APPENDIX C

(Study Flow Chart)

DEMOGRAPHY

Department:

Full name:

Year of birth:

Gender: Male Female

Position of Job:.....

VITAL SIGNS

	Visit 1
	Date /..... /2001
Height (m)	
Weight (kg)	
Body Mass Index (BMI-kg/m ²)	
% Body Fat	
Waist circumference (cm)	
Hip circumference (cm)	
Ratio W/H	

LABORATORY TEST

	Visit 1 Date /..... /2001	Visit 2 Date /..... /2001
Total Cholesterol (mg/dl)		
HDL-Cholesterol (mg/dl)		
Apolipoprotein A1 (mg/dl)		
LDL-Cholesterol (mg/dl)		

Investigator's Signature.....

APPENDIX D

Questionnaire for subjective evaluation on the tolerability of Alpha-PSP

Department:.....

Full name:.....

1. Would you like to tell us during the time of drinking Alpha-PSP, how you have been?

	Better	Normal	Worse
- Sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Appetite	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Feces	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Health in general	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Please tell us, have you had the following disorders before you drank the Alpha-PSP?

- a. Ostealgia or ostoedynia
- b. Headache, dizziness
- c. Fingertip numbness
- d. The others (please specify)

2.1 Have they been improved during the time of drinking Alpha PSP?

Yes No

3. Would you like to continue to use the Alpha-PSP after you have taken part in the study as volunteer?

Yes No

4. Would you like to participate in other research like this study?

Yes No

Why?

APPENDIX E



Cho Ray hospital staff taking Alpha-PSP food supplement

Preparation Instructions: Mix 20 g. Alpha-PSP powder with 250 cc of hot water, stir well and sip or use spoon while the content is still warm.