

FACTORS AFFECTING WEIGHT LOSS MAINTENANCE

by

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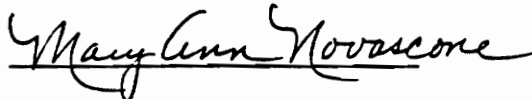
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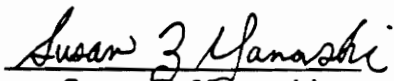
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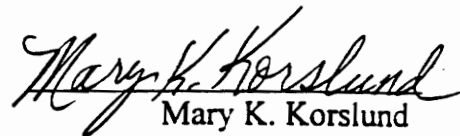
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Maureen Seyford Leser

MaryAnn Novascone, Chair

Human Nutrition, Foods, and Exercise

ABSTRACT

Obesity is one of the most prevalent public health problems, and is widely considered to be refractory to treatment. Inclusion of exercise and behavioral components in treatment programs has increased short term success rates of weight loss efforts, but long term outcome remains poor. Nevertheless, some individuals do maintain weight loss, studies have associated specific behaviors with weight loss maintenance, and practitioners constantly look to research for treatment methods associated with successful weight management. The investigation reported is of an examination of eating, exercise, and social support behaviors in graduates of a six month very low calorie diet research protocol, three years after completing that protocol. Analysis revealed that less weight was regained as fat intake decreased and activity level increased. Correlation between fat intake and regain was statistically significant, with $p = .003$ and $r^2 = 0.301$. Inverse correlation between activity level and regained weight was also significant ($p = .005$ and $r^2 = .275$). Lower energy intake also positively correlated with lower levels of regained weight ($p = .0440$). There was no correlation between social support and weight loss maintenance.

ACKNOWLEDGMENTS

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Special thanks goes to the twenty-six women who participated in this follow-up study. After completing numerous surveys and questionnaires, and being weighed (both underwater and above water), measured, and poked periodically during the original protocol, they readily agreed to complete additional questionnaires and food records for this follow-up study.

Additionally, I would like to thank my husband, Steve, and my daughters, Angela and Christine, for their support and understanding throughout my entire graduate school experience.

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INTRODUCTION

Obesity is the presence of excess body fat. Body weight increases as fat stores accumulate, but weight alone does not confirm obesity because it also includes the weight of skeletal muscle, skeleton, viscera, and remaining tissues. Body composition has traditionally been compartmentalized into Lean Body Mass (LBM), often referred to as Fat Free Mass (FFM), and Body Fat (BF).¹ The average male has 80% fat free mass and 20% body fat, while the average female has 75% fat free mass and 25% body fat.² Obesity is often defined as fat mass greater than 30% in men and greater than 35% in women.²

Indirect methods are typically used to estimate body mass. Since it is assumed that a maximum of one-third of weight gain is lean mass, a 10 to 20% increase above desirable weight standards (for height) has traditionally been used to identify being overweight. Any weight greater than 20% of the desirable standard is considered indicative of obesity.³ Body mass index (BMI), weight in kilograms divided by height (in meters) squared, is a tool increasingly used to evaluate weight. A 1985 NIH conference on obesity recommended that a BMI greater than 27.8 for men and 27.3 for women be used to clinically identify obesity.⁴ These values represent levels greater than the 85th percentile value for BMI at 20-29 years of age.⁵

Some researchers have stratified obesity to further describe degree and incidence.

Wadden and Van Itallie proposed a three tiered classification of obesity⁶ summarized in Table 1.

Table 1: Wadden and Van Itallie's Classification of Obesity⁶

Class	Percentage overweight	Body mass index (BMI)	Prevalence (among obese)
Mild	20-40%	27-30	90%
Moderate	41-100%	30.1-35	9.5%
Severe	>100%	>35	0.5%

Desirable standards used for weight-for-height tables were liberalized in the 1990 US Dietary Guidelines,⁷ following the acceptance of a J or U shaped mortality curve for BMIs from several studies, including the 1979 Build Study.⁸ Unfortunately, the conclusion that someone with a low BMI could have as great a mortality risk as someone with a high BMI suffered from several flaws, including the use of data from individuals with existing disease and from smokers.⁹ Two recent studies, the Nurses Health Study¹⁰ and the Harvard Alumni Study,¹¹ which both confirmed a linear relationship between rising BMIs and mortality, convinced health organizations to revise weight for height standards again. Current US Dietary guidelines¹² advise weight maintenance and designate 19-25 as the “healthy” BMI range for all adults aged 18 and over. These guidelines also eliminate the acceptability of weight gain among Americans in lower

BMI categories (19-20) as they age. They are illustrated in Figure 1 and Table 2.

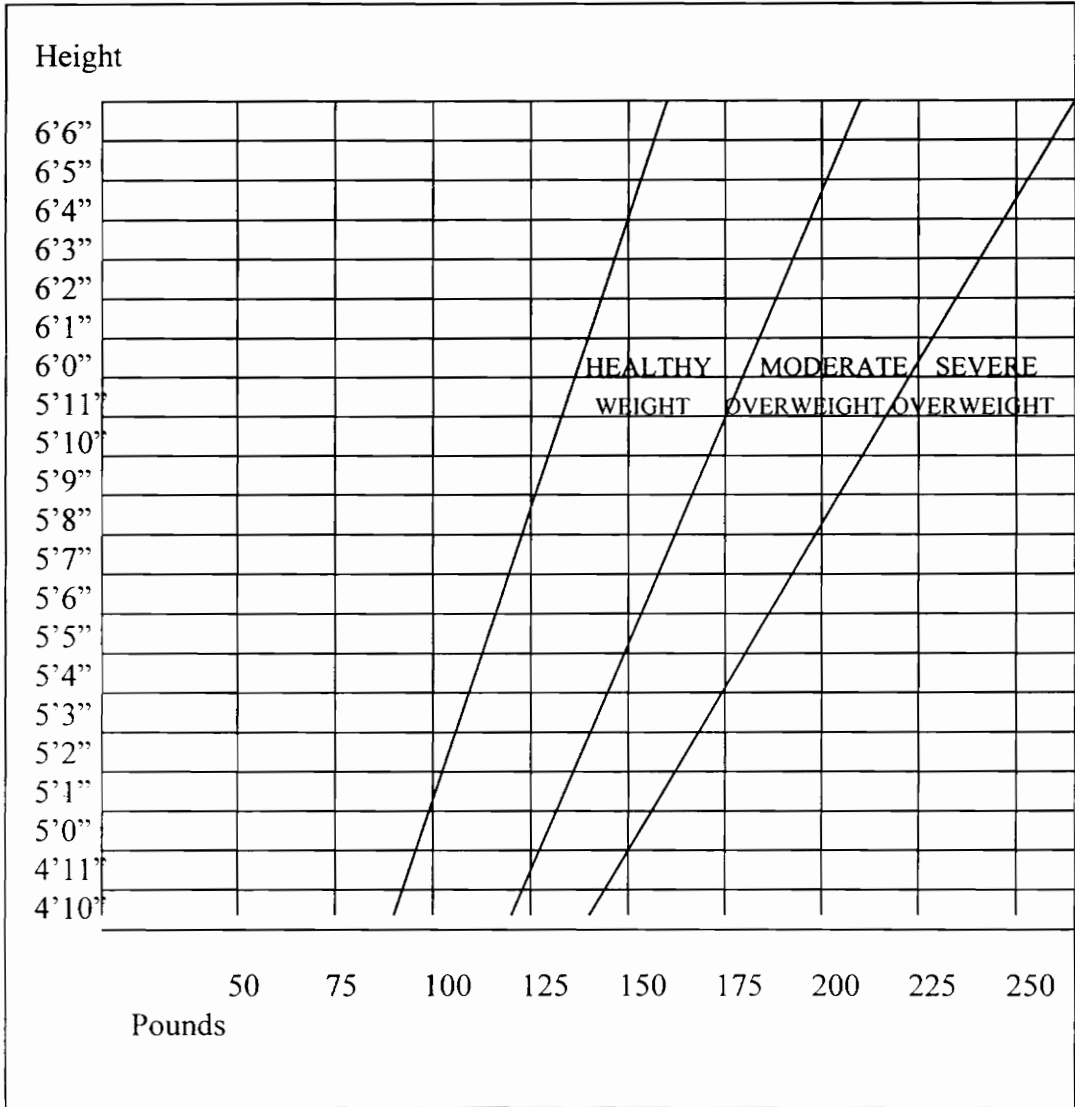


FIGURE 1: ARE YOU OVERWEIGHT ? ¹²

TABLE 2: Healthy Weight Ranges for Men and Women¹²

<u>Height</u>	<u>Weight (in Pounds)</u>
4'10"	91-119
4'11"	94-124
5'0"	97-128
5'1"	101-132
5'2"	104-137
5'3"	107-141
5'4"	111-146
5'5"	114-150
5'6"	118-155
5'7"	121-160
5'8"	125-164
5'9"	129-169
5'10"	132-174
5'11"	136-179
6'0"	140-184
6'1"	144-189
6'2"	148-195
6'3"	152-200
6'4"	156-205
6'5"	160-211
6'6"	164-216

National Health and Nutrition Examination Survey (NHANES III) data from 1988-91¹³ indicate that 33% of adult Americans are obese. This represents an 8% increase in the incidence of obesity since the 1976-80 NHANES II survey.

Obesity has serious health consequences. There is convincing evidence that excess body fat promotes insulin resistance, type II diabetes, hypertension, dyslipidemia, cardiovascular disease, gallstones and cholecystitis, respiratory dysfunction, and certain forms of cancer.¹⁴ The Nurses' Health Study¹⁰ associated excess weight with more than 40% of all disease in US women.

While one would expect concern over those consequences to intensify the pursuit of a healthy weight, concern over possible negative effects of weight cycling and the difficulty associated with weight maintenance has increased the public's skepticism about "dieting".¹⁵ In addition, primary care providers' views of obesity as a disease characterized by a lack of willpower can decrease patients' belief in their ability to succeed.¹⁶

The relapsing nature of obesity has prompted some practitioners to consider more realistic goals. Research indicates that a moderate weight loss of 10% to 15% of body weight may decrease the health risks and medical problems of 90% of obese individuals.¹⁷ Data from the Framingham study¹⁸ further suggests that a 10% reduction in body weight may reduce the risk of developing coronary artery disease by 20%.

Weight is a balance of energy consumed and expended. Total energy expenditure (TEE) includes resting energy expenditure (REE), that energy needed to maintain basic biological processes at rest; thermogenesis, that energy required for food digestion; and non-resting factors, mainly physical activity.¹ Weight loss results from a deficit in calories consumed as compared to those needed for TEE.

Caloric deficits can be achieved by reducing intake or increasing physical activity. A proposed drawback to losing weight through energy restriction is the concern that resting energy expenditure may decline as intake drops, and facilitate easier weight gain following a loss, although there is conflicting evidence to support this concern.¹⁹ Micronutrient intake also decreases as energy restriction increases, leading to possible nutrient deficiencies from un-supplemented low calorie diets.²⁰ Very low calorie diets also increase the risk of depleting visceral protein mass.²¹ In the 1970s, autopsies performed following death from low protein liquid fasts revealed heart muscle atrophy from protein depletion.^{22,23}

Many studies associate exercise with weight loss.^{24,25} Exercise decreases body fat by utilizing larger amounts of consumed or stored energy. Exercise also increases metabolic rate, helping to counteract any negative effect of caloric deprivation on resting metabolic rate (RMR). Studies show that weight loss maintenance consistently benefits from routine exercise.²⁶

Weight loss maintenance can also be influenced by a variety of other factors. Longer treatment programs,²⁷ allow more time to learn new behaviors and have been associated with better outcome. Continuing with a program until the goal weight is reached,²⁸ inclusion of daily breakfast in a usual eating pattern,²⁹ and establishment of low fat eating habits,³⁰ can also improve weight maintenance. Since individuals participating in weight loss programs sometimes score higher on depression index ratings, it is not surprising that some studies indicate a benefit from developing strategies to handle daily stress and “crisis” situations³¹. Some researchers have found that keeping a daily intake log³² can also improve weight loss maintenance.

The purpose of this study was to identify factors supportive of weight loss maintenance in previously overweight individuals, three years after the original loss. Eating, exercise, and social support habits of 26 women who lost weight via a Very Low Calorie Diet (VLCD) three years earlier were analyzed. The hypotheses proposed were that a lower fat intake, indicated by a higher Diet Habit Survey score and estimated from seven day food record analysis; a greater activity level, as indicated by a higher activity score; and social support, indicated by participation in mental health therapy, social support groups, or even a participant’s personal perception of receiving social support, would correlate with a smaller percent of weight regained. These three issues were chosen because weight mechanics are so strongly influenced by fat intake and activity

level, and because lack of support is often mentioned as a cause of relapse.

REVIEW OF LITERATURE

BODY COMPOSITION

Body composition has traditionally been compartmentalized into Lean Body Mass (LBM) or Fat Free Mass (FFM), and Body Fat (BF). Adipose tissue (AT) or total fat (TF) is further broken down into subcutaneous fat (SF) and visceral fat (VF), as shown in Figure 2.¹

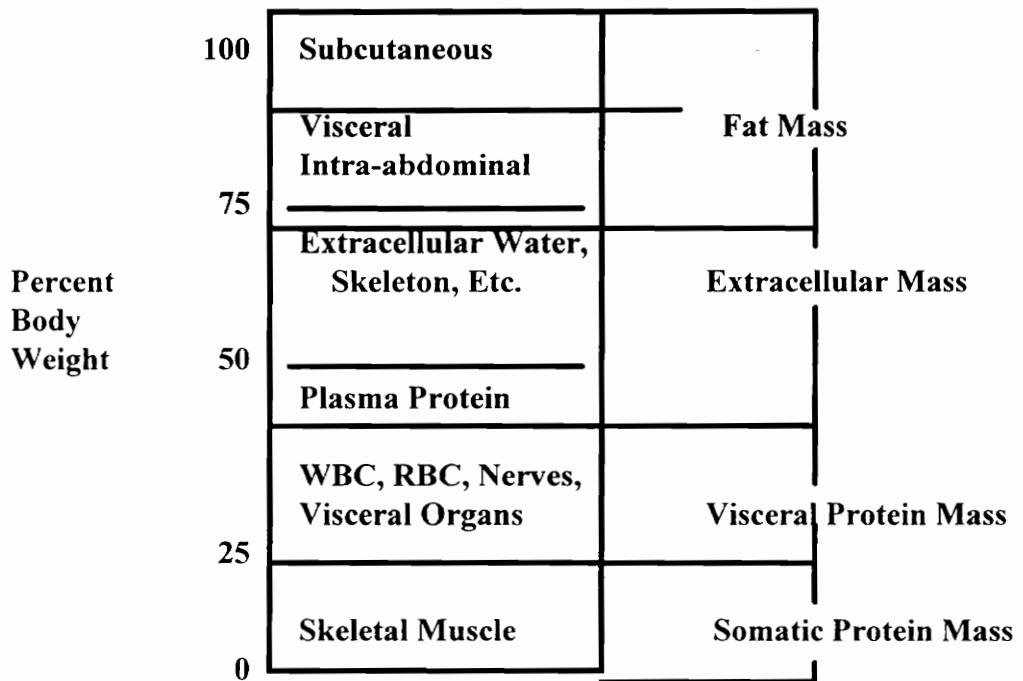


Figure 2: Approximate Body Composition¹

Body composition can be determined indirectly or directly. Indirect methods include

hydrodensitometry, bioelectrical impedance analysis, anthropometric skinfold measurements, water labeled with deuterium oxide, commonly referred to as doubly labeled water (D_2O), and total body potassium (TBK) counting. Direct methods include the measurement of serial multi-scan computed topography (CT scans) and dual-absorption x-ray absorptometry (DEXA).³³⁻³⁶

The concept of body cell mass was developed by Moore³⁷ to identify body tissues that consume oxygen, oxidize glucose, perform work, and are potassium rich. The use of TBK to calculate FFM assumes a constant water and potassium composition. Total body potassium content is determined through isotope exchange or counting the amount of the naturally occurring isotope ^{40}K , which represents 0.0118% of the body's potassium content. From this figure, fat free mass (FFM) or lean body mass (LBM) can be indirectly estimated because potassium is present within the body cell mass in the amount of 64 mmol K^+ per kg FFM for men and 62 mmol K^+ per kg FFM in women.³⁸

Hydrostatic weighing estimates FM from differences in body density. It also assumes a consistent water composition and ratio of bone mineral content to FFM, and involves equations based on differences in body density between FFM and BF. FFM has a density of 1.1 while BF has a density of 0.923.² Following underwater weighing to determine body density, standardized equations are used to calculate the percent body fat.

An increasingly popular method of analyzing body composition is by bioelectrical

impedance analysis (BIA).^{2,39,40} This method estimates FFM based on electrical differences between biological tissues. Measurement is based on Ohm's law, which states that the resistance of a substance is proportional to the voltage drop of an applied current passing through the resistive substance. The greater the drop in voltage, the greater the resistance. Two current introducing electrodes and two voltage sensing electrodes are attached to the body, one of each on the dorsal surface of the right hand and foot. Currents are delivered via the distal introducing electrodes and any voltage drop is detected via the proximal voltage sensing electrodes. Lean body mass has a high water and electrolyte content, making it highly conductive, while fat and bone are poor conductors, and therefore increase resistance. Since electric currents follow the path of least resistance, FFM, with its greater conductivity, has the greatest influence on total body impedance.

While the terms impedance and resistance are often used interchangeably, impedance is really the total of pure resistance and reactance, or opposition to an electric current caused by cell membranes and tissue interfaces. Cell membranes contain both hydrophobic (non-conductive) cores and hydrophilic (conductive) outer layers, thus producing what could be considered intermittent resistance.^{39,40,41}

A single CT scan will directly identify the total fat content of the area scanned. Serial CT scan measurements can be added to define fat content of a larger area. Researchers

have developed a multi-scan method that analyzes 22 serial scans to total the volume of adipose tissue and determine its location.⁴²

Dual-energy x-ray absorptometry (DEXA)⁴³ measurements provide a three compartment assessment of body composition by estimating fat mass, lean body mass, and bone mineral content. It utilizes the different energy absorption capacities of bone and soft tissue to assess body composition. The entire body is scanned, using minimal radiation dose, and measurements obtained for lean tissue mass (LTM), bone mineral content (BMC), and body fat (BF). The percent body fat is then determined through standardized population equations. Normal distribution of body fat and lean mass is summarized in Table 3.

Table 3: Normal and Obese Distribution of Lean and Fat Mass²

	Normal		Obese	
	FFM	FM	FFM	FM
Men	80%	20%	75%	25%
Women	75%	25%	70%	30%

In 1955, doubly labeled water (D₂O) was introduced as a method to estimate total carbon dioxide (CO₂)⁴⁴ production as usually measured by indirect calorimetry. This method uses naturally occurring stable deuterium isotopes of water to assess energy

expenditure, body composition and water flux. It requires only a few blood and urine samples, so is less invasive than many body composition techniques. Water is absorbed so rapidly from the gastrointestinal tract that half of the deuterium steady-state blood concentration is reached within 10-20 minutes. The labeled oxygen is lost from the body in water and carbon dioxide (CO₂), whereas labeled hydrogen is lost only as water. The difference in disappearance rates reflects the CO₂ production and can be used as an index of fat, carbohydrate and protein, oxidation, the three processes that produce CO₂.⁴⁵

OBESITY

Obesity is generally defined as the presence of excess body fat. However, body weight, that measure most commonly used to assess obesity, includes skeletal muscle, bone, and viscera as well as fat. Sjostrom⁴⁶ defined overweight as having increased body weight in relation to height, which could clinically reflect excess fat or muscle.

Overweight and obesity have been categorized differently by researchers. Some consider overweight to represent weight 10% to 20% greater than suggested weight-for-height standards.³ Wadden and Van Itallie⁶ defined obesity as an increase of body fat to 30% or more of body mass in men and 35% in women, usually reflected by a body weight more than 20% above levels recommended in weight-for-height tables.

Body mass index (BMI) is used to evaluate obesity. BMI is a measure of weight adjusted for height and is thought to predict obesity better than weight alone, although its

significance is misleading in the muscular individual. It is thought to be minimally biased by height⁴⁷ and is calculated by dividing weight in kilograms (kg) by height in meters (m) squared. Generally, one BMI unit is equal to about 6.8 pounds (3.00 kg) in males and 5.8 pounds (2.64 kg) in females.

A 1985 NIH consensus conference on obesity⁴⁸ recommended that a BMI greater than 27.8 for men and 27.3 for women be used to clinically identify obesity, the same standards used by the National Center for Health Statistics. These values represent levels greater than the 85th percentile value for BMI at 20-29 years of age, according to NHANES II data.

The major drawback of the BMI is the fact that it does not distinguish between lean mass and fat mass, thereby increasing the possibility of identifying lean but large individuals as obese.

Hortobagyi et al⁴⁹ reviewed the sensitivity and specificity of the Quetelet Index, a standard body mass index, and added data to the proposed drawbacks of using BMI to assess obesity (in Caucasian men and women). After comparing percent body fat from hydrodensitometry to BMI, they concluded that assigning a BMI of 27 as the cut-off point for obesity was only 27% sensitive (likely to indicate a percent body fat greater than 30) and 98% specific (likely to identify normal weight and body fat as such). However, when a BMI cut-off point of 22 was used, sensitivity was 79% and specificity 70%. The

overlap in percent body fat among various BMI ranges that decreased the tool's sensitivity supported concerns that BMI may categorize an obese person as non-obese.

Baumgartner,⁵⁰ pointed out that the sensitivity of BMI decreases with age because older adults have more fat than younger adults at any BMI. Fat free mass decreases with age after about 40 to 50 years of age, and these losses accelerate after 60 years. US national survey data, however, indicate that mean BMIs remain relatively stable, at about 25 to 26, between the ages of 40 and 70 in men and women, suggesting increasing adiposity as a fraction of body weight during the aging process. A BMI >25 always reflects being overweight, but moderately overweight individuals may be heavily muscled or obese while the markedly overweight are almost always obese.

The New Mexico Aging Process Study⁵¹ confirmed a relationship between BMI and percent body fat assessed by DEXA. This relationship is summarized in Table 4.

TABLE 4: Comparison of BMI to percent body fat as measured by DEXA⁵¹

Women (n=185)		Men (n=125)	
BMI	% Body Fat (mean)	BMI	% Body Fat (mean)
≥28.6	47	≥28.5	33.7
26.2-28.6	40.8	25.3-28.4	29.4
24.1-26.2	39.2	23.0-25.2	25.1
<24.1	32.1	<23.0	19.5

These data support the assumption that percent body fat increases with BMI and that BMI is therefore an acceptable tool for identifying obesity. However, the overlap of percent body fat among categories in the New Mexico Aging Study supports the growing concern that BMI may underestimate the risks associated with excess fatness or “obesity” at lower weights. Roche and Siervogel³³ suggested a correlation of 0.7 between BMI and total body fat. Findings of Smalley et al⁴⁷ indicated that a man with a BMI of 27 could have a total body fat ranging from 10% to 31% of body weight, and support the overlap seen in the New Mexico Aging Study.

The Nurses Health Study¹⁰ used an association factor of $r = 0.86$ to relate weight to BMI, and compared BMI to weight percentiles and desirable weight as outlined in TABLE 5.

TABLE 5: Association Between BMI, Weight Percentile, and % Desirable Weight in the Nurses Health Study¹⁰

BMI	Weight Percentile	% Desirable Weight per 1983 Metropolitan Life Insurance Standards
<19.0	0-14	<90%
19-21.9	15-29	90-99%
22.0-24.9	30-54	100-114%
25.0-26.9	55-64	115-119%
27.0-28.9	65-74	120-129%
29.0-31.9	75-89	130-139%
>32.0	90-100	>140%

Wadden and Van Itallie⁶ proposed a three tiered classification of obesity based on data from the National Center for Health Statistics (NHANES II), outlined in Table 6.

TABLE 6: Classification of Obesity from NHANES II Data⁶

Class	% Overweight	Body Mass Index	Prevalence (among obese)
Mild	20-40%	27-30	90%
Moderate	41-100%	30.1-35	9.5%
Severe	>100%	>35	0.5%

Desirable weight-for-height standards were liberalized in 1983 by the Metropolitan Life Insurance Company⁵², and the 1990 USDA guidelines followed their lead by increasing suggested weight standards for adults ages 35 and over.⁷ These changes followed prospective studies indicating a J or U shaped mortality curve for increasing BMI. The Build Study of 1979⁸ studied mortality and weight of 4 million persons from 1954-1972, and found increased mortality at both ends of the BMI spectrum. Data were not controlled for smokers or the presence of sub-clinical disease. Revised ranges of “suggested” BMI standards considered acceptable for individuals over 35 years of age were not originally intended to apply to individuals with other risks for chronic diseases

such as cardiovascular disease, but this qualifier was generally lost in the translation of the 1990 standards.

Unfortunately, the conclusion that someone with a low BMI could have as great a mortality risk as someone with a high BMI suffered from several major biases:

- * Failure to control for existing disease and weight loss secondary to subclinical disease
- * Failure to control for smoking
- * Inappropriate factoring of the biologic effects of obesity such as non-insulin dependent diabetes (NIDDM) and hypertension (HTN)⁹

In recent years, two major prospective reviews have highlighted the inappropriateness of raising the weight standards. After controlling for smoking, the Harvard University Alumni Study¹¹ supported a linear relationship between increasing BMI and mortality.

In addition, a September 1995 “smoking controlled” review of the Nurses Health Study¹⁰ also supported a linear relationship between BMI and mortality. Lowest mortality was seen in women whose weight was 15 % less than the U.S. average and who had maintained a stable weight since early adulthood. These results led health agencies such as the National Institute of Health (NIH) to caution lean individuals (BMI 19-20) against gaining weight as they age.¹²

Due to the association of increased rates of cardiovascular disease and mortality with levels of obesity recently considered “mild”, and the recognized flaws of the studies

prompting the 1990 changes, weight standards were reviewed again. The United States Department of Agriculture's (USDA's) 1995 US Dietary Guidelines recommend that all adults aged 18 years and older maintain a stable weight. In addition, the healthy BMI range for adults > 35 years of age was shifted down from 21-27 to 19-25.¹² An upper limit of 25 was chosen because cardiovascular mortality rates climb steadily above that level. Figure 1 and Table 2 summarize these revised standards (pages 4 and 5).

At any one time, 20 to 40% of adult Americans are trying to lose weight.³ This percent corresponds to the increased prevalence of obesity noted in NHANES III data. (NHANES III - 1988-91) survey data indicate a 33% prevalence of adult obesity in America.¹³ This trend decreases the likelihood that the US will meet the weight goals of Healthy People 2000⁵³, a public health document calling for the reduction in overweight to a prevalence of no more than 20% among people aged 20 and older.

Robinson et al⁵⁴ reported in 1993 that the prevalence of obesity in the United States doubled since 1900.

“Nearly half of women, a fourth of men, and more than two fifths of high school students are dieting to lose weight.”

Twelve percent of men and women between the ages of 21 and 70 have BMIs greater than 30.^{54,55} The mean body weight of US adults has increased by 3.6 kg over the past 15 years.

WEIGHT, MORTALITY AND MORBIDITY

Obesity is recognized as a serious public health problem. Convincing evidence relates excess body fat to diabetes, high blood cholesterol, and hypertension, all of which contribute to our nation's number one cause of death, cardiovascular disease. It is also associated with gallbladder disease and some forms of cancer. Additional consequences include aggravation of orthopedic, pulmonary, and arthritic problems, sleep and digestive disorders, and social and psychological dysfunction.⁵⁶⁻⁵⁹

In the 1940s, women outlived men by 4 years. Today, they outlive men by 7 years, but they also experience a greater incidence of arthritis and degenerative disorders. Since obesity adversely affects both conditions, and increasing numbers of women are in higher BMI categories, morbidity and mortality may be adversely affected. Approximately 32 million women weigh 20 percent more than "desirable" levels.

The Nurses' Health Study¹⁰, a cohort of 121,700 female registered nurses surveyed about their medical history and health behavior, associated being overweight with more than 40% of all disease in US women. While a J or U shaped association of BMI and mortality remained when smokers were included in the analysis, a direct relationship between BMI and mortality was seen when they were excluded. During the period 1980 to 1992, mortality for 'never smokers' was lowest among women whose BMIs were less than 22. The absolute lowest mortality was seen in women whose BMI was <19 (mean

18.7) and whose weight had been stable since early adulthood. Highest mortality was associated with a BMI ≥ 32 (mean 35.8). It was determined that 53 percent of the deaths among women with BMIs > 29 could be attributed to obesity. Cancer mortality among women with body-mass indexes > 29 was twice that of the leanest women, mainly due to high rates of colon, breast, and endometrial cancers, while mortality from cardiovascular disease was four times higher than the leanest women.

These results are in agreement with a recent report from the Framingham offspring Study suggesting that the prevalence of risk factors for cardiovascular disease rise rapidly at body-mass indexes above 20.⁶⁰

As early as 1913, insurance companies correlated obesity with mortality.

Sjostrom⁴⁶ reported in 1993 that all large prospective studies (those with $n > 20,0000$) found that severe obesity (BMI > 35) was associated with a

“twofold increase in total mortality, with a severalfold increase in mortality due to diabetes, cerebro- and cardiovascular disease, and certain forms of cancers.”

The 1984 Norwegian Experience⁶¹ demonstrated a mortality rate two times higher among men and women with BMIs > 31 than subjects of average weight.

Obesity increases biliary secretion of cholesterol, although both cholesterol crystals and cholesterol saturated (lithogenic) bile are required for gallstone formation. While obesity is a strong precursor for gallstone formation, weight loss is associated with

symptoms and cholelithiasis. Weinsier et al⁶² reviewed the literature on weight loss and gallstone formation and concluded that at least four weeks of dieting are required to promote gallstone formation. He concluded that the rate of weight loss explains 98% of the variability in incidence of gallstone formation, with incidence unchanged when weight loss is less than 1.5 kg loss per week.

VISCERAL OBESITY AND INSULIN RESISTANCE

While most clinicians now use BMI to diagnose obesity, there is increasing recognition that the anatomical distribution of body fat may be as important as the total amount of fat.⁶³ Approximately 50% of excess fat is stored subcutaneously, with the remaining fat located in the visceral and muscular component. Baumgartner⁵⁰ goes so far as to suggest that highly centralized fat distribution in individuals with low levels of body fatness may have the greatest health risk.

Body composition data suggest that excess abdominal obesity, estimated by a Waist to Hip Ratio (WHR) greater than 1.0 for men and 0.8 for women, may be a more significant health risk indicator, and therefore a better standard for assessing obesity.⁶⁴ The Iowa Women's Health Study⁶⁵ examined a cohort of 41,837 randomly selected women between the ages of 55 to 69 years. Deaths occurring between 1986 and 1990 (total number of deaths = 1535) were analyzed to compare the associations between BMI, WHR and mortality. A J shaped curve was seen with BMI and mortality, consistent with

curves from data not controlled for subclinical disease and that included individuals with a history of ever smoking, often referred to as “ever smokers”.

On the other hand, even without such adjustments, mortality rates were associated with WHR in a linear fashion. These results contrast with the Nurses Health Study, which showed a strong association between mortality and WHR for deaths from cardiovascular disease but not all causes or cancer. In the Iowa Study⁶⁵, risks of death were more than doubled for the highest WHR quintile as compared to the lowest. In addition, for each 0.15 unit increase in WHR, the relative risk of death increased 1.6 fold. Iowa data revealed an equal relative risk of increasing WHR to mortality for cancer as well as cardiovascular disease.

Women between the ages of 65 - 74 years participating in the NHANES I Epidemiological Follow-Up Study⁶⁶ whose BMIs >29 experienced a 1.5 greater prevalence of coronary heart disease as compared to those with BMIs < 21. However, women with BMIs < 22 had a higher risk compared to those with BMIs between 23 and 24, leading Baumgartner⁵⁰ to question whether incidence of coronary heart disease among elderly women with BMIs < 22 is related to a low LBM and higher fat mass, in particular a centrally distributed fat mass.

WHR is thought to be a better indicator of visceral obesity than BMI, and the health risks of visceral obesity are used to explain the linear mortality risk associated

with increasing WHR. The term android obesity is often used interchangeably with visceral obesity, but more accurately describes anyone with a high WHR.

The metabolic abnormalities and associated health risks described by Reaven as Syndrome X⁶⁷, Kaplan as the deadly quartet⁶⁸, and Matsuzawa et al as Visceral Fat Syndrome⁶⁹ refer to specific endocrine changes commonly seen in people with android obesity, but are clinically associated with visceral obesity. In normal weight subjects, Matsuzawa et al⁶⁹ demonstrated an association between an abnormal metabolic profile and visceral fat, and not age, BMI, subcutaneous fat or the ratio of visceral:subcutaneous fat. This association is summarized in Table 7.

TABLE 7: Association between Visceral Fat and an Abnormal Metabolic Profile⁶⁹

<u>Abnormal</u>	<u>Correlation Coefficient</u>				
	<u>Age</u>	<u>BMI</u>	<u>V.fat</u>	<u>S.fat</u>	<u>V/S</u>
FPG	.08	.20	.43**	.22	.21
TG	.06	.27	.45**	.21	.27
T-Chol	.22	.24	.34*	.27	.13
HDL-Chol	.11	-.03	-.03	.15	-.01

** p<0.01

* p<0.05

(B. fat = total body fat; S. fat = subcutaneous fat; V/S = visceral to subcutaneous fat ratio; FPG = fasting glucose; TG = triglycerides; T-Chol = total cholesterol; HDL-Chol = HDL cholesterol)

They also demonstrated that visceral fat in non-obese subjects with coronary artery disease (CAD) was twice that of control subjects, while BMI and subcutaneous fat area showed no difference⁶⁹. On the other hand, Leibel⁹ argues that since body shape remains the same with weight loss, the degree of adiposity and not the site of fat deposits is most significant, as thin apples do not have medical risks, only fat apples.

Carbohydrates, proteins, and fats are metabolized to glucose. Insulin is required for cells to utilize glucose at the usual rate of 2 mg/kg/minute, and its secretion is increased after eating to maintain glucose level within 70 and 115 mg/dl throughout the day. Insulin regulates glucose metabolism through its influence on three tissues: liver, muscle, and fat. In the liver, insulin inhibits gluconeogenesis and glycogenolysis and promotes glycogen storage. In muscle and fat tissue, insulin stimulates the uptake and use of glucose.

Many researchers believe that the metabolic complications seen in obesity, including diabetes, hypertension, and cardiovascular disease, originate from insulin resistance.

Insulin resistance refers to the inability of insulin to stimulate peripheral glucose utilization

and inhibit hepatic glucose production by the liver.⁷⁰ It is thought that insulin receptor defects decrease the action of insulin in skeletal muscles, leading to compensatory elevation in insulin secretion and, eventually, hyperinsulinemia. Hyperinsulinemia down-regulates and desensitizes insulin receptors, decreasing their ability to stimulate glucose utilization and thereby promoting hyperglycemia.

Inability of normal insulin levels to promote glucose utilization leads to increased serum glucose. Chronic stimulation of the pancreas (to secrete insulin) results in reduced action of the islet cells that produce insulin, leading to type II or non-insulin dependent diabetes. Obesity is present in 70% to 80% of individuals with type II diabetes.⁶ Virtually all patients with diabetes mellitus have some degree of insulin resistance and abnormal glucose homeostasis. This is demonstrated by increased requirements for exogenous insulin and by individuals with endogenous hyperinsulinemia and elevated glucose.⁷¹

Other metabolic aberrations are due to excessive insulin action. Hyperinsulinemia and insulin resistance increase very low density lipoprotein (VLDL) cholesterol levels, thereby increasing the risk of developing atherosclerosis. While the exact etiology of increased VLDL levels is not known, the predominant theory is that elevated insulin levels stimulate hepatic VLDL production and/or inhibit VLDL catabolism. Hyperinsulinemia has been found to correlate with the production rate of VLDL. VLDL₃ particles, which are converted to the atherogenic small dense LDL (LDL₃) particles, are more likely to be formed in individuals with type II diabetes. The dyslipidemia seen in abdominal obesity is similar to the dyslipidemia seen in type II diabetes, with increased concentrations of small VLDL, intermediate density lipoproteins (IDL), small dense LDL particles, and decreased levels of protective HDL₂ cholesterol.^{72,73}

Insulin resistant states are associated with increased catabolic rates of apo A-1, the major apolipoprotein for HDL, and increased levels of hepatic lipase, which can also reduce HDL level. Levels of LDL do not significantly change with insulin resistance unless triglyceride levels are grossly elevated, but the more atherogenic form of LDL (small and dense), predominates.^{72,73} Because type II diabetes and impaired glucose tolerance (without overt diabetes) have similar associations with cardiovascular disease, the additional effect of formally diagnosed diabetes may be minimal.⁷⁴

Obesity is a major risk factor for hypertension. Fifty percent of hypertensives weigh more than recommended, high blood pressure is seen twice as often among young subjects who are overweight as compared to normal weight, and weight loss almost always leads to a reduction in blood pressure. Euglycemic clamp studies indicate that peripheral insulin resistance is present in hypertensives and is associated with reduced glycolysis. Theoretically, hyperinsulinemia may cause the distal nephron to absorb more sodium, thereby expanding Extracellular volume and increasing cardiac output and arterial blood pressure. Hyperinsulinism is also associated with sympathetic stimulation, which increases blood pressure by direct vasoconstriction.⁷⁵ In the Hypertension Prevention Trial⁷⁶, a non-pharmacologic treatment trial, the reduced calorie group experienced the largest net reduction in blood pressure. In addition, the Trial of Antihypertension Intervention and Management⁷⁷ demonstrated that a 4.5 kg weight loss

promoted equal reduction in blood pressure to low dose anti-hypertensive medications. A mean weight loss of 4.7 kg improved the effectiveness of anti-hypertensive drugs.

EXERCISE

Physical activity burns calories, improves insulin utilization, increases resting metabolic rate, has been associated with anorectic side effects, and in many studies has been shown to improve weight maintenance of previously obese subjects.⁷⁸ During prolonged exercise, lipids are mobilized from adipose tissue to supply energy to muscles.⁷⁹ Some studies have suggested that the efficiency of lipolysis can be improved by physical training. Arner⁸⁰ proposed that exercise stimulates catecholamine production, which in turn increases lipid mobilization and lipolysis. He believed that lipid mobilization is further encouraged by the fall in insulin production associated with exercise. In addition to burning calories, physical activity promotes weight loss by preserving muscle mass during the weight loss process. The greater the lean muscle mass, the higher the resting metabolic rate and amount of maintenance calories required daily.

Ewbank et al⁸¹ are among those finding that physical activity predicts weight maintenance. Forty-five subjects who completed a VLCD behavior modification program were divided into calorie expenditure tertiles. The most active group maintained a significantly greater weight loss than the moderate and low activity groups. Calories

burned through exercise predicted weight loss and percent of weight regained. Barlow et al⁸² studied 25,389 men from 1970 to 1989. After an initial preventive medical exam that included measurement of BMI and an exercise treadmill test, participants were followed an average of 8.5 years. Each participant was assigned to a physical fitness category based upon results of the exercise test. The relationship of fitness to mortality in various BMI categories was reviewed, with the authors finding lowest mortality among the higher fitness groups within each BMI strata. The data suggest that fitness is protective in all BMI ranges, and that even overweight individuals benefit from the physiological effects of exercise, such as decreased insulin production and increased insulin sensitivity.

The American Diabetes Association advises that exercise is an important component of the treatment plan for Type I and Type II diabetes.⁸³ They cite weight loss as one of the potential benefits of exercise in type II diabetes, and recommend that an individual perform aerobic activity at 50 to 70% of their maximum oxygen uptake (VO₂ max) for 20 to 45 minutes at least three days per week.⁸³

Americans are trying to lose weight through physical activity as well as through diets. The 1989 Behavioral Risk Factor Surveillance System Survey (BRFSS)⁸⁴ indicated that 60% of men and 62% of women are using activity to lose weight, either alone or combined with dieting. Once again, individuals claiming a higher activity level were leaner. In this telephone survey of 18,682 persons, increasing BMI correlated with lower

activity levels. Interestingly, walking, an exercise often recommended first because of its low risk of injury and low cost, did not correlate with lower BMI. BMI dropped as participation in more vigorous forms of activity increased, with running associated with the lowest BMI levels.

HEALTH BENEFITS OF WEIGHT LOSS

While the social stigma of obesity and the intense desire to be thin motivates most participants in weight loss programs, there is evidence that modest weight loss goals may produce the true benefits of weight loss, improved health.

In 1991 Goldstein¹⁷ reviewed the literature to determine if the health benefits of significant weight loss would be seen with a more modest loss. His 1985-86 record review from the Aberdeen Diabetic Clinic indicated that patients with type II diabetes or impaired glucose tolerance who lost only 1 kg prolonged their survival three to four months. He then proposed the possibility that a 10% weight loss could eliminate the 35% drop in life expectancy associated with the diagnosis of type II diabetes.

A 1974 review of weight changes in the Framingham Study⁸⁵ indicated that a moderate weight loss of 10 to 15% of body weight would decrease the health risks and medical problems in 90% of obese individuals. Framingham data further suggest that a 10% reduction in body weight may correspond to a 20% reduction in the risk of developing coronary artery disease. That significant health benefit could come from a low

to moderate weight loss should not be considered surprising if one looks at Framingham data indicating a 1% increased risk of death per extra pound for ages 30-49 and a 2% increased risk per extra pound for ages 50 to 62.⁸⁵

WEIGHT BALANCE

Weight is the result of the balance between energy consumed and energy expended. Total energy expenditure (TEE) includes resting energy expenditure (REE), thermogenesis and non-resting factors.¹ Contribution of each to TEE is summarized in Table 8.

TABLE 8: Contributions to Energy Expenditure⁸⁶

<u>Energy Factor</u>	<u>Definition</u>	<u>Contribution to TEE</u>
REE	“sleeping” metabolic rate; energy expenditure of wakefulness without physical activity	60-70%
Thermogenesis	thermic effect of food	10%
Non-Resting / Activity Factors	mainly physical activity	20-30%

Body composition has a strong influence on energy expenditure because lean body mass increases metabolic rate, a major determinant of REE. Ravussin and Bogardus⁸⁶ determined that fat-free mass accounted for 80% of 24 hour energy expenditure (24 EE)

variance among individuals. They theorized that the remaining 20% variance is due to undetermined but probably genetic factors, and support the belief that a low metabolic rate may contribute to obesity. However, they also report a discrepancy between actual weight and expected weight, and stress that energy intake is a significant factor in weight balance.

Obesity results from a prolonged imbalance in which energy intake exceeds expenditure. Weight loss results from consuming fewer kilocalories than are needed for TEE. The greater the deficit, the greater the loss, but in theory a deficit of 3200 kilocalories will promote the loss of one pound.⁸⁷

Kilocalorie deficits can be achieved through a smaller energy intake or a greater energy expenditure. One proposed drawback to a lower energy intake is the concern that resting energy expenditure, with its 60% to 70% influence on TEE, is reduced as caloric intake drops. Studies have shown that during Very Low Calorie Diets, when intake typically provide less than 50 % of estimated needs, resting expenditure falls. Leibel et al⁸⁸ found that energy expenditure was 15% below the predicted value for body composition following a 10% or greater weight loss. Though they point out that the efficiency of skeletal muscle may be different at different weights, they also believed that the metabolic changes noted may increase the difficulty of maintaining weight loss. Yanovski⁸⁹ found that BMR rebounds to expected rate for weight following resumption

of normal eating patterns after three months on a Very Low Calorie Diet (unpublished data). Wadden et al⁹⁰ also found that the drop in metabolic rate seen with calorie restriction is not sustained when a calorie maintenance intake is resumed.

Other researchers believe that abnormalities in fuel oxidation have a strong influence on the predisposition to obesity. Schutz⁹¹ investigated the proposition that a low ratio of fat to carbohydrate oxidation, as indicated by a high respiratory quotient (RQ), is predictive for obesity. By combining RQ data with metabolic changes associated with obesity, Schutz developed a diagram relating obesity and fat oxidation, but conceded that current knowledge prevents knowing whether blunted fat oxidation precedes obesity or is secondary to dietary influences, changes in body weight and composition, and genetic factors.

Exercise decreases body fat by converting stored triglycerides in adipose tissue into energy, and increases lean body mass (LBM). A greater LBM increases metabolic rate, helping to counteract any negative effect of calorie deprivation. Aerobic exercise is thought to preserve lean muscle tissue during periods of low caloric intake, although protein intake also influences lean tissue preservation. An intake of 1.5 gram protein/kg ideal body weight (IBW) per day is suggested for preserving muscle mass.⁹² If true, one of the main advantages of exercising while dieting could be its ability to offset the decrease in metabolic rate associated with low caloric intakes. Unfortunately, this benefit

still remains to be confirmed.²⁵ Phinney⁹² suggests a prescription of three hours per week of low-impact sustained activity in the decades that follow diet-induced weight loss.

GENETICS

Bouchard⁹³ estimated that 25% of obesity was genetically linked, but that behavioral and life-style factors influence the development and maintenance of obesity. In Brownell and Rodin's¹⁶ review of dieting, they point to research suggesting that the influence of genetics could be as high as 70% . Studies of twins and adopted children attribute 50% to 80% of adiposity to genetics. Using multivariate genetic modeling techniques, Carmelli et al⁹⁴ reviewed the clustering of hypertension, diabetes, and obesity in adult male twins enrolled in the National Academy of Sciences-National Research Council's twin registry. They found concordance rates of 34.0%, 31.2%, and 32.7% for the joint occurrence of hypertension and diabetes, hypertension and obesity, and diabetes and obesity in identical twins, with significantly lower concordant rates in fraternal twins.

Heritable differences in "set point" have been proposed for explaining weight differences. Leibel⁹ remarked on the stability of weight, given the fact that an adult human "ingests about 214,000 calories per year" and a 5% discrepancy in the balance of intake vs. output could promote a change of 6 kg of adipose tissue per year. He points out that hypothalamic lesions can change body fat content and reflect changes in food intake and energy expenditure. He believed that single gene mutations may be

responsible for alterations in 'set point' or weight regulation.

Rodent models have supported the current belief that obesity is influenced by far more than psycho-social factors. Multiple molecular lesions have been identified that predispose certain strains of rodents toward obesity. Considine, et al⁹⁵ presented evidence regarding an obese (ob) gene expressed exclusively in adipocytes that may influence satiety, although its expression has not been demonstrated in obese humans to date.

Recent investigations into the protein leptin aroused excitement, since obese rodents deficient in this protein show a decreased appetite and intake, increased activity level, and weight loss following leptin infusion. The relevance to humans has not been established, but clinical trials with humans have not yet begun.

There is no doubt that genetics exerts a strong influence on an individual's weight. Nevertheless, the powerful influence of environment on obesity cannot be overlooked. Even if genetics is proven to account for over 50% of the tendency to become obese, a significant influence would remain modifiable.

FAT INTAKE

Dietary fat is associated with taste, pleasure, and obesity. Fat intake is considered one of the most significant, and modifiable, environmental influences on obesity.

Epidemiological studies demonstrate a strong association between fat intake and mean

BMI of populations. A lower fat intake and lower incidence of obesity is seen in countries such as China and Japan, with their traditionally low fat diet. Migration studies show increasing BMI among Japanese immigrants as they adopt a higher fat intake.⁹⁶ In the United States, an increased fat intake paralleled the rise of cardiovascular disease seen in the 1960s. The Nurses Health Study¹⁰ confirmed an association between total fat intake and BMI. Tucker and Kano's cross-sectional study also demonstrated that obese subjects consume more fat than normal weight individuals.⁹⁷

Fat is the most calorie dense macronutrient, with 9 kilocalories per gram as compared to 4 per gram for protein and carbohydrate and 7 kilocalories per gram for alcohol. In addition, fat kilocalories are thought to be more efficiently converted to fat stores than either protein or carbohydrate. Kuller⁹⁸ reported that

“given similar caloric intake, the fat calories are the primary determinant of weight gain and obesity. Increasing carbohydrate or protein calories is not a cause of obesity”.

Sclafani⁹⁹ stated that

“...dietary fat requires less energy to be converted into body fat than does dietary carbohydrate and protein”.

Animal studies add to the association between fat intake and obesity. Salmon and Flatt¹⁰⁰ demonstrated that gradual increases in the fat to energy ratio of ad libitum diets promoted a gradual increase in the body mass and fat mass in mice.

Intervention studies also support the relationship between fat intake and BMI. Lissner

et al¹⁰¹ observed a positive association between dietary fat intake, kilocalorie intake and weight gain during a short term study. When the same group was studied for a longer period (11 weeks), similar results were found. In a feasibility study relating to diet and breast cancer, Sheppard et al¹⁰² observed greater amounts of weight loss in the groups of women on the lowest fat diet.

Not all studies have supported a relationship between fat, kilocalorie intake and weight gain. Jorgensen¹⁰³ examined 7-day food records, food frequency surveys, and weight changes in 2,009 Danish men and women aged 30 to 60 years. Graphical analysis did not indicate an association between fat or energy intake and weight gain over a five year period. The author acknowledged that his results contrast to other studies, such as those by Klesges et al¹⁰⁴ and Heitmann et al¹⁰⁵ that correlated fat intake, energy intake and weight gain.

Astrup et al¹⁰⁶ suggested that the human body's need to guard glycogen stores results in altered fat oxidation during periods of unrestricted food intake, and individuals with a predisposition to obesity exhibit decreased fat oxidation when consuming high fat diets. Their respiratory chamber studies indicated that the obese subjects exhibited a higher ratio of fat to carbohydrate oxidation (lower RQ) at lower fat intakes. Absolute fat oxidation increased as fat mass increased, and was 38% higher in the obese group than the normal weight group. If the work of Flatt et al¹⁰⁷ is accepted, which suggests that a

stable body weight is achieved when dietary fat energy equals oxidative fat energy, individuals with a predisposition to obesity through abnormal fat oxidation will gain weight easier with a high fat diet. For such individuals, a low fat diet would be essential to the maintenance of a normal weight in those individuals.

Much has been written over the past year about NHANES III survey data, which indicate increasing prevalence of obesity while percent fat intake decreased (to 34% of calories).¹⁰⁸ Those questioning the accuracy of the data should consider that the National Center for Health Statistics (NCHS) conducted a thorough review of dietary analysis methods in 1986. Recommendations from their expert committee were incorporated into methodology used during NHANES III.¹⁰⁹ Methodology was more sophisticated, training of interviewers more extensive, and interviews considered more complete than previous NHANES surveys. Data collection was automated to increase the efficiency of the interview and allow for more accurate data collection at the time of the interview. While these changes may have increased the efficiency and accuracy of data collection, they also may have promoted inconsistent data analysis when compared to previous NHANES surveys .

Others question the effect of reduced fat but high sugar foods on body weight. The food industry has invested considerable resources toward developing good tasting reduced fat and nonfat foods, and consumption of these foods is increasing. An analysis

of these foods indicates that lower fat dessert products can be higher in energy content than their traditional version due to their increased sugar content. In addition, many consumers equate kilocalories with fat, and overeat reduced fat foods under the false impression that they are saving kilocalories. Others suggest that the percent fat data is misleading in this case, since total grams of fat intake is similar to NHANES II, and percent decreased due to an increase in total caloric intake.

While genetic studies indicate variable effects of fat intake on weight gain or loss, the caloric density of fat, its associated health consequences, epidemiological and migration studies, and controlled studies supporting the benefits of reduced fat intake on weight loss, support continued recommendation of a low fat diet and research into this area.

RELAPSE AND SOCIAL SUPPORT

The 1990 NIH Conference on Voluntary Methods for Weight Loss¹¹⁰ concluded that one-third of weight lost will most likely be regained within the first year. Conference participants concluded that the rate of regain continues as time elapses, with an estimated 66% regained within two years and 95% within five years. However, Brownell and Rodin¹⁶ state that most data on weight maintenance are from university sponsored clinical trials that have limited follow-up data beyond one year. In addition, the numbers of participants enrolled in these types of studies are small compared to the majority of Americans who attempt weight loss on their own, and may not represent the majority.

Nevertheless, negative publicity about “dieting” have prompted cynicism about the advertisements of “quick” and “easy” solutions claimed by the commercial weight loss industry. Numerous studies have identified strategies that help the formerly overweight individual maintain a loss.

Bjorvell and Rossner¹¹¹ examined obese individuals who had completed a behaviorally based program that included a four year booster follow-up program. Mean weight loss immediately following the program was 12.6 kg, with 10.6 kg of that loss maintained in 72% of the original 68 participants ten years later. The authors believe that their results demonstrate that obese individuals can lose weight and keep it off, an encouraging result but one not always confirmed by other studies or accepted by the public.

Ewbank et al¹¹² examined the association between exercise and weight maintenance two years after weight loss. After dividing their 54 subjects into exercise tertiles, it was found that those in the highest exercise tertile had a lower mean weight than those in the more sedentary tertiles. Average weight loss was twice as great in the most active tertile, and percent of weight regained also was significantly less in the most active tertile. The authors’ data support the theory that the greater the exercise level, the greater the degree of weight loss maintained, a theory also supported by Tremblay et al.¹¹³

In 1991, Daniel Safer¹¹⁴ reviewed 14 studies that indicated a correlation between

continued exercise and weight loss maintenance. In one of the longest follow up studies to date, Colvin and Olson¹¹⁵ noted that 11 of 13 men and 17 of 41 women who maintained a weight loss for 6 years exercised vigorously, defined as greater than 30 minutes at a time, and consistently, defined as 3 to 5 times per week.

Perri et al¹¹⁶ suggested that longer, intense, socially supportive and diverse programs result in greater weight loss. During treatment programs, participants are taught behavioral concepts to deal with situations that trigger overeating, provided support to handle stresses that may lead to overeating, have personal exercise prescriptions developed to increase calories burned in activities of daily living as well as exercise and are taught about low fat eating, cooking, menu selection and meal planning. While every program has drop-outs, the majority of participants thrive on the education and support received, and lose weight.

Goodrick and Foreyt³¹ reported that early relapse studies identify emotional stress as a cause of breakdown of self-control and weight gain. Some, but not all, studies of obese individuals indicate a greater prevalence of depression. Emotional stress could therefore be a significant cause of relapse, underscoring the importance of establishing and maintaining a social support network.

Klesges et al¹⁰⁴ found that although family risk of obesity was a strong and consistent predictor of body mass, higher fat intake was also predictive of body mass. A 5%

increase in fat intake was associated with a body mass increase of about 0.75 kg/m² in women. When both men and women were considered, the most consistent predictor of body mass and weight change was the percent of energy intake from fat.

THE FUTURE OF WEIGHT MANAGEMENT

Studies have demonstrated that the overweight person can lose weight through low fat diets, increased activity levels, vigilant tracking of food intake and weight so that quick lifestyle adjustments can prevent relapse, behavioral strategies, and better management of routine stresses and crisis situations.²⁵⁻²⁹ However, none of these methods works for everyone, and the difficulty of maintaining newly developed habits is evident when one reviews the discouraging rates of relapse.

What is the long term answer, or is there not one answer but many? Perhaps a weight loss program should be selected according to the health and weight profile of the patient, considering not only weight or degree of obesity, but diagnosis of visceral versus gynoid obesity, lipid profile, blood pressure, family history, activity level, eating style, meal schedule, dietary history, binge eating disorder, and psychological factors that may influence food intake.

Researchers are now advising clinicians to consider many issues before making weight loss treatment recommendations. The Institute of Medicine's recently published "Weighing the Options"³ summarizes approaches to obesity treatment and available

programs, and includes suggestions on ‘fitting’ the program to the client. The devastating health effects of obesity and high rates of relapse should prompt clinicians to consider those recommendations to increase their client’s chance of long term weight control.

DIETARY ASSESSMENT

Dietary assessment methods are used to help quantify the intake of individuals in weight and nutrition research studies. They describe and summarize the intake of an individual or group.¹¹⁷ They usually addresses actual, or primary intake but can also address secondary issues that may promote a deficiency or excess. Dietary assessment tools allow the nutrition counselor to accurately consider previous eating habits, the marketplace, advertising, cooking style, and relevant lifestyle habits such as frequency of meals eaten out.

Food frequency questionnaires have been developed to assess intake of specific nutrients without a complete food record.¹¹⁷ Their advantages over a 24 hour recall¹¹⁸ include the ability to capture usual eating habits rather than a sample day’s, which may be atypical. They are also less time consuming than a 24-hour recall.

Critics of this method question its accuracy, as design will determine the data’s validity. As early as the 1940s, frequency questionnaires were used. In the 1960s, JA Heady,¹¹⁹ a British mathematician, documented that frequency was the major determinant of total intake. Willett¹¹⁷ cited a correlation of 0.6 to 0.7 between food frequency

questionnaires currently used and multiple diet records.

What is essential for the success of such studies is the validation of the frequency tool. Questions must reflect exactly what nutrient is being studied. To do that, the author must have a knowledge of dietary sources of that nutrient as well as environmental factors that will influence its intake. A few questions that must be considered include:

- * What does the data bank tell us about the nutrient ?
- * Is the nutrient in question lost during cooking ?
- * Is the nutrient's intake affected by season ?
- * Will the nutrient's intake change between weekdays and weekends ?
- * How is intake of the nutrient affected by eating out ?

Willett¹¹⁷ believed that improvements can most likely be made by adding more items to the frequency questionnaire; subdividing existing items; gathering more detailed information on frequency; and adding further questions on details of specific foods. However, some question whether longer is always better. Pietinen et al¹²⁰ showed similar results with a 44 item questionnaire as a 275 item questionnaire.

A food frequency questionnaire aimed at assessing fat intake must first consider the major food sources of fat. It then must quantify intake of those foods in such a way as to estimate the percent of calories from total fat.

One dietary survey tool aimed at assessing fat intake is the Diet Habit survey¹²¹, which

was developed for the Family Heart Study¹²². This study followed 442 adults from 233 households for five years, during which time they were encouraged to gradually adopt a low fat, high complex carbohydrate diet. Plasma lipid levels were followed throughout the study, and diet assessments made from the Diet Habit Survey were compared to plasma lipid levels throughout the course of the study. The food frequency questionnaire was developed to simplify dietary assessment while still providing accurate data for either research or educational purposes. It was patterned after the Cholesterol Saturated Fat Index (CSI),¹²³ a score based on a mathematical regression equation that highlights the atherogenic potential of food. Questions relating to saturated fat, cholesterol, complex carbohydrate, and dietary fiber are scored and summarized. Final scores are associated with diets of various percents of fat intake.

This frequency questionnaire was designed to identify eating habits for at least the previous month. Diets estimated to follow an average American diet plan at the time of survey (using NHANES II data) were estimated as providing 37% of calories from fat. Increasing scores represented decreasing fat intake

The value of this survey lies in its ability to target specific eating habits that have the most significant affect on fat intake. In addition, it does so in an efficient way, taking only about 30 minutes to complete.

Results from the Family Heart Study¹²² which utilized the Diet Habit Survey indicated

that diet changes that promoted a lower fat intake correlated with parallel drops in plasma cholesterol levels. In particular, as fat intake dropped below 30 percent of calories, cholesterol level decreased. Therefore, changes in plasma cholesterol validated this frequency tool.

ACTIVITY ASSESSMENT

Over the past 20 years, exercise has been added to standard weight loss regimens. Its main benefit is seen during the maintenance phase of weight management.²⁵ Activity accounts for approximately 15-30% of energy expenditure, and can increase basic metabolic rate, which in turn accounts for 60-75% of total expenditure.¹⁰⁴ Phinney⁹² reported that aerobic activity can increase energy expenditure 10 fold over resting metabolic rate in the untrained person.

A few studies have indicated that exercise can influence lean tissue preservation during caloric restriction, but not all studies have supported this finding. Questionnaires are generally used to assess physical activity due to their noninvasive nature, ease of administration, ability to be standardized, and to laboratory results that have allowed researchers to quantify the metabolic effects of various activities. The most common tool used to assess activity is the ratio of work metabolic rate to resting metabolic rate (METs).¹²⁴ This tool allows researchers to quantify energy expenditure in total kilocalories or kilocalories per kilogram body weight for all activities, specific

activities, or activity types. Ainsworth¹²⁴ et al developed a coding system to classify energy costs of physical activities for this purpose.

The validity and reproducibility of such a system was determined using the College Alumnus Questionnaire (PAI-CAQ) by comparing the sum of energy expended in specific activities identified by questionnaire to laboratory measures of cardiorespiratory fitness, body fatness and daily activity records.¹²⁵ Ainsworth¹²⁵ et al found that the correlation between questionnaires and validation criteria were higher for total and heavy-intensity physical activities ($r= 0.34-0.69$) than for lighter intensity activities ($r< 0.35$), indicating less sensitivity for lighter activities.

Paffenbarger al¹²⁶ believed that an epidemiological survey questionnaire can measure energy intake, retention and expenditure when properly designed and administered, and thereby be used to assess physiological fitness and health maintenance.

METHODOLOGY

In the present study, 26 of 38 women enrolled in a six month weight management and research protocol in 1991¹²⁷ were followed to determine factors that facilitated weight maintenance. The original protocol began with a six month weight loss program that provided a VLCD (Optifast 800) for 12 weeks. The formula provided 800 kilocalories, 70 grams (g) protein, 100 g carbohydrate, and 13 g fat daily, as well as 100% of the Recommended Dietary Allowance (RDA) of vitamins and minerals. A fiber supplement was provided, if needed, to maintain regularity. The liquid fast was followed by a six week refeeding phase during which all food groups were gradually introduced. The refeeding phase was then followed by a six week weight stabilization or maintenance period. During this period, participants needing to lose additional weight were counseled on a 1200 kilocalorie diet to promote the additional weight loss, while participants at goal weight were provided with individualized weight maintenance counseling. The original program included behavioral, psychological, exercise, and nutritional components. Each subject's physical health was monitored weekly by a physician. All subjects completed the modified fast, although two subjects dropped out during the refeeding phase.

Prior to participation in the treatment phase of the protocol discussed above, each participant completed an informed consent form allowing analysis of food records,

questionnaires, and laboratory data. These informed consent forms (Appendix I) were approved by the Institutional Review Boards (IRB) of the National Institute of Mental Health (NIMH) and Virginia Tech.

For the follow-up study dietary intake, physical activity, and social support status were assessed and correlated with percent weight regained to identify factors influencing the percent of weight regained three years after completing the six month weight loss phase of the protocol.

The Diet Habit Survey¹²¹ was used in the present study (Appendix II). It was developed in the 1970s by the Oregon Health Sciences University to assess fat and cholesterol intake for the Family Heart Study,¹²² a coronary heart disease prevention project.

Participants of the follow-up study also were asked to record their food intake on standard food record forms (Appendix III) for seven consecutive days. While diet habit survey scores were the primary data used to correlate diet and weight maintenance, energy and percent fat intakes assessed from the food records also were correlated with weight maintenance.

A physical activity questionnaire developed by the research division of Kaiser Permanente (Appendix IV) was used to assess the activity of the women in this study. This questionnaire was developed for women, and includes specific questions relevant to

traditional female roles that often are omitted from general activity questionnaires. Validity testing was completed by the Kaiser Permanente Research Division and communicated per personal correspondence. In this tool, varying scores were assigned to activities based on MET data and frequency of participation. Activity scores were determined by totaling scores for separate activity categories, ranging from activities of daily living to formal exercise programs and sports participation. Total activity scores were then compared to weight status to determine if higher activity levels (indicated by a higher activity score) were positively correlated with a smaller percent of weight regained.

Stress is frequently identified as a risk for relapsed behavior, and behavioral components are now usually included in weight management programs to help the obese individual learn to manage situations that trigger overeating. In this study the relationship between social support and weight maintenance was examined. The type or quality of support was not evaluated, only whether routine consultation health professional (social worker, psychologist, psychiatrist, or “therapist”) frequency of consult, and/or the participants’ personal, subjective sense of receiving the support of friends and/or family correlated with a smaller percent of regained weight.

Data on social support history were derived from a summary questionnaire (Appendix

V) completed by each participant. This questionnaire was used for the follow-up phase of the protocol only. Participants were asked to identify professional support history, and whether or not they believed they received the support of family and/or friends in their weight management efforts. Participants also identified their weighing habits, participation in follow-up weight control programs, and to express in their own words factors they believed influenced their weight loss history since completing the six month weight loss phase of the protocol. These data were analyzed to assess whether those issues contributed to the percent of weight regained, although fat intake, exercise, and social support were expected to be the main determinants of weight maintenance status.

Actual weights were measured during routine follow-up examinations for 23 out of 26 participants. The remaining three participants reported their weight by phone. Participants completed questionnaires approximately three years after completing the treatment phase of this protocol.

The percent of weight regained was calculated by the formula:

$$100 \times \frac{(\text{three year follow-up weight} - \text{weight at end of 6 month weight loss program})}{(\text{original weight} - \text{weight at end of 6 month weight loss program})}$$

Percents of weight regained were then regressed separately against Diet Habit Survey scores, percent fat intake estimated from seven day food records, and activity scores to determine linear relationships. Correlation was confirmed if the relationships formed statistically significant slopes.

RESULTS AND DISCUSSION

Demographic characteristics of the subjects participating in the follow-up phase of the protocol “Binge Eating Disorder Affects Outcome of Comprehensive Very-Low-Calorie Diet Treatment” are shown in Table 9. Of the 38 women participating in the original weight loss protocol, 26 completed the follow-up study. Of the twelve women not participating in follow up, four were lost due to moving without leaving a forwarding address. One original participant died of factors unrelated to the study. One participant completed all questionnaires but declined to return to be weighed and could not be reached to report weight via phone. One participant who did not complete the treatment phase declined to participate in any follow-up, one was unable to participate due to medical reasons, and four who completed the treatment phase declined to complete the surveys and questionnaires. Sixty-eight percent of original participants agreed to continue with the follow-up phase of the protocol.

TABLE 9: Characteristics of Subjects Participating in Follow-Up Study

Number	26
Percent of Original Subjects	68 %
Mean Age in Years (\pm SD)	38 (\pm 7.9)
Mean percent weight regained three years post-treatment (\pm SD)	76 % (\pm 52%)
Range percent weight regained three years post-treatment	-65% to 175 %

Dietary and Activity survey scores are summarized in Table 10.

TABLE 10: Dietary and Activity Scores

<u>Diet Survey Scores:</u>	
Mean (\pm SD)	152 (\pm 29.1)
Range	88 - 220
<u>Food Records:</u>	
Mean Kilocalorie Intake (\pm SD)	1813.6 (\pm) 513.0
Range Kilocalorie Intake	802 - 2667
Mean Percent Fat Intake (\pm SD)	32.3 (\pm 8.0)
Range Percent Fat Intake	6.9 - 44.8
<u>Activity Scores:</u>	
Mean (\pm SD)	63.6 (\pm 11.3)
Range	42.6 - 87.3

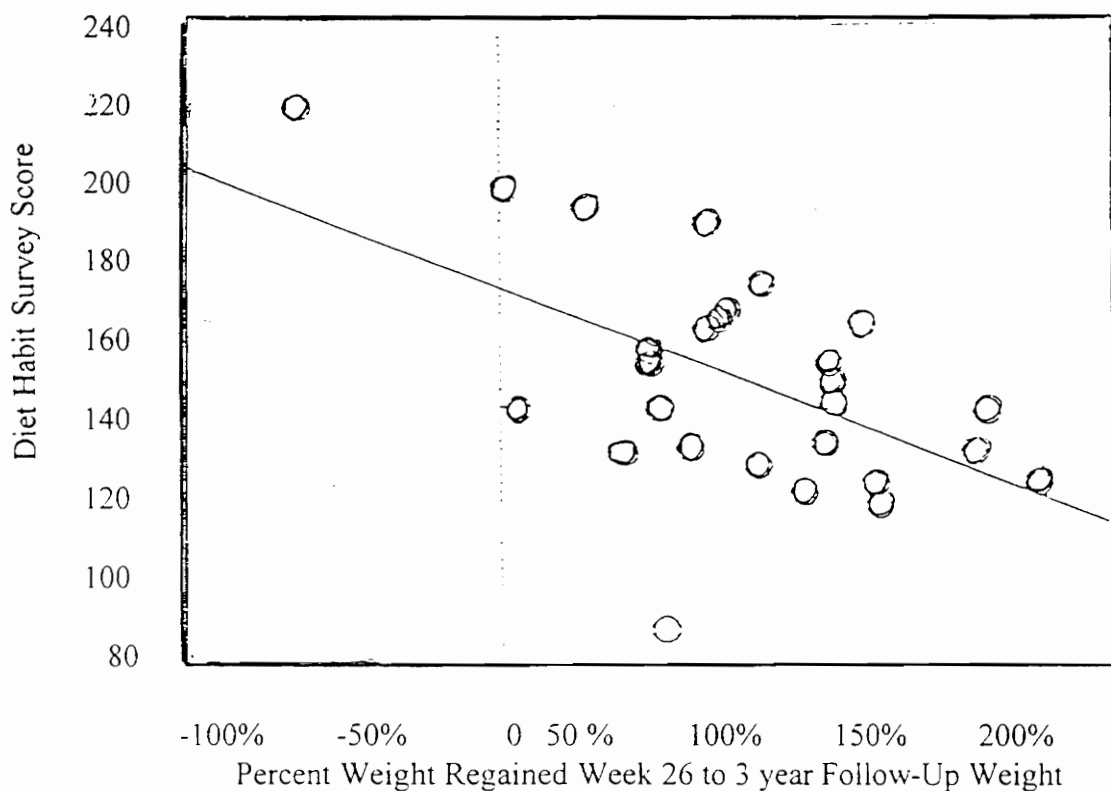
Interpretation of scores from the Diet Habit Survey are given in Table 11.

TABLE 11: Diet Habit Survey Score Standards¹²¹

	Usual American Diet	“New American Diet”		
		I	II	III
Score	127	128-168	169-207	208-242
Fat, % kcalories	40	30	25	20

Diet Habit Survey score decreases as percent fat intake increases.

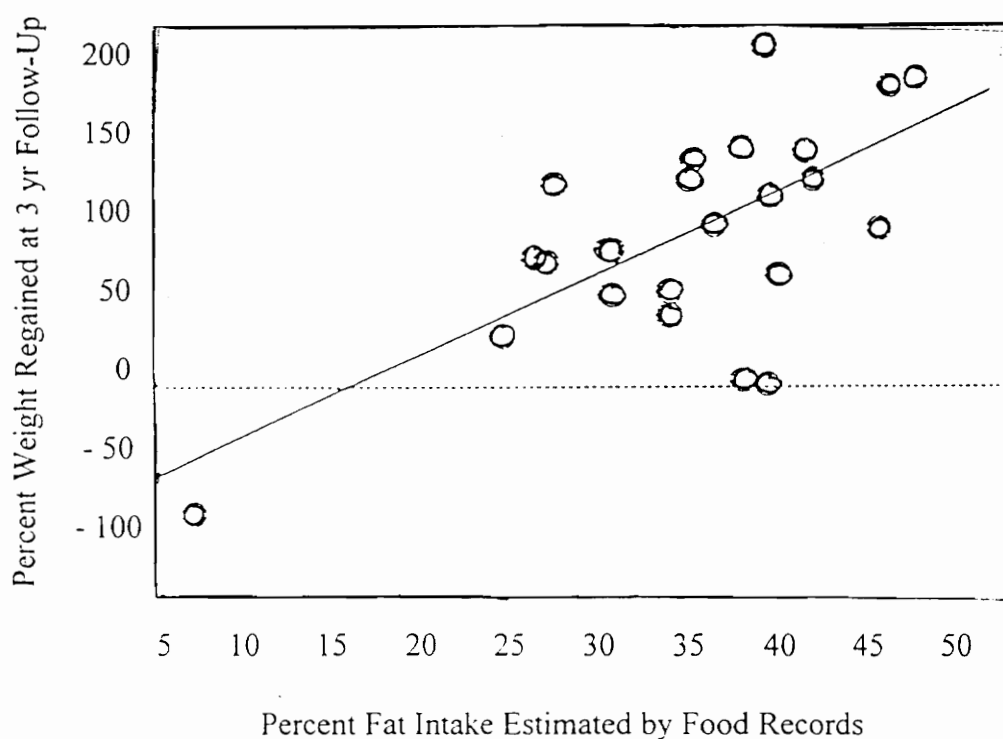
Regression to the mean analysis revealed statistical significance as predicted between percent of fat consumed estimated by the Diet Habit Survey and percent weight regained. As Diet Habits Survey score decreased, indicating an increasing fat intake, percent of weight regained increased. Significance was confirmed by $p = .003$ and $r^2 = .301$. This relationship is graphically displayed in Figure 3.



Regression Equation:
 $Y = 173.67 - 30.084 * X; r^2 = .301$

Figure 3: Relationship of Diet Habit Survey Score to percent weight regained week 26 - 3 year follow-up

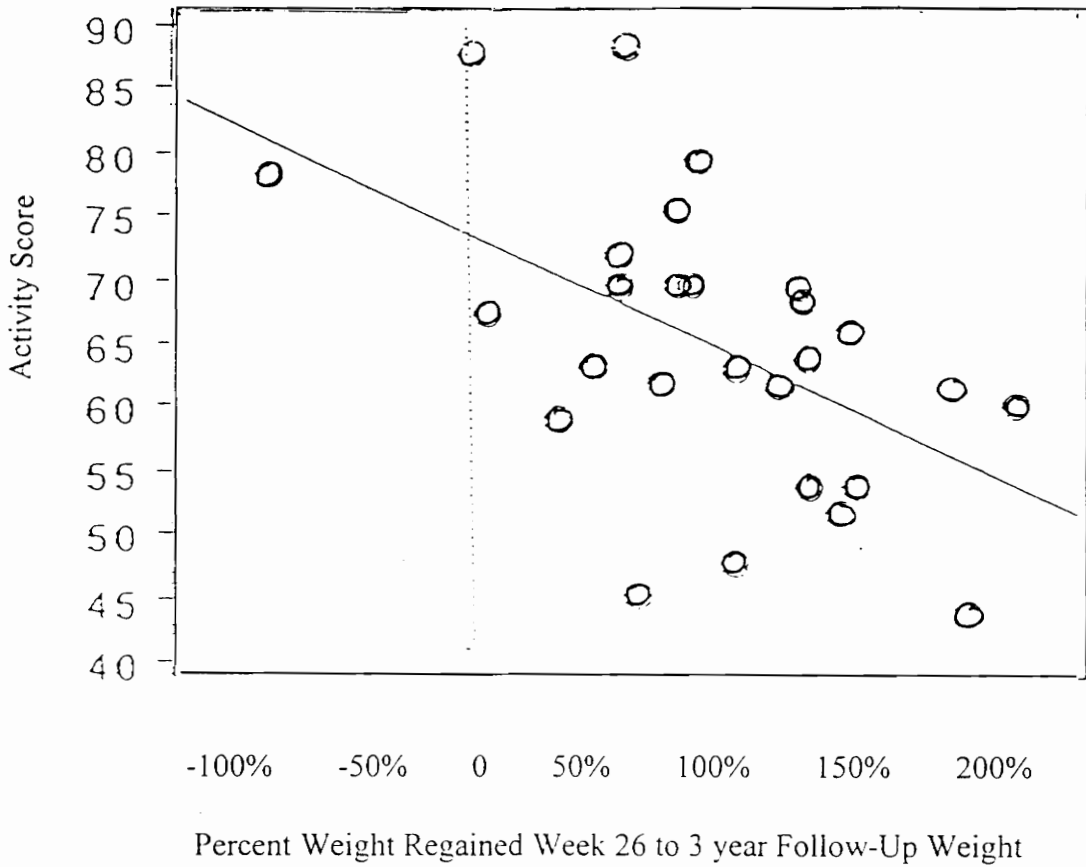
Percent of caloric intake from fat estimated from food records was regressed against the percent of weight regained to determine correlation. Percent of weight regained increased linearly as percent of fat intake estimated from food records increased. Statistical significance was confirmed by $p = .0004$ and $r^2 = .441$. This relationship paralleled the correlation found between percent weight regained and percent fat intake estimated by the Diet Habit Survey score, and is diagrammed in Figure 4.



Regression Equation:
 $Y = -68.353 + 4.478 * X; r^2 = .441$

Figure 4: Relationship of percent of caloric intake from fat (food records) to percent weight regained week 26 - 3 year follow-up

Regression to the mean analysis also revealed statistical significance as predicted between activity level and percent weight regained. As activity survey score decreased, indicating a lower activity level, percent of weight regained increased. Significance was confirmed by $p = .005$ and $r^2 = .275$ and is diagrammed in Figure 5.



Regression Equation:
 $Y = 72.579 - 11.541 * X; r^2 = .275$

Figure 5: Relationship of Activity Score to percent weight regained week 26 - 3 year follow-up

Total caloric intakes estimated from food records were regressed against percent of weight regained to determine correlation. Analysis was completed on data from 24 subjects since food records of 2 subjects contained insufficient data for analysis. Analysis demonstrated significance ($p = .0440$ and $r^2 = .172$) and indicated that a lower energy intake correlated with a smaller percentage of regained weight. The relationship of energy to weight maintenance is diagrammed in Figure 6.

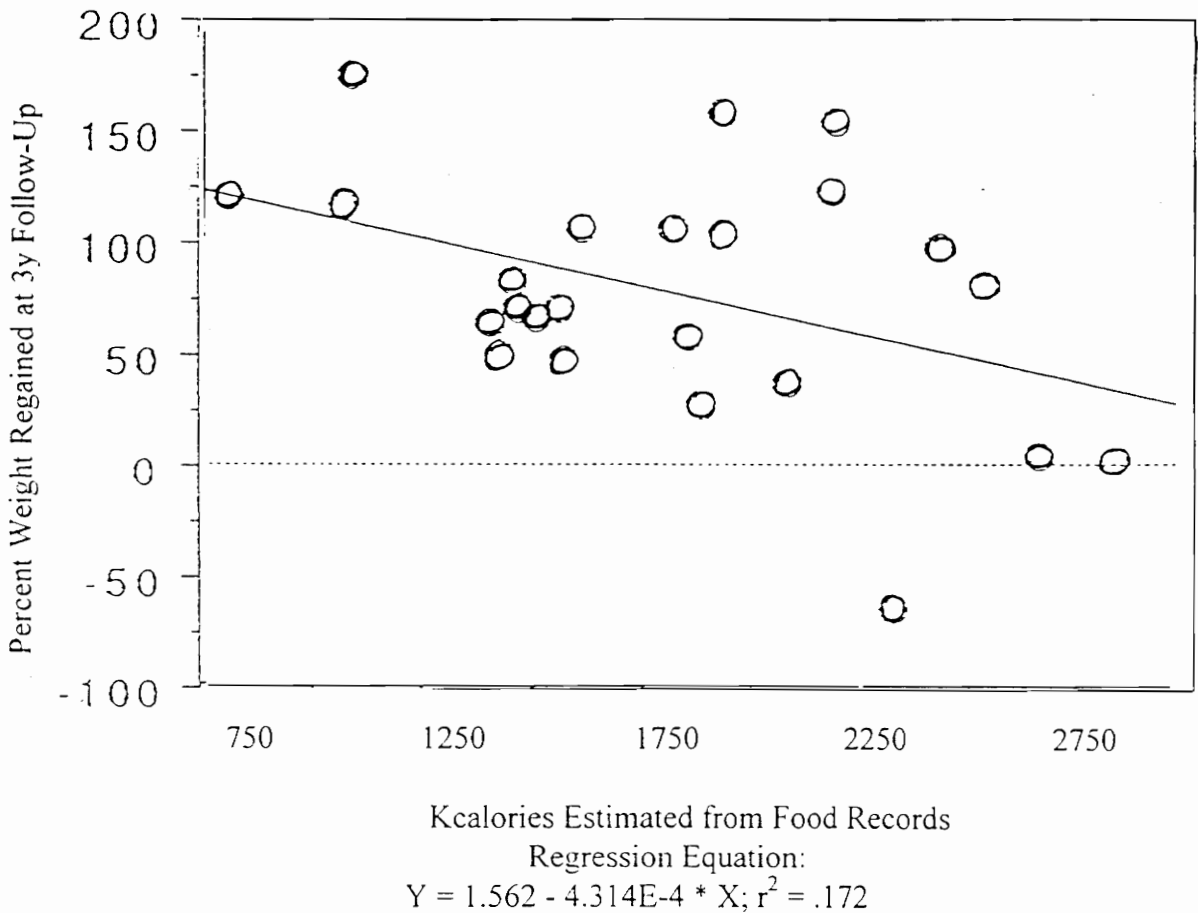


Figure 6: Relationship of Caloric Intake Estimated from Food Records to Percent Weight Regained Week 26 - 3 Year Follow-Up Weight (n=24)

Percent of fat intake estimated from the Diet Habit Survey score and from seven day food records were regressed against each other to determine correlation of the two tools. Analysis revealed a positive correlation between the two, with $p = <.0001$ and $r^2 = .492$. The statistical significance of this correlation confirms the relationship between fat intake and weight maintenance and the ability of a frequency tool such as the Diet Habit Survey to assess fat intake. The relationship between these two tools is diagrammed in figure 7.

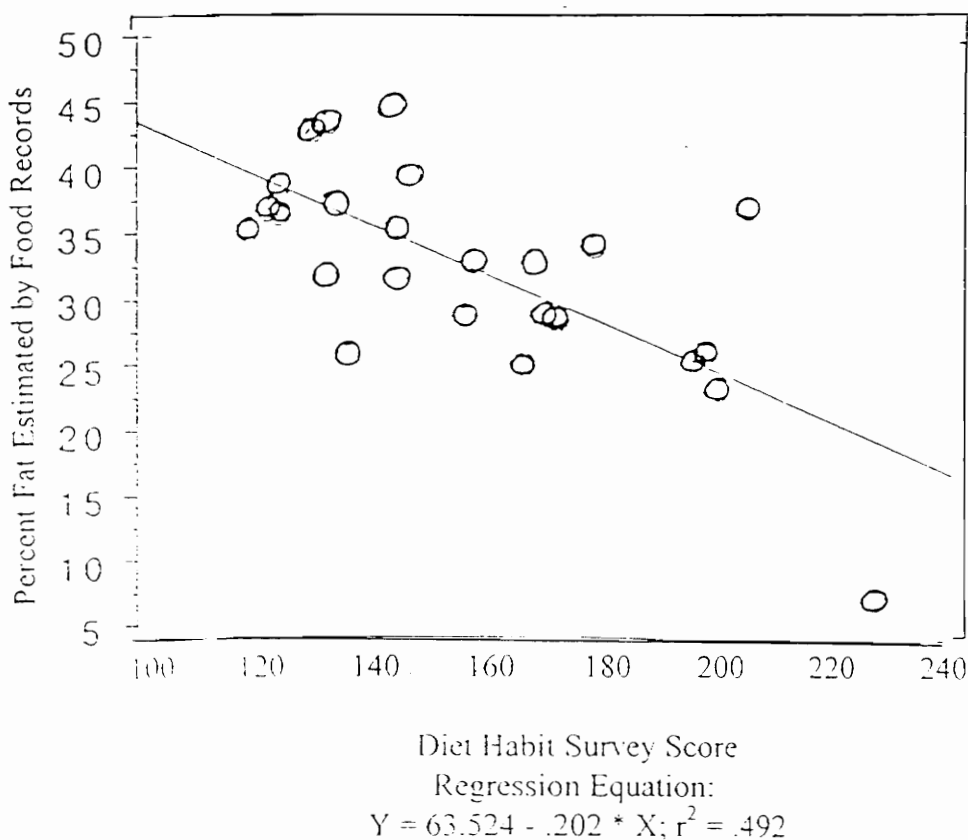


Figure 7: Relationship of Percent of Caloric Intake from Fat Estimated from Food Records to the Diet Habit Survey Score

There was no relationship between energy intake calculated from seven day food records and either percent of kcalories from fat calculated from food records or percent of fat as estimated from the diet habit survey score. This may reflect the inaccuracy of food records, better accuracy from a survey that estimates intake without the participant actually having to record, or admit to, specific eating habits, or a combination of these two phenomena. It also may reflect the effect of low fat and fat free food intake on total caloric intake, since these foods, which often provide more calories than their traditional counterpart, can skew the usual “low fat - low calorie” relationship.

The relationship between percent weight regained and social support was analyzed four ways. Initially, percent weight regained was stratified into percentiles for analysis, as diagrammed in Table 11, which summarizes the percent of weight that was regained at the three year follow-up point in various percentile categories. At the 10th percentile ranking, average percent weight regained was only 9.6 %. At the other end of the percentile rankings, those participants in the 90th percentile ranking regained 147.7 percent of the original weight lost.

TABLE 12

Percentile Ranking of Percent Weight Regained

percentile	percent regained week 26 - 3 year follow-up
10	9.6 %
25	48.0 %
50	71.6 %
75	106.8 %
90	147.7 %

Percentiles were then compared to participation in formal therapy defined as routine consultation with a psychologist, psychiatrist, or psychiatric social worker. The initial analysis did not reveal any association between formal therapy and weight maintenance, although only 5 women participated in such therapy. Analysis indicated that those individuals routinely receiving therapy were not more likely to have maintained a greater percent of weight loss than those who did not. Data regarding participants' (n=10) perception of receiving support from friends and/or family and participation in a weight loss program (n = 12) were then consecutively analyzed, since it is presumed that weight loss programs provide support by their very nature. The n was small, and none of

the analyses showed any significance, whether analyzed alone or when added together. In this study, there was no relationship between social support and weight loss maintenance.

CONCLUSION

Identification of lifestyle habits supportive of weight loss maintenance will provide clinicians with effective treatment tools. This follow-up study of 26 female graduates of a weight loss research protocol found that a lower fat intake, greater activity level, and lower energy intake improved weight loss maintenance three years after completing a six month weight loss protocol, with the most significant relationship being between a lower percent fat intake and/or greater activity level and weight maintenance . These findings are consistent with many published prospective, epidemiological, and survey studies that correlate weight loss maintenance with a reduced fat intake and increased level of exercise. They also correlate with studies utilizing doubly labeled water that indicate a higher energy intake in overweight individuals.

Association between fat intake and weight loss maintenance was strengthened by the fact that two dietary assessment methods, a validated food frequency questionnaire and seven day food records, produced similar results. Both methods assessed percent fat intake, and both methods indicated a positive correlation between decreasing fat intake and increasing percent of weight loss maintenance. These results also confirmed previous validation studies for the Diet Habit Survey, which has been used in research trials and in clinical practice. Published data also support the relationship between higher body weight and higher fat, lower carbohydrate diets.^{128,129}

The present study did not show an additive effect of a low fat diet and greater activity level. While either habit positively correlated with weight loss maintenance, there was not a significant outcome difference between the individual habits or both. This indicates that either approach could benefit weight loss maintenance, and provides clinicians with alternative beneficial treatment options.

The lack of relationship between percent fat intake and caloric intake estimated from the dietary assessment tools used at first seems illogical, since fat is the most concentrated source of calories, making diets high in fat generally high in calories. However, the recent NHANES III survey indicates that weight and calories can increase while fat intake stabilizes or decreases, presumably due to the availability of high calorie but low fat processed foods now marketed, the possibility that overweight individuals may overeat foods labeled “low fat” , and the possibility previously cited regarding potential abnormal fat oxidation in overweight individuals.

The third hypothesis, that social support would also promote weight loss maintenance, did not correlate as expected. While some studies indicate that overweight individuals score higher on depression scale surveys, and lack of support is often identified as a cause for relapsing behaviors, this study indicated that those individuals who eat less fat and calories and exercise more will retain the greatest weight loss, regardless of their support status. This indicates that education on adopting a low fat diet or incorporating exercise

into a lifestyle should be included in all weight management programs, whether or not the need for behavioral/social support appears evident.

This study does not answer why some graduates of a weight loss program were able to continue eating a low fat diet, eat less overall, or exercise while others could not. Social support did not answer that question, because it was not associated with improved outcome. Additional research is needed to determine what strategies support or prevent the adoption of low fat eating habits and routine exercise habits so that clinicians can better focus their treatment.

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APPENDIX I

Consent Forms

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient
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INSTITUTE: NIMH

STUDY NUMBER 91-N-38 PRINCIPAL INVESTIGATOR: Susan E. Yanovski, M.D.

STUDY TITLE: The metabolic rate, hypothalamic-pituitary-adrenal axis, and psychological profile of obese binge-eaters and obese non-binge eaters before and after very low calorie diet

INTRODUCTION

We invite you (or your child) to take part in a research study at the National Institutes of Health. It is important that you read and understand several general principles that apply to all who take part in our studies: (a) taking part in the study is entirely voluntary; (b) personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others; (c) you may withdraw from the study at any time without penalty or loss of any benefits to which you are otherwise entitled. The nature of the study, the risks, inconveniences, discomforts, and other pertinent information about the study are discussed below. You are urged to discuss any questions you have about this study with the staff members who explain it to you.

NATURE OF THE STUDY

The overall goal of this study is to investigate how variations in energy expenditure and certain hormones play a role in regulation of body weight. Specifically, we wish to measure how your metabolic rate, which indicates how fast your body uses up calories, changes during weight loss treatment. We also wish to see how certain hormones, which are related to mood, stress, and metabolic rate, change during the course of weight loss treatment. Corticotropin releasing hormone (CRH) is a hormone produced in the part of the brain called the hypothalamus. CRH causes the pituitary gland, a gland situated at the base of the skull, to secrete adrenocorticotropic hormone (ACTH). ACTH, in turn, causes the adrenal glands to make cortisol. Together, the brain, pituitary, and adrenal glands make up the hypothalamic-pituitary-adrenal axis. Your participation in our study will help us to understand how the hypothalamic-pituitary-adrenal axis changes with weight loss in different groups of overweight people. In addition, the proportion of fat and nonfat components of your body weight, as well as how your body fat is distributed, will be measured to help estimate the caloric cost of weight change. We will also administer psychological tests both before and after treatment, to help to determine the effects of treatment on your mood and thinking. The results of this study may help us to better understand the factors that enable certain overweight people to be able to lose weight or

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
 • Adult Patient or • Parent, for Minor Patient

DICAL RECORD

CONTINUATION SHEET for either:
NIH 2514-1, Consent to Participate In A Clinical Research Study
NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

91-H-38

STUDY NUMBER: _____ CONTINUATION: page 2 of 9 pages.

WHAT WE WANT YOU TO DO

Your participation in this study involves several steps, which are presented schematically on a time line (page 7). You will be sent a packet of materials in the mail, which will include a questionnaire about your medical history, and several questionnaires about your eating patterns and mood. We will also ask you to keep a diet diary for one week, writing down everything you have to eat or drink. All materials in the packet must be filled out and returned to us in order to see if you are eligible for the study.

If you are found to be eligible for the study and are interested in participating, you will be seen at the National Institutes of Health for a review of your general health. You will be provided with a form to be completed by your personal physician and to be brought with you to your first visit to the NIMH. All volunteers will be asked to provide documentation of a pelvic examination and pap smear within the past year prior to your enrollment in the study. Volunteers may not use birth control pills during the study, and we advise you to use an alternative form of birth control, as very low caloric diets may be dangerous in pregnant women. At an outpatient visit at the NIMH, you will receive a complete medical examination by a physician, routine laboratory blood and urine tests, and an electrocardiogram. A research nurse will interview you during your initial clinic visit. You will also be asked to meet with a nutritionist at the time of the outpatient visit and will be instructed in keeping a detailed diet diary, which you will be asked to keep for one week prior to your beginning treatment, and again at the end of treatment.

We will give you urine containers in which to collect all of your urine for 48-hours at home. The nurses in the clinic will instruct you on how this is done. You will be also be given one tablet of dexamethasone, a substance similar to the cortisol produced by your adrenal gland, which you will be asked to take in the evening before you return to the laboratory for an additional blood test. Some of you may be asked to take an additional test, in which you will take one tablet of dexamethasone every six hours for two days, during which time you collect your urine, followed by a repeat blood test. After you have returned for this test, you will be scheduled for a 2-day inpatient admission to the 10-West endocrinology ward for additional studies.

IDENTIFI

CONTINUATION SHEET for either:

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A. 06-75-0099

91-N-33

STUDY NUMBER: _____ CONTINUATION: page 3 of 3 pages.

You will also be asked to meet with a psychologist in his office for the administration of psychological tests. This testing will take several hours. You will do this twice: prior to the start of the weight loss treatment program, and at the conclusion of the program. Some of you may be asked to undergo psychological testing one additional time.

Inpatient hospitalization

Day 1

You will arrive by 5:00 P.M. at the National Institutes of Health to be admitted to the 10-West endocrinology inpatient ward, where you will receive a brief history and physical examination. At some point during your admission, you will be evaluated by a nutritionist, who will measure your body fat by two methods: bioelectrical impedance and body circumference. Measurement of body fat by bioelectrical impedance involves measurement of body impedance or resistance to an electrical current applied through electrocardiogram electrodes placed on your hand and foot. The measurement takes only a few seconds and is not associated with any discomfort. Body circumference measurements will be done with a flexible tape measure and should not cause you any discomfort.

You will be asked to follow a special diet on the day before your admission. You will not have anything to eat or drink after midnight.

Day 2

In the morning, you will be brought by wheelchair to the 3-East Unit for measurement of your resting metabolic rate. You will be asked to rest in bed on 3-East for about one hour before your metabolic rate is determined. Measurement of your body's rate of metabolism takes about 45 minutes. The procedure involves breathing room air through a face mask or in a hood while you are at rest. The face mask is made of clear, soft plastic. The plastic is very pliable and comfortably conforms to your face. After the measurement of your metabolic rate, you will be provided with breakfast. Some of you will be asked to stay for an additional four hours for subsequent measurement of your metabolic rate after eating. If you are scheduled to receive your corticotropin (CRH) stimulation test as an

91-N-33

STUDY NUMBER: _____ CONTINUATION: page 3 of 3 pages.

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STUDY NUMBER: 91-NI-38 CONTINUATION: page 2 of 2 pages.

for this test as an inpatient, your CRH stimulation test will be administered that evening. A small needle will be inserted into a vein of your arm or hand. You will then be given a standard dose of CRH by intravenous injection. CRH causes the pituitary gland to release ACTH. About 20% of people experience some flushing of the face and upper chest which may last for up to 30 minutes. A smaller percentage of people have a metallic taste in their mouths that lasts only a few minutes. We will collect 4 blood samples before and 6 blood samples after the injection of CRH over two hours from the intravenous catheter in your arm. Each blood sample will be about one teaspoon. You will be discharged from the hospital the following morning.

TREATMENT:

One to six weeks after your discharge from the hospital, you will begin a weight-loss treatment program. You will meet weekly, in a group setting, at the NIH with a physician, a psychologist who specializes in eating disorders and a nutritionist. You will be weighed and have your pulse and blood pressure checked weekly, and will have a brief visit with a physician each week to monitor your medical status during the very low calorie diet phase of the study. You will be given an electrocardiogram at least four times during the course of the study, and have blood tests every two weeks while you participate in the very low calorie diet part of the treatment program.

During the first week of treatment, you will follow a 1200 calorie diet. Beginning the second week of treatment, you will be provided with a very low calorie diet (OPTIFAST[®] Program), which you will use to replace all of your meals for twelve weeks. You will also be given a bulk laxative. At the weekly group sessions, you will receive training in behavior modification, a well-established and safe method of helping people to change their eating habits. You will also be provided with education on nutrition and exercise. Most people lose from 1-2% of their total body weight each week during this diet. After twelve weeks on the very low calorie diet, we will gradually introduce new foods over six weeks, while continuing your behavior modification treatment. This will be followed by a six week stabilization period, during which we will focus on helping you to maintain your weight loss. At the conclusion of our weight loss program, we will refer you to an outside program which is free or low-cost so that you can continue treatment if you so desire.

CONTINUATION SHEET for either:

NIH-2514-1 (10-84)

MEDICAL RECORD

CONTINUATION SHEET for either:
NIH 2514-1, Consent to Participate In A Clinical Research Study
NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

91-N-38

STUDY NUMBER: _____ CONTINUATION: page 5 of 6 pages.

One to three weeks before the end of the treatment program, we will repeat some of the psychological tests, body composition measurements, blood tests, and urine tests which were done before beginning the study. You will also be readmitted at that time to the 10-West ward of the Clinical Center for an identical two day admission to that in which you participated before your treatment began.

We will contact you one-month, three months, six months, nine months, and one year after the conclusion of your participation to find out how you have done in maintaining your weight loss.

RISKS AND DISCOMFORTS

Your weight loss treatment program, which consists of a very low calorie diet, behavior modification treatment, and nutrition education, represents standard care for people who are moderately to severely overweight.

Very low calorie diets, such as OPTIFAST[®], are generally recognized as safe and effective when given to properly screened patients under close medical supervision. Serious side effects are rare, but include the possibility of sudden death due to irregular heart beat, mineral and electrolyte abnormalities, wasting of the heart muscle, gout, and gallbladder disease. The well-publicized cases of sudden death attributed to very low calorie diets occurred in patients using older formulations which used protein of poor biologic quality and who did not have adequate medical supervision. We will try to minimize your risk of problems by frequent monitoring of your blood electrolytes and electrocardiogram. Other possible side-effects of very low calorie diets include cold intolerance, headaches, hunger, difficulty concentrating, fatigue, lethargy, bad breath, dry skin, hair loss, low blood pressure, nausea, vomiting, and abdominal discomfort. Patients with pre-existing kidney disease may have their disease made worse by being on this diet. Abnormal menstrual cycles are common in overweight women. Changes may occur in your menstrual cycle as you lose weight, and these changes may be persistent.

CONTINUATION SHEET for either:

NIH-2514-1 (10-84)

MEDICAL RECORD

CONTINUATION SHEET for either:
NIH 2514-1, Consent to Participate In A Clinical Research Study
NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 31-1-38 CONTINUATION: page 5 of 5 pages.

Administration of dexamethasone in the amounts required for your dexamethasone suppression test is usually not associated with any side-effects. Some people may have changes in mood or trouble sleeping during the time they are taking the dexamethasone, but these resolve as soon as they stop taking it.

The hormone CRH will be injected through the heparin lock in the arm vein. CRH has been administered at the NIH and elsewhere to more than 1000 patients and volunteers without any serious effects. About 15-20% of persons receiving CRH describe feeling a hot flash or having a flushed face which lasts no more than 30 minutes. A smaller number of persons describe a metallic taste in their mouths that lasts for only a few minutes. A heparin lock (intravenous catheter) will be placed in one arm or hand before you undergo your CRH-stimulation test. There is a moment of discomfort when the heparin lock is placed in a vein, and you may experience some bruising. The heparin lock will be removed after the test is completed.

The amount of blood drawn per 6-week period will not exceed 1 pint (450 ml), an amount determined safe and routinely taken by blood donation. Blood drawing may cause mild discomfort and bruising. The risk of infection is extremely small.

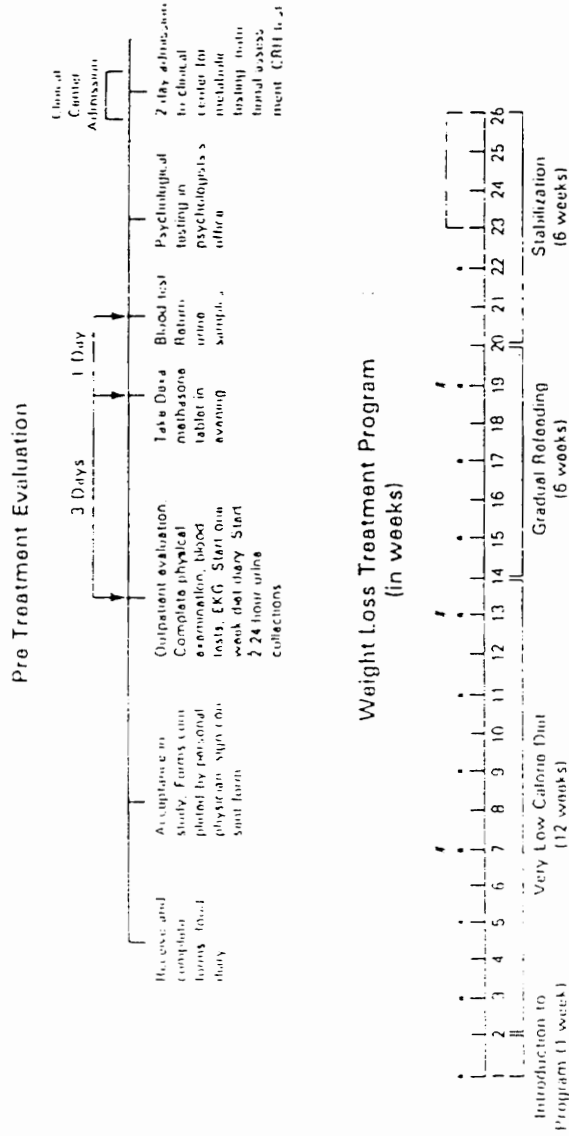
There are no known risks associated with metabolic rate testing. The face mask may feel unnatural and cause you to breathe faster than usual, but this usually disappears after you get used to the apparatus. There are no known risks and only minimal inconvenience associated with measurement of body fat by bioelectric impedance and body circumference with a tape measure. Behavior modification treatment of obesity and nutrition education present no known risks. Collection of urine samples for 48 hours may cause you minimal inconvenience. The psychological tests carry no risk, but may cause inconvenience because of the time required for testing.

CONTINUATION SHEET for either:

NIH 2514-1 (10-84)

STUDY NUMBER: 91-1-33 CONTINUATION: page 7 of 7 pages.

NIMH OBESITY STUDY: Time Line



7

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient	Continuation of Page <u> </u> of <u> </u> pages
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STUDY NUMBER: _____

OTHER PERTINENT INFORMATION

- Confidentiality. When results of a study such as this are reported in medical journals or at meetings, the identification of those taking part is withheld. Medical records of Clinical Center patients are maintained according to current legal requirements, and are made available for review, as required by the Food and Drug Administration or other authorized users, only under the guidelines established by the Federal Privacy Act.
- Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any physical injury resulting from your participation in research here. Neither the Clinical Center nor the Federal government will provide long-term medical care or financial compensation for such injuries, except as may be provided through whatever remedies are normally available under law.
- Payments. You will not be paid for taking part in this study. The Clinical Center does not charge for medications, doctors' care or hospitalization. Exceptions for Normal Volunteers are guided by Clinical Center and Normal Volunteer Office policies.
- Problems or Questions. Should any problem or question arise with regard to this study, with regard to your rights as a participant in clinical research, or with regard to any research-related injury, you should contact the principal investigator, Susan Z. Yanovski, M.D., or these other staff members also involved in this study, Harry E. Gwirtsman, M.D., Phillip Gold, M.D., George Chrousos M.D.
 Building 10, Room 3S221. Telephone: (301) 496-1891.
 National Institutes of Health
 Bethesda, Maryland 20205
- Consent Document. It is suggested that you retain a copy of this document for your later reference and personal records.

COMPLETE APPROPRIATE ITEM BELOW, A or B:

A. Adult Patient's Consent.
 I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

 Signature of Adult Patient & Date Signed

B. Parent's Permission for Minor Patient.
 I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
 (Attach NIH 2514-2, Minor's Assent, if applicable.)

 Signature of Parent(s) & Date Signed

If other than parent, specify relationship:

 Signature of Investigator & Date Signed

 Signature of Witness & Date Signed

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
 • Adult Patient or • Parent, for Minor Patient

NIH-2514-1 6-82

F A 1 25-15-0099

CERTIFICATION OF EXEMPTION OF PROJECTS INVOLVING HUMAN SUBJECTS

74-161
HNF
Committee
Reviews

Principal Investigator(s): Maurice S. Lest, R.D.

MaryAnn Neesevic
Mary K. Erickson

Department(s): HNF

Project Title: Life style Habits Which Support weight loss maintenance

Source of Support: Department Research Sponsored Research _____ Proposal No. _____

The criteria for "exemption" from review by the IRB for a project involving the use of human subjects and with no risk to the subjects are listed below. Please initial all applicable conditions and provide the substantiating statement of principal.

- a. The research will be conducted in established or commonly established educational settings, including normal education practices. For example:
 - 1) Research on regular and special education instructional strategies;
 - 2) Research on effectiveness of instructional techniques, curricula or classroom management techniques;
- b. The research involves use of education tests (cognitive, diagnostic, aptitude, achievement) and the subject cannot be identified directly or through identifiers with the information.
- c. The research involves survey or interview procedures, in which:
 - 1) Subjects cannot be identified directly or through identifiers with the information;
 - 2) Subjects responses, if known, will not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
 - 3) The research does not deal with sensitive aspects of subject's own behavior (illegal conduct, drug use, sexual behavior or alcohol use);
 - 4) The research involves survey or interview procedures with elected or appointed public officials or candidates for public office.
- d. The research involves the observation of public behavior, in which:
 - 1) The subjects cannot be identified directly or through identifiers;
 - 2) The observations recorded about an individual could not put the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
 - 3) The research does not deal with sensitive aspects of the subject's behavior (illegal conduct, drug use, sexual behavior or use of alcohol);
- e. The research involves collection or study of existing data, documents, recording pathological specimens or diagnostic specimens, in which:
 - 1) The sources are publicly available, or
 - 2) The information is recorded such that the subject cannot be identified directly or indirectly through identifiers.

Exemption criteria does not apply if the project will not be changed to increase the risk or extent (exempt conditions) without filing an additional application for approval for use by the Human Subjects Review Board.

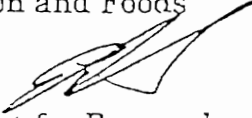
IRB approval is required in any case at risk while this project is underway. The chairman of IRB should be notified immediately in order to take appropriate action.


Principal Investigator(s) Maurice S. Lest, R.D. Date 4/30/97

Principal Investigator(s) MaryAnn Neesevic Date 4/16/97

MEMORANDUM

TO: Maureen S. Leser, Mary Ann Novascone and Mary Korslund
Human Nutrition and Foods

FROM: Ernest R. Stout 
Associate Provost for Research

DATE: June 6, 1994 

SUBJECT: IRB EXEMPTION/"Lifestyle Habits Which Support Weight Loss
Maintenance"
Ref. 94-161

I have reviewed your request to the IRB for exemption for the above referenced project. I concur with Dr. Johnson that the research fall within the exempt status.

Best wishes.

ERS/php

c: Dr. Johnson

APPENDIX II
Diet Habit Survey

OREGON HEALTH SCIENCES UNIVERSITY LIPID CLINIC

THE DIET HABIT SURVEY
(A Quiz to Determine Your Diet Composition)

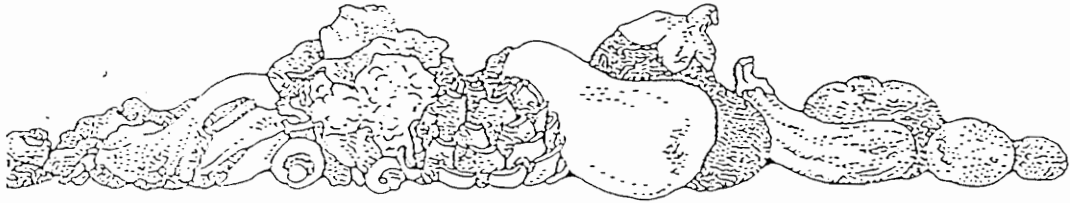
Directions: For each question, circle the numbers or fill in the blanks to the left of the choices that best describe your eating habits during the last month. YOU MAY SELECT MORE THAN ONE CHOICE FOR A QUESTION.

Bring the completed quiz to your Lipid Clinic appointment. A dietitian will:

- 1) Score the quiz and compute your diet composition
- 2) Estimate how much you can lower your blood cholesterol level by diet
- 3) Provide you with low-fat product information and recipes

Patient's Name

Date



Developed by the Lipid-Atherosclerosis Nutrition Staff
Section of Clinical Nutrition and Lipid Metabolism
Department of Medicine
The Oregon Health Sciences University - L465
Portland, Oregon 97201-3098

MEAT, FISH AND POULTRY

each question, circle as many numbers as apply.

Which type of ground beef do you usually eat?

- 1 Regular hamburger (30% fat)
- 2 Lean ground beef (25% fat)
- 3 Extra lean/ground chuck (20% fat)
- 4 Super lean/ground round (15% fat)
- 5 Ground sirloin (10% fat) or eat no ground beef

Score _____

Which best describes your typical lunch?

- 1 Cheeseburger, typical cheeses, egg dishes (egg salad, quiche, etc.)
- 2 Sandwiches (lunch meat, hot dog, hamburger, fried fish, etc.) or entree of meat or chicken (plain or fried)
- 3 Tuna sandwich, fish entree (not fried), entree with small bits of chicken or meat in a soup or casserole
- 4 Peanut butter sandwich, tuna sandwich with fat-free mayonnaise
- 5 Salad, yogurt, cottage cheese, vegetarian dishes (without high-fat cheeses or egg yolk)

Score _____

Circle all of the choices that reflect the entree at your main meal.

- 1 Cheese (Cheddar, Jack, etc.), eggs, liver, heart or brains once a week or more
- 2 Beef, lamb, pork or ham once a week or more
- 3 Very lean red meat (top round or flank steak), veal, venison, or elk once a week or more
- 4 Chicken, turkey, rabbit, crab, lobster or shrimp twice a week or more
- 5 Fish, scallops, oysters, clams, or meatless dishes containing no egg yolk or high fat cheese twice a week or more

Score _____

Estimate the number of ounces of meat, cheese, fish and poultry you eat in a typical day. Include all meals and snacks.

To guide you in your estimate:

4 strips bacon	= 1 oz	1 chicken thigh	= 2-3 oz
1 small burger patty	= 3-4 oz	½ chicken breast	= 3 oz
meat in most sandwiches	= 2-3 oz	1 average T-bone steak	= 8 oz
1 slice cheese	= 1 oz	1-inch cube cheese	= 1 oz

- 1 Eleven or more ounces a day
- 2 Nine to 10 ounces a day
- 3 Six to 8 ounces a day
- 4 Four to 5 ounces a day
- 5 Not more than 1 ounce of cheese, or 3 ounces of red meat, poultry, shrimp, crab, or lobster, or not more than 6 ounces of fish, clams, oysters, scallops a day

Score _____

Which of these have you eaten in the past month?

- 1 Bacon, sausage, bologna and other lunch meats, pepperoni, beef or pork wieners
- 2 Canadian bacon, turkey wieners
- 3 Turkey ham and other poultry lunch meats
- 4 Soy products (breakfast links)
- 5 None

Score _____

TOTAL SCORE (MEAT, FISH AND POULTRY) _____

DAIRY PRODUCTS AND EGGS

Each question, circle as many numbers as apply.

Which kind of milk do you usually use for drinking or cooking?

- 1 Whole milk
- 2 Two percent milk
- 3 One percent milk, buttermilk
- 4 Skim milk, nonfat dry milk or none

Score _____

Which toppings do you use?

- 1 Sour cream (real or imitation including IMO), whipped cream
- 2 Light sour cream
- 3 Nondairy toppings (Cool Whip or Dream Whip)
- 4 Regular cottage cheese, whole milk yogurt
- 5 Low-fat cottage cheese, nonfat or low-fat yogurt or none

Score _____

Which frozen desserts are you most likely to eat at least once a month?

- 1 Ice Cream
- 2 Ice milk, most soft ice cream, Tofutti, Frozen yogurt (cream added)
- 3 Sherbet, Low-fat frozen yogurt, Lite Lite Tofutti
- 4 Nonfat frozen yogurt, Sorbets, Ices, Popsicles, or none

Score _____

Which kind of cheese do you use for snacks or sandwiches?

- 1 Cheddar, Swiss, Jack, Brie, feta, American, cream cheese, regular cheese slices or cheese spreads
- 2 Part-skim mozzarella, Lappi, light cream cheese or Neufchatel, part-skim Cheddar (Kraft Light, Groca River, Olympia's Low Fat or Heidi Ann Low-Fat Ched-Style Cheese)
- 3 Low-cholesterol "filled" cheese (Scandic Mini Chol, Hickory Farms Lyte or imitation Mozzarella)
- 4 No cheese, fat-free cheese, Lite part-skim Mozzarella, Low-fat Ricotta, Reduced Calories Laughing Cow, Dorman's Light, Weight Watchers or the Lite-line series of cheeses

Score _____

Which kind of cheese do you use in cooking (casseroles, vegetables, etc.)?

- 1 Cheddar, Swiss, Jack, Brie, feta, American, cream cheese, processed cheese
- 2 Part-skim mozzarella, Lappi, light cream cheese, part-skim Cheddar, (Groca River, Olympia's Low Fat, Kraft Light or Heidi Ann Low-Fat Ched-Style Cheese)
- 3 Low-cholesterol "filled" cheese (Scandic Mini Chol, Hickory Farms Lyte or imitation Mozzarella)
- 4 No cheese, fat-free cheese, Lite part-skim Mozzarella, Low-fat Ricotta, Dorman's Light, Weight Watchers or the Lite-line series of cheeses

Score _____

Check the type and number of "visible" eggs you eat.

- 1 Six or more whole eggs a week
- 2 Three to five whole eggs a week
- 3 One to two whole eggs a week
- 4 One whole egg a month
- 5 Egg white, egg substitute such as Egg Beaters, Scramblers, Second Nature, or none

Score _____

Check the type of eggs usually used in food prepared at home or bought in grocery stores (baked goods, such as cakes and cookies, potato and pasta salads, pancakes, etc.)

- 1 Whole eggs or mixes containing whole eggs (complete pancake mix, slice-and-bake cookies, etc.)
- 2 Combination of egg white, egg substitute, and whole egg
- 3 Egg white, egg substitute or none

Score _____

TOTAL SCORE (DAIRY PRODUCTS AND EGGS) _____

FATS AND OILS

Each question, circle as many numbers as apply.

Which kinds of fats are used most often to cook your food (vegetables, meats, etc.)?

- 1 Butter, shortening (all brands except Crisco or Fluffo) or lard, bacon grease, chicken fat or fat in restaurants at least 4 times a week
- 2 Soft shortening (Crisco or Fluffo) or inexpensive stick margarine (remains hard at room temperature)
- 3 Tub or soft-stick margarine, vegetable oil (including olive oil)
- 4 None or use nonstick pan or spray

-Score _____

How much of these "added" fats do you eat in the typical day: peanut butter, margarine, mayonnaise, or salad dressing (including those made with olive oil)?

Examples of amounts people often use:

<i>on toast</i>	<i>2 tsp. margarine</i>	<i>on salads</i>	<i>12 tsp. salad dressing (do not include low cal or fat free dressing)</i>
<i>on sandwiches</i>	<i>6 tsp. mayonnaise 6 tsp. peanut butter 2 tsp. margarine</i>	<i>on potatoes, vegetables pasta, rice</i>	<i>3 tsp. margarine</i>

- 1 Ten teaspoons or more
- 2 Eight to 9 teaspoons
- 3 Six to 7 teaspoons
- 4 Four to 5 teaspoons
- 5 Three teaspoons or less

Score _____

How often do you eat potato chips, corn or tortilla chips, fried chicken, fish sticks, French fries, doughnuts, other fried foods, croissants or Danish pastries?

- 1 Two or more times a day
- 2 Once a day
- 3 Two to 4 times a week
- 4 Once a week
- 5 Less than twice a month

Score _____

Which best describes the amount of margarine, peanut butter, mayonnaise, or cream cheese that you put on breads, muffins, bagels, etc.?

- 1 Average (1 teaspoon or more per serving)
- 2 Lightly spread (can see through it)
- 3 "Scrape" (can barely see it)
- 4 None

Score _____

Which kind of salad dressings do you use?

- 1 Real mayonnaise
- 2 Miracle Whip, Ranch, French, Roquefort, blue cheese, and vinegar and oil dressings
- 3 Light mayonnaise, Miracle Whip Light, Thousand Island dressing
- 4 Russian and Italian dressings, Ranch Salad Dressing made with buttermilk and light mayonnaise or Miracle Whip Light
- 5 Fat-free (mayonnaise, Miracle Whip or salad dressing), low-calorie dressing, vinegar, lemon juice, Ranch Dressing made with buttermilk and low fat yogurt or use no salad dressing

Score _____

TOTAL SCORE (FATS AND OILS) _____

SWEETS AND SNACKS

Each question, circle as many numbers as apply.

How often do you eat dessert or baked goods (sweet rolls, doughnuts, cookies, cakes, etc.)?

- Three or more times a day
- Two times a day
- Once a day
- Four to 6 times a week
- Three or 4 times a week or less

Score _____

Which of the following are you most likely to select as a dessert choice?

- Croissants, pies, cheesecake, carrot cake
- Typical cakes, cupcakes, cookies
- Low-fat muffins, desserts from low-fat cookbooks
- Fruits, low-fat cookies (fig bars and ginger snaps), angel food cake or none

Score _____

Which snack items are you most likely to eat in an average month?

- Chocolate
- Potato chips, corn or tortilla chips, nuts, party/snack crackers, doughnuts, French fries, peanut butter, cookies
- Lightly buttered popcorn (1 tsp. for 3 cups), pretzels, low-fat crackers (soda, graham), "home" baked corn chips, low-fat cookies (gingersnaps, fig bars)
- Fruit, vegetables, very low-fat snacks, or none

Score _____

TOTAL SCORE (SWEETS AND SNACKS) _____

GRAINS, BEANS, FRUITS AND VEGETABLES

this part of the quiz, list the number of servings of the following foods you eat each day or week, as specified.

How many pieces of fruit or cups of fruit juice do you consume a day (not "fruit-flavored" drinks)?
___ cups or pieces Score (S/cup) _____

How many cups of vegetables do you eat a day (tossed salad, cooked vegetables, etc.)?
A typical serving size for tossed salad is 1-1½ cups. ___ cups Score (S/cup) _____

How many cups of legumes do you eat a week: (refried beans, split peas, navy beans, lentils, chili, etc.)? ___ cups Score (S/cup) _____

How many servings of cereal, bread, crackers and popcorn do you eat each week? A typical cereal bowl holds 1½ to 2 cups and people typically eat 9 to 12 cups of popcorn. In the right column, list the number of servings you eat per week.

	List the number of <u>Servings eaten per WEEK</u>
cooked cereal	_____ half-cups/week
ready-to-eat cereal	_____ cups/week
slice of bread or toast	_____ slices/week
English muffin	_____ halves/week
four-inch pancake	_____ pancakes/week
hamburger bun	_____ halves/week
Pita or pocket bread	_____ halves/week
six-inch tortilla	_____ tortillas/week
dinner or hard roll	_____ rolls/week
slices of French bread	_____ slices/week
small piece of combread	_____ pieces/week
bagel	_____ halves/week
muffin	_____ muffins/week
low-fat crackers (5 per serving)	_____ servings/week
plain popcorn (5 cups per serving)	_____ servings/week
pretzels	_____ cups/week
	Total _____ servings/week
	Score (svgs x 0.7) _____

How many servings of grains and potatoes do you eat each week?

List the number of
Servings eaten per WEEK

macaroni, spaghetti and other pastas	_____ cups/week
mashed potato	_____ cups/week
baked potato	_____ large potato/week
rice, corn, bulgur, barley, and other grains	_____ cups/week

Score _____

TOTAL SCORE (GRAINS, BEANS, FRUITS AND VEGETABLES) _____

BEVERAGES

each question, circle as many numbers as apply.

Which of the following reflects your habits regarding alcoholic beverages?

- 1 drink = 12 ounces beer
 1½ ounces whiskey, gin, rum, etc.
 4 ounces wine
 1 ounce liqueur

- 1 One or more drinks a day
 2 Four to 6 drinks a week
 3 Three drinks a week
 4 One to 2 drinks a week
 5 None or less than one a week

Score _____

Which of the following reflects your habits regarding soda pop, sweetened seltzers, fruit punch, etc.?
 (Do not include diet drinks.)

- 12 ounce can = 1½ cups
 16 oz. bottle = 2 cups
 32 oz. bottle = 4 cups

- 1 One or more cups a day or 7 cups a week
 2 Four to 6 cups a week
 3 Three cups a week
 4 One to 2 cups a week
 5 None or less than one cup a week

Score _____

How much caffeinated coffee do you drink?

- 1 Six or more cups a day
 2 Four to 5 cups a day
 3 One to 3 cups a day
 4 None or less than 1 cup a day

Score _____

TOTAL SCORE (BEVERAGES) _____

RESTAURANTS AND RECIPES

For each question, circle as many numbers or check the choices that apply.

How often do you eat breakfast at a restaurant?

- 1 More than twice a week
- 2 Twice a week
- 3 Once a week
- 5 Less than once a month or never

Score _____

How often do you eat lunch at a restaurant?

- 1 Daily
- 2 Five days a week
- 3 Two to four days a week
- 4 One day a week
- 5 Less than once a month or never

Score _____

How often do you eat dinner at a restaurant?

- 1 More than 3 times a week
- 2 Two to 3 times a week
- 3 Once a week
- 4 Once or twice a month
- 5 Less than once a month or never

Score _____

Check the choices you make when eating in restaurants.

- Select restaurants that offer low-fat choices and order those choices.
- Order toast, muffins, cereal, pancakes, waffles for breakfast.
- Order soup (not cream), salad or other meatless, cheeseless entrees for lunch.
- When ordering pizza choose vegetarian.
- Avoid cheese, eggs, bacon bits on salads and avoid potato and macaroni salads.
- Put garbanzo or kidney beans on salad at the salad bar.
- Use a very small amount of salad dressing.
- Order a fish, shellfish, chicken, or lean red meat entree (but not fried).
- Use no more than 1 pat of margarine at any meal.
- Order fruit, sorbet, sherbet, frozen yogurt or skip dessert.

NOTE: (0-1 checks = 1; 2-3 checks = 2; 4-5 checks = 3; 6-7 checks = 4;
8-10 checks, or eat out less than once a month = 5)

Score _____

How often do you eat foods made using low-fat recipes?

- 1 Once a month or less
- 2 One to 2 times a week
- 3 Three to 4 times a week
- 4 Five to 6 times a week
- 5 Everyday

Score _____

TOTAL SCORE (RESTAURANTS AND RECIPES) _____

APPENDIX III
Food Record Form

Appendix III

FOOD RECORD	PLACE	TIME	FOODS and BEVERAGES (Skip a line between each meal or snack)	AMOUNT	COMPLETE DESCRIPTION	
Name						
Day of Week:						
Date						
Is this a typical day? <input type="checkbox"/> Yes <input type="checkbox"/> No						
If No, give reason						
*Preferred Abbreviations for amounts cup = C tablespoon = TB teaspoon = TS ounce = OZ						
Additional Information (optional, etc.)						

APPENDIX IV
Activity Survey

ACTIVITY SURVEY

HOUSEHOLD AND FAMILY CARE ACTIVITIES:

During the past year, how much time did you spend...

1. Caring for a child or children under 2 years of age? (Only time when child is awake. If child turned 2 less than 6 months ago, consider him/her less than 2 for the whole year.)

1. ___ None or less than 1 hour a week
2. ___ At least 1 hour but less than 5 hours a week
3. ___ At least 5 hours but less than 20 hours a week
4. ___ 20 hours or more a week

If 20 hours or more, how many hours a day? Weekdays ___ Weekends ___

2. Caring for a child or children between 2 and 5 years of age? (Only count time when child is awake.)

1. ___ None or less than 1 hour a week
2. ___ At least 1 hour but less than 5 hours a week
3. ___ At least 5 hours but less than 20 hours a week
4. ___ 20 hours or more a week

If 20 hours or more, how many hours a day? Weekdays ___ Weekends ___

3. Caring for a disabled child or elderly person (only count time actually spent in feeding, dressing, moving, etc.)

1. ___ None or less than 1 hour a week
2. ___ At least 1 hour but less than 5 hours a week
3. ___ At least 5 hours but less than 20 hours a week
4. ___ 20 hours or more a week

If 20 hours or more, how many hours a day? Weekdays ___ Weekends ___

4. Preparing meals or cleaning up from meals on weekdays?

1. ___ None or less than 1/2 hour a day
2. ___ At least 1/2 hour but less than 1 hour a day
3. ___ At least 1 hour but less than 1 1/2 hours a day
4. ___ At least 1 1/2 hours but less than 2 hours a day
5. ___ 2 hours or more a day

5. Preparing meals or cleaning up from meals on weekends?

1. ___ None or less than 1/2 hour a day
2. ___ At least 1/2 hour but less than 1 hour a day
3. ___ At least 1 hour but less than 1 1/2 hours a day
4. ___ At least 1 1/2 hours but less than 2 hours a day
5. ___ 2 hours or more a day

OCCUPATIONAL ACTIVITIES:

Now, some questions about your employment situation. Again choose the one response which best answers the question for you.

12. Are you currently...

1. Employed at least 32 hours a week?
2. Employed less than 32 but at least 20 hours a week?
3. Employed less than 20 but at least 8 hours a week?
4. Unemployed, laid off or on strike?
5. Retired
6. Unable to work (disabled or ill?)
7. Full-time homemaker/parent
8. Full-time student
9. Other (describe) _____

13. When you are working at your current occupation, how often do you do each of the following?

	Never less than 5% of the time	Seldom More than 5 but less than 25% of the time	Sometimes Between 25% and 75% of the time	Often More than 75% but less than 95% of the time	Always More than 95% of the time
A. sit					
B. stand					
C. walk					
D. Lift heavy objects					
E. Sweat from exertion					

ACTIVE LIVING HABITS:

This next section asks about the general level of physical activity involved in your daily routine.

14. In the past year, have you had to limit your physical activity a month or more because of illness, injury, pregnancy or disability ?

1. ___ No
2. ___ Yes, temporary illness
3. ___ Yes, long-term illness
4. ___ Yes, temporary injury/disability
5. ___ Yes, long-term injury/disability

15. How many minutes a day do you usually walk and/or bicycle to and from work, school or errands?

1. ___ less than 5
2. ___ At least 5 but less than 15
3. ___ At least 15 but less than 30
4. ___ At least 30 but less than 45
5. ___ 45 or more

16. How many flights of stairs do you usually walk up each day? (Count 10 stairs as 1 flight. Going up same flight twice counts as twice)

1. ___ None
2. ___ At least 1 but less than 5
3. ___ At least 5 but less than 10
4. ___ At least 10 but less than 15
5. ___ 15 or more

17. How many city blocks (or their equivalent) do you usually walk each day to and from work or school or doing errands? (10 city blocks is about 1 mile)

1. ___ Less than 5
2. ___ At least 5 but less than 10
3. ___ At least 10 but less than 15
4. ___ At least 15 but less than 20
5. ___ 20 or more

During the past year, when you were not working or doing chores around the house...

18. did you play sports or exercise?
19. Did you walk (for at least 15 minutes at a time)?
20. Did you bike (for at least 15 minutes at a time)?
21. Did you sweat from exertion?

Never or less than once a month	Once a month	2-3 times a month	Once a week	More than once a week
#18				
#19				
#20				
#21				

22. during the past year, did you watch Television...

1. Less than 1 hour a week
2. At least 1 hour a week but less than 1 hour a day
3. At least 1 hour a day but less than 2 hours a day
4. At least 2 hours a day but less than 4 hours a day
5. More than 4 hours a day

23. During a usual week in the past year, about how often did you do physical exercise in your free time for at least 20 minutes without stopping, which was hard enough to make your heart rate and breathing increase a large amount ?

Times a week

PARTICIPATION IN SPORTS AND EXERCISE:

Enclosed is a list of sports, exercises and recreational activities popular among women of different ages. Please refer to this list for answering the following questions.

24. During the past year, did you participate in any of these activities or in any other similar activities not included in this list?

1. Yes
2. No

25. Which sport or exercise did you do most frequently? (Specify only one)

26. When you did this activity, did your heart rate and breathing increase?

1. No
2. Yes, a small increase
3. Yes, a moderate increase
4. Yes, a large increase

27. How many months in this past year did you do this activity?

1. Less than 1
2. At least 1 but less than 2
3. At least 2 but less than 3
4. At least 7 up to and including 9
5. More than 9

28. How many times a week did you usually do this activity?

1. Less than 1
2. At least 1 but less than 2
3. At least 2 but less than 3
4. At least 3 but less than 4
5. More than 4

29. Did you do any other exercise or play any other sport this year?

1. Yes
2. No

30. What was the second most frequent sport or exercise you did?

31. When you did this activity, did your heart rate and breathing increase?

1. No
2. Yes, a small increase
3. Yes, a moderate increase
4. Yes, a large increase

32. How many months in this past year did you do this activity?

1. Less than 1
2. At least 1 but less than 2
3. At least 2 but less than 3
4. At least 7 up to and including 9
5. More than 9

33. How many times a week did you usually do this activity?

1. Less than 1
2. At least 1 but less than 2
3. At least 2 but less than 3
4. At least 3 but less than 4
5. More than 4

34. Did you do any other exercise or play any other sport this year?

1. Yes
2. No

35. What was the third most frequent sport or exercise you did?

36. When you did this activity, did your heart rate and breathing increase?

1. No
2. Yes, a small increase
3. Yes, a moderate increase
4. Yes, a large increase

37. How many months in this past year did you do this activity?

1. Less than 1
2. At least 1 but less than 2
3. At least 2 but less than 3
4. At least 7 up to and including 9
5. More than 9

38. How many times a week did you usually do this activity?

1. Less than 1
2. At least 1 but less than 2
3. At least 2 but less than 3
4. At least 3 but less than 4
5. More than 4

APPENDIX V
Summary Questionnaire

SUMMARY QUESTIONNAIRE

Please place a check or answer in the space indicated.

1. Are you currently participating in a weight loss program? Yes ___ No ___
2. If yes, please identify the program _____
How often do you attend this program? Weekly ___ Biweekly ___
Other (specify) _____
Are you weighed in during the program? Yes ___ No ___
Only if I want to be weighed _____
3. If no, did you attend a weight loss program right after the study? Yes ___ No ___
How long did you attend this program? _____
Why did not stop attending the program? Did not find it helpful _____
Inconvenience ___ Lack of time ___ Other _____
4. Do you keep a food record or diary? Daily ___ Occasionally ___ Never ___
5. Do you currently weigh yourself? Yes ___ No ___
If yes, how often? Daily ___ Weekly ___ Other (specify) _____
6. Do you feel you receive support from important people in your life to help you manage your weight? Yes ___ No ___ Sometimes ___
7. Do you routinely meet with a therapist, psychologist or psychiatrist for support for handling stress or discussing personal concerns? Yes ___ No ___
If yes, how often? Weekly ___ Bimonthly ___ Monthly ___
If yes, do you meet in a group setting or individual setting?
Group ___ Individual ___
8. What was your highest weight since the end of the protocol? _____
What was your lowest weight since the end of the protocol? _____
9. In your own words, what do you think has contributed to any weight changes occurring since the end of the Optifast protocol?

VITA

Maureen Seyford Leser was born on October 10, 1950. She completed her undergraduate studies in Food and Nutrition at the University of Maryland in the Spring of 1973. Following graduation, Maureen participated in the Virginia, Maryland, District of Columbia (VMDC) dietetic traineeship, completing her training in the Fall of 1974. She passed her registration exam to qualify as a registered dietitian in October of 1974, and was employed as a clinical dietitian by the Alexandria Hospital from 1974 through 1977. Mrs. Leser was employed by the Clinical Center of the National Institutes of Health from 1977 to 1980, and again from 1989 to the present. Her career at the NIH was interrupted for childrearing and part time employment as a consultant dietitian. Currently, Maureen provides nutritional care to patients of the National Heart, Lung, and Blood Institute and the National Cancer Institute at the Clinical Center. She began work for her Master's degree in Nutrition in 1991. Between 1991 and 1996 Maureen was enrolled in the Department of Human Nutrition, Foods, and Exercise at the Virginia Polytechnic Institute. Maureen completed her classes for her degree at the Falls Church campus of Virginia Polytechnic Institute, and defended her thesis for partial fulfillment of the requirements toward a Master's Degree in Nutrition in December of 1996.