### CHANGES IN WEIGHT AND BODY FAT DISTRIBUTION WITH THE STEP I DIET

A THESIS

### SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

## FOR THE DEGREE OF MASTER OF SCIENCE

### IN THE GRADUATE SCHOOL OF THE

### TEXAS WOMAN'S UNIVERSITY

## COLLEGE OF HEALTH SCIENCES

BY

PAM CHIN-LAI, B.S., R.D., L.D.

DENTON, TEXAS

MAY 1996

#### ABSTRACT

### CHANGES IN WEIGHT AND BODY FAT DISTRIBUTION WITH THE STEP I DIET

### PAM CHIN-LAI MAY 1996

Seventy four moderately hypercholesterolemic men who were part of a larger cholesterol-lowering, double blind, placebo-controlled drug trial, received intensive group and individual nutritional counseling on the use of the National Cholesterol Education Program (NCEP) Step I diet over the course of 48 weeks. Weight was measured at each visit, dietary compliance was assessed at Week 8 and waist, abdominal, and hip circumferences were measured at Week 10. Assessment of dietary compliance and circumference measurements were repeated at Week 48. The results revealed that 53% of subjects decreased their weight by 2.87 +/- 0.4 kg and 43% of subjects increased their weight by 2.57 + -0.3 kg over the 48 week period. Subjects who lost weight had significantly greater decreases in abdominal, waist, abdominal-to-hip ratio, and waist-tohip ratio compared to subjects who gained weight. Caloric intake and diet composition did not differ significantly between subjects who lost weight and those who gained. Diet composition, particularly percentage of energy from total fat, was associated with higher body weight, BMI, waist, abdominal, and hip circumferences. Percentage of energy from was not related to abdominal-to-hip ratio or waist-to-hip ratio.

## TABLE OF CONTENTS

ABSTR	ACT								iii
LIST O	F TABLES .								vi
LIST O	FFIGURES .								vii
CHAPT	ER								
I.	INTRODUCTION								1
II.	REVIEW OF LITER	RATURE			•				3
	Obesity and th	e Risk of C	Coronary	Disease	÷.				3
	Weight Loss a	nd the Sten	I Diet	IL LOSS	•	•	•	•	8
	Weight Loss a	nd Body Fa	t Distrib	oution					10
	Weight Chang	e and Diet	Compos	ition					11
III.	METHODOLOGY								13
IV.	RESULTS .								22
	Changes in We Relationship E Relationship E Relationship E	eight, WHF Between Nu Between Die	R, and Al atrient In etary Inter reentage	HR . take and ake Con	I Weigh nponent	t Chang s	ge .		22 26 26
	Body Weight,	Body Mass	, and Bo	dy Fat I	Distribut	tion			30
V.	DISCUSSION			•					31
	Conclusions Implications for	 or Further S	Study			•	•		35 35
REFERI	ENCES .								36

APPENDICES		. 40
A. Institutional Approvals		. 41
B. Subject Data		. 45
Mean Weight Change and Standard Deviation in Subjects who Lost Weight Over the 48 Week Experimental Period		. 46
Experimental Period		. 47
Data		. 48

.

## LIST OF TABLES

1.	Initial Characteristics of the 74 Male Study Subjects .	14, 15
2.	Outline of Classes	. 17
3.	Dietary Recommendations of the Adult Treatment Panel of the National Blood Cholesterol Education Program (Step I diet subjects with high blood cholesterol)	. 18
4.	Mean ( $\pm$ Standard Deviation) Physical Characteristics of Nonobese and Obese Subjects at Week 8 and Week 48	. 25
5.	Dietary Intake of Nonobese and ObeseSubjects at Week 8 and Week 48	. 29
6.	Mean Weight Change and Standard Deviation in Subjects Who Lost Weight Over the 48 Week Experimental Period (N = 39)	. 46
7.	Mean Weight Change and Standard Deviation in Subjects Who Gained Weight Over the 48 Week Experimental Period ( $N = 32$ )	. 47

## LIST OF FIGURES

1.	Mean Weight Change in Subjects Who Lost Weight Over the 48 Week Experimental Period $(N = 39)$			23
2.	Mean Weight Change in Subjects Who Gained Weight Over the 48 Week Experimental Period $(N = 32)$			24
3.	Distribution of Souces of Energy in Nonobese Subjects at Week 48 (BMI < 27.8)			27
4.	Distribution of Sources of Energy in Obese Subjects at Week 48 (BMI $\ge$ 27.8)			28

.

#### CHAPTER I

#### **INTRODUCTION**

Obesity is a major risk factor in cardiovascular development and mortality. Abnormal blood lipid concentrations, particularly an elevated ratio of low density lipoprotein cholesterol to high density lipoprotein cholesterol, resulting in increased atherogenic risk are associated with obesity. Additionally, obesity enhances other risk factors such as hypertension, hypertriglyceridemia, diabetes mellitus, and hyperinsulinemia which cause coronary heart morbidity (Pi-Sunyer, 1993a).

Measuring obesity by body weight or body mass index permits only one perspective of the incidence of disease. Prospective studies have shown that the distribution of body fat, particularly abdominal obesity characterized by a greater proportion of adipose tissue distributed on the trunk rather than on the extremities, is also a significant determinant of cardiovascular disease risk (Larrson, Svardsudd, Welin, Wilhelmsen, Bjorntorp, & Tibblin, 1984). Abdominal obesity is associated with adverse concentrations of lipids and lipoproteins, as well as hypertension, and diabetes mellitus (Haffner, Stern, Hazuda, Pugh, & Patterson, 1987). It is also more strongly associated with ischemic heart disease, stroke and death, independent of body mass index (Larrson, 1988; Bjorntorp, 1984).

Weight reduction improves cardiovascular risk. Even modest weight losses of five percent to ten percent of initial weight improves high density lipoprotein cholesterol concentration, hypertension, and glycemic control (Goldstein, 1992; Pi-Sunyer, 1993b). In men weight loss is accompanied by a reduction in waist and hip circumferences and a reduction in waist-to hip ratio (Pascale, Wing, Blair, Harvey, & Guare, 1992; Wing, Jeffery, Burton, Torson, Kuller, & Folsom, 1992).

Treatment of hypercholesteremia as recommended by the National Cholesterol Education Program (NCEP) Expert Panel begins with dietary therapy. The NCEP Expert Panel recommends progressively reducing the intake of total fat, saturated fatty acids, and cholesterol. Weight reduction in overweight patients is emphasized since weight reduction reduces cardiovascular risk ("Summary of the Second Report," 1993).

Despite the evidence supporting weight reduction, data regarding the efficacy of the Step I diet with regard to long-term weight loss is unclear. Additionally there have been limited investigations regarding the relationship between the Step I diet and change in waist-to-hip ratio.

The objectives of this study were as follows:

1) to determine if a one year nutrition intervention program designed to lower serum cholesterol would result in a modest weight loss and reduction in body fat distribution as measured by waist-to-hip ratio, and

2) to investigate the relationship between fat intake, body weight, and abdominal adiposity.

#### CHAPTER II

#### **REVIEW OF LITERATURE**

#### Obesity and the Risk of Coronary Heart Disease

The National Institutes of Health consensus panel reported that an increase of 20% or more above desirable body weight or a body mass index of 27.8 and 27.3 for men and women, respectively, constitutes an established health hazard and is associated with major diseases and health problems (National Institutes of Health, 1985). One of the primary dangers is the strong association between obesity and cardiovascular risk factors. Data from the San Antonio Heart Study showed that normotensive, nondiabetic obese patients have a higher average blood pressure than lean subjects, irrespective of sex and age. A BMI of 25 or greater resulted in a linear increase in both systolic and diastolic blood pressure (Ferrannini, 1995). Additionally, obese middle-aged adults were twice as likely to have hypercholesterolemia and a lower high density lipoprotein than the nonobese. Obesity and diabetes mellitus have been strongly associated. The mildly obese have a two-fold risk for developing diabetes, the moderately obese have a five-fold risk, and the severely obese have a ten-fold risk (Pi-Sunyer, 1993a).

Prospective studies have shown that abdominal obesity, as assessed by waist-to-hip ratio or by truncal skinfold measurement, is a better predictor of coronary heart disease than total body obesity. Vague (1956) was the first to observe that android

obesity was more strongly related to atherosclerosis than gynoid obesity. Android obesity is characterized by an accumulation of excess fat in the upper portion of the body, typically seen in men, but also observed in some women. Gynoid obesity has the excess adipose tissue accumulated mainly in the gluteal-femoral regions, typical of the fat distribution in normal weight women and occasionally seen in some obese men. Vague found that in addition to atherosclerosis a number of obesity complications including hypertension, diabetes, gout, renal and biliary calculus, were found in subjects with android obesity, but not in those with gynoid obesity.

Several long-term studies have confirmed Vague's findings. The Honolulu Heart Study (Donahue, Abbott, Bloom, Reed, & Yano, 1987) examined men over a 12 year period and found that central obesity as determined by subscapular skinfold thickness was a significant predictor of coronary heart disease. This finding was significant at all levels of body mass index and after adjusting for age, total cholesterol, glucose, triglycerides, hypertensive status, and cigarette smoking.

The Study of Men Born in 1913 (Larrson, 1988) further substantiated the relevance of abdominal body fat predominance. In this study central adiposity, as assessed by waist-to-hip ratio, was found to be more strongly associated with ischemic heart disease, stroke, and premature death than total body obesity. The men with the lowest risk were those who were more severely obese but had their excess fat evenly distributed over their body, while the men with the highest risk had a lower relative weight but had more of their fat located in the abdominal region.

Central adiposity was also an independent risk factor for coronary heart disease in participants of the Framingham study. Of the indices used to measure obesity subscapular skinfold thickness was most predictive of the incidence of coronary heart disease over a 22 year period. In men, both subscapular skinfold thickness and serum total cholesterol contributed to the risk of coronary heart disease more than any other risk factor (Van Itallie, 1992).

The Paris Prospective Study (Larrson, 1988) provided similar results in a study examining 6718 men. After six years of followup, fat distribution as assessed by skinfold measurements significantly predicted coronary heart disease. This relationship remained significant after controlling for obesity. The risk of coronary heart disease was 2.4 times higher in subjects in the highest quintile of trunk fat index than subjects in the lowest quintile.

The Health Professionals Follow-up Study (Rimm et al., 1995), a three year prospective study of 29,122 American men, suggested that the indices of measuring obesity are age-related when studying the effects of obesity on coronary heart disease risk. The results suggested that among men younger than 65 years of age, obesity, independent of fat distribution, was a strong risk factor for coronary heart disease. Among men 65 years and older waist-to-hip ratio was found to be a strong predictor of coronary disease.

The results of these studies strongly support central fat distribution as a risk factor for coronary heart disease in men. The strength of the risk factor is almost as powerful

as the other major fisk factors for coronary heart disease, such as serum cholesterol, blood pressure, and smoking. The importance of central fat distribution as a predictor of coronary heart disease may increase with age (Rimm et al., 1995), however, age does not affect the relationship between abdominal obesity and stroke (Larrson, 1988; Pi-Sunyer, 1993a). Additionally, central fat distribution enhances other risk factors which cause coronary heart disease. A high waist-to-hip ratio is associated with increased concentrations of free fatty acids which may lead to hypertriglycerol and other lipid abnormalities. Central obesity is also a strong predictor of increased peripheral insulin resistance, hyperinsulinemia, and glucose intolerance. Data from the Epidemiology of Diabetes Complications Study suggests that a high waist-to-hip ratio promotes the development of diabetes complications, particularly neuropathy and peripheral vascular disease (Stuhldreher et al., 1995). Waist-to-hip ratio has also been shown to predict diastolic blood pressure in normotensive and hypertensive subjects. This relationship remained significant after adjusting for BMI (Licata et al., 1994).

#### Cardiovascular Benefits of Weight Loss

Weight loss decreases cardiovascular risk by improving glycemic control, hypertension, and hyperlipidemia. In patients with noninsulin dependent diabetes mellitus, weight reduction improves insulin sensitivity, insulin secretion by the islet cells, and blood glucose. The decrease in serum glucose occurs within days after starting a weight loss program. Oral medication and insulin can often be greatly reduced or

discontinued with weight loss. Life expectancy is prolonged; a ten kilogram weight loss eliminates the 35 percent reduction in life expectancy that patients with noninsulin dependent diabetes mellitus experience as a result of diagnosis (Goldstein, 1992, Pi-Sunyer, 1993b).

Hypertension symptoms are improved with weight loss in overweight persons. The Framingham study (Pi-Sunyer, 1993b) showed that a 15 percent decrease in weight was associated with a ten percent decrease in systolic blood pressure among men. Other studies have found similar results regardless of sodium intake. Blood pressure symptoms improve even if "ideal weight" is not achieved. In one study an average 10.5 kg weight loss resulted in a 20 mm Hg decrease of both systolic and diastolic pressure even though normal weight was not attained. Another study reported a one mm HG decrease in systolic and diastolic blood pressure per kilogram of weight loss among a group of obese women. Because of the compelling data, the Third Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure now recommends weight reduction as an important goal for obese, hypertensive patients (Pi-Sunyer, 1993b).

Weight reduction also enhances reductions in total serum cholesterol concentrations. The Zutphen Study (Kromhout, 1983) examined the relationship between body weight and serum cholesterol for ten years and found that body weight was the most important determinant of serum cholesterol. Each one kilogram change in body weight was associated with a two mg/dl change in serum cholesterol (Kromhout, 1983). Results from the National Diet-Heart Feasibility Study further confirmed the relationship

between weight loss and a decrease in serum cholesterol. Men with the largest decreases in weight experienced the largest decreases in serum cholesterol. Among subjects in the Multiple Risk Factor Intervention Trial (Caggiula et al., 1981), the men who maintained a five pound weight loss for four years lowered serum cholesterol by almost double to those who did not lose weight.

#### Weight Loss and the Step I Diet

Dietary therapy through the Step I and Step II diets is the first line of treatment for hypercholesterolemia. Weight reduction in overweight patients is a central component of dietary therapy. Despite this strong emphasis there are limited investigations concerning the efficacy of the Step I and II diets with respect to weight loss and only one study, to date, lasted for one year. In a worksite nutritional intervention program, Hartman, Stern, Hazuda, Pugh, & Patterson (1995) demonstrated a mean 0.43 kg weight loss in 119 participants over an eight week period. Intake of dietary fat decreased significantly compared to the control group; however, total energy intake was not measured. Chima, Miller-Kovach, Zeller, Cook, & Schupp (1990) counseled 291 patients in an outpatient lipid management clinic over a three month period. They found that patients who returned for two follow up appointments lost almost twice as much weight as patients who returned for one follow up visit. Mean intake of energy, energy from fat, and energy from saturated fat decreased significantly following the initial visit, but these changes were maintained at the second follow up visit. In another three month study participants

experienced a mean 1.36 kg weight loss following Step I education and counseling. Total energy and percentage of energy from fat and saturated fat decreased significantly from the first month to the third (Shenberger, et a1., 1992).

A longer study demonstrated a mean weight loss of 3.75 kg over a 12 week period. However, after six months with no nutritional intervention, subjects had regained 2.02 kg. Analysis of dietary records revealed that the major deviation from the Step I diet occurred in saturated fatty acids, which increased from 10% of energy during the first three months to greater than 14% of energy at the six month follow up. The authors concluded that continuous support and supervision is necessary for long term compliance (Henkin, Garber, Osterlund, & Darnell, 1992). In a one year study designed to evaluate the efficacy of a worksite nutrition education program, Baer (1993) found a mean five kg weight loss in a small group of management-level male employees compared to controls. Participants were not specifically counseled on losing weight, however, mean intake of energy decreased significantly and aerobic activity increased. Significant decreases in percentage of energy from fat and protein and increases in percentage of energy from carbohydrate and fiber were noted. Finally, a study involving obese middle-aged and older men demonstrated a 9.8 kg weight loss following a three month Step I weight maintenance and nine month Step I weight loss program. Total energy intake did not change from baseline; however, there were significant decreases in percentage of energy from fat, saturated fat, and polyunsaturated fat (Dengel, Katzel, & Goldberg, 1995).

#### Weight Loss and Body Fat Distribution

Body fat distribution is determined by both genetics and environmental factors. Smoking, inactivity, and stress have been associated with upper body fat. Additionally, upper body fat is strongly associated with body weight. To date, there have been few studies investigating the relationship of weight loss in men and change of WHR. Pascale et al., (1992) in a one year weight reduction program for obese men and women with type II diabetes reported men significantly decreased WHR with weight loss. The men with the most adverse body fat distributions experienced the largest decreases in WHR. These changes in fat distribution were independent of caloric intake and activity. A study investigating the relationship between change in WHR with weight loss was significantly correlated with decreases in waist and hip circumferences and WHR Change in WHR did not, however, independently predict changes in cardiovascular risk factors (Wing, et al., 1992).

Another study investigating the relationship between the Step I diet and changes in body fat distribution found that subjects who experienced a 12% weight loss significantly decreased waist and hip circumferences and WHR. Subjects in the weight maintenance group had no changes in weight, circumferences, or WHR (Dengel et al., 1995).

#### Weight Change and Diet Composition

In order to adhere to the Step I guidelines most Americans will need to decrease their intake of total fat by one fifth (National Institute of Health, 1989). According to some researchers this reduction in dietary fat alone, would facilitate a reduction in body adiposity, irrespective of energy intake. This implies that the composition of calories is more important in determining body adiposity than the amount of calories. One explanation for this is that dietary fat is stored more efficiently than dietary carbohydrate (Romieu et al., 1988; Dreon et al., 1988). Dietary fat can be stored at a metabolic cost of three percent of ingested calories, whereas, storing dietary carbohydrates as fat requires 23% of ingested calories (Romieu et al., 1988). Thus, a higher fat diet would require less energy for weight maintenance than a lower fat diet. Additionally, excessive intakes of protein and carbohydrate results in increased oxidation, while fat balance is poorly regulated. There is no short-term metabolic response stimulating fat oxidation following a large change in lipid intake, thus dietary fat is more likely to be stored as adipose tissue (Schutz, 1995).

Several studies have supported these hypothesises. The Multiple Risk Factor Intervention Trial (Caggiula et al., 1981) found that the men with the largest decreases in intake of saturated fat, cholesterol, and polyunsaturated fat lost the most weight. The pattern of weight change parallelled the change of total fat intake. Similarly, the Women's Health Trial (Gorbach et al., 1990) reported a mean 3.1 kg weight loss as the subject's intake of fat reduced from 39% of calories to 22% in one year. The percentage of calories from fat was also a consistent predictor of adiposity as measured by hydrostatic weighing and body mass index in several cross-sectional investigations (Romieu et al., 1988; Dreon et al., 1988; Miller, Linderman, Wallace, & Niederpruem, 1990). In all of the studies the relationship between dietary fat and obesity remained significant irrespective of total energy intake.

In contrast, other studies have demonstrated a negative relationship between dietary fat and adiposity. Manocha and Gupta (1985) examined obese and nonobese men and women and found no significant association between energy intake, protein, fat, or carbohydrate and BMI, even after controlling for height, age, activity, and socioeconomic status. The mean percentage of energy from fat was 30%, irrespective of adiposity or sex. Similarly, Mela and Sacchetti (1991) studied thirty average weight subjects and found no association between fat intake and adiposity as measured by bioelectric impedance. Lastly, in a metabolic ward study Leibel, Hirsch, Appel, & Checani (1992) found that varying the percentage of calories from fat from 0% to 70% did not influence the amount of energy required to maintain body weight.

There has been limited, but consistent, data by regarding the relationship between the intake of dietary fat and body fat distribution. Investigations by Laws, Terry, & Conner., (1990), Slattery et al., (1992), and George et al. (1990) found no association between dietary fat intake and waist-to-hip ratio. Body fat distribution was, however, inversely correlated with percentage of energy from carbohydrate and positively correlated with alcohol consumption.

#### CHAPTER III

#### METHODOLOGY

This study is part of the Texas Coronary Atherosclerosis Prevention Trial (TexCAPS), a randomized, double blinded, placebo-controlled trial of the effect of lovastatin on the incidence of primary coronary heart disease.

#### Subjects

Seventy four participants were randomly selected to participate in the nutrition intervention. Subjects consisted of men who were between the ages of 45 and 73 years (Table 1). All subjects were free of clinically evident coronary disease and had body weights which were less than 50% over ideal "weight for height" based on the 1983 Metropolitan Life Insurance tables. Inclusion criteria included the following fasting serum lipid levels: total cholesterol 180-240 mg/dl, LDL-cholesterol 130-190 mg/dl, HDL-cholesterol equal or less than 45 mg/dl, and triglycerides equal or less than 400 mg/dl. The serum lipid entry criteria was based on fasting values following a minimum of eight weeks on the Step I diet. All subjects voluntarily signed an informed consent statement approved by the Food and Drug Administration and the University of North Texas Health Science Center Institutional Review Board.

	ENTIRE GROUP	NONOBESE	OBESE
AGE	No. (%)	No. (%)	No. (%)
45-49	15 (20.2)	6 (14.6)	9 (27.2)
50-54	16 (21.6)	10 (24.3)	6 (18)
55-59	12 (16.2)	4 (9.7)	8 (24.2)
60-64	15 (20.2)	10 (24.3)	5 (15.1)
65-69	10 (13.5)	6 (14.6)	4 (12.1)
70-73	6 (8.1)	5 (12)	1 (3)
MARITAL STATUS			
single	3 (4.05)	2 (4.8)	1 (3)
married	67 (90.54)	38 (92.6)	29 (87.8)
divorced	2 (2.7)	1 (2.4)	1 (3)
widowed	2 (2.7)	-	2 (6)
EDUCATION			
high school	9 (12.16)	6 (14.6)	3 (9.1)
college undergraduate	20 (27.03)	9 (21.9)	10 (30.3)
college graduate	45 (60.81)	26 (63.4)	20 (60.6)
ETHNICITY			
white	68 (91.89)	37 (90.2)	31 (93.9)
black	4 (5.4)	2 (4.8)	2 (6)
hispanic	1 (1.35)	1 (2.4)	-
other	1 (1.35)	1 (2.4)	

.

 Table 1. Initial characteristics of the 74 male study subjects.

.

	ENTIRE GROUP	NONOBESE	OBESE
HEIGHT (inches) mean <u>+</u> standard deviation	69 <u>+</u> 3	71 <u>+</u> 3	70 <u>+</u> 2
WEIGHT(pounds) mean <u>+</u> standard deviation	190 <u>+</u> 25	177 <u>+</u> 16	208 <u>+</u> 23

••

Table 1. (continued) Initial characteristics of the 74 male study subjects.

.

#### **Experimental Design**

Subjects attended seven group nutrition classes (Table 2) over the course of 48 weeks. Weight was measured at each visit, dietary compliance was assessed at Week 8 and waist, abdominal, and hip circumferences were measured at Week 10. Assessment of dietary compliance and circumference measurements were repeated at Week 48.

#### **Diet Program**

The goal of the Step I diet is to reduce elevated serum cholesterol by reducing intakes of saturated fatty acids and cholesterol and to promote weight loss in patients who are overweight by eliminating excess total calories and increasing physical activity. The diet involves an intake of saturated fat of 8% to 10% of total calories, 30% of less of calories from total fat, and less than 300 mg of cholesterol per day (Table 3) (Summary of the Second Report," 1993). In keeping with the goal of the Step I diet, the seven group nutrition classes (Table 2) in the intervention program were designed to educate participants about the Step I diet, promote appropriate food choices, and encourage attaining or maintaining desirable body weight. During the first class (Week 1) the rationale for changing dietary behaviors and the basic principles of the Step I diet were explained. Topics such as food groups, number of food servings consumed per day, and serving sizes were introduced. Descriptive slides and American Heart Association literature describing the diet in detail was used to facilitate patient understanding. The second class (Week 8) consisted of a review of the basic principles of the Step I diet and

Table 2. Outline of classes.

Week 1	principles of Step I diet introduction to food groups				
Week 8	detailed review of food groups and serving sizes				
Week 10	counting and measuring added fats choosing lower fat foods				
Week 12	portion, selection, and preparation of meat, fish, and poultry mealtless meals increasing soluble fiber				
Week 24	types of fats role of calcium choosing lower fat dairy products				
Week 36	reading and interpreting food labels				
Week 48	adherence strategies for eating out				

**Table 3.** Dietary recommendations of the Adult Treatment Panel of the NationalCholesterol Education Program (Step I diet for subjects with high blood cholesterol).

NUTRIENT	RECOMMENDED INTAKE
total fat	less than 30% of total calories
saturated fatty acids	8% to 10% of total calories
polyunsaturated fatty acids	less than 10% of total calories
monounsaturated fatty acids	10% to 15% of total calories
carbohydrate	50% to 60% of total calories
protein	10% to 20% of total calories
cholesterol	less than 300 mg/day
total calories	to achieve and maintain desirable weight

included a detailed review of food groups and serving sizes. A slide presentation depicting the abundance of fat in common foods was shown (Lowry, E. Lowfat Lifeline Series). Following the second class, the subjects' 24 hour dietary recall data was analyzed. The third class (Week 10) emphasized modifying the subjects' diet by choosing lower fat foods, counting and measuring added fats, and increasing soluble fiber. A video illustrating how healthy foods can taste good was shown (Hall-Foushee Productions, The HeartCare Program: Good and Healthy). After the third class the participants set goals for changing their dietary behavior based on the results of their 24 hour recall. The fourth class (Week 12) focused on selecting and preparing protein-rich foods. Controlling portion sizes was emphasized. Meatless meals were encouraged and participants were counseled on combining foods in order to create complete protein. The visual aids for this class consisted of a short video which illustrated techniques that could be used for healthy cooking and transparencies which depicted portion control techniques (Hall-Foushee Productions, The HeartCare Program: Tomorrow's Kitchen). Saturated, polyunsaturated, and monounsaturated fatty acids were the topic of the fifth class (Week 24). Participants were counseled about the molecular differences and the physiological effects the fatty acids had on the body. Consuming adequate calcium and choosing lower fat dietary products was also reviewed in this class. Behavior goals were set based on results from a self-assessment food frequency questionnaire. The sixth class (Week 36) focused on reading and interpreting food labels. Patients were taught how to identify higher and lower fat foods and how to incorporate higher fat foods in

moderation. The last class (Week 48) consisted of adherence strategies for eating away from home. Participants learned how to recognize healthier food choices at a variety of restaurants and were encouraged to ask questions about food preparation. They were also taught how to order assertively. A short video was used to reinforce these concepts (Hall-Foushee Productions, The HeartCare Program: How to be a Low-fat Eater in a High-fat World).

Following the Week 8 and Week 48 classes the participants' 24 hour dietary recall data was analyzed using the Minnesota Data System 2.3, which contains values for 102 nutrients and nutrient ratios. The recalls were entered by registered dietitians and diet technicians who had completed an intensive training program. Food models, measuring cups and spoons, and models depicting various dimensions were used to estimate portion size. Those subjects whose 24 hour dietary recall exceeded 36% calories from fat and/or 360 mg. cholesterol, and the recall reflected a typical day, were referred to the dietitian for additional counseling and goal setting.

#### Anthropometric Measurements

Weight and height data were obtained using a Detecto electric scale with vertical measuring rods. Both measurements were recorded with the participants wearing light clothing and shoes. Circumference measurements were taken by the same small group of trained physicians using an inelastic tape. Waist circumference was defined as the smallest circumference of the torso, abdominal circumference was defined as the

maximum circumference of the abdomen, and hip circumference was the widest point across the hips. Circumferences were measured with the subjects wearing hospital gowns. Waist-to-hip ratio was determined by diving the waist circumference by the hip circumference (WHR = waist circumference/hip circumference); abdominal-to-hip ratio was determined by diving the abdominal circumference by the hip circumference (AHR = abdominal circumference/hip circumference). Central obesity was defined as within or above the 85th percentile of WHR values as suggested by the Italian Consensus Conference on Obesity (Crepaldi, et al., 1991). In men, this value was considered greater or equal to 0.92. Body mass index was calculated as a measure of weight relative to height.

#### CHAPTER IV

#### RESULTS

The objectives of this study were 1) to determine if a one year nutrition intervention program designed to lower serum cholesterol would result in a modest weight loss and reduction in body fat distribution as measured by waist-to-hip ratios, and 2) to investigate the relationship between fat intake, body weight, and central adiposity in 74 mildly hypercholesteremic middle-aged men.

#### Changes in Weight, WHR, and AHR

Over the 48 week experimental period 53% (n = 39) of the participants lost weight, whereas 43% (n = 32) gained weight. Weight data was missing for 4% (n = 3) of the subjects. Of the subjects who lost weight there was an average reduction of 2.87 +/- 0.4 kg over the 48 week period, whereas subjects who gained weight increased their weight by a mean of 2.57 +/- 0.3 kg (see Figures 1 & 2). Subjects who lost weight had significantly greater decreases in abdominal and waist circumferences (P < 0.01), and AHR and WHR (P < 0.05) compared to subjects who gained weight. Changes in hip circumference did not differ significantly between the groups (see Table 4).

Seventy one percent of the subjects were considered to have central adiposity as defined by WHR greater or equal to 0.92. Mean WHR at Week 10 was 0.97 and was unchanged at Week 48.



Figure 1. Mean weight change in subjects who lost weight over the 48 week experimental period (N = 39).



Figure 2. Mean weight change in subjects who gained weight over the 48 week experimental period (N = 32).

	NONOBESE Week 8	Week 48	OBESE Week 8	Week 48
BMI	25 <u>+</u> 2	25 <u>+</u> 2	30 <u>+</u> 2	30 <u>+</u> 2
waist circumference (cm)	92 <u>+</u> 6	91 <u>+</u> 7	102 <u>+</u> 8	103 <u>+</u> 7
abdominal circumference (cm)	94 <u>+</u> 6	93 <u>+</u> 6	105 <u>+</u> 8	105 <u>+</u> 8
hip circumference (cm)	99 <u>+</u> 5	98 <u>+</u> 5	106 <u>+</u> 7	106 <u>+</u> 6
abdominal to hip ratio	0.95 <u>+</u> .04	0.95 <u>+</u> .04	0.98 <u>+</u> .06	0.98 <u>+</u> .04
waist to hip ratio	0.93 <u>+</u> .05	0.94 <u>+</u> .05	0.97 <u>+</u> .06	0.94 <u>+</u> .04

۰.

Table 4. Mean ( $\pm$  standard deviation) physical characteristics of nonobese and obese subjects at Week 8 and Week 48.

.

#### Relationship between nutrient intake and weight change

Caloric intake and diet composition did not differ significantly between subjects who lost weight and those who gained weight. However, the subjects who lost weight consumed 24% of energy as fat at Week 48 whereas subjects who gained weight consumed 27% of energy as fat (P = 0.177). When divided into groups based on BMI, subjects with a BMI < 27.8 had significantly greater intake of carbohydrates and significantly lower intake of total fat (both P < 0.01) at Week 48 than subjects with a BMI  $\geq$  to 27.8 (see Figures 3 & 4, Table 5). Caloric intake was not related to BMI.

Correlational analysis of anthropometric values showed BMI at Week 1 (r = 0.73, P < 0.001) and 48 (r = 0.81, P < 0.001) were strongly related to waist circumferences at Weeks 10 and 48. There was also a strong relationship between weight at Weeks 1, 10, 12, 24, 36, and 48 and waist circumferences at Weeks 10 and 48 (r > 0.72, P < 0.001). BMI at Weeks 1 and 48 were moderately related to WHR at Weeks 10 and 48 (r > 0.44, P < 0.001).

#### Relationship between dietary intake components

Correlational analysis revealed a strong inverse relationship between dietary fat and dietary carbohydrate intake (r = -0.79, P < 0.001) and a moderate inverse relationship between dietary fat and soluble and insoluble fiber intake (r = -0.77, P < 0.001) at Weeks 8 and 48. Total fat was strongly correlated with monounsaturated fatty acids at Weeks 8 and 48 (r - 0.74 and 0.82, P < 0.001), and saturated fatty acids at Week 8 (r = 0.82, P < 0.001). There was a moderate positive relationship between total fat and



Figure 3. Distribution of sources of energy in nonobese subjects (BMI < 27.8) at Week 48.



Figure 4. Distribution of sources of energy in obese subjects (BMI  $\ge$  27.8) at Week 48.

	NONOBESE Week 8	Week 48	OBESE Week 8	Week 48
energy intake (kcal/d)	2006 <u>+</u> 551	1733 <u>+</u> 463*	1921 <u>+</u> 456	1873 <u>+</u> 581
carbohydrate (%)	56 <u>+</u> 10	60 <u>+</u> 12	55 <u>+</u> 8	53 <u>+</u> 9
protein (%)	16 <u>+</u> 7	17 <u>+</u> 7	18 <u>+</u> 5	18 <u>+ </u> 7
total fat (%)	27 <u>+</u> 8	23 <b>*</b> <u>+</u> 10	27 <u>+</u> 3	29 <u>+</u> 9
saturated fatty acids (%)	9 <u>+</u> 2	8 <u>+</u> 4	9 <u>+</u> 3	10 <u>+</u> 4
monounsaturated fatty acids (%)	10 <u>+</u> 4	9 <u>+</u> 4*	11 <u>+</u> 6	11 <u>+</u> 5
polyunsaturated fatty acids (%)	6 <u>+</u> 3	5 <u>+</u> 3	6 <u>+</u> 4	6 <u>+</u> 3
cholesterol (mg)	191 <u>+</u> 135	169 <u>+</u> 100	198 ± 118	215 <u>+</u> 127
soluble fiber (g)	7 <u>+</u> 4	7 <u>+</u> 3	7 <u>+</u> 3	6 <u>+</u> 3
insoluble fiber (g)	13 <u>+</u> 6	13 <u>+</u> 7	13 <u>+</u> 6	12 <u>+</u> 5

**Table 5.** Mean ( $\pm$  standard deviation) energy and nutrient intake of nonobese and obese subjects at Week 8 and Week 48.

\* P < 0.05; significance between week 8 and week 48

polyunsaturated fatty acids at Weeks 8 and 48 (r = 0.55 and 0.66, P < 0.01). Relationship between percentage of energy from fat and body weight, body mass index, and body fat distribution

With subjects divided into three groups based on percentage of energy from total fat (<20% energy from fat, 20-30% energy from fat, >30% energy from fat) at Week 48, analysis of variance revealed that subjects who exceeded 30% of their energy from fat exhibited significantly higher body weights than subjects who consumed less than 20% of their energy from fat (P < 0.05). BMI, waist and hip circumferences increased progressively and significantly with fat intake (all P < 0.05). Subjects who consumed the most fat per energy had significantly greater abdominal circumferences than subjects who consumed less than 20% of calories from fat (P < 0.05). There was no significant difference in abdominal circumference between the subjects who consumed 20-30% of energy from fat and those who consumed less than 20% of calories from fat and WHR, AHR, or changes in WHR and AHR. The same variables at Week 8 showed no relationship between percentage of energy from fat and weight, BMI, or circumferences.

#### CHAPTER V

#### DISCUSSION

The results of this study showed that with ongoing nutritional education and support the majority of patients experienced a modest decrease in weight. Over the 48 week experimental period 53% of subjects lost an average of 2.87 + 0.4 kg. The largest decrease in weight occurred during Weeks 1 through 24; weight was basically maintained from Week 24 to the end of the study. Total energy intake and diet composition did not differ significantly between the subjects who lost weight and subjects who gained. This is in contrast with investigations by Chima et al., (1990) and Shenberger et al. (1992), where subjects who lost weight also had significant decreases in total energy and percentage of energy from fat. Baer (1993) reported similar results in a one year study. In this study decreases in body weight and body fat were accompanied by significant decreases in daily intake of energy, percentage of energy from total fat, and increases in carbohydrate as compared to the control group. Additionally, the men in the intervention group increased aerobic activity whereas the control group did not. In the present investigation subjects who lost weight consumed less energy from fat (24%) than subjects who gained weight (27%), however, the difference was not significant (P = 0.177). Data on exercise was not studied and this could explain the differences in weight.

Subjects who lost weight experienced significantly greater decreases in abdominal, and waist circumferences compared to subjects who gained weight. Consequently, subjects who lost weight had greater decreases in WHR and AHR. Pascale et al., (1992) reported a 0.03 reduction in WHR in men who lost 13.1 kg. The changes in the present study were smaller and not statistically significant most likely due to the smaller weight loss and also because the initial circumference data was collected at Week 10 rather than at baseline. The present data also found no correlation between the amount of weight loss and the magnitude of WHR reduction. This is in contrast to previous studies where in men there has been a clear association between weight loss and changes in WHR over the entire range of weight losses (Pascale et al., 1992; Wing et al., 1992). Again, in the present investigation incomplete data may have obscured a relationship. Additionally, in the present study used only circumference measures to determine WHR. Further research with more sensitive measures of abdominal fat, such as computed tomography, are needed to examine this issue.

Diet composition, particularly percentage of energy from fat, was found to be positively related to body weight, BMI, waist, abdominal, and hip circumferences. There was no relationship between adiposity and energy consumption. These findings are similar to those by Miller et al., (1990) and others (Tucker et al., 1992; Dreon et al., 1988; Romieu et al, 1988) who have found that dietary fat rather than energy consumption is associated with increased adiposity. These results also support the hypothesis that obese individuals prefer a higher fat diet than normal weight individuals (Tucker et al., 1992). However, it is not clear whether obesity promotes increased dietary fat consumption or high dietary fat intake causes increased body fat. Additionally, in the current study, potential confounders such as age, physical activity, and smoking were not controlled for.

Although dietary fat and adiposity were significantly related there was no relationship between percentage of energy from fat and WHR, AHR, or changes in WHR and AHR. Other studies carried out by George et al., (1990), Laws et al., (1990), and Slattery et al, (1992) demonstrated similar results. Investigations by Laws et al., (1990) and Slattery et al., (1992) found WHR was directly associated with alcohol consumption and inversely correlated with percent energy from carbohydrate (exclusive of alcohol). Heredity, physical activity, and cigarette smoking may also be associated with the distribution of fat within the body.

Nutritional intervention programs have a mixed compliance record. Positive adherence was attained in the Dietary Alternatives Study (Brownell & Cohen, 1995), a two year nutrition and behavior intervention involving hypercholesterolemic men and their spouses. At one year participants' median fat intake was 20% to 28% of energy, and at two years median fat intake was 22% to 28% of calories. Results from the Women's Health Trial (Gorbach et al., 1990) demonstrated that compliance could be achieved with even a strict dietary regimen. In this study women were counseled to reduce dietary fat to 20% of total calories. After one year the control group decreased fat intake slightly, from 39% of energy to 37% of energy, whereas the intervention group reduced dietary fat from 39% of calories to 22% of calories.

The results of a one year worksite nutrition education program were quite different. Nutrition intervention consisted of Step I individual and group counseling every three months and monthly telephone follow-up. The results showed significant reductions in intake of total fat and saturated fat however, after one year, percentage of energy from total fat exceeded Step I guidelines (Baer, 1993). In the Multiple Risk Factor Intervention Trial (Caggiula et al, 1981), adherence to the dietary regimen was also modest. At the six year follow-up 60% of participants did not attain the recommended guidelines.

In the present investigation nutritional intervention resulted in good compliance to the Step I diet at Weeks 8 and 48 in nonobese and obese subjects. Percentage of calories from monounsaturated fatty acids was the only nutrient which fell below the recommended guidelines in nonobese subjects. Brownell and Cohen (1995) summarized the components of making permanent changes in eating behavior to include nutrition education, self-monitoring, stimuli control, relapse prevention, and social support. Each of these components was emphasized throughout the 48 week experimental period. Additionally, continuous support and supervision are necessary of any program designed for lifestyle change. In this study, all participants received ongoing group and individual monitoring which may have facilitated compliance.

#### CONCLUSIONS

A one year nutrition education and counseling program regarding the National Cholesterol Education Program Step I diet resulted in a modest weight loss in 53% of subjects. Those subjects who lost weight experienced decreases in abdominal and waist circumferences and abdominal-to-hip ratio and waist-to-hip ratio. Hip circumference did not change with weight loss. None of the changes were statistically significant.

Diet composition, particularly percentage of energy obtained from fat, was positively associated with body weight and BMI. BMI, waist, abdominal, and hip circumferences increased progressively and significantly with fat intake. Dietary fat intake was not related to abdominal-to-hip ratio or waist-to-hip ratio.

#### IMPLICATIONS FOR FURTHER STUDY

Based on the findings of this study, continuing research regarding the efficacy of the Step I diet is important. Areas of particular emphasis should be: developing programs designed to attain or maintain desirable weight and modify body fat distribution for a greater number of participants, following larger populations over longer periods of time, and including women as well as a variety of other subjects so as to have a more representative sample of the population. Additional research is necessary to clarify the role of diet composition in the development of obesity and the distribution of body fat, and to control for potential confounders, such as physical activity and cigarette smoking.

#### REFERENCES

- Baer, J. (1993). Improved plasma cholesterol levels in men after a nutrition education program at the worksite. Journal of the American Dietetic Association, 93, 658-663.
- Bjorntorp, P. (1984). Obesity and the risk of cardiovascular disease. <u>Annals of</u> <u>Clinical Research, 17</u>, 3-9.
- Brownell, K. & Cohen, L. (1995). Adherence to dietary regimens 2: Components of effective interventions. <u>Behavioral Medicine</u>, 20, 155-162.
- Caggiula, A., Christakis, G., Farrand, M., Hulley, S., Johnson, R., Lasser, N., Stamler, J.,
   & Widdowson, G. (1981). The multiple risk factor intervention trial (MRFIT).
   <u>Preventive Medicine</u>, 10, 443-475.
- Chima, C., Miller-Kovach, K., Zeller, M., Cook, K., & Schupp, K. (1990). Lipid management clinic: Dietary intervention for patients with hypercholesteremia. Journal of the American Dietetic Association, 20, 272-274.

Crepaldi, G., Belfiore, S., Bosello, O. (1991) Special report: Italian consensus conference-overweight, obesity, and health. <u>International Journal of Obesity</u>, <u>15</u>, 781-790.

- Dengel, J., Katzel, L, & Goldberg, A. (1995). Effect of an American Heart Association diet, with or without weight loss, on lipid in obese middle-aged and older men. <u>American Journal of Clinical Nutrition</u>, 62, 715-721.
- Donahue, R., Abbott, R., Bloom, E., Reed, D., & Yano, K. (1987). Central obesity and coronary heart disease in men. <u>The Lancet</u>, 821-824.
- Dreon, D., Frey-Hewitt, B., Ellsworth, N., Williams, P, Terry, R., & Wood, P. (1988). Dietary fat:carbohydrate ratio and obesity in middle-aged men. <u>American Journal of</u> <u>Clinical Nutrition</u>, 47, 995-1000.
- Ferrannini, E. (1995). Physiological and metabolic consequences of obesity. <u>Metabolism, 44</u>, (9) suppl 3, 15-17.

- George, V., Tremblay, A., Despres, J, Leblanc, D., & Bouchard, C. (1990). Effect of dietary fat content on total and regional adiposity in men and women. <u>International</u> Journal of Obesity, 14, 1085-1094.
- Goldstein, D. (1992). Beneficial health effects of modest weight loss. <u>International</u> Journal of Obesity, 16, 397-415.
- Gorbach, S., Morrill-LaBorde, A., Woods, M., Dwyer, J., Selles, W., Henderson, M., Insull, W., Goldman, S., Thompson, D., Clifford, C., & Sheppard, L. (1990).
   Changes in food patterns during a low-fat dietary intervention in women. Journal of the American Dietetic Association, 90, 802-809.
- Haffner, S., Stern, M., Hazuda, H., Pugh, J., & Patterson, J. (1987) Do upper-body and centralized adiposity measure different aspects of regional body-fat distribution? <u>Diabetes</u>, 36, 43-51.
- Hartman, T., Himes, J., McCarthy, P., & Kushi, L. (1995). Effects of a low-fat worksite intervention on blood lipids and lipoproteins. <u>American College of Occupational and</u> <u>Environmental Medicine</u>, 37, 690-695.
- Henkin, Y, Garber, D., Osterlund, L., & Darnell, B. (1992). Saturated fats, cholesterol, and dietary compliance. <u>Archives of Internal Medicine</u>, 152, 1167-1174.
- Kromhout, D. (1983). Body weight, diet, and serum cholesterol in 871 middle-aged men during 10 years of follow-up (the Zutphen Study). <u>American Journal of Clinical</u> <u>Nutrition</u>, <u>38</u>, 591-598.
- Larsson, B., Svardsudd, K., Welin, L., Wilhelmsen, L., Bjorntorp, P. & Tibblin, G. (1984). Abdominal adipose tissue distribution, obesity, and risk of cardiovascular disease and death: 13 year follow up of participants in the study of men born in 1913. <u>British Medical Journal, 288</u>, 1401-1404.
- Larsson, B. (1988). Regional obesity as a health hazard in men-prospective studies. <u>Acta</u> <u>Medica Scandinavica Supplements</u>, 723, 45-51.
- Laws, A., Terry, R., & Conner, E. (1990). Behavioral covariates of waist-to-hip ratio in Rancho Bernardo. <u>American Journal of Public Health</u>, 80, 1358-1362.
- Leibel, R., Hirsch, J., Appel, B., & Checani, G. (1992). Energy intake required to maintain body weight is not affected by wide variation in diet composition. <u>American</u> Journal of Clinical Nutrition, 55, 350-355.

- Licata, G., Scaglione, R., Ganguzza, A., Corrao, S., Donatelli, M., Parrinello, G., Dichiara, M, Merlino, B., & Cecala, M. (1994). Central obesity and hypertension. <u>American Journal of Hypertension, 7</u>, 314-320.
- Manocha, S. & Gupta, M.C. (1985). Dietary intake in obese vs nonobese adults. Indian Journal of Medical Research, 82, 47-50.
- Mela, D. & Sacchetti, D. (1991). Sensory preferences for fats: relationships with diet and body composition. <u>American Journal of Clinical Nutrition</u>, <u>53</u>, 908-915.
- Miller, W., Linderman, A., Wallace, J., & Niederpruem, M. (1990). Diet composition, energy intake, and exercise in relation to body fat in men and women. <u>American</u> <u>Journal of Clinical Nutrition</u>, 52, 426-430.
- National Cholesterol Education Program Adult Treatment Panel II. (1993). Summary of the second report of the National Cholesterol Education Program Expert Panel on detection, evaluation, and treatment of high blood cholesterol in adults. Journal of the American Medical Association, 269, 3015-3023.
- National Institutes of Health. (1985). Health implications of obesity. <u>Annals of Internal</u> <u>Medicine, 103, 147-151</u>.
- Pascale, R., Wing, R., Blair, E., Harvey, J. & Guare, J. (1992). The effect of weight loss on change in waist-to-hip ratio in patients with type II diabetes. <u>International Journal</u> <u>of Obesity</u>, <u>16</u>, 59-65.
- Pi-Sunyer, X. (1993a). Medical hazards of obesity. <u>Annuals of Internal Medicine</u>, <u>119</u>, 655-660.
- Pi-Sunyer, X. (1993b). Short-term medical benefits and adverse effects of weight loss. Annuals of Internal Medicine, 119, 722-726.
- Romieu, I., Willett, W., Stampfer, M., Colditz, G., Sampson, L, Rosner, B., Hennekens, C., & Speizer, F. (1988). Energy intake and other determinants of relative weight. <u>American Journal of Clnical Nutrition</u>, <u>47</u>, 406-412.
- Rimm, E., Stampfer, M., Giovannucci, E., Ascherio, A., Spiegelman, D., Colditz, G., & Willett, W. (1995). Body size and fat distribution as predictors of coronary herat disease among middle-aged and older US men. <u>American Journal of Epidemiology</u>, <u>141</u>, 117-127.

- Schultz, Y. (1995). Macronutrients and energy balance in obesity. <u>Metabolism, 44</u> (9 suppl 3), 1-3.
- Shenberger, D., Herlgren R., Peters, J., Quiter, E., Johnston, E., & Hunninghake, D. (1992). Intense dietary counseling lowers LDL cholesterol in the recrutiment phase of a clinical trial of men who had coronary artery bypass grafts. Journal of the <u>American Dietetic Association</u>, 92, 441-445.
- Slattery, M., McDonald, A., Bild, D., Caan, B., Hilner, J., Jacobs, D., & Liu, K. (1992). Associations of body fat and its distribution with dietary intake, physical activity, alcohol, and smoking in blacks and whites. <u>American Journal of Clinical Nutrition</u>, <u>55</u>, 943-949.
- Stuhldreher, W., Becker, D., Drash, A., Ellis, D., Kuller, L., Wolfson, S., & Orchard, T. (1994). The association of waist/hip ratio with diabets complications in an adult IDDM population. Journal of Clinical Epidemiology, <u>47</u>, 447-456.
- Tucker, L, & Kano, M. (1992). Dietary fat and body fat: A multivariate study of 205 adult females. <u>American Journal of Clinical Nutrition</u>, 56, 616-622.
- Urban, N., White, E., Anderson, G., Curry, S., & Kristal, A. (1992). Correlates of maintenance of a low-fat diet among women in the Women's Health Trial. <u>Preventive Medicine</u>, 21, 279-291.
- Vague, J. (1956). The degree of masculine differentiation of obesities. <u>American Journal</u> of Clinical Nutrition, 4, 20-32.
- Van Itallie, T. (1992). Body weight, morbidity, and longevity. In P. Bjorntorp (Ed.), <u>Obesity.</u> (pp. 361-369). Philadelphia: J. B. Lippincott Co.
- Wing, R., Jeffery, R., Burton, L., Thorson, C., Kuller, L., & Folsom, A. (1992). Change in waist-to-hip ratio with weight loss and its association with change in cardiovascular risk factors. <u>American Journal of Clinical Nutrition</u>, 55, 1086-1092.

## APPENDICES

.

## APPENDIX A

Institution Approvals

.

## **TexCAPS** Texas Coronary Atherosclerosis Prevention Study

June 29, 1994

Pam Chin-Lai, R.D./L.D. Nutrition Research Manager TexCAPS 1049 Clifton St. Fort Worth, Texas 76107

Dear Pam,

I have reviewed your study "Changes in Weight and Body Fat Distribution with the Step One Diet" and found it to be interesting and well designed. All pertinent patient data will be available for your project.

Should you require additional assistance please feel free to contact me.

Sincerely,

Michael B. Clearfield, D. O.

Primary Investigator

TexCAPS Clinic • Texas College of Ostoopathic Medicis 1049 Clifton St., P. Worth, TX 76107 • (817) 735-2005

## IEAAS COLLEGE OF USTEUPATHIC MEDICINE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

#### BOARD ACTION

IRB PROJECT #: \_\_\_\_\_91-08 \_\_\_\_\_ DATE SUBMITTED: \_\_\_\_\_\_ 1992

PRINCIPAL INVESTIGATOR: \_\_\_\_Michael\_B\_\_Clearfield, D\_O\_\_\_

PROJECT TITLE: <u>A Randomized</u>, <u>Double-Blind</u>, <u>Placebo-Controlled Trial of</u> the Effect of Lovastatin on the Incidence of Primary Coronary DEPARTMENT: <u>Internal Medicine</u> TELEPHONE EXTENSION: \_\_\_\_\_

In accordance with the TCOM IRB policy on the protection of human subjects, the following action has been taken on the above referenced protocol:

<u>x</u> Protocol is approved as submitted.

Modified protocol is approved as submitted.

Amendment \_\_\_\_\_\_ to the protocol is approved as submitted.

Based on the recently completed Periodic Project Review (IRB Form 4), protocol has received continued approval through .....

Protocol has been approved, contingent upon the modifications stated below being incorporated. Please submit one copy of the modified protocol to the Chairman of the IRB for review and incorporation into the permanent IRB file.

Protocol is disapproved for the reason(s) stated below.

Signature for the Chairman' Institutional Review Board

February 18, 1992

Date

White Copy - P.I.

Yellow Copy - IRB Office

Pink Copy - Department File IRS Form 2 (revised 69/96)



HUMAN SUBJECTS REVIEW COMMITTEE

July 11, 1994

Pam Chin-Lai 1713 Big Canyon Trail Carrollton, Texas 75007

Dear Pam Chin-Lai:

OFFICE OF RESEARCH AND GRANTS ADMINISTRATION P.O. Box 22939 Denton, TX 76204-0939 Phone: 817/898-3375

Social Security #: 439-92-4232

Your study entitled "Changes in Weight and Body Fat Distribution with the Step 1 Diet" has been reviewed by a committee of the Human Subjects Review Committee and appears to meet our requirements in regard to protection of individuals' rights.

Be reminded that both the University and the Department of Health and Human Services (HHS) regulations typically require that signatures indicating informed consent be obtained from all human subjects in your study. These are to be filed with the Human Subjects Review Committee. Any exception to this requirement is noted below. Furthermore, according to HHS regulations, another review by the Committee is required if your project changes.

Special provisions pertaining to your study are noted below:

- X The filing of signatures of subjects with the Human Subjects Review Committee is not required.
- X Your study is exempt from further TWU Human Subjects Review.
- \_\_\_\_ No special provisions apply.

Sincerely,

atu Hamiton

Chair Human Subjects Review Committee

cc: Graduate School
 Dr. George Liepa, Nutrition and Food Sciences
 Dr. Dorice Czajka-Narins, Nutrition and Food Sciences

A Comprehensive Public University Primarily for Women

An Equal Opportunity/Affirmative Action Employer

# APPENDIX B

Subject Data

•

WEEK	MEAN WEIGHT	STANDARD DEVIATION
1	191	+/- 25
8	188	+/- 25
10	188	+/- 26
12	187	+/- 26
24	185	+/- 26
36	185	+/- 26
48	185	+/- 26

-

Table 6. Mean weight change and standard deviation in subjects who lost weight over the 48 week experimental period (N = 39).

WEEK	MEAN WEIGHT	STANDARD DEVIATION
1	187	+/- 24
8	188	+/- 25
10	189	+/- 26
12	190	+/- 26
24	191	+/- 26
36	191	+/- 26
48	192	+/- 25

.

Table 7. Mean weight change and standard deviation in subjects who gained weight over the 48 week experimental period (N = 32).

Subject	Ethnicity	DOB	M. S.	Educ.	Ht	1 WT	8 WT	10 WT
1	white	11-Jan-46	m	cg	72	215	201.8	207.8
3	white	21-Jun-41	m	cg	67	182	188.8	191.8
4	white	14-May-19	m	cg	74	198	200.75	200
5	white	14-Jun-28	m	cu	65	160	167.25	164.4
6	white	04-Feb-47	d	cg	70	196	200.05	198.4
7	white	09-Nov-24	m	cg	73	199	194.4	196
8	white	21-Jun-35	m	cg	70	169.2	173.2	175.8
9	white	07-Apr-39	m	cg	69	170	176.2	177
10	white	15-Dec-34	m	hs	71	183.4	180.6	179
11	white	11-Aug-26	m	cu	69	198	192	188.6
12	white	21-Dec-34	m	cg	70	216	206	203.4
13	white	03-Oct-35	m	hs	71	182.4	176.5	181
14	white	11-Nov-27	m	cg	72	191	193.4	197.6
15	white	10-Sep-27	m	HS	71	238	235.4	230.6
16	white	03-Jan-44	m	cu	70	164.4	160.4	160.2
17	white	15-Jan-46	S	cu	70	199	201	197.8
18	white	03-Jul-31	m	hs	77	180	176.25	173.2
19	white	21-Apr-41	m	cg	76	207.2	203.8	207.4
20	white	02-Apr-47	m	cu	70	237	238.8	237
21	white	20-Aug-23	m	cg	73	199	192.6	192
22	white	30-Nov-41	m	cg	68	197	192.8	193
23	white	26-Jun-34	S	hs	72	199.6	197.8	199.4
24	white	13-Jan-29	m	cġ	74	232	231	230
25	white	27-Aug-40	m	cg	76	189.2	188	186.6
26	white	01-Oct-30	m	cg	73	186	1/6.4	1/6
27	other	16-Jun-41	m	cg	63	123	123	120
28	white	16-Nov-46	m	cg	69	1/9	181	186.4
29	white	04-Jan-20	m	hs	68	210	208	206.6
30	white	15-Jul-47	m	cg	72	240	233	245.2
31	white	27-Mar-25	m	cu	70	153	150.2	100.8
32	white	12-Apr-41	s	cg	12	100	100.2	192.0
33	white	03-Apri-37	m	cg	69	219.0	230.75	220
34	black	21-May-4:	m	cg	70	170 4	140.4	140
35	black	19-Jun-30	m	cg	70	1/9.4	200 4	201.4
36	black	28-Aug-43	m	cg	70	201	200.4	201.4
37	white	05-Jun-36	m	cg	67	100	170.0	1/9
38	white	03-feb-29	m	cg	00	100.4	1/0.0	100.2
39	white	22-Aug-21	m	cu	69	200	102.2	216.4
40	white	16-Sep-3/	m	cu	69	209	210.0	210.4
41	white	15-Jan-41	m	cu	57	213.0	210.0	214.0
42	white	31-Jul-20	m	cg	70	203	190.10	0.561
43	white	29-Jan-45	m	cg	72	200.4	247.0	24/
44	white	27-Dec-32	m	cg	12	109	100.0	170
45	white	22-Jul-32	m	cg	6/	102	177 4	170 4
47	white	18-Oct-42	w	cu	67	100.0	177.4	1/9.4

Subject	Ethnicity	DOB	M. S.	Educ.	Ht	1 WT	8 WT	10 WT
48	hispa	23-Aug-39	m	hs	69	169	162.25	160.8
49	white	07-Aug-30	m	cu	70	190	190	190.2
50	white	27-Jan-32	m	cg	69	148	146	143.8
51	white	17-Feb-23	m	cg	65	151	154	153
52	white	20-Nov-44	m	cg	74	178	176.5	178.4
53	white	23-Sep-36	m	cu	68	158	161.25	156
54	white	11-Feb-46	m	cg	79	176.8	177.5	179
55	white	25-jan-46	m	cg	68	172.8	174.2	168
56	white	06-Sep-27	m	cg	69	181.2	179	177
57	black	14-Jun-46	m	cg	70	207	202.8	211
58	white	07-Aug-19	m	cg	68	175.2	174	177
59	white	11-Dec-33	m	cg	73	231	235	231.6
60	white	30-Dec-29	m	cg	69	202	201.8	198.6
61	white	11-Oct-23	m	cg	69	209	199.25	199.4
62	white	09-Nov-38	m	cu	70	157.6	162	161.2
63	white	09-May21	m	hs	69	169	164.6	163.6
64	white	15-Jan-25	m	cu	73	187	182.25	181.4
65	white	14-May-28	m	cu	70	180.2	186.25	186
66	white	12-Jul-32	m	cg	73	192.6	180	184.2
67	white	11-May-47	m	cg	65	163	163.6	163.2
68	white	30-Jun-42	d	cu	67	173.4	170.5	172
69	white	05-Apr-40	m	hs	73	211	212	215
70	white	16-may-4(	m	cu	70	188	178.6	181
71	white	31-Mar-30	m	cg	69	175	174.5	171.2
72	white	07-Jun-40	m	cg	71	190	192.75	196
73	white	05-Apr-36	m	cu	76	257	262	264.6

Subject	12 Wt	24 Wt	36 Wt	48 Wt	10 waist	10 abd	10 hip	48 waist
1	204.2	206.2	209.4	209	97.5	97.5	102.5	92
2	192.2	194.6	190	190	no data	no data	no data	no data
3	191	187.4	188.8	189	98	102	98	97.5
4	199.8	203.4	203.4	205	110	110	106.25	107
5	172	172.4	172	171	95	97.5	97.5	97.5
6	195	192.6	196.4	195.2	95	97.5	105	.95
7	194.2	187.2	187.2	184	96	96	104	92.5
8	172.6	175.2	177	180	no data	no data	no data	no data
9	174.8	168.2	164	166	92.5	95	97.5	87.5
10	184.25	183.8	178.6	177	92.5	95	97.5	96
11	199.25	201.2	197.4	195.6	97.5	102.5	105	102.5
12	207.8	202.8	210.2	206	98.5	100	101.8	105
13	185.5	183.2	183.8	187	95	97.5	105	95
14	198.8	198.2	198.6	193	101	99	102	96
15	232.2	235.4	231.2	231	115	120	115	111.25
16	162.8	165.8	168.4	166	86.25	85	92.5	93
17	201.75	205	200	202	105	107.5	107.5	105.5
18	174.5	181	178.2	187.6	no data	no data	no data	no data
19	200.6	196.4	197.2	199	87.5	97.5	107.5	87
20	236.8	241.2	243.8	242	no data	no data	no data	no data
21	194	190.6	189.8	192	95	97.5	97.5	93
22	200	197.6	202.2	203	94	97	95	102.5
23	198.6	200	198.8	197	90	92.5	97.5	87.5
24	238	238.6	236.6	238	103	109	103	112.5
25	187.5	186.2	189.4	186	97.5	100	100	100
26	168	167.4	161	160	88.75	92.5	100	81.25
27	117	115.4	115.2	116.2	83	85	86	73.75
28	189.8	185.6	185.4	186	96.25	96.25	102.5	95
29	204	205.6	206	206.4	105	107.5	117.5	97.5
30	244.6	245.6	242.8	248	107.5	112.5	110	117
31	158.5	157	151.4	158	85	87.5	90	92.5
32	195	195.2	188.4	197	90	92.5	101.25	95
33	232.5	233.5	235	224	122	127	111	117.5
34	149.5	149	149.4	148.4	no data	no data	no data	no data
35	171.6	173	172.6	175.4	97	97.5	94	95
36	198.6	202.4	203.6	204	94	95	99	96
37		174.6	174.2	177	97.5	100	97.5	102.5
38	185	180.6	186	187	105	107.5	102.5	108.75
39	182.25	181	184.4	179	95	90	100	90
40	218.4	221.2	220.4	217	107.5	107.5	108.75	113
41	218	213	212	212	111.25	108.75	107.5	107
42	191.25	194.6	195.4	195	102	103	103	102
43	244.4	247.8	245.4	247	112.5	117.5	112.5	112.5
44	162	160.4	164	158	83	89	96.5	87
45	184	183.2	184.6	190	97.5	97.5	107.5	100
46	210	212.6	212.2	207	97.5	102.5	102.5	105
47	181.2	183.6	183.8	182	95	95	95	97.5

Subject	12 Wt	24 Wt	36 Wt	48 Wt	10 waist	10 abd	10 hip	48 waist
48	161.5	159.4	161.4	161	no data	no data	no data	no data
49	191	187.2	187.6	188.8	100	97.5	102.5	100
50	143.6	146.8	148	148.8	80	82	91	75
51	147	150.6	151.8	154	90	86	92	92
52	172.8	174	173.8	178.6	96.25	97.5	100	93
53	156.6	157.4	152	152	93.75	95	100	92.5
54	180	177.6	177	177	95	98.5	101	91
55	171.4	170.4	168.8	170	92.5	92.5	100	90
56	173	175.4	177.2	178	90	92.5	98.75	95
57	202.2	200.8	199.4	202	93	93	101	95
58	172.25	172.6	172.4	172	92.5	95	97.5	100
59	236	245.2	244.8	243.6	105	107.5	112.5	106.25
60	197.8	197.6	198.8	196	96.25	98.75	105	95
61	198.4	196.8	207.5	208.6	110	107.5	107.5	105
62	153	149.4	152.2	152	85	87.5	93.75	82.5
63	163.25	160.4	161.4	159.4	no data	no data	no data	no data
64	181.6	178.6	177.75	177.4	97.5	97.5	105	90
65	191.8	194.8	194	192	100	102.5	105	100
66	173.6	167	163	168	83.75	85	100	76.25
67	163.75	165.4	165.4	169	89.5	93.5	96	88
68	170	174.2	175	175	90	93.75	95	92.5
69	218	215.8	215.2	220	102.5	110	107.5	104
70	177.5	178.6	177	178	92	99	106	90
71	172.8	174.8	176.8	178.4	no data	no data	no data	no data
72	196.4	191.6	191	197	100	97.5	102.5	96.25
73	260.4	259	258	254.6	123.4	122	115.5	116

Subject	48 abd	48 hip	8 cal	8 %fat	8 %SF	8 mono	8 pufa	8 CHO
1	94	94	2776	14.58	4.65	5.01	3.61	69.67
2	no data	no data	1126	28.52	9.44	12.65	4.73	40.72
3	100	102.5	2799	32.3	10.88	39.24	20.32	58.85
4	106	107	2530	33.14	10.62	14.62	5.83	45.26
5	98.75	100	1789	26.86	7.91	10.56	5.99	57.16
6	97.5	107.5	1475	29.97	15.5	9.29	3.01	54.21
7	92.5	100	2126	25.17	6.3	10.86	6.64	48.73
8	no data	no data	1661	18.86	4.64	6.48	5.72	48.15
9	88.75	92.5	1872	46.97	14.16	18.85	10.64	37.11
10	97	105	2122	30.92	10.1	11.07	6.76	53.19
11	100	105	1664	29.64	9	13.12	4.3	35.48
12	103	107	1840	31.08	6.85	9.22	13.6	57.67
13	97.5	105	1170	24.56	10.33	8.85	3.56	56.31
14	96	101	2795	19.76	9.99	4.88	3.29	70.85
15	112.5	111.25	1493	36,78	10.55	16.12	6.68	45.71
16	92	96	1613	43.08	12.05	17.68	9.45	35.4
17	104.5	103.5	1968	14.12	4.43	3.8	4.47	68.54
18	no data	no data	1380	38.2	11.81	16.14	6.93	51
19	98	106	2251	19.4	7.31	6.86	2.81	54.38
20	no data	no data	931	25.63	5.53	7.88	10.01	59.46
21	99	101	3035	38.53	11.27	14.34	10.47	52.55
22	105	105	1580	22.6	7.55	7.72	5.07	56.88
23	85	95	2261	31.52	10.62	11.48	5.73	56.31
24	112.5	107.5	1500	22.91	10.8	5.7	4.41	62.88
25	100	101.25	2112	26.6	7.98	10.49	6	50.12
26	88.75	92.5	1378	20.35	7.05	4.41	10.85	58.92
27	76.25	87.87	1665	39.1	11.46	16.67	6.95	41.21
28	96.25	96.25	1954	12.36	5.3	2.91	2.27	64.83
29	102.5	115	1611	19.07	6.6	11.47	8.13	61.27
30	128	112	1826	37.08	11.43	16.3	6.25	47.86
31	86 25	92.5	1853	33.65	11.4	14.68	4.68	53.38
32	95	105	1921	28.47	11.3	10.99	4.34	58.8
33	120	118 75	2724	9.78	3.67	3.52	1.11	74.87
34	no data	no data	3216	14.3	4.16	4.08	4.98	80.78
35	97.5	97.5	2502	28.89	8.77	10.75	7.06	57.41
36	94.5	103	1569	25.41	8.05	9.47	6.11	55.21
37	102.5	102.5	1676	28.82	12.77	10.16	2.09	46.98
38	107.5	105	1406	23.15	5.93	8.16	6.46	57.29
30	88 75	97.5	1505	30.32	10.28	11.17	6.08	56.75
40	114	108.5	2560	20.6	7.96	7.45	3.48	61.76
40	114	100.0	1930	29.6	9.92	10.15	7.34	54.93
41	102	103	1852	40 75	13.45	16.75	6.8	42.44
42	105	112.5	2095	34 54	11 43	15.05	4.86	48.68
43	CI I 00	0/	18/1	30 97	9 83	13.05	5.92	58.72
44	83	94 105	1/2/	23.87	7 75	9 18	4 56	60 71
45	104	100 75	17/6	18 32	16.59	18 29	10.2	34.01
46	103.75	103.75	1/40	28 58	10.00	18 87	7 18	44 48
47	96.25	97.5	10/0	30.00	10.07	10.01	1.10	17.40

Subject	48 abd	48 hip	8 cal	8 %fat	8 %SF	8 mono	8 pufa	8 CHO
48	no data	no data	2236	17.56	2.77	9.97	2.3	74.48
49	95	97.5	1861	17.32	9.15	5.37	1.43	63.2
50	83	87	3195	27.99	8.17	11.56	6.51	64.04
51	92	95	1662	40.89	13.31	17.3	6.76	40.61
52	93.5	97.5	1884	26.18	6.12	10.68	6.82	63.44
53	93.75	100	1849	23.34	7.6	8.99	5.08	62.67
54	93	99	2061	31.24	9.83	11.13	6.8	50.6
55	92	97	1660	29.94	6.85	8.18	12.53	50.75
56	90	98	1770	23.33	11.31	7.02	2.18	66.23
57	96	102	2549	44.51	13.24	17.7	10.52	36.82
58	101	97	1675	26.41	9.37	9.66	5.72	45.78
59	110	111.25	2511	30.31	9.91	10.33	7.02	47.22
60	97.5	105	1738	16.37	4.64	6.82	2.99	63.27
61	105	106.25	2616	34.56	10.98	13.28	8.03	49.21
62	83.75	90	3496	31.41	11.17	11.69	5.62	50.46
63	no data	no data	1290	22.07	8.54	8.18	3.47	65.88
64	92.5	98.75	2569	15.7	6.2	5.55	1.98	51.97
65	105	102.5	1676	30.98	9.15	13.17	6.66	54.72
66	82.5	97.5	1599	25.17	6.7	9.65	6.65	67.44
67	93	95	1650	19.6	7.22	5.99	4.7	63.11
68	92.5	97.5	1153	23.55	7.96	9.56	3.66	54.47
69	110	108	1815	29.19	8.66	9.7	7.27	57
70	93.75	95	1949	30.69	7.94	10.72	9.86	57.15
71	no data	no data	1506	21.31	6.1	8.15	5.39	70.21
72	100	100	2414	23.83	8.44	8.7	4.77	61.16
73	114	118	1737	22.39	7.85	16.42	2.85	55.41

Subject	8 sol f	8 insol f	8 chol	48 cal	48 %fat	48 %SF	48 mono	48 pufa
1	3.66	10.67	354.31	2641	18.74	8.24	6.8	2.12
2	3.18	5.81	118.26	1714	16.93	6.75	5.71	2.69
3	8.95	13.84	244.05	1484	36.35	7.67	27.91	15.91
4	6.9	18.95	306.52	1405	34.67	10.61	15.53	6.16
5	3.9	9.18	92.16	1685	29.95	11.62	10.73	4.53
6	3.63	7.86	116.92	2564	29.16	13.15	9.79	4.11
7	5.93	13.51	78.46	2017	32.76	9.29	12.54	8.04
8	8.79	16.68	232.63	1921	12.79	3.04	3.96	3.6
9	5.41	6.38	218.35	909	11.42	3.27	4.54	2.43
10	2.66	6.3	221.39	1003	8.7	2.63	3.17	1.73
11	5.9	13.03	239.62	2339	21.83	8.08	8.6	1.9
12	3.97	9.09	93.66	2035	39.88	13.97	16.26	6.58
13	2.89	5.54	97.53	1543	18.49	7.72	6.47	2.66
14	4.91	15.48	240.31	1971	18.69	5.82	6.96	3.99
15	5.48	10.65	172.67	1702	35.86	11.15	13.27	8.35
16	4.69	5.89	642.04	2040	29.27	8.27	9.77	9.28
17	14.78	29.41	174.34	1245	10.17	2.92	2.91	2.61
18	2.52	4.46	493.21	1959	16.78	5.76	6.93	2.88
19	5.38	8.66	151.29	2125	27.47	7.46	11.7	6.36
20	1.88	5.82	28.53	1709	22.21	6.82	8.54	3.58
21	5.99	9.69	176.71	2102	14.14	3.87	4.56	3.48
22	8.71	23.44	177.05	2042	15.14	5.03	6.04	2.73
23	5.25	10.64	208.64	2863	22.02	7.33	8.1	3.84
24	8.07	10	71.52	4221	38.64	11.74	2.29	1.95
25	9.96	15.34	166.73	1618	20.12	7.13	7.03	4.04
26	6.97	14.19	40.87	2343	11.19	3.88	8.38	6.25
27	6.54	11.78	283.82	2143	18.55	5.82	7.13	3.35
28	5.23	12.23	342.03	1816	32.01	6.72	12.27	10.91
29	7.48	10.42	155.86	1402	37.39	14.7	13.43	7
30	3.94	8.41	154.88	2251	28.77	5.51	9.08	12.28
31	5.11	7.59	194.68	1181	15.64	5	6.17	2.55
32	6.72	11.17	145.95	2091	29.55	8.32	11.28	7.48
33	3.19	4.72	141.66	858	47.41	21.69	16.07	6.81
34	9.24	20.3	88.63	2213	24.14	7.32	9.73	5.19
35	7.27	17.35	180.71	1735	13.27	5.41	3.76	2.21
36	6.1	10.52	155.79	1564	28.52	11.5	18.1	5.03
37	4.95	5.26	471.4	1396	22.38	7.53	7.57	4.54
38	5 98	9.76	152.92	2129	24.85	8.21	9.75	4.43
39	2 85	8.03	154.35	1588	22.06	7.37	8.26	4.66
40	11 65	25.14	239.77	1737	27.94	13.05	9.6	3.38
41	6.96	12.7	190.93	1487	23.95	8.21	8.02	4.38
42	2.96	6.87	231	1869	39.58	11.09	12.49	13.24
42	8 22	14 55	161.04	2150	33.23	1057	13.32	6.68
40	91	16.3	113.93	2311	28.88	7.36	10.44	8.91
44	7 47	18 13	139 57	1529	24.89	6.09	9.58	6.48
40	1 12	6.33	486 15	948	28.79	10.52	11.94	3.42
40 17	3.67	10.25	238.57	1392	22.9	6.62	9.05	5.46

Subject	8 sol f	8 insol f	8 chol	48 cal	48 %fat	48 %SF	48 mono	48 pufa
48	18.04	24.57	6.06	1949	4.64	1.02	1.33	1.46
49	6.41	12.48	123.72	1541	12.33	6.58	2.29	1.95
50	10.23	20.7	66.44	2526	19.15	4.78	5.82	6.85
51	4.96	8.97	297.44	1620	41.77	13.41	14.05	12
52	5.08	15.9	49.38	1221	39.62	19.28	12.58	4.85
53	5.67	19.81	71	1091	26.54	10.18	7.65	10.18
54	12.37	19.47	244.46	2351	32.53	11.37	12.3	5.97
55	3.6	11.16	228.65	1330	19.44	4.3	6.78	6.61
56	6.06	11.92	188.04	1775	20.17	6.34	7.74	4.2
57	4.43	10.67	337.08	1791	40.85	12.58	16.8	8.25
58	2.8	3.09	105.83	1434	15.93	7.16	5.05	2.06
59	13.52	21.28	308.14	1984	39.72	11.84	17.15	8.25
60	8.42	15.2	110.38	1861	25.18	9.73	9.76	3.3
61	5.63	9.64	279.02	1356	40.4	13.6	16.29	6.99
62	8.65	24.82	612.23	1937	31.94	13.93	11.22	4.77
63	7.5	14.27	89.38	989	26.8	11.05	8.72	4.42
64	10.69	17.85	210.73	2249	16.39	7.22	4.53	2.37
65	8.92	11.91	101.31	1259	51.32	16.05	20.63	10.86
66	6.4	9.51	67.32	1040	33.73	15.95	10.41	4.84
67	12.53	28.72	44.34	2057	14.82	4.44	5.43	3.76
68	5.56	14.11	150.77	1324	24.2	8.72	10.47	2.51
69	7.86	14.58	116.64	1981	26.74	9.58	9.73	4.51
70	7.13	13.7	166.17	1652	23.6	5.79	9.3	6.54
71	4.22	7.78	130.82	1472	35.65	10.59	13.96	8.31
72	22.68	33.76	151.09	1384	16.43	4.43	6.7	3.49
73	3.8	7.89	239.56	2017	32.58	10.33	13.83	6.16

Subje	ct	48 %CHO	48 sol f	48 insol f	48 chol	1 BMI	48 BMI	10 AHR	48 AHR
	1	70.65	4.96	11.57	109.84	29.28	28.46	0.95	1
	2	60.35	4.49	7.85	111.06	no data	no data	no data	no data
	3	48.98	5.04	10.4	178.17	28.6	29.7	1.04	0.97
	4	42.74	3.37	8.59	272.8	25.56	26.47	1.03	0.99
	5	50.72	2.92	8.28	196.71	26.7	28.57	0.93	0.97
	6	55.53	6.26	17.37	174.15	28.37	28.25	0.92	0.91
	7	37.25	5.43	8.83	287.8	26.37	24.38	0.92	0.92
	8	46.55	6.48	11.67	204.75	24.37	25.93	no data	no data
	9	72.94	9.69	12.1	61.17	25.25	24.06	0.97	0.96
	10	75.97	3.34	3.89	90.18	25.72	24.83	0.97	0.92
	11	36.29	7.94	14.9	189.6	29.41	29.05	0.98	0.95
	12	46.44	7.63	10.64	703.55	31.27	29.82	0.98	0.96
	13	67.47	4.14	10.05	98.55	25.59	26.23	0.93	0.93
	14	68.05	4.55	11.23	200.89	26.07	26.34	0.97	0.95
	15	40.25	4.46	18.57	273.77	33.38	32.41	1.04	1.01
	16	60.93	6.58	13.89	104.78	23.79	24	0.91	0.96
	17	72.96	9.65	14.99	79.7	28.81	29.24	1	1
	18	73.97	4.14	11.58	82.76	21.47	21.31	no data	no data
	19	49.43	4.8	7.84	302.73	25.32	24.3	0.91	0.92
	20	57.79	10.71	20.72	263.58	34.31	35.03	no data	no data
	21	68.03	15.57	22.07	151.73	26.37	25.44	1	0.98
	22	62.72	13.96	18.16	79.63	30	30.96	1.02	1
	23	58.08	10.37	22.19	277.62	27.24	26.89	0.95	0.89
	24	52.93	3.92	12.05	296.3	29.87	30.64	1.06	1.05
	25	55.35	5.6	3.75	157.49	22.57	22.73	1	0.99
	26	63.81	11.05	28.04	138.31	24.64	21.2	0.93	0.96
	27	67.03	7.94	12.89	189.74	21.93	20.71	0.99	0.93
	28	47.82	4.64	8.29	132.65	26.59	27.63	0.94	1
	29	54.17	3.96	12.09	97.91	32	31.48	0.92	0.89
	30	55.38	6.78	13.55	143.79	32.76	33.85	1.02	1.14
	31	74.54	4.68	12.03	82.1	22.15	22.87	0.97	0.93
	32	54.44	9.69	16.51	319.6	25.66	26.89	0.91	0.9
	33	41.62	0.68	6.21	59.32	32.65	33.27	1.14	1.01
	34	65.11	6.98	17.04	127.75	23	22.63	no data	no data
	35	74.21	8.32	17.54	56.2	25.96	25.39	1.04	1
	36	44.5	4.58	8.48	229.91	29	29.5	0.96	0.92
	37	57.6	5.13	9.14	177.94	28.3	27.8	1.02	1
	38	63.96	15.65	28.83	238.12	28.3	28.5	1.05	1.02
	39	71.59	8.55	19.32	74.59	26.88	26.59	0.9	0.91
	40	54.11	3.27	6.39	217.15	31	32.23	0.99	1.05
	41	56.92	7.61	13.03	175.18	33.6	33.34	1	1
	42	47.08	6.54	9.8	177.29	29.38	28.23	1	1
	43	44.56	5.52	9.02	400.37	34.18	33.71	1.04	1
	44	58.85	9.38	20.14	141.35	23	21.57	0.92	0.88
	45	54.8	7.77	12.55	208.89	28.6	29.88	0.91	0.99
	46	57.97	0.59	1.28	462.74	no data	28.25	1	1
	47	68.32	5.4	7.54	51.88	29.38	28.62	1	0.99

Subject	48 %CHO	48 sol f	48 insol f	48 chol	1 BMI	48 BMI	10 AHR	48 AHR
48	88.12	14.08	24.91	6.98	25.1	23.91	no data	no data
49	69.33	4.67	12.25	112.41	27.5	27.3	0.95	0.97
50	63.31	16.14	33.31	124.08	21.98	22.1	0.9	0.95
51	44.64	4.15	8.6	181.75	25.23	25.73	0.93	0.97
52	51.05	6.25	8.14	168.84	22.92	22.99	0.96	0.96
53	54.02	5.99	7.24	176.97	24.1	23.18	0.95	0.94
54	51.73	5.44	10.55	300.79	19.99	20.01	0.95	0.94
55	68.51	3.58	17.45	79.21	26.36	25.93	0.93	0.95
56	73.43	7.45	16	91.89	26.92	26.44	0.94	0.92
57	40.57	4.78	11.97	391.19	29.96	29.24	0.92	0.94
58	47.08	2.76	5.71	96.5	26.72	26.23	0.97	1.04
59	35.15	5.13	8.17	187.92	30.6	32.28	0.95	0.99
60	58.13	7.34	11.77	198.04	30	29.11	0.94	0.93
61	44.56	3.45	7.02	351.95	31.04	30.98	1	0.99
62	55	5.09	10.82	340.11	22.81	22	0.93	0.93
63	50.15	3.69	8.13	180.3	25	21.12	no data	no data
64	55.9 <b>8</b>	14.47	20.61	298.15	24.78	23.5	0.93	0.94
65	34.78	2.23	3.79	535.74	26.08	27.79	0.98	1.02
66	49.04	4.35	5.52	91.42	25.5	22.26	0.85	0.85
67	61.92	8.45	23.68	200.79	27.2	28.24	0.96	0.99
68	62.4	8.72	14.87	119.21	27.27	27.5	0.97	0.86
69	52.52	4.78	13.32	230.98	27.96	29.15	1.02	1.02
70	62.16	9.04	13.73	163.67	27.2	25.76	0.93	0.99
71	48.67	3.6	6.61	198.03	25.99	26.5	no data	no data
72	65.95	4.48	8.16	101.08	26.65	27.6	0.95	1
73	52.66	5.49	6.86	184.26	31.4	31.1	1.06	0.97

Subject	10 WHR	48 WHR	48 WT (-) 1 WI	48 cal (-) 8 cal	48 fat (-) 8 fat 4	48 SF (-) 8 SF
1	0.95	0.98	-6	-135	4.16	3.59
2	no data	no data	no data	588	-11.59	-2.69
3	1	0.95	7	-1315	4.05	-3.21
4	1.03	1	7	-1125	1.53	-0.01
5	0.97	0.98	11	-104	3.09	3.71
6	0.9	0.88	-0.8	1089	-0.81	-2.35
7	0.92	0.93	-15	-109	7.59	2.99
8	no data	no data	10.8	260	-6.07	-1.6
9	0.95	0.94	-4	-963	-35.55	-10.89
10	0.95	0.91	-6.4	-1119	-22.22	-7.47
11	0.93	0.98	-2.4	675	-7.81	-0.92
12	0.97	0.98	-10	195	8.8	7.12
13	0.9	0.9	4.6	373	-6.07	-2.61
14	0.99	0.95	2	-824	-1.07	-4.17
15	1	1	-7	209	-0.92	0.6
16	0.93	0.97	1.6	427	-13.81	-3.78
17	0.98	1.02	3	-723	-3.95	-1.51
18	no data	no data	7.6	579	-21.42	-6.05
19	0.81	0.82	-8.2	-126	8.07	0.15
20	no data	no data	5	778	-3.42	1.29
21	0.97	0.92	-7	-933	-24.39	-7.4
22	0.99	0.98	6	462	-7.46	-2.52
23	0.92	0.92	-2.6	602	-9.5	-3.29
24	1	1.05	6	2721	15.73	0.94
25	0.98	0.99	-3.2	-494	-6.48	-0.85
26	0.89	0.88	-26	965	-9.16	-3.17
27	0.96	0.9	-6.8	478	-20.55	-5.64
28	0.94	0.99	7	-138	19.65	1.42
29	0.89	0.85	-3.6	-209	18.32	8.1
30	0.98	1.04	8	425	-8.31	-5.92
31	0.94	1	5	-672	-18.01	-6.4
32	0.88	0.9	9	170	1.08	-2.98
33	1.09	0.99	4.2	-1866	37.63	18.02
34	no data	no data	-2.6	-1003	9.84	3.16
35	1.03	0.97	-4	-767	-15.62	-3.36
36	0.95	0.93	3	-5	3.11	3.45
37	1	1	-3	-280	-6.44	-5.24
38	1.02	1.03	1.6	723	1.7	2.28
39	0.95	0.92	-2	83	-8.26	-2.91
40	0.99	1.04	8	-823	7.34	5.09
41	1.03	0.99	-1.6	-443	-5.65	-1.71
42	0.99	0.99	-8	17	-1.17	-2.36
43	1	1	-3.4	55	-1.31	1045.57
44	0.86	0.92	-11	470	-2.09	-2.47
45	0.91	0.95	8	45	1.02	-1.66
46	0.95	1.01	no data	-798	-19.53	-6.07
47	1	1	-4.8	-483	-15.68	-3.75

Subject	10 WHR	48 WHR	48	WT (-) 1 WI 48	cal (-) 8 cal	48 fat (-) 8 fai 48	3 SF (-) 8 SF
48	no data	no data		-8	-287	-12.92	-1.75
49	0.97	1.02		-1.2	-320	-4.99	-2.57
50	0.88	0.86		0.8	-669	-8.84	-3.39
51	0.98	0.97		3	-42	0.88	0.1
52	0.96	0.95		0.6	-663	13.44	13.16
53	0.94	0.93		-6	-758	3.2	2.58
54	0.94	0.92		0.2	290	1.29	1.54
55	0.93	0.93		-2.8	-330	-10.5	-2.55
56	0.91	0.91		-3.2	5	-3.16	-4.97
57	0.92	0.93		-5	-758	-3.66	-0.66
58	0.95	1.03		-3.2	-241	-10.48	-2.21
59	0.93	0.95		12.6	-527	9.41	1.93
60	0.92	0.93		-6	123	8.81	5.09
61	1.02	0.99		-0.4	-1260	5.84	2.62
62	0.91	0.93		-5.6	-1559	0.53	2.76
63	no data	no data		-9.6	-301	4.73	2.51
64	0.93	0.91		-9.6	-320	0.69	1.02
65	0.95	0.96		11.8	-417	20.34	6.9
66	0.84	0.84		-24.6	-559	8.56	9.25
67	0.93	0.93		6	407	-4.78	-2.78
68	0.95	0.95		1.6	171	0.65	0.76
69	0.95	0.96		9	166	-2.45	0.92
70	0.87	0.95		-10	-297	-7.09	-2.15
71	no data	no data		3.4	-34	14.34	4.49
72	0.96	1		7	-1030	-7.4	-4.01
73	1.07	0.98		-2.4	280	10.19	2.48

Subject	48 CHO (-) 8 CHO 48	SolF (-) 8 SolF	48 INSOLF (-) 8 INSOLF	48 chol (-) 8 chol
1	0.98	1.3	0.9	-244.47
2	19.63	1.31	2.04	-7.2
3	-9.87	-3.91	-3.44	-65.88
4	-2.52	-3.53	-10.36	-33.72
5	-6.44	-0.98	-0,9	104.55
6	1.32	2.63	9.51	57.23
7	-11.48	-0.5	-4.68	209.34
8	-1.6	-2.31	-5.01	-27.88
9	35.83	4.28	5.72	-157.18
10	22.78	0.68	-2.41	-131.21
11	0.81	2.04	1.87	-50.02
12	-11.23	3.66	1.55	609.89
13	11.16	1.25	4.51	1.02
14	-2.8	-0.36	-4.25	-39.42
15	-5.46	-1.02	7.92	101.1
16	25.53	1.89	8	-537.26
17	4.42	-5.13	-14.42	-94.64
18	22.97	1.62	7.12	-410.45
19	-4.95	-0.58	-0.82	151.44
20	-1.67	8.83	14.9	235.05
21	15.48	9.58	12.38	-24.98
22	5.84	5.25	-5.28	-97.42
23	1.77	5.12	11.55	68.98
24	-9.95	-4.15	2.05	224.78
25	5.23	-4.36	-11.59	-9.24
26	4.89	4.08	13.85	97.44
27	25.82	1.4	1.11	-94.08
28	-17.01	-0.59	-3.94	-209.38
29	-7.1	-3.52	1.67	-57.95
30	7.52	2.84	5.14	-11.09
31	21.16	-0.43	4.44	-112.58
32	-4.36	2.97	5.34	173.65
33	-33.25	-2.51	1.49	-82.34
34	-15.67	-2.26	-3.26	39.12
35	16.8	1.05	0.19	-124.51
36	-10.71	-1.52	-2.04	74.12
37	10.62	0.18	3.88	-293.46
38	6.67	9.67	19.07	85.2
39	14.84	5.7	11.29	-79.76
40	-7.65	-8.38	-18.75	-22.62
41	1.99	0.65	0.33	-15.75
42	4.64	3.58	2.93	-53.71
43	-4.12	-2.7	-5.53	239.33
44	0.13	0.28	3.84	27.42
45	-5.91	0.3	-5.58	69.32
46	23.96	-0.53	-5.05	-23.41
47	23.84	1.73	-2.71	-186.69

Subject	48 CHO (-) 8 CHO 48	Sol	F (-) 8 SolF	48	<b>INSOLF</b> (-) 8 INSOLF	48 chol (-) 8 chol
48	13.64		-3.96		0.34	0.92
49	6.13		-1.74		-0.23	-11.31
50	-0.73		5.91		12.61	57.64
51	4.03		-0.81		-0.37	-115.69
52	-12.39		1.17		-7.76	119.46
53	-8.65		0.32		-12.57	105.97
54	1.13		-6.93		-8.92	56.33
55	17.76		-0.02		6.29	-149.44
56	7.2		1.39		4.08	-96.15
57	3.75		0.35		1.3	54.11
58	1.3		-0.04		2.62	-9.33
59	-12.07		-8.39		-13.11	-120.22
60	-5.14		-1.08		-3.43	87.66
61	-4.65		-2.18		-2.62	72.93
62	4.54		-3.56		-14	-272.12
63	-15.73		-3.81		-6.14	90.92
64	4.01		3.78		2.76	87.42
65	-19.94		-6.69		-8.12	434.43
66	-18.4		-2.05		-3.99	24.1
67	-1.19		-4.08		-5.04	156.45
68	7.93		3.16		0.76	-31.56
69	-4.48		-3.08		-1.26	114.34
70	5.01		1.91		0	-2.5
71	-21.54		-0.62		-1.17	67.21
72	4.79		-18.2		-25.6	-50.01
73	-2.75		1.69		-1.03	-55.3

Subj	ect	48 waist (-) 10 waist	48 abd (-) 10 a	abd 48 hip (-	) 10 hip 48	AHR (-) 10 AHR
	1	-5.5	-	3.5	-8.5	0.05
	2	no data	no data	no a		no data
	3	-U.S		-2	4.5	-0.07
	4 5	-3	1	-4	0.75	-0.04
	6	2.5	1.	.25	2.5	0.04
	7	-35		35	2.5	-0.01
	8	no data	no data	0.0 no d	ete	no data
	ğ	-5	-6	25	-5	-0.01
	10	35	0.	2	75	-0.05
	11	5	-2	25	0	-0.03
	12	6.5	-	3	5.2	-0.02
	13	0		0	0	0
	14	-5		-3	-1	-0.02
	15	-3.75	-7	7.5	-3.75	-0.03
	16	6.75		7	3.5	0.05
	17	0.5		-3	-4	0
	18	no data	no data	no d	ata	no data
	19	-0.5	(	0.5	-1.5	0.01
	20	no data	no data	no d	ata	no data
	21	-2		1.5	3.5	-0.02
	22	8.5		8	10	-0.02
	23	-2.5	-7	7.5	-2.5	-0.06
	24	9.5		3.5	4.5	-0.01
	25	2.5		0	1.25	-0.01
	26	-7.5	-3.	.75	-7.5	0.035
	27	-9.25	-8.	.75	1.8/	-0.06
	28	-1.25		0	-6.25	0.06
	29	-7.5		-5	-2.5	-0.03
	30	9.5	1:	5.5	2	0.12
	31	7.5	-1.	.20	2.0	-0.04
	32	5	4	Z.5 7	3.75 7.75	-0.01
	33	C.4-	no data	-/ no d	ata	no data
	34		no uata	0	3.5	-0.04
	30	-2	-(	0.5	4	-0.04
	30 27	5		2.5	5	-0.02
	20	3 75	-	0	2.5	-0.03
	30	-5	-1.	.25	-2.5	0.01
	⊿∩	55	e	6.5	-0.25	0.06
	_+0 ⊿1	-4 25	1.	.25	0.5	0
	42			0	0	0
	43	0	-2	2.5	0	-0.04
	44	4		-6	-2.5	-0.04
	45	2.5	e	6.5	-2.5	0.08
	46	7.5	1.	.25	1.25	0
	47	2.5	1.	.25	2.5	-0.01

Subject	48 waist (-) 10 waist	48 abd (-) 10 abd	48 hip (-) 10 hip	48 AHR (-) 10 AHR
48	no data	no data	no data	no data
49	0	-2.5	-5	0.02
50	-5	1	-4	0.05
51	2	6	3	0.04
52	-3.25	-4	-2.5	0.003
53	-1.25	-1.25	0	-0.01
54	-4	-5.5	-2	-0.01
55	-2.5	-0.5	-3	0.025
56	5	-2.5	-0.75	-0.02
57	2	3	1	0.02
58	7.5	6	-0.5	0.07
59	1.25	2.5	-1.25	0.04
60	-1.25	-1.25	0	-0.01
61	-5	-2.5	-1.25	-0.01
62	-2.5	-3.75	-3.75	0
63	no data	no data	no data	no data
64	-7.5	-5	-6.247431	0.01
65	0	2.5	-2.5	0.04
66	-7.5	-2.5	-2.5	0
67	-1.5	-0.5	-1	0.03
68	2.5	-1.25	2.5	-0.11
69	1.5	0	0.5	0
70	-2	-5.25	-11	0.06
71	no data	no data	no data	no data
72	-3.75	2.5	-2.5	0.05
73	-7.4	-8	2.5	-0.09