A LOW CARBOHYDRATE DIET: TREATING OBESITY

RELATED DISORDERS IN ADULTS

by

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A DISSERTATION

IN

FAMILY AND CONSUMER SCIENCES EDUCATION

Submitted to the Graduate Faculty
of Texas Tech University in
Partial Fulfillment of
the Requirements for
the Degree of

DOCTOR OF PHILOSOPHY

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AUGUST, 2005

ACKNOWLEDGEMENTS

Without the love, support, and assistance of God, family and, and friends I would have never made it through this process. I would like to acknowledge that without the mercy and love of our Lord and Savior, Jesus Christ I would have never achieved this goal. Many times over the past five years I have been discouraged, but through prayer I gained strength in the knowledge that everything is in God's hands.

My wife is the glue that holds my family together. Throughout this project she has provided love and encouragement. She has been there to proof read, collect data, and provide reassurance. All the while she has put up with the emotional roller coaster I have subjected her to on an almost daily basis. She is my best friend and a wonderful mother and I would be lost without her. I love you very much!

I would like to thank Emily and Buck, who were just babies when this process started. We have missed out on a lot of time over the past five years, but you have always understood. It is now time for us to start catching up!

To my sister-in-law, Jan Cannon, what can I say? You attended every night of the study. You never griped. You did not expect any payment in return and you were always there with moral support. Now that you are on the same journey, I hope the process goes fast and smooth.

Amy Hawkins, thank you for being a part of the study. Without your help and expertise there is no way we could have collected all that data. Your smiling face made everyone feel welcome and you expected nothing in return. God bless you!

Dr. Venita Bowie, thank you for your contribution to the study. Your education materials were excellent and you were a great reference. Thank you for listening when I was having a problem. You are a wonderful friend and I miss you a bunch!

To Dr. Lynn Huffman, thank you so much for agreeing to be my committee chair. I cannot say enough nice things about you. You demonstrated how an educator should support a student. Through your guidance I

made it through this process, and for that I am forever grateful. Thank you for all your work, time, and support.

Dr. Du Fang, your expertise and patience was invaluable in completing this project. Thank you for the many hours of guidance you provided. May God bless you for your generosity.

I would like to thank my mom and dad (Elise and Homer Rushing) for their love and direction. You had faith in me before I had any in myself. You are wonderful parents and you have always been there for me. I love you dearly!

I would like to offer a special thanks to John Grant, a friend and colleague. If it was not for our daily bantering about the value of nursing versus nutrition, you may have never suggested that I undertake this project. It was your idea. There, I said it! Next time I will come up with the idea and you can do the research.

I would like to offer a special thanks to Dr. Virginia Sicola, who was always there with words of inspiration. You bolstered my confidence, lifted my spirits, and helped me keep my cool during the committee reviews. You are a gracious person! Thanks!

To the staff of the ICU at the Amarillo VA Health Care System, thanks, you are my pals and comrades. From the very start you made me feel welcome. You make work fun. Now that this process is over, I think I need a bigger office.

To my brother, sister, AJ, and Granny Bernice I want to say thanks. You are always there. I love you. To the rest of my family and friends I would like to say thanks for being there. Now that this is over I hope to be there too.

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ABSTRACT

The prevalence of obesity in United States adults from 1988 to 2000 skyrocketed from 22.9% to 30.5%. The healthcare community is struggling to find solutions to combat this epidemic. Several weight loss diet studies have demonstrated that low carbohydrate diets may be a reasonable alternative for individuals (including those with diabetes, hyperlipidemia, and high blood pressure) who have not had success losing with standard low-fat and diabetic diets. The purpose of this study was to determine the suitability of an ultra-low-carbohydrate diet for treating obesity adults. Participants were overweight or obese, non-pregnant, English speaking adults. They were randomly divided into two diet groups: (a) ultra-low carbohydrate (no calorie limit, 5% CHO, 35% protein, and 60% fat) and (b) balanced low calorie (1100 calorie, 55% CHO, 15% protein, and 30% fat, ≤ 10% saturated fat, ≤ 300 mg cholesterol, and ≥ 25 grams fiber). At baseline, study participants received instruction on specified diets, and they had anthropometric measurements taken (weight, blood pressure, and body fat using bioimpedance). Laboratory data was solicited throughout the study to determine an impact of each diet on blood glucose, total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides. The study lasted 20 weeks, with subjects receiving follow-up group counseling on specified diets and routine measurement of anthropometrics data. At each group meeting subjects were asked to complete a questionnaire to either gather baseline data, measure diet compliance and satisfaction, or to evaluate the study. Although both diet groups demonstrated weight loss, body fat loss and blood pressure reductions, the differences between the diet groups were not significant. Both HDL cholesterol and triglycerides demonstrated significant positive outcomes between the two diet groups ($p < .05$). Cronbach's Alpha demonstrated poor reliability for the satiety and compliance survey. Participation retention declined throughout the study with an average dropout rate of 14.9% per meeting.

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CHAPTER I

INTRODUCTION

Since the 1960's the rate of overweight and obesity in children and adults has been growing at alarming rates within most industrialized countries. Obesity (body mass index [BMI] > 30) in United States adults increased from 22.9% to 30.5% from 1988 to 2000 (Flegal, Carroll, Ogden, & Johnson, 2002). The positive relationship between obesity and negative psychosocial issues, discrimination, chronic diseases, and morbidity are well documented (Pi-Sunyer, 1999). Many health professionals believe the increase in the rate of obesity is not related to genetics, but instead to a reduction in daily caloric expenditure associated with twentieth century industrial and domestic technology and an increased availability of calorically dense convenience foods (Ebbeling, Pawlak, & Ludwig, 2002).

The available treatments for weight loss, virtually limitless and expanding daily, include fad diets, pharmacology, surgery, nutritional supplementation, exercise, behavior modification, acupuncture, and hypnosis. However, the success of weight loss treatments is marginal. Researchers reported that dieters on average achieve a 12% weight loss, but maintain only 4% of their losses after four years (Jeffery et al., 2000). The foundation for traditional weight loss diets has typically consisted of three components: (a) reduced calories, (b) reduced fat, and (c) carbohydrate density. Healthcare professionals have generally discounted the safety and efficacy of diet regimes that vary from this model, particularly the low carbohydrate, high fat diets. Despite these objections, research demonstrates that a low carbohydrate diets may be a realistic alternative for patients trying to lose weight, maintain diabetic control, and reduce risk factors associated with heart disease (Garg et al., 1994). Advocates of low carbohydrate diets insist that the high fat content helps maintain satiety, while the ketotic effects of low-carbohydrate diets help control appetite (Diet Information, 2003a).

Phenomena of Interest

With all the technologic advances and medical breakthroughs achieved by modern society in the past 100 years, it is ironic that scientists cannot agree on the best method or methods for patients to achieve long-term weight loss. To further confuse the issue, the weight loss and fitness industry continues to market new unproven concepts and products to help consumers lose weight. In this age of on-line shopping and take-out, consumers want simple solutions to solve all their problems. Many consumers are willing to try fad diets or unregulated nutritional supplements if they think it will help them lose weight. With the obesity rates rising, the weight-loss industry will continue to expand the number of weight loss products and programs available. Such growth may further distract consumers from safe realistic weight-loss options.

Statement of Need

The healthcare industry has yet to develop a successful long-term weight loss solution (Spake, 2002). Obviously prevention should be a large part of the plan to solve the obesity crisis; however, a large number of overweight individuals remain in need assistance. Although numerous studies have shown promise for low-carbohydrate diets as an alternative to conventional low-calorie diabetic-based weight loss plans, expert health and wellness organizations such as the American Dietetic Association, the American Heart Association (AHA), an the American Diabetic Association have yet to endorse low-carbohydrate diets (Harvard Men's Health Watch, 2003). The American Medical Association (AMA) has however, acknowledged the positive outcomes of some low-carbohydrate diets for weight loss and has called for researchers to continue to develop studies on this topic (Peck, 2002) until enough evidence is amassed to prove or disprove their viability.

Purpose of the Study

The purpose of this study was to compare the effectiveness of an ultra-low-carbohydrate diet and a balanced hypocaloric diet on weight loss, body fat, blood pressure, satiety, and diet compliance in overweight and obese adults. The objective was to determine the suitability of an ultra-low-carbohydrate diet for treating overweight and obesity in adults. The specific objectives were to:

1. Describe the sample population in terms of demographics (i.e., gender, race, income level, education level, and marital status)
2. Determine the impact of diet on retention rates.
3. Determine the impact of each diet on blood glucose, total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides.
4. Evaluate the effectiveness of each diet for reducing body weight, body fat, and blood pressure.
5. Measure the relationship of gender, race, and socioeconomic status (income level and education level) on weight loss, blood pressure reduction, and body fat reduction.
6. Measure the affect of each diet on hunger satiety and diet compliance.
7. Measure the relationship of gender, race, and socioeconomic status (income level and education level) on hunger satiety and diet compliance.
8. Assess the effectiveness of education developed for study for addressing the needs of adult learners in a group setting.

Hypothesis Statements

Based on the objectives listed above, the following hypothesis statements were developed.

1. A low carbohydrate diet will be as or more effective than a low fat low calorie diet for promoting membership retention (reduced dropout rates).

2. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for controlling blood glucose within a healthy range.
3. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for reducing total cholesterol.
4. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for reducing total HDL cholesterol.
5. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for reducing total LDL cholesterol.
6. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for reducing total triglycerides.
7. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for promoting weight loss.
8. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for promoting a reduction in body fat.
9. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for promoting a reduction in blood pressure.
10. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for promoting hunger satiety.
11. A low carbohydrate diet will be as or more effective than a low fat-low calorie diet for promoting diet compliance.

Key Terms

Anthropometry – The science that deals with measurement of the size, weight, and proportions of the human body (Dorland's Illustrated Medical Dictionary, 2000).

Body Mass Index (BMI) – An index for evaluating obesity. Weight in kilograms is divided by height in meters squared (Manual of Clinical Dietetics, 1996).

Compliance - The consistency and accuracy with which a patient follows the regimen prescribed by a physician or other healthcare professional (Steadman's Concise Medical Dictionary, 2001).

Diet – A prescribed allowance of food adapted for a particular state of health or disease (Taber's Cyclopedic Medical Dictionary, 1993).

Glycemia – The presence of glucose in the blood (Steadman's Concise Medical Dictionary, 2001).

Glycemic Index – An indicator of the ability of different types of foods that contain carbohydrate to raise the blood glucose levels within two hours. Foods containing carbohydrates that break down most quickly during digestion have the highest glycemic index. Also called the dietary glycemic index (Steadman's Concise Medical Dictionary, 2001).

Hyperlipidemia – A general term for elevated concentrations of any or all of the lipids in the plasma including triglycerides, total cholesterol, LDL cholesterol, and VLDL cholesterol (Dorland's Illustrated Medical Dictionary, 2000).

Obesity – BMI between 30 and 40 (Manual of Clinical Dietetics, 1996).

Overweight – BMI between 25 and 29.9 (Manual of Clinical Dietetics, 1996).

Morbidly obese - BMI greater than 40 (Manual of Clinical Dietetics, 1996).

Renal insufficiency – The reduced capacity of the kidney to perform its functions (Taber's Cyclopedic Medical Dictionary, 1993).

Satiety – Being full to satisfaction (Taber's Cyclopedic Medical Dictionary, 1993).

Eicosanoids – A general term for the metabolites of arachidonic acid; includes prostaglandins, thromboxane, and leukotrienes (Taber's Cyclopedic Medical Dictionary, 1993).

Assumptions

A variety of assumptions were made in developing this study. It was expected that all participants would make concerted effort to comply with dietary recommendations and answer all survey questions honestly. Researchers presumed that all participants would be eager and determined to make healthy weight and lifestyle changes. It was also counted on that a portion of participants would dropout as the study proceeded.

Limitations

Several limitations must be considered when analyzing this study.

- Because subjects for this study were solicited from the Amarillo VA Health Care System and Internal Medicine Clinics in the city of Amarillo, the generalizability of the results is limited to the population Amarillo VA Health Care System and Internal Medicine Clinics within the city of Amarillo.
- Due to inadequate funding, laboratory analyses were not performed as a part of the study. Instead, existing laboratory data was solicited from participants, relying on them to provide this data when it was available. There was no control on who had lab tests and when they were performed.
- Due to time constraints and a lack of available existing survey tools on the study topic, surveys were validated using a professional panel instead of a pilot study.
- Poor weather conditions prevented many participants from attending meeting twelve.
- Halloween and Thanksgiving holidays fell in the middle of the study, which made dietary compliance around those dates difficult.

- Since participation declined throughout the study, data gathered for satiety and compliance (which were analyzed as average scores for over the entire study) were more a reflection of participant's feelings during weeks one through four of the study.
- Due to limitations with time and the amount of people able to help with this study, the researchers chose not contact participants who dropped out of the study to encourage them return. Participants were reminded of the time and date of the following meeting at the end of each meeting, but due to manpower no effort was made to contact participants prior to each meeting to encourage participation.

CHAPTER II

LITERATURE REVIEW

The Incidence of Obesity

The message in fashion magazines and television advertising is that people have to be thin to be attractive or successful. Most health experts agree that these standards are distorted, unrealistic, and potentially harmful. However, this inordinate attention to thinness should not conceal the fact that overweight and obesity is a global problem affecting children and adults of all ages and all ethnic backgrounds.

In June of 1998 the federal government announced guidelines, which created an official definition of healthy weight using Body Mass Index (BMI). BMI is an index for evaluating obesity (Figure 1). The index is divided into the six categories: underweight, healthy weight, overweight, obese, extreme obese, and morbid obese (Calorie Count Council, 2003) (Table 1).

The American Association of Obesity (2003) defines overweight and obesity for children and adolescents as being at or above the 85^{th} and 95^{th} percentile of BMI respectively. They justify this decision because the 85^{th} percentile in youth corresponds to a BMI of 25 (overweight adult) and the 95^{th} percentile in youth corresponds to a BMI of 30 (obese adult).

	WEIGHT (lbs.)																															
HT	100	105	110	115	120	125	130	135	140	145	150	155	160	165	170	175	180	185	190	195	200	205	210	215	220	225	230	235	240			
5'0"	20	21	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47			
5'1"	19	20	21	22	23	24	25	26	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	43	44	45			
5'2"	18	19	20	21	22	23	24	25	26	27	27	28	29	30	31	32	33	34	35	36	37	37	38	39	40	41	42	43	44			
5'3"	18	19	19	20	21	22	23	24	25	26	27	27	28	29	30	31	32	33	34	35	35	36	37	38	39	40	41	42	43			
5'4"	17	18	19	20	21	21	22	23	24	25	26	27	27	28	29	30	31	32	33	33	34	35	36	37	38	39	39	40	41			
5'5"	17	17	18	19	20	21	22	22	23	24	25	26	27	27	28	29	30	31	32	32	33	34	35	36	37	37	38	39	40			
5'6"	16	17	18	19	19	20	21	22	23	23	24	25	26	27	27	28	29	30	31	31	32	33	34	35	36	36	37	38	39			
5'7"	16	16	17	18	19	20	20	21	22	23	23	24	25	26	27	27	28	29	30	31	31	32	33	34	34	35	36	37	38			
5'8"	15	16	17	17	18	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	33	33	34	35	36	36			
5'9"	15	16	16	17	18	18	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	32	33	34	35	35			
5'10"	14	15	16	17	17	18	19	19	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	32	32	33	34	34			
5'11"	14	15	15	16	17	17	18	19	20	20	21	22	22	23	24	24	25	26	26	27	28	29	29	30	31	31	32	33	33			
6'0"	14	14	15	16	16	17	18	18	19	20	20	21	22	22	23	24	24	25	26	26	27	28	28	29	30	31	31	32	33			
6'1"	13	14	15	15	16	16	17	18	18	19	20	20	21	22	22	23	24	24	25	26	26	27	28	28	29	30	30	31	32			
6'2"	13	13	14	15	15	16	17	17	18	19	19	20	21	21	22	22	23	24	24	25	26	26	27	28	28	29	30	30	31			
6'3"	12	13	14	14	15	16	16	17	17	18	19	19	20	21	21	22	22	23	24	24	25	26	26	27	27	28	29	29	30			
6'4"	12	13	13	14	15	15	16	16	17	18	18	19	19	20	21	21	22	23	23	24	24	25	26	26	27	27	28	29	29			

Source: National institute of Health, 2005. http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm

Figure 1. Body Mass Index Chart

Table 1. Weight Classifications Based on Body Mass Index.

BMI	Weight Classification
≤ 18.4	Underweight
18.5 – 24.9	Healthy weight
25.0 – 29.9	Overweight
30.0 – 34.9	Obese (obesity level I)
35.0 – 39.9	Extreme obese (obesity level II)
≥ 40	Morbid Obese (obesity level III)

Source: Excerpted from Calorie Count Council, **"**Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risks**,** 2003.

Adult Obesity

In the United States approximately 127 million people are overweight, 60 million are obese, and nine million are severely obese. The prevalence of overweight and obesity in the United States has increased steadily in the past 30 years for all regions of the country, for both genders, for all ethnic groups, and disproportionately for people of low-socioeconomic status. Currently, 64.5% of American adults are overweight and 30.5% of these individuals are obese. Severe obesity is now 4.7%, up from the 2.9% recorded in the 1988-1994 period. Furthermore, overweight and obesity have increased steadily with age for both men and women (Tables 2-4). Over half of all age groups are overweight, and at least 20% are obese. The age group for men with the highest prevalence of overweight and obesity is 65 to 74 years of age, while in women it is 55 to 64 years of age.

Table 2. Increase in the prevalence of obesity among United States adults.

Period	Overweight (BMI > 25)	Obese (BMI > 30)	Severely Obese (BMI >40)
1999 to 2000	64.5%	30.5%	4.7%
1988 to 1994	56.0%	23.0%	2.9%
1976 to 1980	46.0%	14.4%	No Data

Source: Excerpted from the National Center for Chronic Disease Prevention and Health Promotion, "Obesity Trends," 2003.

Table 3. Increase in the prevalence of overweight (BMI > 25) in men and women.

	Prevalence of Overweight			
	Men (%)		Women (%)	
Age (Years)	1988-1994	1999-2000	1988-1994	1999-2000
20 – 34	47.5	58.0	37.0	51.5
35 – 44	65.5	67.6	49.6	63.6
45 – 54	66.1	71.3	60.3	64.7
55 – 64	70.5	72.5	66.3	73.1
65 – 74	68.5	77.2	60.3	70.1
≥ 75	56.5	66.4	52.3	59.6

Source: Excerpted from the National Center for Chronic Disease Prevention and Health Promotion, "Obesity Trends," 2003.

Table 4. Increase in the prevalence of obesity (BMI > 30) in men and women.

	Prevalence of Obesity			
	Men (%)		Women (%)	
Age (Years)	1988-1994	1999-2000	1988-1994	1999-2000
20 – 34	14.1	24.1	18.5	25.8
35 – 44	21.5	25.2	25.5	33.9
45 – 54	23.2	30.1	32.4	38.1
55 – 64	27.2	32.9	33.7	43.1
65 – 74	24.1	33.4	26.9	38.8
≥ 75	13.2	20.4	19.2	25.1

Source: Excerpted from the National Center for Chronic Disease Prevention and Health Promotion, "Obesity Trends," 2003.

Overweight and obesity were not equally distributed among men and women. The prevalence of overweight was higher for men than women (67% compared to 62% respectively). With obesity, however, the prevalence was higher in women than in men (34 % compared to 27.7% respectively). The same was true for severe obesity (6.3% in women compared to 3.1% in men). Obesity has been shown to decrease with education level, but the prevalence continues to increase over time (Appendix A, Table A1). The prevalence of obesity has increased over time for all regions of the United States and is highest in the East South Central area (Appendix A, Table A2).

Overweight and obesity occur at higher rates in racial-ethnic minority populations such as African American and Hispanic Americans compared with Caucasian Americans (Table 5). Asian Americans

Table 5. Increase in the prevalence of overweight and obesity among racial-ethnic groups.

	Overweight (BMI >25) Prevalence (%)		Obesity (BMI >30) Prevalence (%)	
Racial-Ethnic Group	1988-1994	1999-2000	1988-1994	1999-2000
African Americans	62.5	69.6	30.2	39.9
Mexican American	67.4	73.4	28.4	34.4
Caucasian American	52.6	62.3	21.2	28.7

Source: Excerpted from the National Center for Chronic Disease Prevention and Health Promotion, "Obesity in Minority Populations," 2003.

tend to have the lowest levels of obesity compared to all other ethnic groups including Caucasian Americans. The racial-ethnic group with the highest prevalence of obese women is African Americans, while Mexican Americans has the highest prevalence of obese men. Severe obesity increased for men and women in African American, Mexican American, and Caucasian American populations, but the increase in the prevalence of severe obesity was disproportionately highest among African American women. Research indicates that socioeconomic status and overweight/obesity rates are positively correlated. Women with low-income levels from minority groups appear to have the greatest likelihood of being overweight. The incidence of overweight is 13% higher for Mexican American women living below the poverty line, compared to Mexican American women living above the poverty line (Appendix A, Table A3 and A4) (American Obesity Association, 2003; Freedman, Khan, Serdula, Galuska, & Dietz, 2002; International Obesity Task Force, 2002, August; Flegal, et al., 2002; National Center for Chronic Disease Prevention and Health Promotion, 2003; National Institute of

Diabetes and Digestive and Kidney Diseases, 2003; North American Association for the Study of Obesity, 2003).

In developed countries such as the United States, the incidence of obesity in women tends to increase as income levels drop. As women become older, they are more likely to be overweight. In the past decade the incidence of obesity has increased for all age groups of United States women (Appendix A, Table A5). Middle age women (ages 35 to 64) are at the highest risk of becoming obese. Table 6 illustrates the increase in the prevalence of obesity in middle-aged women over the past forty years. Compared to Caucasian American women, African American and Mexican American women have a greater risk for overweight and obesity (Appendix A, Table A6) (American Obesity Association, 2003; Flegal, et al., 2002; Freedman, et al., 2002; National Center for Chronic Disease Prevention and Health Promotion, 2003; National Institute of Diabetes and Digestive and Kidney Diseases, 2003; North American Association for the Study of Obesity, 2003).

Table 6. Increase in the prevalence of obesity among middle-aged women in the United States over the past 40 years.

Age (In years)	1960-1962	1999-2000	Percentage Point Change
35-44	14.7	33.9	19.2
45-54	20.3	38.1	17.8
55-64	24.4	43.1	18.7

Source: Excerpted from the American Association for Obesity, "Women and Obesity," 2003.

Obesity in Children and Adolescents

The incidence of overweight and obesity in United States youth is alarming. Overweight in youth is defined as BMI > the 85th percentile and obesity for youth is defined as BMI > the 95th percentile. Approximately 30.3% of children (ages 6-11) and 30.4% of adolescents (ages 12-19) are overweight. Approximately 15.3% of children (ages 6-11) and 15.5% of adolescents (ages 12-19) are obese. The prevalence for overweight is higher

in boys (32.7%) than girls (27.8%), while in adolescents the prevalence for overweight is about the same in males (30.5%) and females (30.2%). In the past 25 years the incidence of obesity increased by 400% in children, while the incidence of obesity more than doubled in adolescents (Table 7).

Table 7. The prevalence of obesity in children and adolescents (ages 6-11) in the past 25 years.

Prevalence in Children (age 6-11)		
Time Period	Boys (%)	Girls (%)
1999-2000	15.5	15.5
1988-1994	11.3	9.7
1971-1974	6.1	6.2
Prevalence in Adolescents ages 12-19		
Time Period	Boys (%)	Girls (%)
1999-2000	15.5	15.5
1988-1994	11.3	9.7
1971-1974	6.1	6.2

Source: Excerpted from the American Association for Obesity, "Obesity in Youth," 2003.

Racial-ethnic minority (African American and Hispanic American) youth have a higher prevalence of overweight and obesity compared to Caucasian American youth. Among youth, the highest prevalence of overweight and obesity was observed in African American females (37.6% overweight and 22.2% obese) and Mexican American males (45.5% overweight and 26.6% obese). Approximately 38.5% of Native American youth (children and adolescents) and 20.6% of Asia American adolescents are overweight (Appendix A, Table A7) (American Obesity Association, 2003; August; Flegal et al., 2002; Freedman et al., 2002; National Center for Chronic Disease Prevention and Health Promotion, 2003; National Institute of Diabetes and Digestive and Kidney Diseases, 2003; North American Association for the study of obesity, 2003).

Obesity as a Global Problem

In developing and developed countries worldwide, the prevalence of overweight and obesity is escalating for all ages and both genders. In 1995 the number of obese adults worldwide was estimated at 200 million; that number increased to 300 million by 2000. Research indicates that the root of this problem is environmental and behavioral changes brought about by economic development, modernization, and urbanization. Economic development increases the availability of food and increases access to food. Modernization has added to the abundance of food and a reduction of physical activity associated with work and leisure. Urbanization has lead to a reliance on non-traditional foods and a more sedentary lifestyle. This abundance of high-calorie high-fat foods and decreased physical activity has led to an increase in obesity globally. In many developing countries obesity and under-nutrition (BMI < 18) coexist. In the United States, it is likely that under and over-nutrition could coexist because of the great economic diversity within the population. Comparatively speaking, the United States is one of the wealthiest and most developed countries in the world, yet nearly 33 million residents and 12 million children live in poverty (Appendix A, Table A8) (Poverty USA, 2003).

Global obesity it not just an adult problem. The number of children worldwide under the age of five who were obese in 1995 was approximately 18 million. Research indicates global childhood obesity rates are on the rise. England, Scotland, Egypt, Japan, and China are just a few of the countries that have observed significant increases in the percentage of overweight in their youth populations in the last 20 years (Appendix A, Table A9) (Ebbeling et al., 2002; International Obesity Task Force, 2002).

The Impact of Obesity on Health and Quality of Life

The health complications associated with obesity are well documented, affecting both adults and children. Obesity is considered a chronic disease for several reasons. It carries an annual healthcare cost of approximately 100 billion dollars; it is the second leading cause of unnecessary deaths (300,000 annually); it

causes many other serious health problems; and it affects over 25% of the United States population. Research suggests that obesity is more damaging to health than smoking, excessive alcohol use, and poverty. Self-perceptions, ridicule, and discrimination associated with obesity can lead to serious psychosocial problems including depression and eating disorders. In general, obesity causes poor health, reduces the quality of life, and causes premature death (American Obesity Association, 2003; National Center for Chronic Disease Prevention and Health Promotion, 2003; North American Association for the Study of Obesity, 2003).

Adults

In adults there is strong evidence that obesity results in several medical conditions that can reduce the quality of daily living and shorten life span. Overweight and obesity are positively associated with rheumatoid arthritis and the development of osteoarthritis of the knee, back, hip, and hand. The risk of developing cancer of the esophagus, stomach, colon, rectum, and kidney increases as BMI increases above 25. Obesity has been shown to increase the risk of hyperlipidemia, coronary artery disease, and heart attack. The odds of having carpal tunnel syndrome are four times higher for obese persons compared to non-obese persons. In many elderly individuals, obesity promotes chronic venous stasis (inadequate blood flow through the veins). Fatigue and daytime sleepiness are common complaints of people with obesity. Increases in the incidence of deep vein thrombosis (a condition that disturbs the normal blood clotting process) are seen in obese patients. Approximately 90% of the patents with type II diabetes are overweight or obese, and obesity complicates type II diabetes by increasing insulin resistance and decreasing glucose tolerance. It is thought that obesity may play a role in initiating or progressing renal disease. Obesity contributes to the cause of gout by promoting an increased production of uric acid. Weight in association with age is the strongest indicator for high blood pressure in adults. Obesity reduces the activity of bacteria destroying scavenger cells, reducing the body's resistance to harmful organisms. In burn patients, obesity has been reported to double the incidence of

pneumonia and wound infection. Overweight and obesity increase the potential for cirrhosis and hepatitis in alcoholics.

Obesity can be at least partially to blame for many other medical problems. It promotes pain in the lower back, joints, and feet and increases the potential for complications associated with pancreatitis including respiratory failure. It increases the risk of complications after surgery, such as respiratory distress, infections, and poor wound healing. Obesity is positively associated with urinary stress incontinence and involuntary urine loss. Table 8 denotes the prevalence of type II diabetes, coronary heart disease, high blood pressure, and osteoarthritis by gender and age in relation to BMI (American Obesity Association, 2003; August; Flegal et al., 2002; Han, Tijhuis, and Seidell, 1998; National Center for Chronic Disease Prevention and Health Promotion, 2003; National Institute of Diabetes and Digestive and Kidney Diseases, 2003; North American Association for the Study of Obesity, 2003; Pi-Sunyer, 1999).

Women

Obesity plays a significant role in adversely affecting the health of women. It reduces the quality and quantity of life. The risk of mortality increases by 50% when BMI exceeds 30. The risk of osteoarthritis increases by 400% in obese women compared to non-obese women, though the correlation between obesity and osteoarthritis is greater in men than in women. After menopause, obese women are at greater risk of developing breast cancer than women with a lower BMI. The risk of developing endometrial cancer is four times greater in obese women than women with a lower BMI. Obesity in women has been shown to increase the incidence of abnormal ovulation, infertility, and negative pregnancy outcomes. Elevated pre-pregnancy weight is associated with an increased risk of pregnancy hypertension, gestational diabetes, urinary infection,

Table 8. The percent prevalence of several medical conditions by BMI for women and men.

Medical condition	BMI in Women			
	18.5-24.9	25.0-29.9	30.0-34.9	≥ 40
Type II Diabetes	2.38	7.12	7.24	19.89
Coronary Heart Disease	6.87	11.13	12.56	19.22
High Blood Pressure	23.26	38.77	47.95	63.16
Osteoarthritis	5.22	8.51	9.94	17.19

Medical condition	BMI in Men			
	18.5-24.9	25.0-29.9	30.0-34.9	≥ 40
Type II Diabetes	2.03	4.93	10.10	10.65
Coronary Heart Disease	8.84	9.60	16.01	13.97
High Blood Pressure	23.47	34.16	48.95	64.53
Osteoarthritis	2.59	4.55	4.66	10.04

Source: Excerpted from the American Association for Obesity, "Health Effects of Obesity," 2003.

Cesarean section delivery, and toxemia. The incidence of prejudice and discrimination directed at obese women appears to be much greater than that directed at obese men. Obesity is positively related to unemployment in women. Obese women face significant barriers in establishing and maintaining social relationships in a society obsessed with thinness and physical beauty. Women with obesity are less likely to complete college or receive financial assistance for higher education compared to non-obese women (National Center for Chronic Disease Prevention and Health Promotion, 2003).

Children and Adolescents

Excess weight in childhood and adolescents has been shown to be predictor of overweight in adults. Overweight children with at least one overweight parent were reported to have a 79% likelihood of becoming an overweight adult (American Obesity Association, 2003). Obesity in childhood can lead to a cluster of adverse health effects that reduce the quality of life and cause premature death. Although no cause or effect relationship has been established, the incidence of overweight is significantly higher in children and adolescents with moderate to severe asthma compared to non-asthmatic youths. Obesity in children is reported to be the most significant factor for the recent rise in childhood type II diabetes. Obese children are 12.6 times more likely than non-obese children to suffer from hyperglycemia. Obese youths are nine times more likely to have persistent elevated blood pressure compared to their non-obese peers. Excess weight in youth with developing bones and cartilage can lead to bowing and overgrowth of leg bones and pain and limited range of motion in the hip growth plate. American youth who are overweight are at high risk for negative body image and potential eating disorders. Many overweight and obese adolescents are stigmatized by intentional ridicule and negative assumptions made about their personalities including laziness and poor hygiene. Sleep apnea (a condition characterized by period of interrupted breathing during sleep) occurs in about seven percent of obese children (American Obesity Association, 2003; Flegal et al., 2002; National Center for Chronic Disease Prevention and Health Promotion, 2003; National Institute of Diabetes and Digestive and Kidney Diseases, 2003; North American Association for the Study of Obesity, 2003).

Psychosocial

The relationship between obesity and chronic diseases is well established; however, the relationship between psychosocial health and obesity is less clear. Using data from the National Health and Examination Survey (NHANES) in conducted in 1999-2000, researchers analyzed self-rated health responses in 10,298

participants consisting of white, African American, and Hispanic adults. In this study participants were asked to rate their health by answering the question "Would you say your health in general is excellent, very good, good, fair, or poor?" Results showed a significant positive relationship between obesity and poor self-rated health in all ethnic groups ($P>0.05$) with self-rated health deteriorating as the level of obesity increased. Compared to whites, the odds of reduced self-rated health increased by 23% in black men, 45% in black women, 175% in Hispanic men, and 177% in Hispanic women (Okosun, Choi, Matamoros, & Dever, 2001). Han et al. (1998) reported that large waist circumferences and high BMIs are positively associated with characteristics of depression including low vitality and a lack of happiness.

Discrimination

Obese persons are often the victims of discrimination. Many people believe that obesity is the last acceptable form of discrimination. Three areas that underscore the presence of obesity discrimination are the job market, the health care industry, and the educational system.

Obesity discrimination can be found at every stage of the employment cycle including selection, placement, compensation, promotion, discipline, and discharge. Overweight persons have been stereotyped as emotionally impaired and socially handicapped. Wages of mildly obese white women are 5.9% less than their standard weight counterparts, while morbidly obese women make 24.1% less. Weight related wage discrimination was not observed in black or white males (American Obesity Association, 2003; Okosun et al., 2001).

Since persons with obesity have many health-related problems, health care provider discrimination can be a serious issue. Research suggests that many physicians and nurses view obese patients as lazy and lacking self-control. Other research suggests that physicians are unlikely to discuss weight loss management or refer their patients to a weight loss program (Ebbeling et al., 2002).

Harsh treatment by peers (including rejection, ostracism, and taunting) for being overweight or obese is a common experience for many students from elementary school all the way through college. A majority of overweight adolescent girls experience hurtful comments about their weight such as derogatory teasing, jokes, and name-calling. In some cases the negative impact of this abuse and rejection has led to poor self-esteem, depression, eating disorders, and suicide (American Obesity Association, 2003; Ebbeling et al., 2002).

Morbidity

According to a study published in the New England Journal of Medicine, overweight people are at an increased risk of premature death, even among people who did not smoke and were otherwise healthy during their middle years (Jet, 1999). Obesity is closing the gap with smoking as a major cause of death in the United States. In 2000, about 300,000 deaths were associated with obesity, compared to 400,000 deaths associated with cigarette smoking (FDA Consumer, 2002).

Potential Causes of Obesity

Why are we getting fatter? The answer seems simple enough, eat more food to gain weight, eat less food to lose weight. However, upon further study, the problem becomes more complicated. Why can some people eat more than others and not gain weight. This suggests genetics probably play a factor. Others point out that environmental factors are to blame. Sixty years ago, the incidence of obesity was less, but our environment was much different. Fast food, king size, and all-you-can-eat had not yet flourished, and many Americans still earned a living on the family farm or working at jobs that required extensive manual labor. Some people say the types of food available today are more calorically dense and with fewer nutrients; however sixty years ago many people still cooked with lard, drank only whole milk, and demanded their children clean their plates before leaving the table. Weight also seems to be affected by education level and

income status. The relationship between weight, genetics, individual behaviors, and environmental factors should be considered when exploring causes of obesity (National Center for Chronic Disease Prevention and Health Promotion, 2003).

Genetics

Bodyweight is regulated by a multitude of physiological mechanisms that maintain a balance between energy consumption and energy expenditure. This system is quite precise and any factor that raises energy consumption or reduces energy expenditure over an extended period of time can cause weight gain. Genetics has an impact on body size and weight distribution. If the parents of a child are overweight, the child has an increased risk of becoming overweight. Genetics can affect individual metabolism (the rate at which a person burns calories at rest). This is the reason some people can eat indiscriminately and not become obese, while others overeat and become obese. In disorders such as Bardet-Biedl syndrome and Prader-Willi syndrome, genetics are known to cause obesity (National Center for Chronic Disease Prevention and Health Promotion, 2003).

Education Level/Income/Socioeconomic Status

In general, lack of education or earning potential can have an adverse relationship with health. Mortality risks for American men who work in laboring occupations are 80% higher than those in professional and managerial occupations. Socioeconomic status (SES) based on occupational class (professional, managerial, non-manual unskilled, manual skilled, and manual unskilled) over a lifetime has a positive relationship to self-rated health (as SES increases self-rated health improves). A long duration of low family income was shown to adversely affect an offspring's cognitive development, school achievement, and adult earnings (Power, Manor, & Mathews, 1999).

Other research demonstrates strong association between SES and weight. Goodman (1999) reported a positive and linear relationship among family income level and weight and depression in adolescents. Researchers with the World Health Organization found that low education was associated with a higher BMI in approximately 50% of adult male populations and almost all female populations (Molarius, Seidell, & Sans, 2000). In a study conducted in 1983 -1989, the prevalence of obesity was 15% in participants with a low level of education, 12% in those with a moderate level of education, and 9% among the best-educated respondents.

The association between weight and SES is multifactoral. In one study, individuals with less education reported lower incomes, limited availability of affordable nutritious foods in local supermarkets, higher alcohol consumption, and more sedentary lifestyles (Everson, Maty, Lynch, & Kaplan, 2002). Other researchers claim that social and cultural norms surrounding desirable weight and diet play a significant role in SES and obesity (Reddy, 1998; Winkleby, Gardner, & Taylor, 1996). It is likely that part of the problem is a high availability of low cost calorically dense foods (i.e., sodas, chips, cookies, cakes, pies, candy, and fried convenience store foods). Furthermore, a lack of understanding of healthy food choices and other factors that contribute to overweight and obesity must be partly to blame for the relationship between SES and obesity (Winkleby et al., 1996).

Physical Activity

Researchers at The Center for Nutrition at Colorado Health Sciences Center in Denver (Hill & Melanson, 1999) concluded that decreased physical activity, rather than an increase in energy consumption, genetics, or metabolic abnormalities, is to blame for the trends in increased obesity in the United States. Furthermore, they suggested that participation in leisure time physical activity has remained low but constant, and that the true culprit for the rise in overweight and obesity is the increased reliance on technology that has reduced work-related physical activity.

In a nationally representative cross-sectional survey, U.S. children who engaged in the least vigorous physical activity or the most television viewing tended to be the most overweight. Television watching was thought to promote weight gain by displacing physical activity and promoting increased snacking encouraged through commercials promoting calorically dense snack foods (Anderson, Crespo, Bartlett, Cheskin, & Pratt, 1988). As noted in Table 9, staying active either through sports, exercise, or routine activities will help burn calories, which will help prevent weight gain or promote weight maintenance or weight loss.

However, not all researchers agree that a lack of physical activity throughout the population is to blame for the fattening of America. Research conducted using U.S. military personnel as subjects suggests that changes in physical activity may not be a factor in the rise of obesity in America. Researchers reported that the trend in obesity among U.S. military personnel between 1995 and 1998 mirrors that of civilian personnel, though the physical activity level of military personnel did not change during the same period (Lindquist, 2001).

Consumption of Energy Nutrients

The three macronutrients from which calories are derived are protein (four calories per gram), carbohydrates (four calories per gram), and fat (nine calories per gram). Alcohol, which has the chemical name ethanol, is not considered a nutrient; however it provides approximately seven calories per gram (Whitney, Cataldo, & Rolfes, 1987).

For many years it has been accepted practice in the medical community to recommend low fat diets to their patients for weight loss and reduction of cardiovascular disease risk factors. Since fat is the most calorically dense nutrient and because it requires minimal chemical alteration for body storage, it been the obvious target for a weight reduction strategy.

Data from National Health and Examination Survey (NHANES) in conducted in 1999-2000 demonstrated that while the prevalence of obesity in American children increased, the proportion of total calories consumed as fat decreased with a compensatory increase in the percentage of carbohydrate calories. Aggravating this situation was the increase in the consumption of refined carbohydrates such as breads, ready to eat cereals, potatoes, soft drinks, and cakes (Cavadini, Siega-Riz, & Popkin, 2000).

Eating Out

There is not any conclusive research on the relationship between eating out and obesity, but as suggested by some authors (Ebbeling et al., 2002), the relationship is worth considering. In the United States the trend toward eating out is increasing (34% of the national budget in the 1970's versus 47% of the national budget in the late 1990s), and when people eat out, they may be consuming more calories than when they eat at home. The rise in consumption of fast food may be related to childhood obesity since fast food typically incorporates several potentially adverse dietary factors such as saturated and transaminated fat, high glycemic index, high energy density, and increasingly large portion sizes. To meet the demands of consumers and to keep up with the competition, many moderately priced and fine-dining restaurants have increased the serving sizes and the number of menu items offered. The availability of all-you-can eat buffet restaurants continues to increase as well, especially in the oriental foods market (Ebbeling et al., 2002).

Portion Sizes

According to Young and Nestle (2002), sizes of current marketplace foods almost universally exceed sizes offered in the past. And most food portions, with the exception of sliced white bread, dramatically exceeded United States Department of Agriculture (USDA) standards. Some of the larger excesses over USDA standards were as follows: cookies 700%, cooked pasta 480%, muffins 333%, steaks

Table 9. Examples of activities that burn approximately 150-calories.

Physical Activity	Length of the Activity (In minutes)
Washing and Waxing a car	45-60
Washing windows and floors	45-60
Gardening	30-45
Wheeling self in a wheel chair	30-40
Pushing a stroller	30
Playing volleyball	45
Raking leaves	30
Walking	30
Shoveling snow	15
Stair walking	15
Playing Basketball	15
Dancing	30
Water Aerobics	30
Swimming	20
Bicycling	15
Jumping rope	15
Running	15

Source: Excerpt from the Office of the Surgeon General "Physical Activity," 2003.

224%, and bagels 194%. Other direct indicators of increasing availability of larger portion sizes were fast food restaurants and convenience stores promoting larger serving sizes, national chain restaurants promoting larger serving sizes on their menus, restaurants using larger dinner plates, pizzerias using larger pans, and fast food restaurants using larger drink and french fry containers. Restaurant food manufacturers are skewing consumer's perceptions of what a normal serving sizes looks like, thus leading many individuals to transfer these larger serving sizes to home meal preparation. In addition, standardized food labels based on USDA serving sizes, report nutrient quantities based on much smaller serving sizes than those seen in restaurants (i.e., ½ cup cooked of pasta on a label, versus two cups of pasta for a restaurant entrée). If a customer looks at the label for calories or fat per serving without confirming serving sizes, they are likely to significantly underestimate the amount of fat and calories they are consuming.

Snacking

Snacking may play a factor in the rise in obesity. Based on results of a study conducted at the University of North Carolina at Chapel Hill (Zizza, Siega-Riz, & Popkin, 2001), the prevalence of snacking among young adults (ages 19 to 29 years old) increased from 77% to 84% between 1977-1978 and 1994-1996. As seen in Table 10, the number of snack times, calories per snacking occasion, and caloric density of snacks increased from the period of 1977 through 1978 to 1994 through 1996. During this period calorie consumption per snacking period increased by 26%, the number of snacks daily increased by 14%, and the consumption of high-fat salty snacks doubled. Sweetened foods and alcoholic beverages were significant energy contributors in the snack category.

Table 10. Change in snacking consumption of young adults over time.

Snacking Variable	1977-1978	1989-1991	1994-1996
Number of snacks per day	1.7	1.69	1.92
Average calories per snack	247	265	313

Source: Excerpted from Zizza, Siega-Riz, & Popkin, "Significant increase in young adults snacking between 1977-1978 and 1994-1996 represents a cause for concern," 2001.

The Economic Cost of Obesity

Researchers at the American Obesity Association (2003) estimated the direct economic cost of obesity for the United States in 1999 totaled approximately $102.2 billion. This equaled 12% of the United States healthcare budget. Colditz (1999) estimated that the indirect costs of obesity-associated situations such as with lost days of work and lost earnings caused by premature death totaled 48 billion dollars. As previously noted, obesity has a causal effect on numerous health conditions (Table 11). According to the American Obesity Association, obesity comprised a significant component of diagnosis including: arthritis, cancer, diabetes, gallstones, hypertension, liver disease, sleep apnea, and renal disease (Appendix O). Quesenberry and Jacobson (1998) reported that average annual healthcare costs were 25% higher for overweight individuals (BMI of 30 to 34.9) and 44% higher for obese individuals (BMI > 35) compared to people with a BMI of 20 to 24.9.

As employee BMI increases, indirect and direct costs to the employer increase. The prevalence of absenteeism from work due to illness is higher among obese individuals. According to Tucker and Friedman (1998) obese employees are more than twice as likely to experience high absenteeism (seven or more absences due to illness in the past six months) and 1.49 times more likely to experience moderate absenteeism (three to six absences due to illness in the past six moths) compared to lean employees. Burton, Chen, Shultz, and Edington (1999) reported that a BMI > 27 for men and women was associated with a $2,274 average annual employee health care cost, compared to $1,499 for employee with a BMI between 18.5 and 27.

In an article published in the American Journal of Public Health, researchers indicated that the cumulative value of direct healthcare costs over the period of life from 20 to 85 years of age attributable to obesity was 4.32%. Furthermore they explained that if obesity were eliminated, direct healthcare costs would be lower during each year of life from age 20 to 79. After that point, cost would actually be higher than if obesity were not eliminated because larger numbers of people would live to older ages (Allison, Zannolli, & Narayan, 1999).

Most private health insurers will pay for treating complications associated with obesity (such as arthritis and diabetes) yet they will not pay for treating the cause, overweight/obesity. Medicare (the federal program for health services for the elderly and disabled) and Medicaid (a joint federal and state program for the coverage of the poor and disabled) will not cover any services associated with obesity treatment because they do not consider obesity to be a disease or illness. However, in some situations, Medicare and Medicaid will cover gastric bypass surgery for treatment of diabetes or heart disease and pharmaceutical treatment to promote fertility or smoking cession (American Obesity Association, 2003). It is ironic that many health care plans cover conditions that are not associated with morbidity or mortality such as prescription medications for erectile dysfunction.

Table 11. The cost of obesity associated with different medical conditions.

Disease	Direct Cost of Obesity	Direct Cost of a Disease	Direct Cost of Obesity as a Percentage of Total Direct Cause of a Disease (%)
	1999 dollars in billions		
Arthritis	7.4	23.1	32
Breast Cancer	2.1	10.2	21
Heart Disease	30.6	101.8	30
Colorectal Cancer	2.0	10.0	20
Type II Diabetes	20.5	47.2	43
Endometrial Cancer	0.6	2.5	24
ESRD	3.0	14.9	20
Gallstones	3.5	7.7	45
Hypertension	9.6	24.5	39
Liver Disease	3.4	9.7	35
Low Back Pain	3.5	19.2	18
Renal Cell Cancer	0.5	1.6	31
Sleep Apnea	0.2	0.4	50
Stroke	8.1	29.5	27
Urinary Incontinence	7.6	29.2	26

Source: Excerpted from the American Association for Obesity, “Costs of Obesity,” 2003

The Weight Loss Industry

According to the National Institute of Diabetes and Digestive and Kidney Diseases (2003), Americans annually spend $33 billion dollars on weight loss products and services. This figure includes low calorie foods, artificially sweetened products such as diet sodas, and memberships to commercial weight-loss centers. Seventy-nine percent of the population spent money on weight loss products or supplements in 1999 (Nutrition Business Journal, 2003). As the rate of obesity grows, so does the market trying to promote weight loss while turning a profit. The number of people following a diet is continually rising, while consumer spending on weight loss products and services continues to escalate. The number and type of weight loss treatments seems to be limitless. Many fad diet books have made their authors wealthy, but the weight loss problem does not appear to be diminishing. For the individuals looking for solutions other than diet, alternative approaches such as surgery, pharmacology, nutritional supplements (Table 12), and homeopathy are options. The health risks and costs associated with these techniques may raise new problems.

Table 12. Weight-loss claims and clinical evidence of a variety of nutritional supplements.

Nutritional Supplements	Weight-loss Claim	General Facts & Clinical Evidence
Bladderwrack	is widely used as a weight loss product that may promote weight loss through thyroid stimulating effects	there is little data to support its use, and it's high iodine content might result in disease.
Chitosan	promotes weight loss	a derivative of shells of crab, shrimp, and lobsters, was shown in clinical studies to slightly reduce serum lipids
Hydroxycitrate (HCA)	has been touted to increase hepatic glycogen synthesis, suppress appetite, and promote weight loss.	is a fruit acid extracted from the rind of the brindall berry. The research with this product is mixed and inconclusive.

Table 12 continued. Weight-loss claims and clinical evidence of a variety of nutritional supplements

Germander	promotes weight reduction	is a mint herb used in teas, capsules. The research on weight-loss is inconclusive. It has been positively linked with hepatitis, hepatoxicity, and jaundice and is banned in France.
HMB	marketers claim it increases the ability of the body to build lean tissue and burn fat.	is a metabolite of the amino acid leucine. It is found in plants, animal products, and human breast milk. Human researcher supports these claims on a modest level when the supplement is combined with resistance training in non-obese individuals.
Psyllium	is reported to reduce appetite and promote weight loss.	is the seed of the leafy plant plantain. Controlled research demonstrates only minor benefits in the form of short-term appetite suppression and large dosages were shown to cause abdominal distress.
Pyruvate	has been marketed as a nutritional supplement for weight loss and glucose control.	research for this product was mixed and inconclusive.
St. John's Wort	because of it's presumed serotonergic action, it has been claimed by some to control appetite.	is an extract from flowing plants that is commonly used to treat depression, however there is no research to support appetite suppression.
Sunflower	is suggested to be beneficial for treating obesity, constipation, and diabetes,	no research to support this claim.

Source: Excerpt from Dyck, "Dietary Fat Intake, Supplements, and Weight Loss," 2001.

Fad Diets

The definition of a fad diet is any diet not endorsed by at least one of the following associations: The American Dietetic Association, The American Heart Association, The American Diabetic Association, or the United States Department of Agriculture. Fad diets usually include at least one of the following claims: large and rapid weight loss, claims of miraculous curing of disease, last only a few days, up to the minute and revolutionary, no exercise required, required assistance of special garments or passive exercise equipment, and eat all the calories you want and still lose weight (Tumolo, 2001). Margaret Gibbs (1990) a representative for the National Heart Foundation, suggests that consumers should beware of any diet that requires combining specific foods, consuming an exotic range of expensive or unusual foods, or purchasing special powders, pills, meal replacements, or food supplements. Editors of Harvard Women's Health Watch (1998) suggests that calorie cutting is the most important factor in achieving weight loss, and that the only reason fad diets show limited success is because they are usually hypocaloric. Supporters of fad diets suggest the conservative medical community is too slow to accept new ideas, even if the new ideas are based on sound scientific reasoning. With the multitude of fad diets available, it would be cumbersome to develop a system to accurately categorize all fad diets. In the interest of highlighting some of the more popular or recognizable diets, the follow categories were established: high carbohydrate diets, low carbohydrate diets, and other fad diets. Diets that did not fit neatly into one category were placed in one of the following based on major claim or primary characteristics of the diet.

High Carbohydrate Diets

Most high carbohydrate diets contain enough starches and sweets to satisfy cravings, and their high fiber and water content tend to increase bulk, which is reported to help control appetite. Examples of diets that fall into this category include the Pritikin Maximum Weight Loss Diet (PMWLD), the Pritikin Permanent

Weight Loss diet (PPWLD), the F-Plan Diet, and Dr. Cooper's Fabulous Fructose Diet. The PMWLD provides up to 85% of its calories from complex carbohydrates, 5% to 10% of calories from fat, and about 10% of calories from protein. The PMWLD diet has two versions, 600 calories and 1,000 calories. The PPWLD is more liberal with the calorie levels increased to 700 and 1,200 respectively and an increase in protein content. The F-Plan Diet contains 1,000 to 1,250 calories is low in protein, and high in fiber (35 to 50 grams per day). The developer of this diet suggests that the high fiber content will promote satiety, while decreasing the absorption of some of the calories consumed, thus promoting weight loss. Dr. Cooper's Fabulous Fructose Diet advocates promote increased intake of fructose as a carbohydrate source (American Obesity Association, 2003).

Low Carbohydrate Diets

Diets in this category contain little or no carbohydrates and therefore cause ketogenesis (incomplete oxidation of fats resulting in the accumulation of intermediary acetyl-Coa molecules called ketone bodies). These diets also tend to be high in protein and fat. Advocates report that these diets promote satiety and reduced calorie consumption through ketosis and high fat consumption, while high protein content reduces muscle catabolism. Examples of diets that fall into this category include: Dr. Atkins Diet Revolution, The Zone, Protein Power, Sugar Busters, The Doctors Quick Weight loss Diet, The Stillman Diet, South Beach Diet, and The Complete Scarsdale Medical Diet (American Obesity Association, 2003).

The Dr. Atkins Diet Revolution. This diet, developed by Dr. Robert Atkins requires participants to consume 60% of their calories from fat, 35% of their calories from protein, and 5% of the calories from carbohydrates. The diet does not restrict calories and does not specify the distribution of the type of fat (saturated, unsaturated, and monounsaturated). The Atkins Diet suggests that participants experience early

satiety with the high fat levels and therefore are less likely to overeat. It is reported that participants achieve lower insulin levels, which will reduce fat storage and promote weight loss (Associated Press, 2002).

The Zone Diet. The Zone is a low carbohydrate plan with sales placing it among the most popular diet books in recent history. The diet contains 40% carbohydrate, 30% protein, 30% fat, and only a sparse amount of grains and starches. Dr. Barry Spears, the author of the Zone Diet book, states that the diet, which is a precise 0.75 protein to carbohydrate ratio, reduces insulin to glucagons ratio, enhances immunity, promotes increased production of "good" eicosanoids, maximizes physical and mental performance, increases longevity, and promotes permanent weight loss (Cheuvront, 2003).

Protein Power. Written by a husband and wife doctor team (the Eades) in 1996, Protein Power is a low carbohydrate, high protein diet. The diet regulates protein based on activity level and carbohydrates are restricted to 30 to 50 grams per day. The Eades state that the diet causes an individual to achieve a healthy normal weight by controlling insulin levels. Supplements are recommended with this diet plan (Diet Information, 2003b).

Sugar Busters. Developed in 1995, this diet is based on the claim that sugar is toxic. Dieters following this diet are prohibited from eating potatoes, white bread, pasta, white rice, carrots, and all sugars. Small amounts of whole grains are permitted. The calorie distribution is 30% protein, 40% fat, and 30% carbohydrates. Like many of the other low carbohydrate diets, the authors of this diet suggest that insulin causes weight gain, and by reducing carbohydrates, insulin production is reduced, thus causing weight loss (Diet Information, 2003a).

The Doctor's Quick Weight Loss Diet. Dr. Irwin Stillman created this diet, which is a 1,500 to 1,800-calorie plan consisting of up to 90% of the calories as protein. The diet also requires participants to drink 64 ounces of fluid a day to prevent dehydration. Dr. Stillman's theory behind the diet is protein molecules are large and complex and therefore harder to digest. Dr. Stillman claims that up to 30% of the calories from

protein are burned up in the digestive process. Due to the low consumption of fruit and vegetables, Dr. Stillman suggests taking vitamin and mineral supplements to prevent deficiencies (Friedman, 1986).

The South Beach Diet. Created by Dr. Arthur Agatston, this is a three-phase low carbohydrate diet. Phase-one lasts two weeks and consists on lean meat, low fat cheese, nuts, eggs, and vegetables with low Glycemic-index vegetables. Phase-two incorporates some of the foods banned in phase one such as fresh fruit. Phase-three is a low fat low refined carbohydrate diet for maintenance, once a weight goal is achieved (South Beach, 2005).

The Scarsdale Medical Diet. This diet, developed by Dr. Herman Tarnover restricts carbohydrate consumption to 80 to 90 grams per day. With this diet, planned menus detail specific daily food consumption. Aside from carbohydrates, the diet does not clearly identify the quantity of foods to consume (Diet Information, 2003a).

The Last Chance Diet. Dr. Robert Linn developed this liquid protein plan. The protein source reported to be high in essential amino acids was extracted from sow underbellies and beef hides. The over the counter protein mixture was commercially produced as Prolinn, Windmill, Pro-fast, Gro-Lean, and Slim-Powder. More than 60 deaths were attributed to this diet, with autopsy findings showing degenerated heart muscles, potassium depletion, amino acid imbalance, and trace mineral depletion (Friedman, 1986).

The Cambridge diet. Dr. McLean Baird and Dr. Alan Howard developed this plan that provides 330 calories and 30 grams of protein per day from a liquid formula. Other formulations provide 420 and 800 calories and 50 grams of protein per day. The formula contains all essential vitamins and minerals and directions on the over-the-counter product indicate that a physician should approve and supervise patients on this diet. The Food and Drug Administration in conjunction with the American Society of Bariatric Physicians warn that this diet is extremely dangerous and poses significant health hazard if not supervised by a physician.

Other liquid diets similar to this diet but only available through a licensed physician include Optifast, Medifast, Nutrimed, and Proti-15 (Friedman, 1986).

The Cabbage Soup Diet. The cabbage soup diet requires dieters to follow bizarre combinations each day, while allowing unlimited consumption of cabbage soup. The soup recipe includes a cabbage, onions, tomatoes, flavored bouillon, onion soup mix, and tomato juice. This diet is very low calorie and inadequate in a variety of nutrients including protein (Diet Information, 2003a).

Eat Right 4 Your Type. Dr. Peter D'Adamo, the developer of this diet claims that individuals should eat food based on their blood type. Dr. D'Adamo claims the diet will improve overall health and shrink a person down to their proper size. The diet is complicated and would be difficult to follow if family members have different blood types (Diet Information, 2003a).

The Grapefruit Diet. The grapefruit diet is a 21-day low protein, very low calorie plan. Breakfast includes a half a grapefruit and plain black coffee; lunch includes a half a grapefruit, an egg, raw vegetables, a piece of toast, and plain black coffee or tea. Supper is the same as breakfast, except it includes two eggs. This diet is high in vitamin C, but it is inadequate in iron, calcium, and many other vitamins (Diet Information, 2003a).

The Hollywood 48-hour Miracle Diet. This plan is a formula diet consisting of a mixture of fruit juices, vitamins, minerals, and essential oils. The diet is hypocaloric and diuretic and claims to cause dramatic weight loss in 48 hours. Health professionals warn that this diet causes nothing more than temporary fluid losses (Diet Information, 2003a).

Balanced Hypocaloric Diets

Balanced hypocaloric diets are not considered fad diets because they generally contain the recommended daily allowance of protein, fats, carbohydrates, minerals, and vitamins outlined by the United

States Department of Agriculture. Diets in this category consist of 1,000 to 1,200 calories for adults and 1,500 to 1,800 for very active or large framed individuals. The caloric distribution of macronutrients fall within the following ranges: 50% to 55% carbohydrates, 15% to 20% protein, 20% to 35% fat, and 25 to 30 grams of fiber.

Examples of diets that fall in this category include: Prudent Diet, La Costa Spa Diet, Diets advocated by Weight Watchers and TOPS (Take Off Pounds Sensibly), I Love America Diet, Dr. Rechtschaffen's Diet, Redbook's Do-It-Yourself Wise Woman's Diet, Setpoint Diet. Dietary recommendations of the American Diabetic Association, the American Heart Association, The American Cancer Association, and the America Diabetic Association, which are based on the Recommended Daily Allowances for Americans, fall into the balanced hypocaloric category (Friedman, 1986).

Conservative Management

Aside from diet, the professional health community considers exercise and behavior modifications as the cornerstones of weight management (Moloney, 2000).

Exercise

Only one-third of Americans actively participate in an exercise program (Office of the Surgeon General, 2002). However, this statistic seems to improve when looking at the percentage of individuals who use exercise as part of a weight loss plan. In a multistate telephone survey conducted in 1994, 44% of women and 45% of men trying to maintain their weight were participating in routinely daily exercise, while 61% of women and 60% of men trying to lose weight were exercising routinely (Serdula, et al., 2000). For those participating in exercise routines, walking, gardening, and cycling were the most popular forms (Moloney, 2000).

Research confirms that exercise contributes significantly to weight loss and the most beneficial effects of physical activity on cardiovascular disease mortality can be attained through daily low to moderate intensity activity. The United States Surgeon General recommends moderate physical activity five days a week for 30 minutes per day for adults (60 minutes per day for children) to prevent obesity and promote optimal health. Weight loss requires consuming fewer calories than energy expenditure. Following the Surgeon General's recommendations for physical activity will increase calorie expenditure by 150 calories per day, which is equivalent to approximately five pounds weight loss in six months and ten pounds weight loss in one year. When combined with 150-calorie reduction in diet a day, this can add up to a ten-pound weight loss in six months or a twenty pound weight loss in one year. Raking leaves, walking, gardening, and dancing an example of several activities that burn approximately 150-calories in 30-minutes time (Appendix P) (Office of the Surgeon General, 2002).

According to the National Center for Chronic Disease Prevention and Health Promotion (2003) routine regular physical activity such as walking or cycling for 30 minutes daily can improve health by promoting healthy bones, muscles, and joints and by reducing the risk of dying prematurely from heart disease, high blood pressure, or colon cancer.

Behavior Modification

Behavior modification is the emphasis on processes that are necessary for lifelong change. It includes establishing long and short-term goals, self-monitoring strategies (i.e., food and exercise diaries), rewards for success, limitation of cues that prompt overeating, overcoming negative self-talk, and relapse prevention. As a minimum, long-term and short-term goals should include improved eating habits and exercise. Short term-goals should be specific and measurable. Rewards should be desirable, tangible, non-edible, and available only if the goal is met. The success of behavior modification programs is well documented; however, its popularity

is limited due to the long-term nature of the processes and the lack of quick solution desired by an on-the-run generation (Moloney, 2000).

Medical/Surgical Weight Loss Treatments

Prescription of weight loss medications and bariatric surgery are two weight-loss treatments that are utilized for patients in conjunction with diet and exercise, when conservative management by itself is unsuccessful, or when an individual's weight is considered at high risk for premature death.

Pharmacology

Typically physicians will not use prescription drugs as a first line of treatment for obesity. Most drugs are not advised as long-term solution for weight loss, but rather a temporary tool until short-term goals are reached. There are currently three drugs or classes of drugs regarded as effective for treating obesity: cerebral stimulants, orlistat, and sibutramines. Cerebral stimulants (Amphetamine Sulfate, Diethylpropion, Mazindol, and Phendimetrazine) are powerful appetite suppressants that have a strong effect on the central nervous system. Side effects of amphetamines include excitability, cardiac disorders, and dependence; therefore, they are contraindicated for patients with psychiatric or cardiac problems. Fenfluramine, brand name Redux or Pondimin, is also a cerebral stimulant. This medication was shown to be effective in treating obesity; however it is presently banned in the United States due to adverse side effects, including pulmonary hypertension, cardiomyopathy, and death. Orlistat, brand name Xenical, inhibit fat digesting enzyme lipase, reducing up to 30% of fat particles digested in the small bowel. Research demonstrates positive weight loss outcomes, however, it also indicates negative side effects including: urgent diarrhea, fatty stool, anal leakage, and potential deficiency of vitamins A, D, E, and K, and beta-carotene. Sibutramine, brand name Meridia, is an appetite suppressant that is meant for long-term use, since appetite-suppression effects do not fade after 3 to

12 weeks as with other appetite suppression drugs. (Diet Information, 2003b; Drug Handbook, 1991; Dujovne & Bays, 2002; Haller & Schwartz, 2002; Obesity-Diet, 2003; Patten, 2002).

Surgery

Gastric surgery, also called bariatric surgery, is a risky, last resort treatment reserved for patients who are morbidly obese. To be eligible for bariatric surgery it is recommend that a patient meet the following criteria: between the ages of 18 and 60, documented failure with a dietary weight loss plan lasting at least one year, have a BMI of 40 or above, free of chronic disease such as cancer, free of addiction to alcohol or drugs, not pregnant, and sufficiently motivated. There are three main bariatric procedures: laparoscopic adjustable banding (LAGB), stapling gastroplasty, and gastric bypass. Each of the surgeries involves limiting the capacity of the stomach, thus reducing food consumption. With LAGB a band is placed around the superior part of the stomach, creating a pouch through which only small quantities of food will pass. Consuming food quantities beyond the capacity of the pouch will cause gastric pain and vomiting. Stapling gastroplasty, a procedure usually performed through laparotomy (a small opening in the abdominal wall) involves creating a small upper gastric pouch using a small ring and a staple line. The concept is the same as the gastric band, but more invasive. Gastric bypass is the most complex and invasive of the bariatric surgeries. It is also considered a permanent solution, although it is reversible if necessary. It entails sewing up a large part of the stomach and reattaching the small bowel to the smaller stomach pouch formed by the suture (Obesity-Diet, 2003).

Intragastric balloon placement is another type of laparoscopic bariatric surgery that has been around since 1982. The concept is to place a balloon in the stomach to temporarily limit the volume of the stomach. However, this type of surgery was abandoned after a few years due to complications such as spontaneous early deflation, balloon displacement, and intestinal obstruction. Recently a new type of balloon was designed and developed that was supposed to reduce or eliminate these problems. One difference of this surgery compared

to the traditional bariatric surgery is that it is being targeted at patients with a BMI of 35 or greater versus 40. (Obesity-Diet, 2003)

According to Mun, Blackburn, and Matthews (2001) surgical therapy is the most effective treatment in terms of the extent and duration of weight loss in selected patients with acceptable operative risk. The most common surgical procedure, Roux-en-Y gastric bypass has shown a 90% success rate with patients losing more than 50% excess body weight and maintaining weight loss for more than 14 years.

Alternative Weight Loss Treatments

Alternative weight loss treatments (nutritional supplements, acupuncture, acupressure, aromatherapy, hypnosis, subliminal suggestions, and thigh creams) accounted for 42% of adult weight loss treatments in the United States in 1997 and $27 billion in consumer spending in 1997 (Allison, Fontain, Heshka, Mentore, & Heymsfield, 2001).

Nutritional Supplements

According to Blanck, Khan, and Serdula (2001) a many Americans purchase nutrition supplements, and multivitamins, vitamin C and vitamin E are the most popular choices. In 1982 approximately 66% of adults in the western United States were using some type of food supplements and as many as to 40% of adults were consuming up to three different supplements per day. Within the nutrition supplement market there are a variety of products called fat burners. Ephedra and Phenylpropanolamine (PPA) are two common examples of fat burners that have raised health concerns in the recent past. In a multistate survey conducted in 2001, 2% of participants reported PPA use, and 1% reported ephedra use (Blanck et al., 2001). Products containing ephedra have stimulant properties and are purported to decrease weight when used in combination with caffeine through thermogenesis and reduced appetite. PPA, the primary ingredient in over-the-counter (OTC) weight loss aids Dexatrim and Acutrim, is a synthetic ephedrine alkaloid with stimulant properties that may decrease

appetite. In 2003, the Food and Drug Administration (FDA), restricted dietary supplements containing ephedra due to health concerns. In November of 2000, manufacturers of Dexatrim and Acutrim voluntarily withdrew PPA containing products off the market after reports of increased cerebrovascular and cardiac events associated with PPA product usage. Examples of other products that fall into this category are Liquid Clenbutrx, MD6, Metabolite Compete, Hydroxycut, Xenadrine, RFA-1, and Stacker 3 (Blanck et al., 2001; Smith, 2001).

Examples of other nutrition supplements touted to promote weight loss include chromium, conjugated linoleic acid (CLA), and dehydroepiandrosterone (DHEA). Chromium is an essential element that is required for carbohydrate and lipid metabolism. Deficiency of chromium produces elevated blood glucose, and elevated serum lipids. Many people believe chromium's effect of increasing insulin sensitivity and decreasing circulating insulin may help with weight control. The literature with respect to chromium for supporting weight loss is equivocal, with a minority of studies supporting a beneficial effect.

CLA are naturally occurring trans-fatty acids found in meat and dairy products of ruminant animals. In animal studies, CLA has been shown to reduce adiposity and improve glucose tolerance. Among humans, there is preliminary evidence that CLA may have a mild anabolic affect on bodybuilders.

DHEA is a steroid hormone secreted by the adrenal glands that is suggested to reduce adiposity. It is marketed as a nutritional supplement. There is a small amount of research to support such claims, and safe amounts are not understood. Bladderwack, chitin, hydoxycitrate, germander, β-hydroxy-β-methylbutyrate (HMB), psyllium, pyruvate, St. Johns Wart, and sunflower are other nutritional supplements touted to promote weight loss (Allison et al., 2001; Crawford, Scheckenbeck, & Preuss, 1999; Dyck, 2000).

Acupuncture /Acupressure

Acupuncture is the insertion of small needles into specified locations on the body for therapeutic purposes. Acupressure is the application of needless pressure to the same anatomical locations. Advocates of

these therapies report that the pressure or puncture stimulate the auricular branch of the vagal nerve, raising serotonin levels, increasing smooth muscle tone of the stomach, and thus reducing appetite. The research results for these therapies as appetite suppressants have been mixed. The more controlled studies demonstrated no effect (Allison, et al., 2001).

Aromatherapy

Aromatherapy has many definitions within the world of marketing and complementary medicine. For weight loss treatment, it is defined as exposure to particular olfactory stimuli with the intent of producing weight loss. There is research to support aromatic inhalants in producing weight loss, though the results were not statistically significant. The mechanism that may promote weight loss is not well defined (Allison, et al., 2001).

Hypnosis

Evidence from controlled studies suggests that hypnosis may play a modest role in weight loss when combined with cognitive behavioral treatment. Anxiety, depersonalization, and dissociation were side effects observed in obese adolescents treated with hypnotherapy (Allison et al., 2001).

Subliminal Suggestions

It has been suggested that audio stimuli below the level of limin (sensory threshold) may stimulate the unconscious to produce desired effects. Research using subliminal audiotapes for weight control consistently demonstrated no difference from placebo and treatment tapes (Allison et al., 2001).

Thigh Creams

In 2000 approximately $17 million dollars was spent on thigh creams in the United States. Thigh creams are ointments containing adrenergic modulators meant to stimulate lipolyis from fat cells. Developers claim that by increasing the local concentration of beta antagonists or inhibiting receptors to fat cells on the

thigh, fatty acids could be released more readily. Research results demonstrate at best only minute reductions, which is of no significance to the medical health professionals (Allison et al., 2001).

Weight-Loss Success Rates (Short-Term and Long-Term)

Weight loss success is a subjective concept. Many health professionals consider a 10% loss a good baseline because of the frequently observed reductions in health risk factors at this level. Furthermore, the best point for distinguishing long-term and short-term success is unclear. Some researchers believe that six months is an ideal time frame for assessing initial loss, 18 months and 30 months are good follow-up periods, and five years is ideal for evaluating long-term success. While long-term success has been observed on a very limited basis, most studies indicate that such success is much more the exception than the rule. Increases in prevalence of overweight within the population, despite high rates of dieting, also suggest successful weight losses are being offset by failures. A review of behavior weight loss treatment plans shows a 75% increase in short term success rates (from 5% in 1974 to 9% in 1994). Studies evaluating long-term success have demonstrated that dieters often lose up to 12% of their weight, but then maintain only 4% losses after four years (Jeffery et al. 2000). A study by Miller and Maropis (1998) revealed over the past 40 years, dieters on a 15-week diet or diet and exercise programs lose an average of 11kg with about 60 - 80% maintenance after one year, and almost 100% relapse after three to five years.

Impact of Low-Carbohydrate Diets

At a recent conference of the American Heart Association (AHA), researchers presented promising evidence of the benefits of low carbohydrate diets. They suggested the rising global incidence of obesity and the limited success in curbing this epidemic highlights the need for continuing research in the area of obesity treatment (Associated Press, 2002). In a new unpublished study, conducted by doctors Gary Foster, Samuel

Klein, and James Hill (current and past presidents of the North American Association for the Study of Obesity) found that a low carbohydrate diet outperformed a standard high carbohydrate diet. In this study men lost an average of 19 pounds on the low-carbohydrate diet, which was 10 more pounds than participants on a standard high carbohydrate diet. Foster, who has published more than 50 scientific papers on obesity treatment, was quoted as saying "I'm part of the obesity establishment, I've spent my life researching ways to treat obesity, and 100% of them have been low-fat and high-carbohydrate. Now I'm beginning to think, it isn't as it appeared" (Haney, 2003).

Low Carbohydrate Versus High Carbohydrate

Weight Loss

Proponents of ultra-low carbohydrate (ULC) diets, such as the Dr. Atkins diet (5% CHO, 35% protein, and, 60% fat) claim ULC diets cause weight loss by naturally reducing caloric intake. They suggest that insulin levels are positively related to hunger levels and low CHO consumption reduce insulin levels. Next, they claim fat consumption produces early satiety, which further reduces total caloric consumption. Furthermore advocates suggest that ULC diets, which are often high in saturated fat and sodium, and low in fiber and fruits and vegetables are safe and that the benefits of such diets outweigh the potential health risks (Harvard Men's Health Watch, 2003).

Opponents of low carbohydrate diets claim that these diets have short-term success because low CHO consumption causes dehydration and secondary water weight losses. Furthermore, they claim that ULC diets may increase the risk or heart disease, kidney disease, and nutrient deficiencies because ULC diet are usually high in saturated fat, sodium, and protein, and low in fiber, fruits, and vegetables (Harvard Men's Health Watch, 2003).

The majority of research related to low carbohydrate diets is positive for weight loss, but in none of the studies reviewed was there an attempt to measure weight changes attributable to changes in

hydration status. In a study utilizing 120 overweight volunteers conducted at Duke University by Dr. William Yancy, subjects following a low-CHO diet lost a mean weight of 13.3 kg and 9.7kg fat mass compared to 8.6kg average weight loss and 6.5kg fat mass loss for subjects following a low-fat diet (Peck, 2002). Another study conducted at Duke, and funded by an unrestricted grant from the Atkins Center for Complementary Medicine, demonstrated a mean 5.9% weight decrease in a group of 51 overweight subjects following an ULC diet for six months (Westman, Yancy, Edman, Tomlin, & Perkins, 2002).

In other studies, diets with carbohydrates and fat modifications different from those in ULC and ULF diets were compared. In a study comparing very low-calorie-very-low-CHO diets (< 1,000 kcal/day, 10% to 21% CHO) with very-low-calorie-high-CHO- (< 1,000 Kcal/day, 66% to 70% CHO), hospitalized and free living subjects receiving either formula or solid foods lost significantly more weight on the very low-calorie-very-low-CHO diets (Kasper, Thiel, & Ehl, 1973; Baron, Schori, Crow, Mist, & Mann, 1986; Rabast, Kasper, & Schonborn, 1978; Rabast, Schonborn, & Kasper, 1979). In other studies utilizing either very-low-calorie diets (≤ 1,000 kcal/day) or high-calorie diets (4,000 to 5,000 calories / day), where CHO intake per day ranged from 15% to 55%, observed weight was slightly greater with the reduced CHO diets or there was no significant difference between the low and high CHO diets (Biakowsk, Szostal, Chotkowsk, Szczyglow, & Medrzejew, 1977; Golay, Allaz, Morel, Tonnac, Tankova, 1996; Golay , Eigenheer, et al, 1996; Lean, Han, Richmond, & Avebell, 1997).

Low CHO Diets and Cardiovascular Disease

The high total fat and high saturated fat content of ULC diets goes directly against recommendations by the American Heart Association (AHA). According to the AHA, diet high in total fat, saturated fat, and transaminated fatty acid increase risk factors associated with heart disease. Specifically, a diet low in total fat,

saturated fat, and transaminated fatty acids help to lower total cholesterol, LDL cholesterol, trigylcerides, and increase HDL cholesterol. (American Heart Association, 2002)

The research regarding the impact of low carbohydrate diets on total cholesterol, LDL cholesterol, trigylcerides, and increase HDL cholesterol is mixed. There are numerous studies that show a positive, or at least no negative, impact of low carbohydrate diets. In the study utilizing 120 overweight volunteers conducted at Duke University by Dr. William Yancy, trigylcerides were significantly lower in both groups (low-CHO and low-fat diet groups), total cholesterol decreased significantly in the low fat group, and ratio of total cholesterol to HDL cholesterol decreased significantly in the low CHO group (Peck, 2002). In the study funded by an unrestricted grant from the Atkins Center for Complementary Medicine at Duke University, overweight subjects following an ULC diet for six months had the following serum lipid changes: (a) serum total cholesterol decrease of 11± 26mg/dl, (b) a serum LDL decrease of 10 ± 25 mg/dl, (c) a serum trigylcerides decrease of 56 ± 45 mg/dl, and (d) an serum HDL increase of 10 ± 8 mg/dl (Westman et al, 2002). Other studies suggested that low-CHO-diets may not have a negative impact on cardiovascular disease risk factors and may be more beneficial in helping to reduce trigylcerides compared to high CHO diets (Biakowsk et al., 1977; Brown & Cox, 1998; Garg, Grunday, & Unger, 1992; Golay et al., 1996; Lean, et al., 1997; Rabast et al., 1978; Rabast et al., 1979; Sharman et al., 2002; Vidon et al, 2001). In studies comparing low and high carbohydrate diets, as patients lost weight, total cholesterol and LDL cholesterol reduced equally regardless of CHO modifications (Brown et al., 1998; Garg et al., 1992; Golay et al., 1996; Lean et al., 1997; Rabast et al., 1978; Sharman et al., 2002; and Vidon et al., 2001).

There are, however, studies demonstrating a negative impact of low CHO diets on cardiovascular disease risk factors. In a study supported by a grant from the Washington Heart Association, researchers asked 24 subjects to follow a ULC diet for 12 weeks. The results demonstrated significant weight reductions, but significant increases in total cholesterol (12.3 mg/dl ± 2.6), LDL cholesterol (23 mg/dl ± 2.7), and a significant

decrease in HDL cholesterol (-2.9 mg/dl ± .66) were observed (Larosa, Fry, Muesing, & Rosing, 1980). In a second study, in which ten men followed low CHO diets rich in monounsaturated fatty acids for eight weeks, transient increases were observed in total cholesterol and LDL cholesterol (Volek, Gomez, Kraemer, 2000). In a third study, 93 subjects were randomly divided into two groups, a low CHO and a low fat. After one month both groups showed decreases in total cholesterol, but after one year only the low fat group showed sustained reductions in total cholesterol (Hockaday, Hockaday, Mann, & Turner, 1978).

Diabetic Control

In recent years, the American Diabetic Association (ADA) liberalized guidelines for diabetic diets and further research suggests diabetics may benefit by even further modifications. The standard diabetic diet has been similar to the American Heart Association (AHA) diet (55% CHO, 15% protein, and 30% fat). However, unlike the AHA diet, ADA diet stresses limited intake of refined carbohydrates and balanced distribution of carbohydrates and meals throughout the day. Now the ADA says it is better to consider the total grams of CHO per day rather than the source. The new guidelines reject mandatory percentages and instead suggest calories should be apportioned based on an individual's specific goals, glucose control, lipids, and weight. When standard diabetic diets were compared to reduced CHO diets, the reduced CHO diets showed great promise in controlling symptoms of diabetes mellitus. A study utilizing 28 subjects following a 28% CHO diet (versus the standard 55% CHO diet) for eight weeks demonstrated the lower CHO diet was more effective in reducing fasting blood glucose and hemoglobin A_{1c} (Gutierrez, Akhavan, Jovanovic, & Peterson, 1998). In another study, 21 subjects were divided into two diet groups for 14 weeks. One group followed a standard diabetic diet (55% CHO, 15% protein, and 30% fat), while the other group followed a 40% CHO, 15% protein, 45% fat (mostly monounsaturated fat) diet. The higher CHO diet group displayed higher plasma glucose, higher plasma insulin, and higher and plasma triglyceride levels (Garg et al., 1994). In a study

conducted by Fujita, Gotto, and Unger (1975), twenty-two volunteers were divided into two diet groups (1% CHO diet and a 55% CHO diet). After one week the low CHO diet group realized reductions in insulin and triglyceride levels with increased glucagons levels, while the high CHO diet group realized significant increases in insulin and triglyceride levels and decreased glucagons levels.

Renal Function

In many of the low carbohydrate diets promoted today, protein levels are elevated above ranges recommended as necessary by nutrition professionals (American Dietetic Association, 2002). It is well agreed upon in the scientific and medical community that excess protein is hazardous to patients with impaired kidney function (Zeman, 1991). The understanding that is less clear is the impact of high protein diets on healthy kidney function.

Recent research suggests that healthy adults may be able to tolerate high protein diets without adverse effects to kidney function. According to research done by Poortmans and Dellalieux in 2000, a protein intake of up to 2.8kg / kg of body weight does not have an adverse affect on creatinine clearance or blood urea nitrogen (BUN), and therefore does not appear to impair renal function in healthy kidneys. According to Skov et al., (1999), moderate changes in dietary protein (± 20 grams per day) cause adaptive alteration in renal size and function without any evidence of adverse effects. Millward (1999) suggested that that high protein diets (up to 3gms/ kg /day) may be beneficial in reducing blood pressure and stroke mortality, while not having negative effects on healthy kidneys. Other research shows that high protein diets may increase the potential kidney stone formation.

Bone Loss

According to some researchers, bone loss may be a negative consequence of high-protein weight loss diets (Shalini, Wang, Sakhaee, Brinkley, & Pak, 2002). However, other research disputes this theory. A six-

month study of high-protein weight loss diets by researchers (Skov, Haulrik, Toubro, Molgaard, & Astrup, 2002) indicated that high-protein diets did not have an effect on bone mineral content. Roughhead, Johnson, Lykken, and Hunt (2003) demonstrated high protein/high meat diets did not affect calcium retention or other indices of bone status in healthy postmenopausal women.

Mood and Satiety

In a study conducted by Rolls (1995), it was observed that when normal weight unrestrained men were given equal volumes of sugar and fat, that both sugar and fat had the same effect on hunger and satiety. In obese restrained subjects, preloads of high carbohydrate yogurts suppressed subsequent intake more than the high fat yogurts, suggesting a relative insensitivity to the satiety value of fat.

In another study, 20 obese out-patients followed a baseline free-feeding diet, followed by alternating 2-week periods of minimal carbohydrate diets (800 calorie, 58% protein, and 42% fat) and of a carbohydrate supplemented diet (1000 calories, 42% protein, 30% fat, and 28% carbohydrate). The initial two week period of dieting was associated with a decrease in appetite and an elevation in feelings of well-being regardless of the compositions of the diets. Thereafter, appetite and mood approached baseline levels. Further changes in physiological reactions to diet did not vary with the type of diet. These results suggest that low CHO diets are no more beneficial than regular low calories diets for decreasing appetite or elevating mood (Rosen, Gross, Loew, & Sims, 1985).

Update 2003-2004

During an updated literature review conducted for the period 2003 to 2005, six research articles that compared low carbohydrate and low fat diets were identified. The overall results indicated several potential benefits of low carbohydrate diet over a low fat diet including: increased weight reduction, increased visceral fat loss, improved insulin sensitivity, HDL cholesterol elevation and, increases in reduction of triglycerides,

total cholesterol, and LDL cholesterol. The research studies ranged in length from four weeks to one year, while the number of subject varied from 13 to 87 participants. Five of the six studies utilized low carbohydrate diets ranging from 20 to 30 grams per day, while one of the studies defined low carbohydrate as 40% (110 grams) of an 1100 calorie diet. Only one of the six studies established a caloric limit for the low carbohydrate diet. Caloric restrictions for the low fat diets ranged from 1100 calories to 1800 calories, with the majority of researchers selecting a 500-calorie deficit from average participant energy needs as a basis. Each of the six articles is discussed in more detail below (Brehm, Seeley, Daniels, & Dalessio, 2003; Foster et al., 2003; Miyashita et al., 2004; Vancy, Olsen, Guyton, Bakst, & Westman, 2004; Stern et al., 2004; Volek et al., 2004).

In a study in which both diet groups were assigned the same calorie level (Miyashita, et al. 2004), type two diabetic patients were randomly divided into two groups: low calorie/low carbohydrate (n= 11, 1000 kcal/day, protein:carbohydrate:fat = 25:40:35) or low calorie/high carbohydrate (n= 11, 1000 kcal/day, protein:carbohydrate:fat = 25:65:10) for four weeks. Similar reductions in weight, serum glucose, total cholesterol, and triglycerides were observed in both groups. HDL cholesterol increased in the low carbohydrate group but not the high carbohydrate group (+15% versus 0%, $P<0.01$). Fasting serum insulin levels decreased in the low carbohydrate group compared to the high carbohydrate group (-30% versus –10%, $P<0.05$). There was a larger decrease in area of visceral fat and the ratio of visceral fat area to subcutaneous fat area (computed by tomography) in the low carbohydrate group compared to the high carbohydrate group (-40cm^2 versus -10cm^2 , $P<0.05$, and –0.22 versus –0.02, $P<0.05$). A low carbohydrate low calorie diet was more effective than a high carbohydrate, low calorie diet in reducing visceral fat, improving insulin sensitivity, and improving HDL cholesterol in obese patients with type II diabetes. Vancy et al. (2004), randomly divided one-hundred fifty nine overweight, hyperlipidemic volunteers into two groups: low-carbohydrate (n=59, <20gm of carbohydrate daily) or low-fat (n=60, <30% energy from fat, <300mg cholesterol daily, and deficit 500 to 1000 kcal/day). At the end of six months retention rates were higher for the low-carbohydrate group

compared to the low-fat group (76% versus 57%). Weight loss was also greater for the low-carbohydrate group compared to the low-fat group (-12.9% versus –6.7%, P<0.001). Compared with low-fat diet recipients, low-carbohydrate recipients had greater decreases in serum triglycerides levels (-74.2mg/dl versus –27.9mg/dl, P=0.004) and greater increases in HDL cholesterol (5.5mg/dl versus –1.6mg/dl, P<0.001). The low-carbohydrate diet was more effective than a low-fat, low-calorie diet for maintaining participant retention, lowing weight, reducing serum triglycerides, and improving HDL cholesterol in overweight patients with hyperlipidemia.

In a third study, researchers solicited thirteen normolipidemic, overweight women and randomly divided them into two low-calorie (500 kcal deficit/day) diet groups: very low-carbohydrate (<10% carbohydrate) and low-fat (<30% fat) four weeks. Both diet groups significantly reduced total cholesterol and LDL cholesterol, but only the low-carbohydrate group showed an improvement in HDL cholesterol (1.0mg/dl versus –4.0mg/dl), insulin sensitivity (-3.6mg/dl versus 9.5mg/dl), and insulin resistance (-0.18mg/dl versus 0.35mg/dl)(P<0.05). Compared to a low-fat diet, a low-carbohydrate diet may be beneficial for preventing a decline in HDL, while improving insulin sensitivity (Volek et al, 2004).

Foster et al. (2003), published the results of the following study in *The New England Journal of Medicine*. In a one-year study, 63 men and women were randomly divided in two diet groups: low-carbohydrate, high-protein, high-fat (<20gm carbohydrate) or low-calorie, high-carbohydrate, low-fat (1200-1600 kcal/day, 60% carbohydrate, 25% fat, 15% protein). Subjects on the low-carbohydrate diet lost more weight than the subjects on the conventional diet at three months (-6.8% versus –2.3%, P=0.02), and six months (-7.0% versus –3.2%, 0.02), but the difference at 12 months was not significant –4.4% versus –2.5%, P=0.26). After three months, neither diet group showed significant differences or improvements in LDL cholesterol. The low carbohydrate group maintained significant differences and improvements in HDL

cholesterol and triglycerides throughout most of the study. Both diet groups showed improvement in blood pressure and significant, but decreasing improvements in insulin sensitivity as the study progressed.

In a six month randomized study, Brehm et al. (2003), divided 53 obese women into two diet groups: low carbohydrate (<20gms of carbohydrate; after two weeks if ketosis was reached then 40-60gms carbohydrates) or a low fat, low calorie (1600-1800 kcal/day, 30% fat, 55% carbohydrate, 15% protein). Forty-two women (79% of volunteers) completed the trial. The low carbohydrate group lost more weight (8.5kg versus 3.9kg, $P<0.001$) and more body fat (4.8kg versus 2.0kg, $P<0.01$) than the low fat group. In both diet groups, mean blood pressure, lipids, fasting glucose, and insulin were within normal ranges at baseline. Each of these parameters improved over the course of the study, but there were no significant differences observed between the two diet groups. Based on this data, a low carbohydrate diet is more effective than a low fat diet for short term weight loss and, over six months, is not associated with adverse effects on cardiovascular risk factors in women.

In a second one-year study, Stern et al. (2004) randomly divided 132 obese adults into two diet groups: low-carbohydrate (<30gm carbohydrate) or low-calorie, low-fat (500 kcal/day deficit, 55% carbohydrate, 30% fat, 15% protein). At the end of one year, 87 volunteers (66%) completed the study. Although both diet groups lost weight, differences between the groups were not significant (low- carbohydrate –5.1kg versus –3.1kg for the conventional diet). For participants on the low-carbohydrate diet, triglycerides decreased more ($P=0.044$) and HDL cholesterol decreased less ($P=0.025$). For participants with diabetes, hemoglobin A_{1c} levels improved more for persons on the low-carbohydrate diet. The low carbohydrate diet demonstrated more overall favorable outcomes at one year than did the conventional diet.

While the results of the preceding six studies strengthen the argument in favor of short-term carbohydrate reduced diets, results also indicate increasing levels of non-compliance with low carbohydrate

and low fat diets after the three and six month marks. Furthermore, there is a completed void of diet studies comparing these two diets for greater than two years.

Summary

Obesity is an epidemic facing all age groups, of all socioeconomic backgrounds throughout the world. The impact of this epidemic will continue to increase healthcare cost, while reducing the quality and quantity of human life. The weight loss industry is not at a loss to provide potential solutions or products to solve the problem, however the medical community as a whole has yet to find an effective treatment solution. Traditional treatment of overweight and obesity has consisted of low fat, low calorie diet that emphasizes complex carbohydrate as a primary calorie source. However, traditional management is not solving the problem. A potential solution may be to offer a variety of diets to meet the needs of a diverse population. The positive outcomes seen in some research suggests that low carbohydrate diets maybe a treatment that needs to be added to a new traditional mix of treatments.

CHAPTER III

METHODOLOGY

The purpose of this study was to evaluate the effectiveness of a low carbohydrate diet for treating overweight/obesity, high blood pressure, type II diabetes, and hypercholesterolemia. A low calorie/low fat diet was selected as a control diet because that has been the standard recommendation of the American Heart Association and the American Diabetic Association for treating overweight/obesity (American Diabetes Association, 2002; American Heart Association 2002). Fasting blood glucose and fasting lipid profile were selected as dependent variables.

Subject Solicitation

Participants were solicited for this study using three primary routes (Appendix B): poster displays, presentations to physician's groups, and mailings to physician clinics. After securing the consent from each facility's administration, poster displays were set up at the Amarillo Veterans Affairs Health Care System and the Texas Tech School of Medicine Internal Medicine Clinic to solicit participants. Each poster display contained the following materials: a detailed explanation and outline of the study, participant prescreen form within inclusion criteria, contact information, and address of the study location (Appendix B). The inclusion critera for the study included: (a) non-pregnant adults between the ages of 21 to 70 years of age, (b) with a body mass index (BMI) greater than or equal to 30; (c) no history of heart problems (such as angina or heart attack) in the past three months; (d) no history of acute renal failure or chronic renal insufficiency; and (e) ability to read, write, and speak the English language. Potential participants were given the choice to mail in the prescreen applications with self-addressed stamped envelopes (provided) or bring the prescreen applications to the first group meeting.

Physicians and residents at the Amarillo VA health Care System and Texas Tech Schools of Family Medicine and Internal Medicine Clinic attend marketing presentations requesting referral of patients that met the inclusion criteria and would benefit from weight loss. At these presentations, attendees received packets (Appendix B) to give to their patients, which contained the same information available at the poster displays. Other physician's clinics (Internal Medicine Associates of Amarillo, Amarillo Family Physician's Clinic, and Amarillo Diagnostic Clinic) were contacted by phone and were mailed packets containing the same information provided at the poster displays and marketing presentation. Again, these physicians were encouraged to refer any patients they felt might benefit from participation in this study. A Total of 375 patient participation packets were distributed.

Design

The study was conducted at the Texas Tech Medical School, in Amarillo Texas. Table 13 provides the meeting schedule, including dates and activities that occurred at each meeting. The study lasted 21 weeks. During this period there were 12 meetings (the initial meeting, 10 follow-meetings, and final meeting/reception). The first meeting lasted from 5:30pm until 8:00pm. At meetings two through eleven, diet group A (the low fat diet group) met from 5:30pm to 6:30pm, and diet group B met from 7:00pm to 8:00pm. At the last meeting, both diet groups met together from 6:00pm to 7:30pm.

Table 13. Schedule of weekly meetings including: meeting number, meeting week, meeting date (2004), and activities that occurred at each meeting.

Meeting Number	→	1	2	3	4	5	6	7	8	9	10	11	12
Week Number	→	1	2	3	4	6	8	10	12	14	16	18	21
Meeting Date	→	07/27	08/03	08/10	08/17	08/31	09/14	09/28	10/12	10/26	11/09	11/23	12/14
Activities	↓												
1. Request for submission of pre-existing laboratory data (Blood glucose and fasting lipid profile)		√	√	√	√	√	√	√	√	√	√	√	√
2. Complete consent forms (including a study overview)		√*											
3. Complete initial surveys		√*											
4. Receive assigned identification number		√											
5. Use identification number in place of your signature			√	√	√	√	√	√	√	√	√	√	√
6. Body measurement: weight		√	√	√	√	√	√	√	√	√	√	√	√*
7. Body measurement: blood pressure		√	√	√	√	√	√	√	√	√	√	√	√*
8. Body measurement: body fat		√			√							√	√*
9. Diet education			√	√	√	√	√	√	√	√	√	√	
10. Time for participants to ask questions		√	√	√	√	√	√	√	√	√	√	√	√
11. Follow-up surveys (diet compliance, hunger/ satisfaction)				√	√	√	√	√	√	√	√	√	√
12. Program evaluation												√*	√
13. Reception													√

2. & 3. Consent forms and initial surveys were completed anytime someone new joined the study. There was no cut-off date for new participants.

6., 7., & 8. Participants who were unable to attend due to poor weather on the night of meeting, had their weight blood pressure, and body fat taken at meeting number 12.

12. Participants who would not be able to attend meeting 12 were asked to completed program evaluations at meeting 11

The primary objective of the first meeting was to explain the study, answer questions, complete participant consent forms, randomly distribute group diet assignments, and gather initial anthropometric data. At the beginning of the meeting potential participants were greeted, asked to submit any prescreen forms completed prior to the meeting, given study packets containing a consent form and a Health Insurance Portability and Accountability Act of 1966 (HIPPA) privacy form (Appendix C), a prescreen form (the same one used in the participant solicitation packet located in Appendix B), an initial survey (Appendix D), a study schedule (Table 13), and a BMI chart (Figure 1). They were asked to be seated in a classroom reserved for the study. Following the initial seating, a presentation of the consent and HIPPA forms including an overview of potential risks, inclusion criteria, and researcher confidentiality guidelines was given. At the end of the presentation potential participants were asked to calculate their BMI using the BMI chart, review the inclusion criteria included in the consent form, and sign and turn in the completed and signed consent forms, HIPPA forms, and prescreen forms. Individuals who did not wish to participate or who did not meet the inclusion criteria were excused. Any duplicate prescreen-forms or completed forms from non-participating attendees were shredded. Participants were asked to complete the initial survey. While initial surveys were being completed, researchers mixed the prescreen forms, assigned participants to each diet group by means of stratified randomization, and created a master list.

Stratified randomization was accomplished by organizing prescreen forms into three categories: diabetes, high blood pressure, and hyperlipidemia (based on information reported in the medical history section of the prescreen form). Forms listing more than one of these diagnoses were held until all forms listing only one of these diagnoses were organized. Forms listing multiple diagnoses were distributed as equally as possible among the three diagnosis categories. Each individual diagnosis set was shuffled and divided into two stacks, diet group A and diet group B. Next, all prescreen forms for diet group A were combined and all

prescreen forms for diet group B were combined. Finally, prescreen forms listing none of the three diagnoses, were shuffled and equally distributed into one of the two diet groups.

After the initial surveys were collected, participants were given their group assignments and identification numbers. By individual request, spouses, siblings, and carpool members were placed in the same groups. For privacy reasons, participants were asked to use their identification number in place of their name on all future paperwork involved in this study. Diet group A consisted of 64 participants and diet group B consisted of 67 participants (N=131). Following each stage of the meeting, participants were encouraged to ask questions. After completing all the forms in the packet, participants were directed to the anthropometric data collection area. Each participant was weighed and had blood pressure and body fat measured by a registered nurse. Each of these measures was taken in an area that provided individual participant privacy. After anthropometric data were collected, participants were asked to bring a copy (to any of our meetings) of any laboratory data taken during the last six months or over the course of the study relating to diabetes (blood glucose) or hypercholesterolemia (a fasting lipid profile). At the end of the meeting, the group was thanked for participating and encouraged to return.

At meetings two through eleven the bulk of data was collected. At these meetings diet groups met individually. Participants received education and materials specific to their assigned diet group (Appendix E). At each of these meetings participants were encouraged to ask questions. Information was also shared on appropriate exercise for different stages of the adult lifecycle. With the exception of meeting two (because participants had not yet started the study diets), participants were asked to complete surveys designed to measure diet compliance and hunger satiety (Appendix F). Weight and blood pressure were measured at each of these meetings. Due to time and logistics constraints, body fat was measured at only meetings one, three, four, and eleven. Participants who miss meetings when body fat was measured were given the opportunity to measure there body fat at the next meeting they attended. Between weeks eight through fourteen, the body fat

scale was not available since it was being used by faculty and students in the nutrition department at Texas Tech University in Lubbock At the end of each of these meetings participants were reminded to bring a copy of any laboratory data taken during the last six months or over the course of the study relating to diabetes (blood glucose) or hypercholesterolemia (a fasting lipid profile) to the next meeting.

At meeting twelve, participants from both groups met together. Any anthropometric measurements not taken at meeting eleven were taken at this meeting. Participants were asked to complete a final survey and a study evaluation (Appendix G). Healthy snacks were offered, and participants were thanked for volunteering their time and encouraged to continue to strive towards their weight goals.

The meeting scheduled was changed from weekly to bimonthly after meeting four. The purpose of this change was to promote participation by reducing the burden of attendance from four times a month two twice a month. After the study concluded, the researchers realized this probably hurt participation, since the largest dropout rate (38%) occurred between meetings four and six.

Several researchers worked on this study. Dr. Venita Bowie, a doctor of pharmacy from Texas Tech School of Pharmacy prepared and presented three blocks of education to participants including: Ketosis-Signs and Symptoms, Hypoglycemia-signs and symptoms, and Hypotension—signs and symptoms. Doctoral candidate, Keith Rushing developed the study, worked as a research coordinator, and provided education on diet and menu planning. Three nurses gathered all the anthropometric data. Jill Rushing, MSN, RN, collected weight and body fat, while, Jan Cannon, MSN, RN, and Amy Hawkins, BSN, RN, collected blood pressure. Each nurse maintained the same duties weekly to promote consistency. Dr. Misty Evans, assistant professor at Texas Medical School was the initial primary investigator for the study. Dr. Evans was integral in getting the study started and promoted in the Texas Tech Medical Clinics. When Dr. Evans moved in August 2005, Dr. Andrew Stenhouse, Medical Director at the VA Hospital, agreed to replace Dr. Evans as primary investigator.

Diet Groups

Participants were divided into two diet groups: A and B. Group-A was a low fat/low calorie diet consisting of 1100 calories, 55% carbohydrates, 15% protein, and 30% fat. The calorie distribution for this diet was based on recommendations of the American Heart Association (2002). Serving sizes and education materials were drawn from the diabetic exchange system (American Diabetes Association, 2002). The calorie level was set intentionally low so that when participants overindulged, there would be a margin of error, which might still allow for weight loss. Participants following this diet were instructed to consume grains and rice from whole grain sources, fruits and vegetables from mostly fresh sources (as finances would allow), fat from mostly non-hydrogenated vegetable sources, and meat and dairy from low fat or skim sources.

Group-B was an ultra low carbohydrate diet consisting of 60% fat, 35% protein, and 5% carbohydrate with no calorie limit. This diet was based on the initiation phase of the Atkins Revolution low carbohydrate diet (Atkins, 2000). Group members were encouraged to consume meat from low fat sources, fat mostly from non-hydrogenated vegetable sources, and vegetables mostly from fresh sources (when finances would allow).

It was recommended that members of both diet groups consume eight or more eight-ounce glasses of water per day and limit sodium intake to three to four grams per day. Everyone was encouraged to participate in some form of daily physical activity such as walking, swimming, or riding a bicycle for 45 to 60 minutes per day, five days a week based on their physician's approval and as their mobility would allow. All facets of each diet and exercise recommendation were outlined on education materials handed out at the group meetings.

This study was designed with the adult learner in mind. Meetings were scheduled on weeknights to work around most participant's jobs and family obligations. Education presentations were created on colorful Power Point-based slides (Appendix E), and participants were encouraged to join in group discussions related

to diet and weight loss. Education materials were designed on an eighth-grade reading level. For each diet, group participants received sample menus and recipes to make following the diets a little easier.

Instruments

The instruments developed or modified for this for this study included: (a) prescreen, (b) Texas Tech University (TTU) consent form, (c) Veterans Administration (VA) consent form, (d) HIPPA form, (e) initial survey, (f) follow-up survey, (g) final survey. The prescreen form was designed to explain the inclusion criteria and gather personal identification information such as name, address, and phone numbers in case of an emergency. The data from the prescreen form were combined with the random assignment of diet groups and identification numbers so a master list could be prepared. To protect participant privacy, the master list was maintained by the study coordinator and kept in a secure location with limited access.

The TTU and VA consent forms were designed to outline the study and explain any potential risks and benefits of the study. The forms also contained inclusion and exclusion criteria to be used by potential participants in deciding their eligibility and willingness to participate in the study. By signing this document, participants acknowledged they understood what was to be involved in the study including the potential risks and benefits, and they were agreeing not to hold TTU or the VA liable if any of the outlined risks occurred. Inclusion and maintenance of these forms in the study were a requirement of the Amarillo chapter of the Texas Tech University Internal Review Board (IRB). The VA required that all VA employees and patients participating in research sign the VA consent form. The study participants not employed or followed by the VA for health care completed the TTU consent forms.

The HIPPA (Health Insurance Portability and Accountability Act) form was designed to explain that any and all participant information would be kept private and not given to another person or agency for any use. This form, signed by all participants, was also a requirement of the Amarillo IRB

Three survey tools were created for this study. The initial survey, a 25-question document, was designed to gather information about the participant's socioeconomic status and a history of the participant's diet, weight, participation in and success with weight loss diets, and overall health. The follow-up survey, containing 25 questions, was designed to gather baseline compliance and satiety throughout the study. The final survey, a 20-question document, was designed to evaluate participant satisfaction with the education programs and overall study. The surveys were validated using an expert panel of professionals at Texas Tech University in Lubbock and the Veterans Administration Medical Center in Amarillo. The panel consisted of two nurse managers, a nurse practitioner, and four university professors.

Measurement Devices

Three devices were used to measure anthropometrics. Blood pressure was assessed using four Omron Automatic Blood Pressure Monitors (Model HEM-712C) (Appendix H, Figure A1) provided by the VA Healthcare system of Amarillo. Weights were measured with a HealthOMeter (402-Series) Mechanical Beam Medical Scale (Appendix H, Figure A2) provided by the Texas Tech School of Medicine Internal Medicine Clinic. Body fat was measured using a RJL Systems that presents the Quantum II Tetrapolar bioelectrical impedance analysis (BIA) (Appendix H, Figures A2 and A4) device provided by Texas Tech University Department of Nutrition, Hospitality, and Retailing.

Several options were available to measure body fat including: skin fold thickness, hydrostatic weighing, dual energy X-ray absortiometry (DEXA), and BIA. With the skin fold thickness method, a caliper is used to measure how much subcutaneous fat can be pulled away from the body in two or more sites. The accuracy of this measure fluctuates with the number of test administrators and the number of tests preformed.

Hydrostatic weighing is considered to be the gold standard in measuring body fat. This technique requires subjects to blow air out of their lungs, while sitting on a chair that is lowered onto a scale in a pool of

water. Since lean tissue weighs more than fat, a person with more lean tissue or body mass, which includes bones, organs, muscles, connective tissues and fluids, will weigh more underwater, thus provided a measure of body fat. Hydrostatic weighing is costly, time-consuming, and unpopular with research subjects.

DEXA scan is an X-ray that can be used to determine the density of fat, along with bone and other tissues, by scanning the body as a subject lies on a table. Although this method has a high degree of accuracy, it is expensive and time consuming.

Another fat-measuring method is total body potassium, which based on the principle that lean body mass has constant amounts of potassium. A radiation isotope containing potassium is measured to calculate body fat. This measure is invasive, expensive, and time consuming.

With BIA, electrodes are attached to the feet or to a hand and foot to send an imperceptible electrical current through the body. Since fat is a weak conductor of electricity, when an electrical current is sent through body tissue, it slows down when moving from lean to fat tissue, which allows digital monitoring. Fluid intake, exercise, and the time of day the test is taken can affect accuracy. BIA was used in this study because of accuracy, cost, and ease of measure.

Statistical Analysis

A variety of statistical methods were used to analyze the data collected in this study: frequency, mean, standard deviation, independent sample *t*-test, one-way ANOVA (analysis of variance), and Cronbach's Alpha. Frequencies were selected to report three primary areas: (a) distribution of gender, race, marital status, income level, and education level for the full sample and each diet group, (b) retention rates of participants throughout the study for the full sample and by diet group, and (c) apportionment of participant responses to study evaluation questions for the full sample.

The mean and standard deviation were used to describe the central tendency and spread of the satiety and compliance subscales and differences between starting and ending dependent variables (weight, body fat,

blood pressure) and independent variables (diet group, gender, race, marital status, income level, and education level). Both mean and standard deviation were necessary preliminary statistics for calculating the independent sample *t*-test and one-way ANOVA.

Independent sample *t*-tests were used to compare the group differences in the change scores in weight, body fat, and blood pressure by the dichotomous independent variables (i.e., gender, diet group, etc.). The decision to use a t-test was made because all the dependant variables analyzed were treated as continuous variables, and many of the independent variables were dichotomous.

One-way ANOVA was employed to test differences in the independent variables that contained three or more categories (education level, family income level) and interval dependent variables (change in weight, body fat, and blood pressure). ANOVA was selected for its adaptability to show the effects of categorical independent variables on an interval dependent variable. Cronbach's Alpha was applied to determine the internal consistency and reliability of the satiety and compliance subscales.

Satiety and compliance were analyzed as average scores for over the entire study. Since participation was higher in the early stages of the study, satiety and compliance were more a reflection of participant's feelings during weeks one through four of the study.

CHAPTER IV

RESULTS

Since the 1960's the rate of overweight and obesity in children and adults has been growing at alarming rates within most industrialized countries. The positive relationship between obesity and negative psychosocial issues, discrimination, chronic diseases, and morbidity are well documented. The foundation for traditional weight loss diets has typically consisted of a diet comprised of reduced calories, reduced fat, and carbohydrate density. Healthcare professionals have generally discounted the safety and efficacy of diet regimes that vary from this model, particularly the low carbohydrate, high fat diets. In order to investigate the efficacy of two major diets, this study examined the impact of a traditional and a low carbohydrate diet.

The study started strong with 131 participants; by the last week only 22 remained. Seven participants provided beginning and ending serum laboratory data. Overall, results suggested that that a low carbohydrate diet was at least no less effective and sometime more effective than a low fat/low calorie diet for treating overweight/obesity, high blood pressure, and hypercholesterolemia.

Demographic Measures of the Sample

One hundred and thirty one participants joined the study initially. Table 14 provides the demographic characteristics of the study participants for the entire sample as compared to Randall and Potter County, Texas (the study location). Tables 15 and 16 present the demographic characteristics of the sample by diet groups (Podunk, 2005; Potter County demographics, 2005; Randall County demographics, 2005).

Retention

Table 17 illustrates that participant retention declined steadily throughout the study. The sharpest drop (35.48%) was observed between weeks five and seven, the same period the meeting frequency switched from

weekly to bimonthly. The average percent drop out rate between each meeting was 14.90% and the range was 3.30% to 35.28%. Although diet group A exhibited a slightly higher dropout rate, there was not a significant difference between dropout rates of the two diet groups ($p = .196$). There is a large difference between the number of diet group A participants who attended week 18 and week 20 and diet group B participants for the same meetings. The reason for this may be that the weather at week 18 became hazardous around the 7:00PM, which is the time diet group B met. Therefore attendance for diet group B was low at week 18 (n=7 diet group B versus n= 17 diet group A). At week 21 attendance was opposite of week 17 (n=2 diet group A versus n= 20 diet group A). The increase of diet group B participation at week 21 may be because participants who were not able to attend week 18 because of poor weather conditions attended week 21. Any participants from either diet group were allowed to fill out final surveys at week 18 if they were not planning to attend meeting 21. This may have promoted a reduction in group A participation at week 21.

The Effect of Diet on Laboratory Data

For the entire sample, only seven participants (diet group A, $n = 4$ and diet group B, $n = 3$) provided starting and ending fasting laboratory data. Of those submitting laboratory data, only five submitted beginning and ending blood glucose (diet group A, $n = 3$ and diet group B $n = 2$), while six submitted laboratory data for LDL cholesterol (diet group A, $n = 4$ and diet group B $n = 2$). The average range between beginning and ending fasting blood testing was four months, with the range spanning two to five months. Independent t-tests were used to analyze the following laboratory results.

There was a mean increase in blood glucose for both diet groups over time (diet group A, $M = 2.67$, $SD = 5.66$, diet group B, $M = 4$, $SD = 8$). However, in only one case was the increase above the acceptable range of 80 to 120mg/dl. There was not a significant difference between the mean increases in blood glucose for the two diet groups ($p > .05$).

Table 14. Demographic Characteristics of Study Participants (N = 131) compared to the two Texas counties (Potter and Randall) combined.

Category	Sub-category	Sample (N)	Study Percent	Potter/Randall County Percent
Gender	Female	104	79.4	50.2
	Male	24	18.3	49.8
	Missing Data	3	2.3	
Race	African American	4	3.1	9.7
	Hispanic	31	23.7	28.5
	Caucasian	84	64.1	57.3
	Missing Data	12	9.2	
Marital Status	Single	44	33.6	40.3
	Married	75	57.3	59.7
	Missing Data	12	12	
Annual Family Income Level	$34,999 or less	38	29.0	58.4
	$35,000 to $59,999	39	29.8	30.7
	$60,000 or higher	38	29	10.9
	Missing Data	16	12.2	
Highest Level of Education Received	High School Degree or less	27	20.6	33.8
	Some College	54	41.2	29.9
	College Degree or Higher	37	28.2	36.3
	Missing Data	13	9.9	

Table 15. Demographic Characteristics of Study Participants for Diet Group A, n = 64.

Category	Sub-category	N	Percent
Gender	Female	53	82.8
	Male	11	17.2
	Missing Data	0	0
Race	Black	2	3.1
	Hispanic	12	18.8
	Caucasian	45	70.3
	Missing Data	5	7.8
Marital Status	Single	22	34.4
	Married	37	57.8
	Missing Data	5	7.8
Annual Family	$34,999 or less	19	29.7
Income Level	$35,000 to $59,999	17	26.6
	$60,000 or higher	22	34.4
	Missing Data	6	9.4
Highest Level of	High School Degree or	14	21.9
Education	less	24	37.5
Received	Some College	21	32.8
	College Degree or Higher	5	7.8
	Missing Data		

Table 16. Demographic Characteristics of Study Participants for Diet Group B, n = 67.

Category	Sub-category	N	Percent
Gender	Female	51	76.1
	Male	13	19.4
	Missing Data	3	4.5
Race	Black	2	3.0
	Hispanic	19	28.4
	Caucasian	39	58.2
	Missing Data	7	10.4
Marital Status	Single	22	32.8
	Married	38	56.7
	Missing Data	7	10.4
Annual Family Income Level	$34,999 or less	19	28.4
	$35,000 to $59,999	22	32.8
	$60,000 or higher	16	23.9
	Missing Data	10	14.9
Highest Level of Education Received	High School Degree or less	13	19.4
	Some College	30	44.2
	College Degree or Higher	16	23.9
	Missing Data	8	11.9

Table 17. Number and Percentage of Participants in the Study for Each Diet Group by Meeting Week.

Source	Study Weeks											
	1	2	3	4	6	8	10	12	14	16	18	21
Diet Group A (n)	53	42	44	38	34	20	16	14	13	11	17	2
Diet Group B (n)	55	49	44	37	28	20	15	18	14	11	7	20
A & B Combined	108	91	88	75	62	40	31	32	27	22	24	22
% Retention	100	84.25	81.48	69.44	57.41	37.04	28.70	12.96	25.00	20.37	22.22	20.37
% Change From Previous meeting	0%	-15.74	-3.30	-14.77	-17.33	-35.48	-22.50	-3.23	-15.62	-18.52	9.10	8.33

Each diet group experienced a mean reduction in total cholesterol over time (diet group A, M = -6, SD = 13.9, and diet group B, M = -4, SD 8.49). While this was a positive outcome for both groups, the mean difference in total cholesterol between the two diet groups was not significant ($p > .05$).

HDL cholesterol and triglycerides were the only two laboratory tests to demonstrate a significant and inverse difference in mean change between the two diet groups ($p < .05$). Diet group B had a mean increase in HDL cholesterol (M = 3.67, SD 7.79), while diet group A had a mean decrease (M = -1, SD = 2.31). Triglycerides exhibited a mean increase of 12 (SD 36.4) for diet group A and a mean decrease of negative 1 (SD = 2.31) for diet group B. LDL cholesterol decreased in both diet groups, however, the differences in means changes between these two groups was not significant (diet group A, M = -12.6, SD = 28.3 and diet group B, M = -11.5, SD = 23) ($p > .05$).

The Effect of Diet on Anthropometric Measures

Both diet groups showed positive differences in weight loss, body fat loss, systolic blood pressure reduction, and diastolic blood pressure (Table 18). Between each diet group, the differences in weight loss, body fat reduction, systolic blood pressure reduction, and diastolic blood pressure reduction were not significant (Table 19). However, significant differences were observed in weight loss ($p < .025$), body fat ($p < .025$), systolic blood pressure reduction ($p < .025$), and diastolic blood pressure reduction ($p < .025$) for the entire sample (Table 20).

Table 18. Mean and Standard Deviation of Changes in Anthropometric Dependent Variables by Diet Groups A & B.

Anthropometric Dependant variables	Diet Group	N	Mean	Std. Deviation	Std. Error Mean	Levene's Test for Equality of Variances	
						F	Sig.
Weight Loss	A	61	8.1311	21.32329	2.73017	.143	.706
	B	62	7.1548	18.37184	2.33323		
Body Fat Reduction	A	61	1.0754	6.86818	.87938	.954	.331
	B	61	1.7623	7.08725	.90743		
Systolic Blood Pressure Red.	A	61	3.8361	21.04533	2.69458	1.059	.306
	B	61	5.1148	13.25154	1.69669		
Diastolic Blood Pressure Red.	A	61	8.1475	12.29747	1.57453	1.290	.258
	B	61	8.1967	19.54211	2.50211		

Table 19. *t*-Test for Equality of Means: Comparing Changes in Anthropometric Dependant Variables by Individual Diet groups (A & B) with Equal variances Assumed.

Anthropometric Dependant variables	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Weight Loss	.272	121	.786	.97631	3.58699	-6.12509	8.07771
Body Fat Reduction	-.544	120	.588	-.68689	1.26362	-3.18877	1.81500
Systolic Blood Pressure Reduction	-.402	120	.689	-1.27869	3.18426	-7.58330	5.02592
Diastolic Blood Pressure Reduction	-.017	120	.987	-.04918	2.95630	-5.90245	5.80409

Table 20. *t*-Test for Equality of Means: Comparing Changes in Anthropometric Variables by the Full Sample.

Anthropometric Dependant variables	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Weight Loss	7.639	19.815	1.787	4.102	11.176	4.276	122	**.000**
Body Fat Reduction	1.4189	6.9582	.6300	.1717	2.6660	2.252	121	**.026**
Systolic Blood Pressure Reduction	4.475	17.525	1.587	1.334	7.617	2.821	121	**.006**
Diastolic Blood Pressure Reduction	8.172	16.259	1.472	5.258	11.086	5.552	121	**.000**

Bold numbers indicate significance ($p<.05$)

The Effect of Demographics on Anthropometric Measures

Anthropometrics changes (weight loss, body fat reduction, and reduction in blood pressure) were evaluated based on the demographic groups: gender, race, family income level, and marital status. Due to skewed sample distributions, race was dichotomized to Caucasians and non-Caucasians, and marital status was dichotomized to married and non-married. Independent t-tests were used to analyze the dichotomized

variables and One-way ANOVA was applied to measure family income level (i.e., the annual combined income of members of one household) and education level.

The only significant differences in anthropometric and demographic measures were between weight loss and gender and weight loss and family income level. Men lost more weight than women. However, due to the disproportionate distribution of women and men (100 and 22 respectively), the Type I error rate may be inflated (Tables 21 and 22).

Table 21. Mean and Standard Deviation of Changes in Anthropometric Dependant Variables by Gender.

Anthropometric Dependant variables	Gender	N	Mean	Std. Deviation	Std. Error Mean	Levene's Test for Equality of Variances	
						F	Sig.
Weight Loss	Female	101	5.5901	18.21804	1.81276	2.235	.138
	Male	22	17.0455	24.23983	5.16795		
Body Fat Reduction	Female	100	1.3080	7.54952	.75495	3.039	.084
	Male	22	1.9227	3.15548	.67275		
Systolic Blood Pressure Reduction	Female	100	4.3200	18.30487	1.83049	.619	.433
	Male	22	5.1818	13.75859	2.93334		
Diastolic Blood Pressure Reduction	Female	100	8.4100	17.47211	1.74721	1.969	.163
	Male	22	7.0909	9.08641	1.93723		

Table 22. *t*-Test for the Equality of Means: Comparing Changes in Anthropometric Dependant Variables by the full sample with Equal variances Assumed.

Anthropometric Dependant variables	*t*-test for Equality of Means						
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Weight Loss	-2.510	121	**.013**	-11.45536	4.56384	-20.49068	-2.42003
Body Fat Reduction	-.374	120	.709	-.61473	1.64443	-3.87059	2.64114
Systolic Blood Pressure Reduction	-.208	120	.836	-.86182	4.14324	-9.06514	7.34151
Diastolic Blood Pressure Reduction	.343	120	.732	1.31909	3.84286	-6.28950	8.92768

Bold numbers indicate significance ($p<.05$)

Participants in the middle family income range ($35,000 to $59,000) had the least mean weight loss of 0.158 pounds, compared to the upper family income range ($60,000 or higher) with a mean weight loss of 11.07 pounds, and the lower family income range with a mean weight loss of 11.71 pounds (Tables 23 and 24).

Table 23. Mean Weight Loss by Annual Family Income Level.

Annual Family Income Level	Mean Pounds Lost	N	Std. Deviation
$34,999 or less	11.7167	36	20.71628
$35,000 to $59,999	.1579	38	23.10555
$60,000 or higher	11.0737	36	15.45.45.8

Table 24. One-way ANOVA for Comparing Changes in Anthropometric Dependant Variables by Family Income Level.

Source	df	F	p
Between Groups			
Weight Loss	2	3.965	**.022**
Body Fat Reduction	2	2.722	.070
Reduction in Systolic Blood Pressure	2	1.071	.346
Reduction in diastolic Blood Pressure	2	2.154	.121
Within Groups			
Weight Loss	109	3.965	**.022**
Body Fat Reduction	108	2.722	.070
Reduction in Systolic Blood Pressure	108	1.071	.346
Reduction in diastolic Blood Pressure	108	2.154	.121

Bold numbers indicate significance ($p<.05$)

Although positive outcomes in anthropometric changes were observed for the full sample, no significant differences were seen between the following demographic variables: gender, marital status, race, and education level (Appendix I, Tables A11-A14).

Diet, Satiety, and Compliance

Seven questions from the ten follow-up surveys were used to assess diet satiety and compliance of participants (Tables 25 and26). When Cronbach's Alpha was applied to the compliance and satiety instrument in order to measure reliability, the average score was 0.156, with a range of .049 to .351. Since a score of 0.70 is necessary to ensure reliability, it assumed that reliability for these questions to assess compliance and satiety was poor. Even though these measures where shown to have poor reliability, the results of the questions were reported in an attempt to gain some insight into participant opinion on issues related to satiety and compliance. It is understood that any conclusions drawn from this data must take into consideration the flaw in the instrument.

Table 25 Questions from the Follow-up Survey Used to Measure Compliance.

1. How would you rate your overall diet compliance for the past week? A. Very Good B. Good C. Barely Acceptable D. Poor E. Very Poor	2. How often at meal or snack times would you say you did not stay on your diet? A. Every time B. Most time C. About half the time D. Rarely E. Never

Table 26 Questions from the Follow-up Survey Used to Measure Satiety.

1. How would you rate your level of hunger in the MORNING? A. Very strong B. Strong C. Moderate D. Low E. No hunger	3. How would you rate your level of hunger at NIGHT? A. Very strong B. Strong C. Moderate D. Low E. No hunger
2. How would you rate your level of hunger in the AFTERNOON? A. Very strong B. Strong C. Moderate D. Low E. No hunger	4. How would you rate your feelings of fullness after meals and snacks when you complied with your assigned diet? A. Stuffed B. Full C. Not full or hungry D. Hungry E. Very Hungry 5.How would you rate your satisfaction with the food choices allowed on your assigned die at meals and snacks? A. Very Satisfied B. Satisfied C. Neither satisfied or dissatisfied D. Dissatisfied E. Very dissatisfied

Diet group A reported higher ratings for satiety compared to diet group B. Diet group A also reported greater compliance compared to diet group B. Based on an independent t-test, differences were shown to be significant $t(106) = 4.43$, $p = .00$ for satiety and $t(106) = 2.50$, $p = .014$ for compliance (Tables 27 and 28)

Items in this section were scored on a scale of one to five for satiety: 1=stuffed, 2=full, 3=not full or hungry, 4=hungry, and 5=very hungry and for compliance: 1=very good, 2-good, 3=barely acceptable, 4-poor, and 5=very poor. Since participants at meeting two through eleven filled out these surveys, survey scores were

averaged over time. The average number of respondents over time for diet group A was 52, while the average number of respondents over time for diet group B was 56.

Table 27. Mean, Sample Size, and Standard Deviation (Averages Over Time) of Subscales of Satiety and Compliance Scores by Diet Group.

			Satiety 1 = Stuffed 2 = Full 3 = Not full or hungry 4 = Hungry 5 = Very hungry	Compliance 1 = Very good 2 = Good 3 = Barely acceptable 4 = Poor 5 = Very poor	Levene's Test for Equality of Variances	
					F	Sig.
Diet Group	A	Mean	2.693	2.609	4.317	**.040**
		N	52	52		
		Std. Deviation	.536	.497		
	B	Mean	2.268	2.342	1.22	.271
		N	56	56		
		Std. Deviation	.447	.606		

Bold numbers indicate significance ($p<.05$)

Table 28. *t*-tests for Equality of Means: Comparing Subscales of Satiety and Compliance Scores by Diet Group with Equal variances Assumed.

	t-test for Equality of Means						
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Satiety	4.483	106	.000	.42516	.09483	.23715	.61317
Compliance	2.495	106	.014	.26769	.10730	.05496	.48043

Demographic Data, Satiety, and Compliance

Satiety and compliance were evaluated for the entire sample and for the demographic groups: gender, race, family income level, and marital status. Due to skewed sample distributions, race was dichotomized to Caucasians and Non-Caucasians, and marital status was dichotomized to married and non-married. Once these variables were dichotomized, statistical analysis was conducted using independent t-tests. One-way ANOVA was applied to measure the variables more than two levels (i.e., family income level and education).

Men rated satiety higher than women, but women rated compliance higher than men. However, these differences were not shown to be significant between either satiety or compliance (Tables 29 and 30).

Table 29. Mean, Sample Size, and Standard Deviation (Averages Over Time) of Subscales Satiety and Compliance Scores by Gender.

			Satiety 1 = Stuffed 2 = Full 3 = Not full / hungry 4 = Hungry 5 = Very hungry	Compliance 1 = Very good 2 = Good 3 = Barely acceptable 4 = Poor 5 = Very poor	Levene's Test for Equality of Variances	
					F	Sig.
Gender	Female	Mean	2.433	2.494	.473	.493
		N	89	89		
		Std. Deviation	.517	.578		
	Male	Mean	2.658	2.359	.164	.687
		N	19	19		
		Std. Deviation	.587	.531		

Table 30. *t*-tests for Equality of Means: Comparing Subscales of Satiety and Compliance Scores by Gender with Equal variances Assumed.

	t-test for Equality of Means						
						95% Confidence Interval of the Difference	
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Satiety	-1.682	106	.096	-.22531	.13395	-.49088	.04027
Compliance	.937	106	.351	.13514	.14429	-.15092	.42120

Non-Caucasians rated satiety higher than Caucasians, but Caucasians rated compliance higher than non-Caucasians. As with gender, these differences were not shown to be significant for satiety or compliance (Tables 31 and 32).

Table 31. Mean, Sample Size, and Standard Deviation (Averages Over Time) of Subscales of Satiety and Compliance Scores by Race.

				Satiety 1 = Stuffed 2 = Full 3 = Not full / hungry 4 = Hungry 5 = Very hungry	Compliance 1 = Very good 2 = Good 3 = Barely acceptable 4 = Poor 5 = Very poor	Levene's Test for Equality of Variances	
						F	Sig.
Race	Non-Caucasian	Mean	2.437	2.600	2.437	2.064	.154
		N	29	29	29		
		Std. Deviation	.542	.597	.542		
	Caucasian	Mean	2.477	2.401	2.477	.392	.533
		N	73	73	73		
		Std. Deviation	.598	.503	.598		

Table 32. t-tests for the Equality of Means: Comparing Subscales of Satiety and Compliance Ratings by Race with Equal variances Assumed.

	t-test for Equality of Means						
						95% Confidence Interval of the Difference	
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Satiety	1.704	100	.092	.19891	.11675	-.03271	.43053
Compliance	-.308	100	.759	-.03944	.12799	-.29337	.21450

The middle-income level group ($39,000 to $59,000) rated satiety higher than lower-income level group ($34,000 or less) or the higher-income level group. For compliance, the lower-level income group gave the highest ratings, followed by the higher-income-level group, and then the middle-income level group. These differences were not shown to be significant for or compliance (Table 33).

Table 33. One-way ANOVA for Comparing Subscales of Satiety and Compliance Scores by Family Income Level (Diet Groups A & B Combined, n=102).

Source	df	F	p
		Between Groups	
Satiety	2	.330	.719
Compliance	2	1.673	.193
		Within Groups	
Satiety	95	.330	.719
Compliance	95	1.673	.193

Participants in the high school or less education group rated satiety higher than the college degree or higher group or some college group. The rating order for compliance was the same as that for satiety, high school or less group, followed by the college degree or higher group, followed by the some college group. These differences were not shown to be significant for satiety or compliance (Table 34).

Married participants rated satiety higher than non-married participants, but non-married participants rated compliance higher than married participants. As with gender and race, these differences were not shown to be significant for or compliance (Tables 35 and 36).

Table 34. One-way ANOVA for Comparing Subscales of Compliance and Satiety Scores by Education Level (Diet Groups A & B Combined, n=102).

Source	df	F	p
		Between Groups	
Satiety	2	.445	.642
Compliance	2	.217	.805
		Within Groups	
Satiety	98	.445	.642
Compliance	98	.217	.805

Table 35. Mean, Sample Size, and Standard Deviation (Averages Over Time) of Subscales Satiety and Compliance Scores by Marital status.

	Marital Status	N	Mean	Std. Deviation	Std. Error Mean	Levene's Test for Equality of Variances F	Sig.
Satiety 1 = Stuffed 2 = Full 3 = Not full / hungry 4 = Hungry 5 = Very hungry	Not Married	34	2.3136	.50763	.08706	1.678	.198
	Married	68	2.5297	.54013	.06550		
Compliance 1 = Very good 2 = Good 3 = Barely acceptable 4 = Poor 5 = Very poor	Not Married	34	2.5007	.64804	.11114	1.056	.307
	Married	68	2.4486	.54790	.06644		

Table 36. *t*-Test for Comparing Compliance and Satiety by Marital Status (Diet Groups A & B Combined) with Equal variances Assumed .

	t-test for Equality of Means						
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Satiety	-1.943	100	.055	-.21614	.11124	-.43684	.00457
Compliance	.425	100	.672	.05206	.12242	-.19082	.29495

Program Evaluation

Thirty-eight people completed the final survey. Eighteen of the questions on the final survey dealt with program evaluation. Almost all of the respondents rated the study favorably; therefore the following system was developed to determine potential improvements. Any answer, other than the highest rating, that received five or more responses was considered an area for potential improvement. Missing responses were not included in this system. The following areas were listed as areas for improvement: Did you learn what you expected to learn (7 responses), Was there an adequate amount of time allocated on each topic (6 responses), Were there opportunities for you to actively participate in the various sessions, Were the presenters well prepared (5 responses), Was the program schedule well planned (6 responses), and Will you be able to apply what you learned (11 responses) (Appendix J, Table A15).

Summary

The results of this study revealed several interesting points.

- Women outnumber men in the study six to one.
- Participants were evenly distributed among income groups and their racial backgrounds were similar to those found in the Amarillo area.
- Retention dropped consistently throughout the study, with the highest dropout rates seen between weeks four and six of the study.
- Members of the low carbohydrate diet group and the low fat, low calorie group had positive changes in total cholesterol, LDL cholesterol, weight loss, blood pressure reduction, and body fat reduction; however, the difference between the two diet groups were not significant.
- The low carbohydrate diet group had significantly better outcomes for HLD cholesterol and triglycerides.
- Men lost significantly more weight than women and the middle-income group lost significantly less weight the lower and upper income groups.
- The satiety and compliance measure was shown not to be reliable.
- Program evaluation demonstrated a high level of participant satisfaction.

CHAPTER V

SUMMARY, DISCUSSION, AND IMPLICATIONS

Demographic Measures of the Study Sample

Summary

The demographic information analyzed in this study were gender, race, income level, education level, and marital status. The study sample was similar to population of Amarillo and the surrounding area (Randall and Potter County Texas, study location) with regards to race and marital status. However, gender, family income, and education level differed between the sample and the greater Amarillo area. The sample had a large percentage of women (70% versus 50%), and a smaller percentage of males (18.3% versus 49.8%) compared to the greater Amarillo area. A much smaller percentage of the lower family income category ($34,999 or less) participated in the study compared to the greater Amarillo area (29% versus 58.4% respectively), while a larger percentage of the higher family income group ($60,000 or higher) participated in the study than was representative of the Amarillo area (29% versus 10.9% respectively). The differences in education level were similar to those seen with income level, except, individuals in the highest education category (a college degree or higher) participated at a lower rate (28.2%) compared to the actual population 36.3%.

Discussion

The disparities between the sample and the population for gender, education, and income level suggested that men and people with a lower earning potential are less interested in weight loss compared to women and people at higher socioeconomic levels. This is consistent with our current culture. Women are more interested is losing weight because of the constant societal pressure for women to look slim, young, and

beautiful. Underweight, teenage models are often featured in the top fashion magazines. The pressure to be slim and fit is also present for men, but not to the degree that it is for women (National Center for Disease Prevention and Health Promotion, 2003). The rational for low participation of individuals in the lowest family income group may be attributed to Maslow's Hierarchy of Needs theory (Deeper Mind, 2005). Individuals of lower socioeconomic status may be more interested in taking care of the most basic needs (i.e., warmth, shelter, food, protection from danger) to worry about the higher level need such as vanity and desire to meet society's definition of beauty. The aesthetic component, more than the health component, seems to motivate people to attempt weight loss. This further supports the Maslow's theory, since beauty falls in Maslow's highest category "self-actualization" and poor health associated with obesity would fall into the more basic need category "security."

Based on the above rational and the common racial and marital distributions of the sample and the Amarillo area population, the study sample was reflective of the Amarillo are population who are interested in loosing weight. Therefore, results of this study can be inferred to the greater Amarillo area.

Implications

Society has to take responsibility for what we view as beauty. The fashion industry needs to invest greater effort into demonstrating women's beauty to include featuring more women above the age of thirty and featuring women who are at a healthy weight. Furthermore, health organizations must continue to advocate for the health as the necessary rationale for people who are overweight or obese to loose weight. Children should be the focus of this effort since they are our future. It will be easier for them to prevent weight gain rather than achieve weight loss.

Study Population Retention

Summary

The results of the study support the hypothesis "a low carbohydrate diet will be as or more effective than a low fat low calorie diet for promoting membership retention (reduced dropout rates)." Participants from both diet groups dropped out of this study throughout the research, but the difference between the two diet groups was not shown to be significant.

Discussion

Participant retention declined throughout the study with an average dropout rate of 14.9% per meeting. However, the dropout rate difference between the two diet groups was not significant ($p = .196$), therefore we must accept the hypothesis statement "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for reduced dropout rates" The dropout rate has serious implications for the study. Based on a power analysis, it was estimated that the sample population would need to be greater than 67 participants by the end of the study to have valid results. This objective was easily met at the beginning of the study, however by the end of the study our participation total was 22. The largest dropout rate (35.48%) was experienced between weeks five and seven when the meeting frequency switched from weekly to bimonthly. Based on previous research, the expected participant dropout should have been between 31% and 40% for a study lasting four to five months (Honas, Early, Frederikson, and O'Brien, 2003; Landers & Landers, 2004).The major drop at this point may have happened for different reasons. One reason may be that participants enjoyed the support of meeting weekly, and once the meeting frequency decreased, the reduced support lowered motivation and some participants stopped attending. Another possible reason may have been that the switch in frequency was poorly communicated, causing participants to come when there was no a meeting, get annoyed, and decide to stop attending. Others may have felt they learned what they needed and decided to continue the

diet on their own. Retention is a serious concern because is suggests an individual has stopped before meeting their weight goal.

The consistent dropout rates throughout the study point to a significant contributing factor to the global problem of solving the overweight/obesity crisis. No matter how effective the diet, if individuals are not willing to comply, failure is imminent. Compliance, satiety, and retention are linked and vital to the success of any diet therapy.

Implications

If weight loss research is successful, we must find a way to retain larger percentages of participants. Some of the areas that must be considered are holidays, peak diet seasons, consistency of meetings, frequency of meeting, alternative modes of data collection, and follow-up correspondence. The best time to initiate a 5-month study may be between the months of January and May, because the major eating holidays (Thanksgiving, Halloween, Christmas, and New Year) are over, some people will be making New Years resolutions, and may people will be motivated to loose weight for the more revealing summer fashions and swimsuits.

As demonstrated in this study, retention rates dropped when the frequency routines of meetings was changed. This may be attributed to a perceived reduction in the group support environment, inadequate communication of meeting changes, or people greeting out of the habit of attending. Whatever the cause, meeting frequency should be consistent in future studies. If a meeting must be canceled due to bad weather, a contingency plan should be established. However, afterwards, meets should resume at the same frequency.

Establishing alternative means of reporting such as Internet based surveys or e-mail contact with participants who cannot attend may help with gathering survey data and distributing education materials. However, the most important aspect of retaining participants in future studies would be following up with

participants between meetings, through mailings, phone calls, or e-mails. This contact would encourage continued participation by making people feel they were not just another number. Furthermore, it may help remind participants who would otherwise forget to attend a meeting.

The Effect of Diet on Laboratory Data

Summary

When examining laboratory values, the study demonstrated mixed results. Blood glucose increased for both diet groups over time, but the differences between the groups were not significant and only one case was above the acceptable range of 80 to 120mg/dl (Steadman's Concise Medical Dictionary, 2001). Therefore the hypothesis statement "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for controlling blood glucose within a healthy range" must be accepted. There was a mean reduction in total cholesterol and LDL cholesterol, but again differences between the diet groups were not significant. Therefore, the hypothesis statements: "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for reducing total cholesterol" and "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for reducing total LDL cholesterol" must be accepted. Both HDL cholesterol and triglycerides demonstrated significant differences between the two diet groups ($p < .05$ for both groups). Furthermore, these differences supported the following hypothesis statements: "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for reducing HDL cholesterol" and "A low carbohydrate diet will as or be more effective than a low fat low calorie diet for reducing triglycerides."

Discussion

When considering the laboratory results, the first thing that must be considered is the limitations associated with this data. Because of the cost associated with drawing blood for laboratory tests, researchers

were forced to rely on lab data ordered and drawn by physicians and medical clinics as part of routine treatment of existing medical conditions. Based on these conditions, three significant limitations were observed.

First, only seven participants (5.3% of the beginning sample, N=131) provided beginning and ending laboratory data. Second, researchers had no control over when labs were drawn. The study started on June 27, 2005 and ran through December 14, 2005. The dates beginning lab tests were conducted spanned from May 10, 2004 (77 days prior to the start of the study) to July 13, 2004 (5 days after the study began). The dates for ending laboratory tests ranged from September 29, 2004 (76 days prior to the end of the study to November 24, 2004 (21 days prior to the end of the study). The average range between beginning and ending lab draws was four months, with the range spanning two to five months.

Third, researchers were unable to ensure that participants fasted 12-hours before blood draws or determine which participants fasted for 12-hours prior to blood testing and which did not. Fasting has a significant impact on blood glucose. While levels normally decrease during fasting, they remain persistently high in people with diabetes. A fasting glucose value above 125 mg/dl is characteristic of diabetes (Steadman's Concise Medical Dictionary, 2001). The 12-hour fasting blood glucose test is ideal for determining improvements in diabetic control over time. If a 12-hour fast is not done prior to drawing blood for a lipid panel, calculations for determining LDL cholesterol will be inaccurate due to the affects of triglycerides levels in the blood (Office of the Surgeon General, 2002). These limitations severely inhibit what can be inferred from the data.

Realizing the significance of the above limitations, the following inferences were drawn. The elevations observed in ending blood glucose values of both diet groups were unexpected based on previous research (Brehm et al., 2003; Foster et al., 2003; Miyashita et al., 2004; Sharman et al., 2002; Stern et al., 2004; Vancy et al., 2004; Volek et al., 2004; Westman et al., 2002). This especially true since both diet

groups evidenced weight loss. This anomaly may be attributed to non-diet compliance, other physiological factors causing gluconeogenesis (the process by which glucose is formed from a non-carbohydrate source) such as stress or illness, or the limitations previously addressed (Steadman's Concise Medical Dictionary, 2001).

Changes in total cholesterol, LDL cholesterol, and triglycerides agreed with the research hypotheses and were expected based on the literature review (Brehm et al., 2003; Foster et al., 2003; Miyashita et al., 2004; Sharman et al., 2002; Stern et al., 2004; Vancy et al., 2004; Volek et al., 2004; Westman et al., 2002). As demonstrated in previous research, when participants lost weight, it was not uncommon to see a reduction in total cholesterol, LDL cholesterol, or triglycerides whether participants followed a low fat diet or a low carbohydrate diet. As noted in the results section, participants in both diet groups of this study lost weight (Brehm et al., 2003Foster et al., 2003; Garg et al., 1992; Golay et al., 1996; Harvard Men's Health Watch, 2003; Lean et al., 1997; Rabast et al., 1978; Sharman er al., 2002; Stern et al., 2004; Vancy et al., 2004; Volek et al., 2004; Westman et al., 2002).

The low-carbohydrate diet group experienced an increase in HDL cholesterol level, whereas the low fat/low calorie diet group experienced a decrease in HDL cholesterol. Although an HDL increase is uncommon in the setting of weight loss, the HDL cholesterol level has been known to increase when dietary carbohydrate is replaced by saturated, monounsaturated, or polyunsaturated fat (Brehm et al., 2003; Stern et al., 2004; Vancy et al., 2004) With traditional low-fat diets, the HDL cholesterol level generally decreases from baseline during active weight loss and then increases during weight stabilization when the diet is maintained. Similarly, levels of LDL cholesterol and triglycerides decrease during active weight loss, then increase during weight stabilization but remain lower than baseline levels if the low-fat diet is maintained (Brown et al., 1998; Foster et al., 2003; Garg et al., 1992; Harvard Men's Health Watch, 2003; Lean et al.,; Sharman et al., 2002; Stern et al., 2004; Vancy et al., 2004; Vidon et al., 2001).

Implications

The laboratory results are severely limited. However, when added to the body of previous research it may be inferred that a low carbohydrate diet is an alternative treatment to the traditional low fat diet for treating overweight and obese patients with diabetes and hyperlipidemia (Biakowsk et al., 1977; Brehm et al., 2003; Brown et al., 1998; Foster et al., 2003; Garg et al., 1992; Golay et al., 1996; Haney, 2003; Harvard Men's Health Watch, 2003; Lean et al., 1997; Miyashita et al., 2004; Rabast et al., 1978; Sharman er al., 2002; Stern et al., 2004; Vancy et al., 2004; Vidon et al., 200; Volek et al., 2004; Westman et al., 2002). Considering the relationship between diabetes, heart disease, overweight, and obesity, it is important the future research on this topic including adequate funding to support laboratory analysis of fasting blood glucose and serum lipids.

The Effect of Diet on Anthropometric Measures

Summary

Both diet groups demonstrated weight loss, body fat reductions, and blood pressure reductions, although the differences between the diet groups were not significant. Consequently, the first three hypotheses ("A low carbohydrate diet will be as or more effective than a low fat low calorie diet for promoting weight loss, body fat loss, and blood pressure reduction") must be accepted.

Discussion

While these anthropometric results are positive for both diet groups, neither diet clearly out performed the other. This supports the theory that one diet is not right for everyone (Everson et al., 2002; Reddy et al., 1998; Winkleby et al., 1996). Since personal characteristics such as taste, activity level, and self-control vary from individual, it is to be expected that diets catering to individual preferences will promote higher success rates. If

participants had been allowed to choose their diet, versus random diet assignment, diet satisfaction may have improved. As satisfaction improved, participants may have been more compliant with their diet, yielding more success with weight loss, body fat reduction, and management of diseases such as diabetes, high blood pressure, and hyperlipidemia.

The reason men lost significantly more weight than women may have been due to the uneven distribution of men (n = 24) versus women (n = 100). If a few of the men with a high BMI lost a lot of weight, this number could have skewed the results making it appear that the men lost more weight than the women. Another reason could be the fact the men typically carry more muscle than women. The amount of muscle an individual carries is positively correlated with energy needs. Therefore, men have a metabolic advantage to weight loss (National Center for Chronic Disease Prevention and Health Promotion, 2003). The differences in weight loss among the different income levels may be more related to environmental factors than to study constructs, since the distribution among the income groups was fairly close. The middle-income group should have had adequate resources to purchase the necessary items to follow a diet; therefore, this phenomenon is difficult to explain. Perhaps the people who made up the middle-income group had the busiest lifestyles, which may have made it harder to comply with a diet (Molarius et al., 2000; Power et al., 1999).

Implications

This research demonstrates that a low carbohydrate diet as well as a low fat/low calorie diet is beneficial for improving anthropometric measures (weight, body fat, and blood pressure As addressed in the literature review, overweight, obesity, high body fat levels, and elevated blood pressure are all interrelated health problems that exacerbate or cause many other health problems (American Obesity Association, 2003; Flegal et al., 2002; Han et al., 1998; National Center for Chronic Disease Prevention and Health Promotion, 2003; National Institute of Diabetes and Digestive and Kidney Disease, 2003; North American Association for

the Study of Obesity, 2003; Pi-Sunyer, 1999). Finding solutions to these problems are at the top of the agenda of international and national heath organizations. Because the problem of overweight and obesity continue to grow, it is to the health care professional's advantage to have multiple treatments. Whether caused by genetics, metabolism, compliance, or preference, many people are not successful on traditional weight loss diets. Offering a variety of solutions increases the opportunity for success. Much research has been done on this topic in the short term (six months or less), but little is understood about the long-term impact of low carbohydrate diet (Biakowsk et al., 1977; Brehm et al., 2003; Brown et al., 1998; Foster et al., 2003; Garg et al., 1992; Golay et al., 1996; Haney, 2003; Harvard Men's Health Watch, 2003; Hockaday et al., 1978; Jeffery et al., 2000; Larosa et al., 1980; Lean et al., 1997; Miller, 1998; Miyashita et al., 2004; Rabast et al., 1978; Sharman et al., 2002; Stern et al., 2004; Vancy et al., 2004; Vidon et al., 200; Volek et al., 2004; Westman et al., 2002). Future research should look at analyzing low carbohydrate diets for a five-year or longer period. It needs to be determined if a low carbohydrate diet would be appropriate as a lifestyle change and not just a short-term solution.

The Effect of Demographic Measures on Anthropometric Measures

Summary

The relationship of gender, race, marital status, and socioeconomic status (income level and education level) on weight loss, blood pressure reduction, and body fat reduction, these factors should be addressed. Participants of each gender, race, marital status, and socioeconomic status demonstrate positive changes in weight loss, blood pressure reduction, and body fat reduction. However, the only significant differences between demographic measures and anthropometric measures were observed between gender and weight loss and family income level and weight loss. In this study men lost significantly more weight than women, and

participants in the middle family-income range ($35,000 to $59,000) lost significantly less weight the participants in the upper family-income range and the lower family-income range ($34,999 and less).

Discussion

Women out numbered men by four to one in the study. This may partially explain why men faired so much better at weight reduction. If just a few men lost a significant amount of weight, this would have skewed the results. Taking that into consideration, there is another possibility why men were more successful at weight loss. Men typically care more muscle than women (National Center for Chronic Disease Prevention and Health Promotion, 2003). Since muscle increases metabolic needs (Whitney, 1987), once men began to reduce their caloric intake weight loss would incur with less effort.

Family-income level is a complex issue. Maslow's Hierarchy of Needs Theory offers a possible explanation for the difference in weight loss between participants in the different family-income levels. Individuals from the lower family-income group who participated in the study may have been motivated by the more basic need of safety and security, and perceived overweight and obesity as a major threat to their health. Participants in the higher family-income range may have perceived achieving weight loss as an esteem need (i.e., gaining the respect, recognition, and attention of others, or gaining their own self-respect, confidence, and sense of achievement) through weight loss. Participants in the middle family-income group may have lost the least amount of weight because they were more motivated and concerned by Maslow's midlevel needs (love and belonging). In midlevel people are concerned about their membership in a family and community. Participants in the middle family-income group may have prioritized the need to lose weight lower than the need to prepare family meals, take care of aging parents, and provide for family members by working longer hours at work.

Implications

Since the middle-income group is the largest segment of our population (National Center for Chronic Disease Prevention and Health Promotion, 2003), this raises some serious concerns. If the problem of overweight weight and obesity continues to increase and the largest segment of the population is the least motivated to solve it, our society is in trouble. Researchers, educators, legislators, and government agencies need to increase their efforts to make the public aware of this problem and find more and better solutions to solve it. Parents need to take the lead and set examples for their children to follow. Healthy diet and exercise should be modeled at every opportunity and research to solve the problem of overweight and obesity must continue.

Diet, Satiety, and Compliance

Summary

Because low scores were observed when testing the satiety and compliance subscales with Cronbach's Alpha, instrument reliability was determined to be poor. This limitation severely inhibits what can be inferred from the data. Realizing the significance of this limitation, the following inferences were drawn.

Diet group A (the low fat/low calorie diet) reported significantly higher ratings for satiety and compliance compared to diet group B. Based on these results, the hypothesis for satiety "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for promoting hunger satiety" and the hypothesis for compliance "A low carbohydrate diet will be as or more effective than a low fat low calorie diet for promoting diet compliance" must be rejected.

Discussion

The decision to use the term satiety versus satisfaction was based on the generally accepted definitions (Meridian-Webster, 2005). Satiety was defined as "the quality or state of being fed or gratified to or beyond capacity," while satisfaction was defined as "fulfillment of a need or want." The definition of satiety better suited the needs of this study.

The low carbohydrate diet may have received lower satiety and compliance scores due to the limited variety of foods offered in the low carbohydrate diet. The most common comment heard from participants on the low carbohydrate diet was "all we get to eat is meat and vegetables." While the low calorie/low fat diet offered limited quantities of food, participants on this diet plan had many more choices of foods from each of the food groups.

Summary

Satiety and compliance are important aspects of diet success, and a pilot test should have been implemented to ensure instrument reliability. The study was examined by a panel of nutrition experts to examine content. However, a pilot test was not completed due to time constraints. The research was held for almost 14 months waiting approval from the Amarillo Internal Review Board (IRB), which was established to ensure safe implementation of human subject research. Because of the long delay, the researchers were not able to postpone the study start date to conduct a pilot for the surveys. Since the reliability score was so low, no conclusions will be drawn from this section.

Demographic Measures, Satiety and Compliance

Summary

None of the differences between demographic measures, satiety, and compliance were shown to be significant. Taking into account the limited value of the satiety and compliance methodology, the following results were noted.

- Men rated satiety higher than women.
- Women rated compliance higher than men.
- Non-Caucasians rated satiety higher than Caucasians.
- Caucasians rated compliance higher than non-Caucasians.
- The middle-income level group rated satiety higher than lower and higher-income level group.
- The lower-level income group gave the highest ratings for compliance.
- Participants in the high school or less education group rated satiety the highest.
- Married participants rated satiety higher than non-married Participants.
- Non-married participants rated compliance higher than married participants.

Discussion

Because there were no significant differences observed among demographic measures, satiety, and compliance, no substantial conclusions can be drawn

Implications

Satiety and compliance are important aspects of diet success. Future researchers should strive to develop a reliable measure of these components.

Program Evaluation

Summary

While majority of participants attending the final meeting rated the study favorably, six categories were identified as areas for potential improvement. These included: (a) learning expectations, (b) time allocated on each topic, (c) opportunities for individual participation, (d) presenter preparedness, (e) study planning and scheduling, and (f) practical application.

Discussion

Participants came to the diet study with a variety of expectations. Many individuals requested specific menus to follow at home. This was a consideration when preparing for the study, and several sample menus were made to make compliance easier. However, daily menus were not created, because it was thought that this would reduce compliance in individuals who did not like the menu selections. At each study meeting approximately twenty minutes was allocated to providing education and seventy minutes to gathering data. When participation was high, all of this time was needed, however, when retention was low, the sessions sometimes finished early. Participants may have been happier with a lengthier education section and a shorter data collecting section. This could have been accomplished if the researchers would have alternated the nights that body fat, weight, and blood pressure were collected to allow more time for education. At each meeting an effort was made by presenters to solicit participant questions. In addition, specific education activities were designed to promote group interaction. The study meetings were planned in advance, with the majority of the formal education provided in the first seven meetings. After that point, participants were provided menus and other references to support the dieting process. Some participants may have wished that a structured lecture be provided at each of the 12 study meetings. As addressed in the retention section, study dropout rates peaked when meeting frequency was reduced from weekly to bimonthly.

Implications

In a future study, if more time was allocated for education, group activities could be planned that would promote participant interaction. For future studies, a weekly schedule may promote group support and participant satisfaction. Practical application is difficult because individual lifestyles and tastes are so different. A possible way to address this and other participant concerns would be to conduct a pilot survey to determine participant expectations of a diet study.

Implications for Future Research

The results of this study will add to the very perplexing and incomplete body of knowledge regarding weight loss and maintenance. There are many questions yet unanswered. The following suggestions are offered to future researchers as they continue the investigation into this complex topic.

1. There should be a concerted effort to determine the long-term impact of a low carbohydrate diet on health and safety of individual dieters.
2. A valid and reliable instrument to measure satiety and diet compliance is needed.
3. Further investigation is needed to discover a mechanism that helps determine what type of diet is appropriate for a particular dieter.

Project Summary

Obesity is an epidemic facing all age groups, of all socioeconomic backgrounds throughout the world. The impact of this epidemic will continue to increase healthcare cost, while reducing the quality and quantity of human life. With all the technologic advances and medical breakthroughs achieved by modern society in the past 100 years, it is ironic that scientists cannot agree on the best method or methods for patients to achieve long-term weight loss.

Traditional treatment of overweight and obesity has consisted of low fat, low calorie diet that emphasizes complex carbohydrate as a primary calorie source. However, traditional diet management is not solving the problem. A potential solution may be to offer a variety of diets to meet the needs of a diverse population. The positive outcomes seen in this and other research suggests that low carbohydrate diets maybe a treatment that needs to be added to a new traditional mix of treatments.

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APPENDIX A

PREVALENCE OF OBESITY AND TABLES A1-A9

Table A1. Prevalence of obesity over time based on education level.

Education level	1991 (%)	1998 (%)	2000 (%)
Less Than High School	16.5	24.1	26.1
High School	13.3	19.4	21.7
Some College	10.6	17.8	19.5
College Graduate	8.0	13.1	15.2

Source: Excerpted from the American Association for Obesity, "Obesity Trends," 2003.

Table A2. Prevalence of adult obesity by United States Region and Time.

Region of the United States	1991 (%)	1998 (%)	2000 (%)
New England (Connecticut, Massachusetts, Main, New Hampshire, Rhode Island, & Vermont)	9.9	11.4	16.9
Middle Atlantic (New Jersey, New York, & Pennsylvania)	12.7	16.7	18.4
East North Central (Illinois, Indiana, Michigan, Ohio, & Wisconsin)	14.1	19.1	21.0
West North Central (Iowa, Kansas, Minnesota, Missouri, North Dakota, Nebraska, & South Dakota)	12.2	18.0	19.8
South Atlantic (District of Columbia, Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, & West Virginia)	11.1	18.6	19.5
East South Central (Alabama, Kentucky, Mississippi, & Tennessee)	13.1	20.0	23.0
West South Central (Arkansas, Louisiana, Oklahoma, & Texas)	13.1	20.0	22.2
Mountain (Arizona, Colorado, Idaho, Montana, New Mexico, Utah, & Wyoming)	9.6	14.1	17.1
Pacific (Alaska, California, Hawaii, Nevada, Oregon, & Washington)	10.2	17.0	19.1

Source: Excerpted from the National Center for Chronic Disease Prevention and Health Promotion, "Obesity in the United States," 2003.

Table A3. Increase in the prevalence of obesity among men and women of different racial-ethnic groups.

	Obesity Prevalence			
	Men (%)		Women (%)	
Racial-Ethnic Group	1988-1994	1999-2000	1988-1994	1999-2000
African Americans	21.3	28.8	39.1	50.8
Mexican American	24.2	29.4	36.1	40.1
Caucasian American	20.7	27.7	23.3	30.6

Source: Excerpted from the American Association for Obesity, "Obesity in Minority Populations," 2003.

Table A4. Increase in the prevalence of severe obesity among men and women of different racial-ethnic groups.

	Severe Obesity Prevalence			
	Men (%)		Women (%)	
Racial-Ethnic Group	1988-1994	1999-2000	1988-1994	1999-2000
African Americans	2.4	3.5	7.9	15.1
Mexican American	1.1	2.4	4.8	5.5
Caucasian American	1.8	3	3.4	4.9

Source: Excerpted from the American Association for Obesity, "Obesity in Minority Populations," 2003.

Table A5. The prevalence of overweight with age among United States women from 1999 to 2000 and over the past decade.

From 1999 to 2000	
Age (years)	Prevalence (%)
20-39	54.3
40-59	66.1

Over the Past Decade

Age (In years)	1988-1994 Prevalence (%)	1999-2000 Prevalence (%)
20-29	14.6	23.3
30-39	25.8	32.5
40-49	26.9	35.4
50-59	35.6	41.2
60-69	29.8	42.5
70-79	25.0	31.9
≥ 80	15.1	19.5

Source: Excerpted from the American Association for Obesity, "Women and Obesity," 2003.

Table A6. The incidence of overweight and obesity of American women of different racial-ethnic backgrounds.

Racial-Ethnic Group	Overweight (BMI > 25)	Obese (BMI > 30)
African American	78.0	50.8
Mexican American	71.8	40.1
Caucasian American	57.5	30.6

Source: Excerpted from the American Association for Obesity, "Obesity in Youth," 2003.

Table A7. The prevalence of overweight and obesity among racial-ethnic minority youth in the United States.

	Children (Ages 6-11) Prevalence (%)		Adolescents (Ages 12-19) Prevalence (%)	
Racial-Ethnic Group	Overweight	Obese	Overweight	Obese
African Americans	35.9	19.5	40.4	23.6
Mexican American	39.3	23.7	43.8	23.4
Caucasian American	26.2	11.8	26.5	12.7

Source: Excerpted from the American Association for Obesity, "Obesity in Minority Populations," 2003.

Table A8. Obesity prevalence for several countries around the world.

Country	Obesity Percent	Country	Obesity Percent
Columbia	40	Japan	2
Brazil	8	China	1.3
Europe	23	South Africa	44 (women)
Quebec	12	Saudi Arabia	14
England	15	Netherlands	11
East Germany	23	Kuwait	38

Source: Excerpted from the American Association for Obesity, "Obesity- A Global Epidemic," 2003.

Table A9. Percent increase in overweight youth in several countries around the world in the past 20 years.

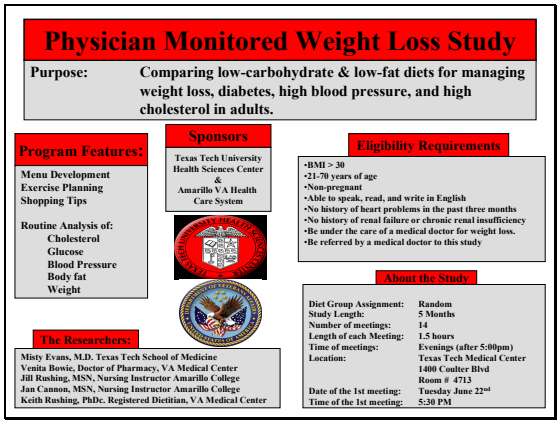
Country	Percent (%) Increase in Overweight Youth	Country	Percent (%) Increase in Overweight Youth
England	2.4	Ghana	3.8
Scotland	2.0	Morocco	2.5
China	1.3	Brazil	3.5
Japan	2.4	Chile	1.6
Egypt	3.9	Costa Rica	2.7
Australia	4.0	Haiti	3.5

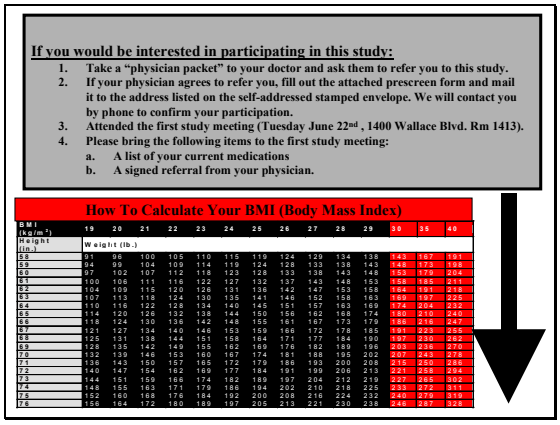
Source: Excerpted from the American Association for Obesity, "Obesity- A Global Epidemic," 2003.

APPENDIX B

PARTICIPANT SOLICITATION MATERIALS

Slide 1





BMI (kg/m²)	19	20	21	22	23	24	25	26	27	28	29	30	35	40
Height (in.)	Weight (lb.)													
58	91	96	100	105	110	115	119	124	129	134	138	143	167	191
59	94	99	104	109	114	119	124	128	133	138	143	148	174	198
60	97	102	107	112	118	123	128	133	138	143	148	153	179	204
61	100	106	111	116	122	127	132	137	143	148	153	158	185	211
62	104	109	115	120	126	131	136	142	147	153	158	164	191	218
63	107	113	118	124	130	135	141	146	152	158	163	169	197	225
64	110	116	122	128	134	140	145	151	157	163	169	174	204	233
65	114	120	126	132	138	144	150	156	162	168	174	180	211	240
66	118	124	130	136	142	148	155	161	167	173	179	186	218	247
67	121	127	134	140	146	153	159	166	172	178	185	191	225	255
68	125	131	138	144	151	158	164	171	177	184	190	197	232	262
69	128	135	142	149	155	162	169	176	182	189	196	203	238	270
70	132	139	146	153	160	167	174	181	188	195	202	207	243	278
71	136	143	150	157	165	172	179	186	193	200	208	214	254	285
72	140	147	154	162	169	177	184	191	199	206	213	221	261	293
73	144	151	159	166	174	182	189	197	204	212	219	227	268	303
74	148	155	163	171	179	186	194	202	210	218	225	233	272	311
75	152	160	168	176	184	192	200	208	216	224	232	240	279	319
76	156	164	172	180	189	197	205	213	221	230	238	246	287	328


Other Objectives:
Assess acceptability of each diet (satiety, complaints, and compliance).
Assess changes in medical management (changes in medication dosages) of DM, HTN, & hyperlipidemia
Diet Groups:
Random Group Assignment
Low Carbohydrate
20 grams CHO
No calorie restriction
Low Fat
1100 calorie
55% CHO
30% Fat
15% Protein
A Low Carbohydrate Diet: Treating obesity related disorders in adults
Principle Investigators:
Dr. Misty Evans (Internal Medicine TTUHSC)
Dr. Andrew Stenhouse (Internal Medicine TTUHSC)
Study Coordinator:
Keith Rushing PhDc. (Dietetics TTU / VA)
Purpose:
To compare the effectiveness of a low carbohydrate diet and a low fat diet for treating:
•Overweight / Obesity
•Diabetes
•Hyperlipidemia
•High Blood Pressure
Subject Solicitation
Physician Referral (documentation preferred)
Goal: 100 to 150 participants
VA Hospital
Texas Tech Internal Medicine Clinic
Texas Tech Family Practice Clinic
Endocrinologists
Inclusion Criteria
21 to 70 years old.
Non-pregnant
BMI greater than or equal to 30
No heart problems in the past three months
No renal failure or chronic renal insufficiency
Fluent in English
Education
Diet
Menu Planning
Labels
Shopping
Cooking
Exercise
Inclusion Criteria (Continued)
Being treated by a physician for weight loss.
Physician referral to this study (documentation preferred)
Inclusion Criteria (Continued)
If diabetic, lab draws (fasting blood Gluc, BUN, serum creat., and urinalysis) at baseline (July 20) & 4 months later (November 30).
If hyperlipidemic, lab draws (Tot Chol, LDL, HDL, and TG) at baseline (July 20) & 4 months later (November 30).
Study Length----------22 weeks
Number of Meetings-----14
Meeting 1 (consent, ht, wt, body fat, BP, group division)
Meetings 2-7 (weekly, divided groups, diet education, anthropometrics, BP, survey)
Meetings8-13 (bi-monthly, divided groups, follow-up, anthropometrics, BP, survey)
Meetings 14 (review results, combined group reception)
Meeting Information
Tuesdays
5:30 PM – 7:00 PM
7:15 PM – 8:45 PM
First meeting: June 22, 2004
Last meeting: December 14, 2004
Texas Tech 1400 Coulter
Room 4713

PHYSICIAN MAILINGS

June 4, 2004

Dear Physicians and Healthcare Providers:

Starting on July 27, 2004 myself along with other medical and health care professional at Texas Tech Health Sciences Center and the Amarillo Veterans Administration Healthcare system will be conducting a 5-month weight loss study evaluating the effectiveness of a low-carbohydrate diet for treating overweight and obesity in adults. The objective is to determine the impact of an low-carbohydrate diet on weight loss, blood glucose control, blood pressure, cholesterol, hunger, satiety, and diet compliance in overweight and obsese adults.

Participants in this study will be randomly divided into two diet groups (low fat low calorie and low carbohydrate). The low fat diet will consist of 1100 calories, 55% carbohydrates, 15% protein, and 30% fat and will be based on the diabetic exchange system. The low carbohydrate diet will contain the follow macronutrient distribution: 60% fat, 35% protein, and 5% carbohydrate (approximately 20 grams), with no calorie restriction.

The study will last 20 weeks with 14 group meetings. During the course of the study, participants will:

- Receive an initial overview of the study including potential risks.
- Be encouraged to ask questions and voice concerns.
- Complete an initial survey (i.e. demographics, medical history, diet history, physical activities)
- Complete follow-up surveys (diet compliance, activity-exercise records, and hunger-satisfaction levels).
- Complete a final survey (i.e. changes in medication usage, evaluation of the study)
- Receive diet education on their specified diet including menu planning, shopping, label reading, food preparation, eating out, and behavior modification.
- Receive education on signs, symptoms, and treatment of hypoglycemia and hypotension.
- Receive routine measurement of anthropometric data (weight, height, and body fat using bioimpedance) and blood pressure collected by a registered nurse.
- Receive a final reception with healthy refreshments to recognize successes and thank participants.

In order to be eligible to participate in this study, participants must:

- Be between the ages of 21 to 70 years old.
- Have a BMI greater than or equal to 30 (approximately 20 pounds or more overweight)
- Have no history of heart problems in the past three months
- Have no history of renal failure or chronic renal insufficiency
- Be able to read, write, and speak the English language (This criteria was established to eliminate extra printing, translating, and communicating costs associated with including non-English speaking participants.)

To determine the impact of the study diets on diabetes, high blood pressure, and hyperlipidemia, we will be asking to review the participant's routine laboratory data as appropriate based on the participant's medical history (i.e. fasting blood glucose and urinalysis with diabetes, lipid panel with hyperlipidemia). In an ideal setting we would ask that laboratory analysis be drawn at baseline (around the study start date) and five months later. However, such a request may incur costs that standard health insurance will not cover.

If you have patients that you believe will benefit from participation in this study please give them an enclosed packet and ask the to complete mail the attached prescreen letter to the address listed on the self-addressed stamped envelope.

The study will be conducted at the following location:

Texas Tech Medical School
1400 Coulter
Room # 4713
Amarillo, TX 79106

The first study meeting will be Tuesday July 27, 2004 at 5:30PM. The study will run through December 14.

The study team is as follows:

Dr. Andrew Stenhouse-	Principle Investigator
Dr. Misty Evans -	Medical Advisor
Dr. Venita Bowie-	Pharmaceutical Advisor
Keith Rushing PhDc, RD-	Study Coordinator
Jill Rushing, MSN, RN-	Researcher
Jan Cannon, MSN, RN-	Researcher

Keith Rushing will be in contact with you be phone later this week. If you would like more participant packets please let him know.

Thank you for your time and consideration. If you have any questions please contact me at 354-5660.

Dr. Andrew Stenhouse
Assistant Professor
Department of Internal Medicine,
Texas Tech Medical Center, Amarillo Texas

PARTICIPANT SOLICITATION PACKET

Dear Potential Participant

You are invited to participate in a 5-month weight loss study (starting July 27, 2004) comparing the effectiveness of two diets (a low-carbohydrate diet and a low-fat low calorie diet) for treating overweight and obesity in adults. The objective is to determine the impact of an low-carbohydrate diet on weight loss, blood glucose control, blood pressure, cholesterol, hunger, satiety, and diet compliance in overweight and obsese adults.

You qualify for the study if you must be:

1. Referred by a medical doctor
2. Overweight
3. Not pregnant
4. 21 to 70 years of age
5. No history of heart problems in the past three months
6. No history of kidney problems

The study will last 20 weeks. During the course of the study, you will:

- Receive menu plans and education on diet, exercise, and shopping.
- Receive measurement of weight, body fat, and blood pressure routinely by a registered nurse (in a private location).
- Receive a final reception with healthy refreshments to recognize successes and thank participants.

As a part of standard medical management, we are asking that referring physician draw standard laboratory analysis on participating patients with diabetes and high cholesterol at the beginning of the study and four months later.

All information collected during the study will be confidential. . If you are interested in participating in this study, please complete the following tasks:

1. Take a "physician packet" to your primary care doctor and ask them to refer you to this study.
2. If your physician agrees to refer you, fill out the attached prescreen form and mail it to the address listed on the self-addressed stamped envelope. We will contact you by phone to confirm your participation.
3. Attended the first study meeting (see the time, date, and location below).
4. Please bring the following items to the first study meeting:
    a. A list of your current medications
    b. A signed referral from your physician.

The first study meeting will be held at the following date, time, and location:

Tuesday July 27, 2004
Texas Tech Medical School
1400 Coulter
Room 4713

Sincerely,

Keith Rushing (Study Coordinator)
6010 Amarillo Blvd West
Amarillo, Texas 79106
(806) 379-7574

WEIGHT LOSS STUDY PRESCREEN

Please print your information in the blanks provided below. This information will be kept completely confidential and only used to determine your eligibility and report that information to you.

Last Name: _____ First Name:_____

Address: _____

City: _____State: _____Zip Code: _____

Home Phone Number:_____E-mail Address_____

Referring Physician:_____

Referring Physician's Address:_____City:_____State:_____

Referring Physician's Phone Number:_____

1. What is your age?_____
2. What is you gender? Male:_____ Female:_____
3. What is your current height:_____
4. What is your current weight in pounds:_____
5. Have you been diagnosed with one or more of the following health conditions: hyperlipidemia (high cholesterol or tryglicerides), high blood pressure, or type II diabetes? Yes_____ No:_____

   If your answer to question five was yes, which of the three medical conditions do you have and when were you diagnosed? _____
6. Have you had any heart related health problems in the past three months such as a heart attack, a stroke, or heart surgery, or do you have kidney disease? Yes_____ No:_____
7. Are you a student or employee of Texas Tech Medical School or Health Sciences center? Yes:_____ No:_____
8. Are you pregnant or breast feeding? Yes:_____No:_____
9. Are you able to speak, read, and write the English language? Yes:_____ No:_____

APPENDIX C

CONSENT / HIPPA FORMS

INFORMED CONSENT FOR RESEARCH STUDY

This is a research study, which includes subjects who voluntarily choose to take part. Please take your time to make a decision, and discuss this proposal with your personal doctor, family members, and friends if you wish.

STUDY TITLE: A Low Carbohydrate Diet: Treating Obesity Related Disorders in Adults

Comment [JH1]:

INVESTIGATOR(s):

Principle Investigator: Andrew Stenhouse
Assistant Professor
Department of Internal Medicine
Texas Tech Medical Center, Amarillo Texas
(806) 354-5489

Study Coordinator: Keith Rushing
Doctoral Candidate
Registered Dietitian
Amarillo Veterans Administration Hospital
(806) 379-7574

INSTITUTION: Texas Tech University Health Sciences Center

1. What is this research and why is this research being done?

The purpose of this study is to assess the results of an ultra-low-carbohydrate diet (no calorie limit, 5% carbohydrate, 35% protein, and 60% fat) compared to a traditional low-fat low calorie diet (1100 calorie, 55% carbohydrate, 15% protein, and 30% fat) on weight loss and risk factors for heart disease and diabetes.

2. Why am I being asked to take part in this research study?

You are being asked to participate because you have stated you are interested in losing weight and because your physician has referred you to this study for diet education, weight management, and follow-up.

3. What is involved in this research? What parts of this research would not normally be done? (Indicated by bold text)

Participants will be randomly (by chance, not by choice) divided into two diet groups: a) ultra-low carbohydrate (no calorie limit, 5% carbohydrate, 35% protein, and 60% fat) and b) balanced low calorie (1100 calorie, 55% carbohydrate, 15% protein, and 30% fat).

The study will require attending fourteen group meetings. Each session will take place at a large classroom at Texas Tech Medical School in Amarillo. At the first meeting, you as a potential participant will asked to read and sign an overview of the study including eligibility requirements and potential risks. You will receive a presentation about laboratory tests evaluated during this study.

As a part of standard medical management, your referring physician has agreed to order the following fasting laboratory analysis at the beginning of this study and five months later: blood glucose, blood urea nitrogen, and serum creatinine and a urine sample (for diabetic patients only); total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides (in hyperlipidemic patients only). At the end of this study these laboratory results will be requested to help evaluate the impact of diet on management of participants with diabetes and elevated cholesterol.

At the end of the first meeting, you will be randomly assigned into one of two groups (ultra low carbohydrate diet and low fat diet), assigned an identification number, and asked to complete an initial survey (ask you questions about your age, income, ethnic background], medical history, and diet history). You will be asked to use your identification number instead of your name on all future study questionnaires and surveys so that this information will be private. You will then be given information on the time, date, and location of future meetings, and dismissed for the evening. A list will be compiled with identification numbers and corresponding names. This list will be used to request your medical records and reference your identification number in case you lose it.

At meetings two through seven (each one week apart), you will meet with your assigned diet group. At the beginning of each meeting you will receive a 30-minute block of diet education including education materials (you will be encouraged to asked questions throughout each meeting). At sessions three through seven you will be asked to complete diet compliance/activity-exercise/hunger-satisfaction surveys. Next, a registered nurse will gather your following body measurements individually in a private room: height, weight, blood pressure, and percent body fat.

At meetings eight through twelve (each two weeks apart), you will meet with your assigned diet group. At the beginning of each meeting there will be a period for you to get the answers to questions and concerns you have about your assigned diet. You will be asked to complete diet compliance/activity-exercise/hunger-satisfaction surveys. Next, a registered nurse will gather your following body measurements individually in a private room: height, weight, blood pressure, and percent body fat.

At meetings thirteen (two weeks after meeting twelve), you will meet with your assigned diet group. At the beginning of each meeting there will be a period for you to get the answers to questions and concerns you have about your assigned diet. You will be asked to complete a final survey including questions about any medication changes you have undergone during the study.

At meeting 14, you will get a chance to find out how your laboratory data and body measurements changed over time. You will receive this Information individually in a private room by a registered nurse. Afterwards, participants who had the greatest improvements in body measurements and laboratory data will be recognized. Healthy refreshments will be served.

Diagram of activities that will take place each session and the corresponding week of the activity

Meeting Number	→	1	2	3	4	5	6	7	8	9	10	11	12
Week Number	→	1	2	3	4	6	8	10	12	14	16	18	21
Meeting Date (2004)	→	07/27	08/03	08/10	08/17	08/31	09/14	09/28	10/12	10/26	11/09	11/23	12/14
Activities	↓												
1.	Request for submission of pre-existing laboratory data (Blood glucose and fasting lipid profile)	√	√	√	√	√	√	√	√	√	√	√	√
2.	Complete consent forms (including a study overview)	√*											
3.	Complete initial surveys	√*											
4.	Receive assigned identification number	√											
5.	Use identification number in place of your signature		√	√	√	√	√	√	√	√	√	√	√
6.	Body measurement: weight	√	√	√	√	√	√	√	√	√	√	√	√*
7.	Body measurement: blood pressure	√	√	√	√	√	√	√	√	√	√	√	√*
8.	Body measurement: body fat	√			√							√	√*
9.	Diet education		√	√	√	√	√	√	√	√	√	√	
10.	Time for participants to ask questions	√	√	√	√	√	√	√	√	√	√	√	√
11.	Follow-up surveys (diet compliance, hunger/ satisfaction)			√	√	√	√	√	√	√	√	√	√
12.	Program evaluation											√*	√
13.	Reception												√

Diagram of activities continued.	
Notes:	
2. & 3.	Consent forms and initial surveys were completed anytime someone new joined the study. There was no cut-off date for new participants.
6., 7., & 8.	Participants who were unable to attend due to poor weather on the night of meeting, had their weight blood pressure, and body fat taken at meeting number 12.
12.	Participants who would not be able to attend meeting 12 were asked to completed program evaluations at meeting 11.

Education

Meetings will be scheduled on weeknights to work around most participant's jobs and family obligations. Presentations will include lectures along with group activities to increase participant interest. During and after all sessions you will be encouraged to ask questions. You will receive sample menus for your assigned diet.

The low fat / low calorie diet will consist of 1100 calories, 55% carbohydrates, 15% protein, and 30% fat and based on the diabetic exchange system.

The ultra low carbohydrate diet (60% fat, 35% protein, and 5% carbohydrate) will have no calorie limit. If you are assigned this diet, you will receive fact sheets stating what and how much of specific carbohydrate containing foods you have a choice of eating each day. Meats and fats will not be limited on this diet.

4. How long will I be in this study? How much of my time will this take?

This study will last 5 months. There will be 14 group meetings that will last one and one-half hours. The other time the study will take is the time you choose to engage in meal planning, meal preparation, and exercise.

5. What are the risks and discomforts/pain to me if I participate in this study?

Just because you participate in this study does not guarantee you will lose weight. By participating in this study, you may experience a positive or negative change in any one of the following labatory values: blood urea nitrogen, creatinine, blood glucose, total cholesterol, LDL cholesterol, HDL cholesterol, trigylcerides, and urinalysis. Changes in these blood or urine values may aggravate a pre-existing chronic disease condition such as diabetes, hypertension, and cardiovascular disease. Participation in this study may put you at increased risk for kidney stones.

Discomforts may be caused by diet compliance. Diet compliance may cause abdominal distress (gas, bloating, diarrhea, and abdominal pain) hunger, and mood irritation. There may also be some discomfort in having information about your body measurements recorded, however to reduce discomfort, you will have this done individually by a female nurse in a private room.

6. Will there be any added risks to me from this study if I am a female? If so, what?

The added risk to females is minimal, however you may experience alterations in your normal menstrual cycle if drastic weight loss occurs.

7. Are there any benefits to me if I take part in this study? What are they?

By participating in this study you have the potential to reduce your weight and percentage of body fat. If you have diabetes you may achieve better glucose control. If you have hyperlipedemia you may achieve better lipid control. Furthermore, you may learn health behaviors and strategies for losing weight and maintaining a healthy weight.

8. What options are available to me if I do not participate in this study?

If you are interested in losing weight or having better control of a chronic health condition such as diabetes or heart disease, you may ask your healthcare provider to schedule an appointment for you to meet with a dietitian, diabetic educator, or other healthcare expert who can provide you with the information you need.

9. What about confidentiality and the privacy of my records?

Federal officials do have the right to inspect and/or photocopy research records, including consent forms and individual medical records to assure that all the research rules and standards are followed. You are protected from being personally identified by the Privacy Act of 1974. Reasonable measures to protect the confidentiality of your records and your identity related to your participation in this research study will be taken by the investigators and Texas Tech University Health Sciences Center and affiliates. You will not be identified in any publication or presentation due to taking part in this research study. The method used to identify you on all research study records will be a code. Your identity cannot be kept totally anonymous. However, the sponsor will not be allowed to remove or copy information that identifies you by name.

Only physical data (body measurements), written data (from surveys) and laboratory data (blood analysis) gathered from participants during the course of the study will be available to study investigators. Participant's medical records and other data not gathered directly from participants during the course of the study will not be available to investigators.

10. Who is sponsoring this study?

The study is sponsored by Texas Tech University Health Sciences Center.

11. What will it cost me, if anything, to participate in this research?

The cost of participating in the study will include:

- Increased food cost: It is difficult to calculate the increased food cost associated with following one of the prescribed diets. However, it is

estimated that participants may increase their monthly grocery expenditures by up to 20% if they strictly adhere to our dietary recommendations.

- Charges for medical care and laboratory tests are not reimbursed by this study. This study will request copies of that information only.

12. Will I be compensated? If so, in what way?

There will be no monetary compensation for participating in this study. However, you will be provided free nutrition and diet counseling.

13. What if I am hurt by participating in this study?

If you get hurt or become ill as a direct result of your participation in this study, other than what might occur in the normal progression of your condition, emergency care will be available, but you will be charged in the regular way. You should check on any limitations of coverage that your insurance company might impose. Texas Tech University Health Sciences Center and it's affiliates do not offer financial compensation or cover the cost of medical treatment. No funds have been set aside to compensate you in the event of such injury or illness unless specifically stated below.

14. What are my rights as a voluntary participant?

Taking part in this study is your choice. If you sign this form it means that you wish to participate in this research study. If you decide not to participate, this will not affect any medical care or benefits to which you are entitled. You may leave the study at any time, but if you do so, discuss it with the investigator who will help you do so in the safest way. Some information may be collected without being identified as belonging to you. We have no way of telling which data is yours and we cannot remove it. The data that is identified as yours can be removed if you submit a request in writing. If you leave the study, your right to standard medical care will continue. If new information becomes available during the study that may affect your health, or your willingness to continue to take part in the study, you will be informed. For general questions about the study, contact the Principal Investigator, Dr. Misty Evans at the following telephone number: (806) 354-5489

If you would like to speak to someone not associated with the study about your rights as a participant, or any other matter related to the study, you can contact the Institutional Review Board (IRB) Chairperson at (806) 354-5419, Texas Tech University Health Sciences Center, Amarillo, Texas 79106 during normal work hours.

Printed Name of Subject

Signature of Subject Date Time

Signature of Parent/Guardian or Authorized Representative Date Time

I have discussed this research study with the subject and his or her authorized representative, using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation.

HIPPA FORM

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER ("TTUHSC")

AUTHORIZATION TO USE AND/OR DISCLOSE
YOUR PROTECTED HEALTH INFORMATION
for
RESEARCH STUDY

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information** (PHI) if you decide to participate in the research study described below. The health information about you that may be used or disclosed is described on the next page, and this information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel listed below for this research study. This Authorization specifically relates to the research study described below, and should be kept with your copy of the Informed Consent document.

[These numbered items must be completed by the Principal Investigator prior to giving you this form:]

Study Protocol # and Title: IRB #3045: A Low Carbohydrate Diet: Treating Obesity Related Disorders in Adults

1. **Principal Investigator:** **Dr. Andrew Stenhouse**
Professor
Department of Internal Medicine
Texas Tech Medical Center, Amarillo, Texas
(806) 354-5489

2. **Other Research Personnel:** **Keith Rushing**
Study Coordinator
Doctoral Candidate
Registered Dietitian
Amarillo Veterans Administration Hospital
(806) 379-7574

Dr. Lynn Huffman
Chairperson, Education, Restaurant, Hotel, and Institution Management
Texas Tech University, Lubbock Texas
(806) 742-3068

Venetia Bowie
Doctor of Pharmacy
Instructor
Texas Tech School of Pharmacy, Amarillo Texas

Jill Rushing, MSN
Instructor
Amarillo College of Nursing

Jan Cannon, MSN
Instructor
Amarillo College of Nursing

3. **Name of Study Sponsor: None.**

   What is this research and why is this research being done? Numerous studies have shown promise for low-carbohydrate diets as an alternative to conventional low-calorie diabetic-based weight loss plans, however, expert health and wellness organizations such as the American Dietetic Association, the American Heart Association (AHA), and the American Diabetic Association have yet to endorse low-carbohydrate diets.

   The purpose of this study is to assess the results using an ultra-low-carbohydrate diet (no calorie limit, 5% carbohydrate, 35% protein, and 60% fat) compared to a traditional low-fat low calorie diet (1100 calorie, 55% carbohydrate, 35% protein, and 60% fat) for treating overweight and obesity in women.

4. **This Authorization is valid until:**

   i. __X__End of the Study;
   ii. _____Date:_____;
   iii. _____Indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.

5. **If you choose to cancel this Authorization, please give notice <u>in writing</u> to:**

   Name: Keith Rushing

   Street Address: 1509 South Bryan
   City, State Zip: Amarillo, Texas 79102
   Phone: (806) 379-7574

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

• hospital records and reports • admission history, and physical examination • X-ray films and reports; operative reports • laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS) • any other Protected Health Information needed by the research personnel listed above. (* use separate form for disclosure of psychotherapy notes)	• immunizations • allergy reports • prescriptions • consultations • clinic notes • mental health records • alcohol / substance abuse records

For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations outside of TTUHSC who sponsor, approve, assist with, monitor or oversee the conduct of research studies. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC is required to meet.

Only physical data (body measurements), written data (from surveys) and laboratory data (blood analysis) gathered from participants during the course of the study will be available to study investigators. Participant's medical records and other data not gathered directly from participants during the course of the study will not be available to investigators.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

Signature of Individual or Authorized Representative	Date
Printed Name	
If applicable, Relationship of Authorized Representative or Authority to Sign	Witness to Oral Presentation

APPENDIX D

INITIAL SURVEY

Initial Survey

Please place your assigned 5-digit identification number here

→_____

In this section please place an X next to the **answer or answers** that best describe you or your situation.

1. Which **item or items** best describe your race/ethnic background?

_____Black / African American
_____Asian
_____Hispanic
_____Other Pacific Islander
_____White/Caucasian
_____American Indian
_____ Other (Please specify) _____

2. Which range best describes your family income last year before taxes?

_____Less than $10,000
_____$10,000 to $14,999
_____$15,000 to $19,999
_____$20,000 to $25,999
_____$25,000 to $29,999
_____$30,000 to $34,999
_____$35,000 to $39,999
_____$40,000 to $44,999
_____$45,000 to $49,999
_____$50,000 to $59,999
_____$60,000 to $74,999
_____$75,000 to $99,999
_____$100,000 to $124,999
_____$125,000 to $149,999
_____$150,000 to $199,999
_____$200,000 or Greater

3. What is your marital status?

_____Married
_____Separated
_____Divorced
_____Widowed
_____ Single / Never Married

4. What best describes the level of success you have achieved with diets in the past?

_____Excellent
_____Good
_____Fair
_____Poor
_____Very poor

5. What is the highest level of education that you have received?

_____Less than a high school degree
_____A GED
_____A high school degree
_____1 year of higher education
_____2 years of higher education
_____3 years of higher education
_____4 years of higher education
_____5 years of higher education
_____6 years of higher education
_____8 years of higher education
_____ More than 8 yrs of higher education
Other☹Please explain):_____

6. Do you have any of these health **conditions**?

_____ Kidney Failure / Insufficiency
_____ Gallstones
_____ Heart Disease
_____ High Blood Pressure
_____ High Cholesterol
_____ High Trigylcerides
_____ Hypoglycemia "low blood sugar"
_____ Type 2 Diabetes

In this section please fill in the blank with the answer that best describe you or your situation.

7. In what year were you born? _____

8. What is your occupation? _____

9. How many people including you live in your household? _____

10. How many pounds would you realistically like to lose in six months? _____

11. How many pounds would you ultimately like to lose?_____

12. On average, how many meals (not snacks) do you eat daily?_____

13. On average how often do you snack daily?_____

14. On average how many times do you eat food prepared away from home per week? (including eating out and delivery/food you take home to eat)_____

In this section, please place an X to the answer that best describes you or your situation. If you answer yes, please elaborate in the **space/spaces** provided.

15. Have you lost weight in the past 6 months?
_____Yes (If yes, how many pounds? _____)
_____No

16. Have you gained weight in the last 6 months?
_____Yes (If yes, how many pounds _____)
_____No

17. Are you currently on a diet?
_____Yes (If yes, what kind of diet _____and for how long _____)
_____ No

18. Have you ever followed a diet or diets in the past?
_____Yes (If yes, which_____)
_____ No

19. Are you currently a member of a weight loss organization (i.e., Weight Watchers, TOPS, Jenny Craig, etc.)?
_____Yes (If yes, which organization _____ and for how long _____)
_____ No

20. Have you been a member of a weight loss organization in the past (i.e., Weight Watchers, TOPS, Jenny Craig, etc.)?
_____Yes (if yes, which organization_____)
_____ No

21. Do you take vitamin or mineral supplements?
_____Yes (if yes, what_____)
_____ No

22. Do you take herbal supplements?
_____Yes (if yes, what_____)
_____ No

23. Do you take any other nutritional supplements (i.e., protein powders, meal replacement bars, sports supplements, creatine, fat-burners)?
_____Yes (if yes, what_____)
_____ No

24. Do you exercise?
_____Yes (if yes, what type _____, how many times per week_____, and how many minutes per session_____?
_____ No

25. Do you smoke?
_____Yes (if yes, for how many years and how many packs per day _____/____)
_____ No

APPENDIX E

POWER POINT EDUCATION PRESENTATIONS FOR

LOW CARBOHYDRATE DIET

TRADITIONAL LOW FAT DIET

Diet Group A

WEEK # 1

1000 Calorie Diet

55% Carbohydrate

15% Protein

30% Fat

Exchange List

	Carb. (Grams)	Protein (Grams)	Fat (Grams)	Calories
Starch	15	3	1	80
Fruit	15	0	0	60
Veg.	5	2	0	25
Protein	0	7	3	55
Milk	12	8	3	90
Fat	0	0	5	45

4

Agenda

- Sign in
- New member packet completion / diet assignment
- Diet education
- Weighing
- Blood pressure body fat measure

2

1100 CALORIE PLAN

BREAKFAST	LUNCH	SUPPER
2 Protein	2 Protein	2 Protein
1 Starch	1 Starch	1 Starch
1 Fruit	1 Fruit	1 Fat
1 Milk	1 Milk	2 Vegetables
1 Fat	1 Vegetable	

3

Substituting

- Milk, fruit, and Starch can be interchanged
- Starchy Beans can be switched for protein at up to two meals per day (this is encouraged)
- At least one serving of animal protein is needed per day

5

Number of Serving and Serving Sizes Are The Key!!!

6

STARCH

(Only 100% Whole Grain, Peel, or Husk)

- **100% Whole Grain Bread, 1 slice**
- **100% Whole Grain Bun, ½**
- **100% Whole Grain Roll, 1-small**
- **100% Whole Grain English Muffin, ½**
- **100% Whole Grain Dry Cereal (no sugar added), ¾ cup**
- **100% Whole Grain Pasta, ½ cup**
- **100% Whole Grain Rice, ½ cup**
- **100% Whole Grain Crackers, 6**

7

NON-STARCHEY VEGTABLES (Fresh is Best)

(½ cup cooked or 1 cup raw)

Broccoli
Cauliflower
Cabbage
Greens / Spinach
Carrots
Beets
Lettuce
Tomatoes
Cucumber
Mushrooms
Onions
Asparagus
Okra
Peppers
Squash
Celery
Eggplant

10

STARCH-- continued

(Only 100% Whole Grain, Peel, or Husk)

- **Oatmeal, ½ cup**
- **Sweet or Other Potato With Peel, ½ cup**
- **All Starchy Beans and Peas, ½ cup**
- **Corn, ½ cup**
- **Fat Free Popcorn, 3 cups**

8

FRUIT

(Only Fresh Fruit With Peel)

- **Apple, 1-small**
- **Orange, 1-small**
- **Grapefruit, ½**
- **Banana, ½-medium**
- **Pear, ½-large**
- **Peach, 1-medium**
- **Grapes, 10**
- **Melon, 1-cup**
- **Berries, 1-cup**
- **Cherries, 10**
- **Apricots, 4**
- **Plums, 2-small**

9

PROTEIN

(Remove Visible Fat, Cook So Fat Drips Away)

- **Skinless Chicken, 1 oz**
- **Skinless Turkey, 1 oz**
- **Beef Sirloin, 1 oz**
- **Lean Ground Beef (Drained), 1oz**
- **Pork Tenderloin, 1 oz**
- **Lean Ham, 1oz**
- **White Fish, 1 oz**
- **Tuna (in water), 1 oz**
- **Shellfish, 1 oz**
- **Lean Lunch Meat 1oz (<1gm fat/oz)**

11

OTHER PROTEIN

- **Fat-Free Cheese, 1 oz**
- **Non-fat Cottage Cheese, ¼ cup**
- **Egg Whites, 2**
- **Egg Substitute, ¼ cup**
- **Firm Tofu, 1 oz**

12

BREAKFAST

- **Ham, 2 oz**
- **Whole Wheat Toast, 1 slice**
- **Peanut butter, 2 tsp**
- **Orange, 1-small**
- **Light, Non-Fat Yogurt, 8 oz**
- **Water, 16 ounces**

16

MILK

- **Skim Milk, 1 cup**
- **Light, Non-fat Yogurt, 8 oz**
- **Powdered Milk, ½ cup dry**

13

FAT
(Non-Hydrogenated Vegetable Fat Is The Best)

- **Butter, 1 tsp**
- **Oil (Vegetable), 1 tsp**
- **100% Natural Peanut butter, 2 tsp**
- **Nuts, 1/3 cup**
- **Avocado, 1/8 medium**
- **Olives, 8**
- **Sour Cream, 2 tbsp**
- **Mayonnaise, 1 tsp**
- **Salad Dressing, 1 tbsp**
- **Cream Cheese, 1 tbsp**

14

SAMPLE MENUS

15

LUNCH

- **Vegetable Soup, 1 cup**
- **½ sandwich (1 slice 100% rye bread, 1 ounce sliced turkey, 1 ounce Swiss cheese, 1 tsp mustard, 1 slice lettuce, 1 slice tomato, 1slice onion)**
- **Strawberries, 1 cup**
- **Light, Non-Fat Yogurt, 8 oz**
- **Water, 16 ounces**

17

SUPPER

Beef Fajita

- **2 ounce lean steak**
- **1 cup cook sautéed peppers**
- **1 tsp vegetable oil**
- **1 tortilla**
- **2 tsp fat free sour cream**

Water, 16 ounces

18

Notes

- Multivitamin -vital
- Water – at least 8 glasses
- Fiber -essential
- Exercise -5 days per week (get started)
- Sleep -8 hours per night
- Beans- often
- Fresh ---fruit / vegetables – Best
- Fruit Juice –avoid
- Sodas –only diet, do not abuse
- 100% Whole Grains –always
- Fudging

19

We Need

- A list of your current medications
- A copy of your most recent labs if you have diabetes of high cholesterol / triglycerides.

20

Procedures and Preparing for Weight, Blood Pressure, and Body Fat Measurement

21

WEEK # 1

Low-Carbohydrate Dieting

1

Option:

- Avoiding excess animal fats may help improve overall results

4

The Rules

Eat liberal amounts of protein and fat from the following sources:

- Poultry
- Fish
- Shellfish
- Eggs
- Red Meat
- Cream
- Mayonnaise
- Olive Oil
- Safflower Oil
- Sunflower Oil
- Canola Oil
- Butter
- (Avoid Corn Oil)

2

Agenda

- Sign in
- New member packet completion / diet assignment
- Diet education
- Weighing
- Blood pressure body fat measure

3

The Rules

Eat Liberally

Fish	Poultry	Shellfish	Meat	Eggs
Tuna	Chicken	Oysters*	Beef	Scrambled
Salmon	Turkey	Mussels*	Pork	Fried
Sole	Duck	Lobster	Lamb	Poached
Trout	Goose	Clams	Bacon*	Soft-boiled
Flounder	Cornish hen	Squid	Veal	Hard-boiled
Sardines	Quail	Shrimp	Ham*	Deviled
herring	pheasant	Crabmeat	Venison	Omelettes

No more than 4 ounces per day of organ meat, oysters, or mussels. Avoid meats cured with sugar.

5

The Rules

Eat no more than 20 grams of Carbohydrates a day.

- This should come from 3 cups of loosely packed salad vegetables

or

- 2 cups of loosely packed salad vegetables and and one cup of other vegetables (see the next slide).

6

The Rules

Absolutely No

- **Fruit or Fruit Juice**
- **Bread, Pasta, or Grains**
- **Starchy Vegetables or Legumes**
- **Nuts or Seeds**
- **Dairy Products other than Cheese, Cream, or Butter**

No Exceptions

10

The Rules

Salad Vegetables: 2-3 cups/day

- Alfalfa Sprouts
- Arugula
- Bok Choy
- Celery
- Chicory
- Chives
- Cucumber
- Daikon
- Endive
- Escarole
- Fennel
- Jicama
- Lettuce
- Mache
- Mushrooms
- Parsley
- Peppers
- Radicchio
- Radishes
- Romaine
- Sorrel

7

The Rules

Other Vegetables: 1 cup/day (with 2 cups salad vegetables)

- Artichoke hearts
- Asparagus
- Bamboo Shoots
- Bean Sprouts
- Beet Greens
- Broccoli
- Brussels Sprouts
- Cabbage
- Cauliflower
- Celery Root
- Chard
- Collard Greens
- Dandelion Greens
- Eggplant
- Kale
- Leeks
- Okra
- Onion
- Pumpkin
- Rhubarb
- Sauerkraut
- Scallions
- Snow Peas
- Spinach
- String Beans
- Summer Squash
- Tomato
- Turnips
- Zucchini

8

The Rules

Cheese

Cheddar
Cow, Sheep, and Goat Cheese
Cream Cheese
Gouda
Mozzarella
Roquefort and other blue cheeses
Swiss

No more than 4 ounces per day.

9

The Rules

- **Eat until full not stuffed**
- **Don't assume, check labels**
- **Remember, gravy is often made with flour, ask your waiter.**
- **Eat out, but use caution.**
- **Instead of aspartame, use sucralose or saccharin (count as 1 gm of carb/serving)**
- **Avoid caffine**

No Exceptions

11

The Rules

Drink at least 8 (8-ounce) glasses of water per day

No Exceptions

12

The Rules

Take a Multivitamin

- High in B-complex factors
- High in Vitamin C
- Containing no iron

16

The Rules

For Constipation:

- 1 TBSP psyllum husks mixed in 1 cup of water daily

or

- Sprinkle flaxseeds or wheat bran on vegetables.

13

The Rules — Avoid Pitfalls

- Stay away from diet products unless they say "NO Carbohydrates"
- Sugar free, sugarless, and no sugar are not sufficient; check the carbohydrate content
- Avoid chewing gum, breath mints, cough syrups, and cough drops with sugar or caloric sweeteners

14

The Rules — Sample Menu

- Breakfast: 3-egg cheese and onion omelet; 1 cup decaffeinated coffee with cream.
- Lunch: 8 ounces chopped sirloin patties; spinach salad with cheese, olives, and vinegar & oil
- Supper: 10 ounces broiled catfish with garlic butter sauce; ¾ cup of string beans

15

The Rules

- **Count carbohydrates not calories.**
- **No more than 20 grams of carbohydrates per day.**

17

We Need:

- A list of your current medications
- A copy of your most recent labs if you have diabetes of high cholesterol / triglycerides.

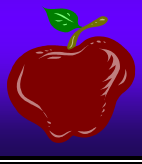
18

Procedures and Preparing for Weight, Blood Pressure, and Body Fat Measurement

19

Low Calorie / Low Fat Diet

WEEK 2



Breakfast Menu: Fruit Delight

2 Protein
1 Starch
1 Fruit
*1 Milk
1 Fat

- 2 ounces skim cottage cheese or 4 ounces strawberry banana yogurt (LFLC)
- ¾ Cup favorite cereal (100%WG)
- *2 cups berries (blueberries, raspberries, blackberries, strawberries)
- 1/3 cup of raw nuts (walnuts or cashews)

Directions: Layer in a bowl-- cottage cheese, cereal, berries, & nuts

*1 milk exchanged for 1 fruit

Welcome

- Are there any new participants?
- If you missed last week pick-up a handout.
- How was week one?
- What are your questions & concerns ?
- Body fat measuring monthly
- Body fat results from last week are posted

Agenda

- Follow-up Surveys (Note corrections)
- New Menus
- Exercise
- Labels
- Eating Out
- Ketones –not this presentation
- Weight
- Blood pressure

Lunch Menu: Bean Burrito

*2 Protein
1 Starch
1 Fruit
1 Milk
1 Vegetable

- 1 whole wheat tortilla
- *½ cup black beans
- ½ cup sautéed peppers
- 1 tbsp salsa
- 1 tbsp Pico de Gallo
- 2 tbsp diced tomatoes
- 10 Globe grapes
- 16 ounces water

*2 proteins exchanged for 1 starch---beans

Supper Menu: Cajun Broiled Fish

*2 Protein
1 Starch
1 Fat
2 Vegetables

- *3 ounces broiled tilapia (season with lime juice and Cajun jerk seasoning)
- 1 cup stir fried summer squash, tomatoes, yellow onions
- 1/3 cup lima beans

*1 fat exchanged for 1 protein

Exercise

- Walk
- Swim
- Bike
- Floor routine
- Low impact
- Variety
- Interval train
- Music / talk radio / news
- Clothing

•20 minutes /day X 6-7 days / week beginners

•Work up to 1 hour per day or 30 minutes twice a day

•Just Do It, but be sensible.

Labels

Nutrition Facts

Serving size: 1/4 Recipe (188g)
Servings Per Recipe 4

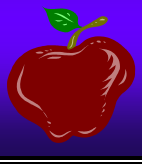
Amount Per Serving	
Calories 193	Cal. from Fat 45
	% Daily Value*
Total Fat 5g	**8%**
Saturated Fat 1g	**4%**
Cholesterol 0mg	**0%**
Sodium 245mg	**10%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 8g	**35%**
Sugars 0g	
Protein 10g	

Vitamin A	75%	Vitamin C	40%
Calcium	10%	Iron	20%

* Percent Daily Values is based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Low Carbohydrate

WEEK 2



Breakfast Menu:

Western Cheese Omelet

- 1 egg yoke
- 4 egg whites
- ½ cup chopped lean ham
- 1 fat free Kraft single
- 1 tbsp salsa
- ½ cup chopped onions and peppers

Welcome

- Are there any new participants?
- If you missed last week pick-up a handout.
- How was week one?
- What are your questions & concerns ?
- Body fat measuring monthly
- Body fat results from last week are posted

Agenda

- Follow-up Surveys (Note corrections)
- New Menus
- Exercise
- Labels
- Eating Out
- Ketones
- Weight
- Blood pressure

Lunch Menu:

Chicken Salad Stuffed Pepper

Mix:

- 4 ounces canned white meal chicken
- 2 tsp peanut oil
- Pinch salt and lemon pepper
- Cilantro
- ½ tsp chopped garlic
- 1/3 cup chopped celery
- 1/3 cup chopped green onions
- 1 tsp capers
- 1 tbsp mayo

Hollow out 1 large red pepper and stuff with mixture
16 ounces Crystal Light

Supper Menu: Sirloin K-bobs

- 10 ounces of lean sirloin steak cubes
- 2 cup k-bob vegetables (mushrooms, peppers, cucumbers)
- 16 ounces water

Exercise

- Walk
- Swim
- Bike
- Floor routine
- Low impact
- Variety
- Interval train
- Music / talk radio / news
- Clothing

•20 minutes /day X 6-7 days / week beginners
•Work up to 1 hour per day or 30 minutes twice a day
•Just Do It, but be sensible.

Labels

Nutrition Facts

Serving size: 1/4 Recipe (188g)
Servings Per Recipe 4

Amount Per Serving	
Calories 199	Cal. from Fat 45
	% Daily Value*
Total Fat 5g	**8%**
Saturated Fat 1g	**4%**
Cholesterol 0mg	**0%**
Sodium 245mg	**10%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 8g	**35%**
Sugars 0g	
Protein 10g	

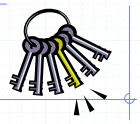
Vitamin A	75%	Vitamin C	40%
Calcium	10%	Iron	20%

* Percent Daily Values is based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Eating Out

Low Calorie / Low Fat Diet

WEEK 3



Welcome

- Are there any new participants?
- How was the past two weeks?
- What are your questions & concerns ?

Agenda

- Weight
- Blood Pressure
- Surveys
- CDC website
- AHA website
- Menus / Recipes

http://www.cdc.gov/
http://www.deliciousdecisions.org/

Breakfast

2 Protein	Apple Coffee Cake (see recipe handout)
1 Starch	(1 starch, 1 fruit, 1 milk, 1 fat)
1 Fruit	
1 Milk	Grilled Ham 2 ounces
1 Fat	(2 protein)
	16 ounces water

Lunch

1 Vegetable	Grilled Cheese & Cilantro Sandwiches (See recipe handout)
2 Protein	(2 protein, 1 starch, 1 milk)
1 Starch	
1 Fruit	
1 Milk	Tomato Soup (See recipe handout)
	(1 vegetable, 1 fruit)
	16 ounces water

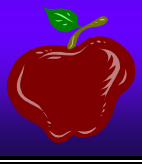
Supper

2 Vegetables	Meat Loaf with Roasted Vegetables (See recipe handout)
2 Protein	(2 protein, 1 starch, 1 milk, 2 vegetables, 1 fat)
1 Starch	
1 Milk	16 ounces water
1 Fat	

Labs and Medications

Low Carbohydrate Diet

WEEK 3



Welcome

- Are there any new participants?
- If you missed last week pick-up a handout.
- How was week two?
- What are your questions & concerns ?
- Body fat measuring monthly
- New Body fat results are posted

Agenda

- New Menus
- Behavior Modification
- Hypotension
- Weight
- Blood pressure

Breakfast Menu: Steak & Eggs

- 6 ounce lean steak
- 1 egg over easy with 2 extra egg white
- 1 cup sautéed onions and peppers
- 16 ounces water

Lunch Menu: Breadless Club

2 ounces sliced turkey
2 ounces sliced ham
2 ounces low fat cheese
2 strips bacon
2 thin slices tomato
2 thin slices onion
Lettuce leaves (enough to support the contents)
1 tsp mayo

16 ounces crystal lite or water

Supper Menu: Beef Vegetable Soup

12 ounces can low sodium chicken broth
10 ounces lean cubed roast
1 cup chopped vegetables (onions, peppers, cabbage, mushrooms, okra, tomatoes)

16 ounces water

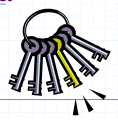
Behavior Modification

- Eat in one place set aside for meals
- Use smaller dinner plates
- Keep serving dishes off the table
- Do not watch TV or read while you eat
- Eat an appetizer of raw veggies before your meal
- Swallow each bite before you pick up your fork
- Split restaurant meals with a friend
- Do not shop hungry
- Concentrate on short term goals and reward success
- Be more active
- Keep your tennis shoes in your care

Labs and Medications

Low Calorie / Low Fat Diet
&
Low Carbohydrate Diet

Week 4



Welcome

- Are there any new participants?
- If you missed last week pick-up a handout.
- How was week three?
- What are your questions & concerns ?

Agenda

- Weight
- Body Fat
- Calendar
- Encouragement

On May 25, 2001, Erik became the first blind climber in history to reach the summit of the world's highest mountain, Mt. Everest. At the age of 34, Erik became one of less then 100 individuals to climb all of the Seven Summits - the highest peaks on each of the seven continents.

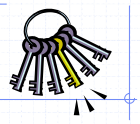
Amy Dodson began developing cancerous tumors in her left foot at age 10. When she was 19, her doctor amputated her leg just below the knee. At 22, Dodson lost her left lung to the same disease. On Oct. 5, 2002, Dodson - now a 40-year-old fifth-grade teacher from Adrian - ran 26.2 miles in 3:53:2

Donna Harkness lost 90 pounds in 40 weeks

Labs and Medications

Low Calorie / Low Fat Diet

WEEK 6



Welcome

- Are there any new participants?
- How was the past two weeks?
- What are your questions & concerns ?

Agenda

- Weight
- Blood Pressure
- Surveys
- website
- Menus / Recipes

http://www.healthychoice.com/recipes/index.jsp

Breakfast: Peach Blintzes

1/4 cup Egg Beaters®, defrosted
1 cup fat-free milk
1 dash salt
3/4 cup all-purpose flour
3 tablespoons granulated sugar, divided
PAM® for Baking Spray
1/4 cup finely chopped peeled fresh pea
1 1/2 cups low-fat cottage cheese, drained
1/4 teaspoon vanilla extract
1 tablespoon Knott's Berry Farm® Orange Marmalade
1/2 cup low-fat vanilla yogurt
1 tablespoon honey
2 peeled and pitted fresh peaches, sliced thin

Directions

1. Combine blintz ingredients in medium mixing bowl: egg product, milk, salt, flour and 1 tablespoon sugar. Beat with whisk until batter is smooth.
2. Coat an 8-inch nonstick skillet with cooking spray. Heat skillet over medium-high heat.
3. Add 3 scant tablespoons batter to skillet, tilting skillet to coat bottom. Cook for 30 seconds to 1 minute, or until blintz is lightly browned on both sides, turning blintz over after half the time. Repeat with remaining batter, stacking blintzes between sheets of wax paper. (Spray skillet with nonstick vegetable cooking spray between blintzes.) Set aside.

Directions continued

4. Combine filling ingredients in small mixing bowl: 1/4 cup chopped peaches, cottage cheese, 2 tablespoons sugar, vanilla, and marmalade. Set aside. In small bowl, combine sauce ingredients: yogurt and honey. Set aside. Spoon 3 scant tablespoons filling down center of each blintz. Roll up. Place blintzes on serving plates. Arrange peach slices and spoon sauce evenly over blintzes.
5. Note: Drained, canned peaches in juice or frozen peaches can be substituted for fresh peaches.

Directions:

1. Cut loaf in half crosswise. Cut circle 1 inch from outer edge of crust. Remove bread from circle to 1-inch depth. Reserve bread for future use. Set halves aside.
2. Combine yogurt cheese, onion, garlic, mustard, chili powder, cumin and turmeric in small mixing bowl. Spread evenly over inside of top and bottom halves of loaf.
3. Layer 2 chicken slices, half of chilies, 2 tomato slices and lettuce on bottom half of loaf. Repeat layers once. Top with 2 chicken slices and 1 cheese slice. Place top half of loaf over filling. Serve in wedges.

Nutrient Breakdown

Amount per Serving	
CALORIES	220
Total Fat	1.5 grams
Saturated Fat	0.5 grams
Cholesterol	5 milligrams
Sodium	290 milligrams
Total Carbohydrate	38 grams
Dietary Fiber	90 grams
Proteins	13 grams

Diet:
2 Protein
1 Starch
1 Fruit
1 Milk
1 Fat

Actual:
2 protein
2.5 carb ser
+1 cup skim milk = 310 calories

Lunch: South of the Border Muffuletta

1 pound sourdough bread, round loaf
1/4 cup plain yogurt cheese*
1 tablespoon green onions, finely chopped
1 cloves garlic, minced
1 teaspoon Gulden's® Dijon mustard
1/8 teaspoon Gebhardt® Chili Powder
1/8 teaspoon ground cumin
1/8 teaspoon ground turmeric
6 slices, Country Pride® fully cooked chicken breast, (1/2 oz. each)
1 can (4 ounces) Rosarita® whole green chilis, sliced lengthwise
4 tomato slice
2 lettuce leaves
3 (1 ounce) slices reduced fat Monterey jack cheese, or mozzarella cheese

Directions continued:

4. * Yogurt Cheese: 1 carton (16 oz.) plain nonfat or lowfat yogurt (no added gelatin). Line mesh strainer with 3 paper towels. Place strainer over bowl. Spoon yogurt into prepared strainer. Cover with plastic wrap. Let drain overnight in refrigerator. Discard liquid. Store cheese in sealed container. Use yogurt cheese instead of sour cream or cream cheese in recipes. Yield: 1 cup

Nutrient Breakdown:

Amount per Serving	
CALORIES	220
Total Fat	4.0 grams
Saturated Fat	2.0 grams
Cholesterol	15 milligrams
Sodium	460 milligrams
Total Carbohydrate	32 grams
Dietary Fiber	2 grams
Proteins	12 grams

Diet:
1 Vegetable
2 Protein
1 Starch
1 Fruit
1 Milk

Actual:
2 carb serv
2 protein
1 veg
+ 1 milk =
310 cals

Supper: Szechuan Barbecue Pork and Vegetables

1/2 cup Hunt's® Barbecue Sauce
3 tablespoons honey
2 tablespoons La Choy® Reduced-Sodium Soy Sauce
1/4 teaspoon crushed red peppers
PAM® No-Stick Cooking Spray
12 ounces Armour® pork tenderloin, sliced (1/2" slices)
1 package frozen baby carrots, (10 ounce)
4 ounces fresh snow pea pods, (1 1/2 cups)

Nutrient Breakdown:

Yield: 4 servings (1 1/4 cups each)

Amount per Serving		Diet:
CALORIES	210	2 Vegetables
Total Fat	3.0 grams	2 Protein
Saturated Fat	1.0 grams	1 Starch
Cholesterol	55 milligrams	1 Milk
Sodium	490 milligrams	1 Fat
Total Carbohydrate	24 grams	
Proteins	21 grams	

+ 1 cup of cook rice =370 calories, 25 grams protein, & 54 grams carbohydrates

Directions:

1. Combine barbecue sauce, honey, soy sauce and red pepper flakes in 2-cup measure. Set aside.
2. Spray 12-inch nonstick skillet or wok skillet with nonstick vegetable cooking spray. Heat skillet over medium heat. Add pork slices. Cook for 4 to 6 minutes, or just until no longer pink, stirring occasionally.
3. Add sauce mixture and carrots. Cook for 10 minutes. Add pea pods and cook for 2 minutes or until pea pods are bright green and mixture is hot, stirring occasionally. Serve over hot cooked rice, if desired.

Directions Continued:

Instead of serving the traditional way with the rice on the bottom, reverse it to give a fresh look. Place pork and vegetable mixture in center of serving platter, mound rice on top and garnish with a few additional pea pods set into the rice.

Labs and Medications

KETONES
Signs and Symptoms

WEEK 8

Low Fat / Low Calorie and Low Carbohydrate diet

Objectives

- Definition
- Causes
- Description
- Normal test values
- Monitoring

What are Ketones?

- Ketones are the end-product of fatty acid breakdown
- Ketones can occur when there is an excessive amount of fatty acids that are being released from the body
- Also seen when fat is metabolized
- Ketones are normally NOT PRESENT in the urine

Causes of ketone production or "Ketosis"

- uncontrolled diabetes
- Starvation, fasting anorexia
- High protein diets
- Low carbohydrate diets
- Excessive vomiting

Other Causes of Ketone production "Ketosis"

- Thyroid gland problems (hyperthyroid)
- Increase metabolism, burns
- Pregnancy
- an acute or severe illness
- surgery

Description of Ketosis

- Ketones are present in the urine when the blood levels reaches a certain level
- Fatty acids are released from certain areas in the body. "Adipose tissue"

How are ketones produced in the body

- fat tissues release fatty acids
- Certain hormones in the body are released
  - Glucagon
  - Epineprhine
  - Growth Hormone

Normal values for Ketones

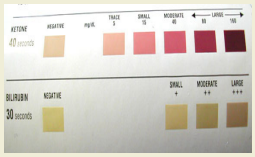
- A negative test is normal
- Small amount = less than 20 mg/dl
- Moderate amount = 30-40 mg/dl
- Large amount = less than 80 mg/dl

Signs and Symptoms

- Bad breath odor
- Fruity breath odor
- Severe symptoms **Call your doctor or SEEK MEDICAL ATTENTION**
  - Nausea
  - Vomiting
  - Abdominal pain
  - confusion

Ketone Testing Strips

Urine Ketone Results



Ketosis and weight loss

- Low carbohydrate diet cause ketosis
- Ketosis is not dangerous
- KETOACIDOSIS IS DANGEROUS TO THE BODY
- Ketones will be used as a source of energy instead of glucose
- Ketosis will help you to lose FAT

Monitoring

- Ketones will spill into the urine once it reaches a certain level
- If ketones are not present that is ok
- Monitor for the signs and symptoms we discussed
- Drink plenty of fluids- **Water**
- **Check your urine for the presence of ketones**
- **Also Check blood sugar to rule out hypoglycemia**
- **Notify your physician if you begin to experience any of the severe signs or symptoms**

Treatment

- **Ketosis does not require treatment**
- **Monitor for any severe signs or symptoms**
- **SEEK MEDICAL ATTENTION IF YOU EXPERIENCE ANY SEVERE SYMPTOMS**

References

http://www.nlm.nih.gov/medlineplus/ency/article/003585.htm#Definition
http://www.nhsdirect.nhs.uk/en.asp?TopicID=274
http://www.lowcarb.ca/tips/tips011.html
achms.org:4306/pte/ Diabone/Ketones.gif
http://www.ilpi.com/msds/ref/ketosis.html

Hypoglycemia

WEEK 10

Low Fat / Low Calorie and Low Carbohydrate

Signs and Symptoms
Treatment
Prevention

Objectives

- Definition
- Causes
- Description
- Treatment
- Prevention

What is hypoglycemia?

- An abnormally small concentration of glucose in the circulating blood stream
- Also called low blood sugar
- Occasionally called reactive hypoglycemia

Causes of hypoglycemia

- Too much insulin or diabetes medication
- Skipped or delay in meals
- Meals or snacks are too small
  - While dieting must properly balance meals and snacks
- Weight loss
  - Daily medication requirement can be less after losing weight

Causes of hypoglycemia

- Increased activity or exercise
- Excessive intake of alcohol
- Pregnancy
- Medical causes

Description of hypoglycemia

- Normal fasting blood sugar
  - Range from 70-100 mg/dl
- Blood sugar in patients with diabetes
  - Before meals: range from 90-130 mg/dl
  - After meals: usually < 180 mg/dl
- Hypoglycemia occurs when blood sugar is : < 70 mg/dl (less than)

What happens when the blood sugar < 70 mg/dl?

- The brain depends on glucose for fuel
- The brain has limited ability to store glucose
  - It depends on the glucose in the blood stream
  - It extracts glucose from the blood stream
- Hypoglycemia is a protective measurement of the brain

What happens when the blood sugar < 70 mg/dl?

- The brain senses that the glucose is low and will cause a chain of events to occur
- The brain will send signals to the body for help
- The brain will cause counter regulatory hormones to be released

Signs and symptoms of hypoglycemia

- Shaking

Signs and symptoms of hypoglycemia

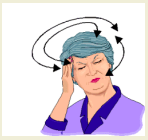
- Fast heartbeat

Symptoms

- Sweating

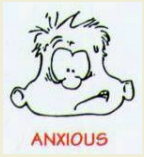
Symptoms

- Dizziness



Symptoms

- Anxious



Symptoms

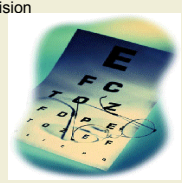
- Hunger

Symptoms

- Weakness
- Fatigue

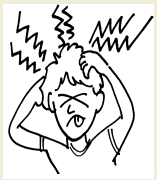
Symptoms

- Impaired Vision



Symptoms

- Headache



Symptoms

- Irritable

Ways to Treat Hypoglycemia

- Drink ½ glass of **one** of the following
  - Juice
  - Regular soft drink
  - Milk (can drink up to 1 cup)
- Eat 5-6 pieces of hard candy ***(not chocolate)***
- 2 or 3 glucose tablets
- **One** or **Two** teaspoons of sugar or honey

Treatment

- After 15 minutes, recheck your blood sugar
- If it is still too low < 70 mg/dl
  - **REPEAT THE STEPS AGAIN UNTIL BLOOD SUGAR IS ABOVE 70 MG/DL**
  - **IF SYMPTOMS PERSIST CALLED YOUR DOCTOR**

Treatment

- When your blood is above 70 mg/dl
- Eat a light snack
  - Cheese and crackers
  - ½ peanut butter sandwich
  - ½ turkey or ham sandwich
  - Bowl of cereal
- Resume regularly scheduled meals

Prevention

- Eat at least 3 regular spaced meals according to your diet plan.
  - **Space meals 3 to 6 hours apart**
  - **Include snacks**
  - **Eat at the same time**
  - **Avoid skipping meals**
- Limit alcohol
- Avoid caffeine

Prevention

- Eat 1 to 3 hours before exercise
- Keep a daily diary
- **Continue to consult with your physician**
- **Monitor your blood sugar consistently especially while dieting**

References

- www.google.com/ images
- www.indiana-edu/health/hypogly.htlr
- www.niddk.nih.gov/health/diabetes/pubs/hypo/hypo.htm
- www.emedicine.com/emerg/topic272.htu
- www.fred.net/stowup/causes.tx
- www.merck.com/pubs/mmanual/section2/chapter13/
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- www.hud.ac.uk/has/ oh/stress.htm
- www.stedman's.com

WEEK # 12 (Low Calorie / Low Fat and Low Carbohydrate Diet)

Behavior Modification

Objectives

After completing this lesson, participants will be able to:

- Identify behaviors that promote a healthy weight
- List creative ways to handle stress
- Define factors necessary to slow eating

More Ways To Think Thin

- Plan meals and snacks
- Split restaurant meals with a friend
- Drink no calorie beverages
- Get high carbohydrate snacks out of the house
- Cook healthfully
- Brush after eating
- Make food look attractive
- Be active
- Plan a reward for meeting your goals

Ways To Think Thin

- List reasons why
- Keep a diary
- Weigh 1-2 times/week
- Take a before picture
- Set goals
- Make a shopping list
- Don't shop hungry
- Eat slowly
- Don't skip meals
- Eat before social func.
- Eat with the TV off
- Serve plates from the kitchen
- Exercise

Respond to stress with activities other than eating:

- Walk the dog
- Go the the movie
- Call a friend
- Listen to music
- Take a drive
- Read a book
- Ride a bike
- Work in a garden

Eating slowly

Twenty minute Rule:

The body has a internal satiety mechanism. Make your meal last at least 20-minutes by eating slowly and you will be full.

- Put the utensil or food down between bites
- Cut food as it is needed
- Swallow before preparing the next bite
- Pause during the meal (.5 to 3 minutes)
- Eat meal in courses, low to high calorie

Emotions and Eating

Anxiety, Boredom, and Anger trigger eating when there is no hunger.

- Pause and think
- Identify feelings
- Trace the source of feelings
- Deal with the real problem
- Remind yourself of your diet goals

Do you have any:

- Questions
- Concerns
- Complications

References

- U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
  National Institutes of Health
- NIH Publication No. 98-3700
  January 1998
- This e-text updated: December 2002
- http://www.niddk.nih.gov/health/nutrit/pubs/wtloss/wtloss.htm

Hypotension

WEEK 14

Low Fat / Low calorie and Low Carbohydrate

Signs and Symptoms

Objectives

- Definition
- Causes
- Description
- Prevention
- Treatment

Causes of hypotension

- Heart problems
- Low blood sugar "Hypoglycemia"
- Thyroid problems
- Anti-hypertensive medications
- Sudden posture changes **(rising quickly after sitting or lying)**
- **Diet pills**
- Anemia (Low iron in the blood stream)

What is hypotension?

- Means low blood pressure
- Hypotension occurs usually when the blood pressure is below <90/60 mmHg
  - Normal Blood pressure Range: 90/60 to 130/80 mmHg
- Symptoms can occur **before blood pressure falls below 90 mm**
- If hypotension occurs continuously can be harmful if not treated

Other Causes of hypotension

- Weight loss
  - Blood pressure lowering
  - Can lead to a decrease in antihypertensive medication requirement
- Dehydration
- Excessive intake of alcohol
- Pain medications

Description of hypotension

- Occurs when the blood vessels dilate, thus causing the blood pressure to be reduced or decreased
  - Normal Blood pressure range from 120/80 mmHg
- Occurs rising up too quickly after sitting or lying
- Hypotension can also develop if the body sends out signals to the brain and the heart when it senses something is out of order

What happens when the blood pressure becomes to low?

- Blood vessels are dilated
- The body sends out signals to the brain and the heart
  - Your heart rate increases
  - Blood flow to the heart increases causing other events to occur
- Hypotension is not a **normal**

Signs and Symptoms

- Light headedness
- Dizziness
- Faintness
- Blurry vision
- Rapid or weak pulse

Prevention

- Monitor blood pressure daily
- Watch for signs and symptoms especially when weight loss is occurring
- Rise up slowly after prolonged sitting or lying
- Drink plenty of fluids- **Water**
- **Check blood sugar to rule out hypoglycemia**
- **Notify your physician if you begin to experience any signs or symptoms**

Signs and symptoms

- Headache
- Altered sensation
- Fatigue
- Cold clammy skin
- Confusion
- Severe symptoms
  - Shock
  - Coma

Treatment

- **Hypotension should be treated by your physician.**

Weight-Loss Study WEEK 21

Post Study Diet

Agenda

- Weight
- Blood Pressure
- Body Fat
- Final Surveys
- Post-Study Diet

Post Study Diet

- 1200-1500 calories
- Low fat
- No concentrated sweets
- No white flour / white rice
- High fiber
- Lean meat, fresh fruit, fresh vegetable, whole grain,
- Exercise

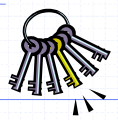
Internet Links

- \\Vhaamafpc3\DIETITICS\Web Page\Diet Plans\1500 Calorie Plan.doc
- http://www.umassmed.edu/diabeteshandbook/chap06.htm

Labs and Medications

Low Calorie / Low Fat Diet

EXTRA MENU



http://www.foodfit.com/default.asp

Menu

Lunch:
Fiesta Quesadillas with Black Beans

Supper:
Baby Greens with Grilled Turkey, Cranberries and Roasted Shallot Vinaigrette

Serves: 5
Preparation time: 15 minutes
Cooking time: 25 minutes

Ingredients
For the apple sizzle:
1 1/2 tablespoons butter
2 cups peeled, cored and sliced apples
3/4 cup maple syrup
dash of nutmeg

Ingredients Continued

- **For the golden grain griddle cakes:**
  1/2 cup buckwheat flour
  1/2 cup flour
  2 teaspoons baking powder
  1/2 teaspoon salt
  2/3 cup skim milk
  1 large egg
  1 tablespoon unsalted butter, melted
  2 tablespoons honey

Directions:

1. In a small skillet, melt the butter over medium heat. Add the fruit and cook until it begins to soften slightly, about 2 to 3 minutes.
2. Add the maple syrup and nutmeg. Bring to a boil. Set aside and keep warm.
3. For the golden grain griddle cakes:
4. Mix the flours, baking powder and salt in a bowl. (This can be done the night before and kept covered on the counter.)

Directions Continued:

4. Lightly beat the milk, egg, butter and honey together.

5. Add the liquid ingredients all at once to the flour mixture. Stir with a wooden spoon until just moistened. Do not overmix, a few lumps are fine.

6. Warm a lightly greased griddle pan over medium heat. The pan is ready when a few drops of water sprinkled on the griddle form fast-moving bubbles.

Nutrition Facts

Nutrition Facts
Serving Size 3 small cakes topped with apple sizzle

Amount Per Serving	
Calories	341
Total Fat	8 g
Saturated Fat	4 g
Cholesterol	59 mg
Sodium	362 mg
Total Carbohydrate	66 g
Dietary Fiber	3 g
Protein	5 g

Diet:
2 Protein
1 Starch
1 Fruit
1 Milk
1 Fat

Lunch: Fiesta Quesadillas with Black Beans

- This recipe serves: 4
  Preparation time : 20 minutes
  Cooking time : 10 minutes

Ingredients

For the salsa:
1/2 cup chopped tomatoes
3 tablespoons chopped red onion
1 teaspoon minced jalapeño chili pepper, or to taste
3 tablespoons diced red or green peppers
1 teaspoon chopped fresh cilantro leaves
1 tablespoon fresh lime juice
salt to taste
freshly ground black pepper
hot sauce (optional), to taste

Ingredients Continued:

For the quesadillas:
4 large whole wheat flour tortillas
1 cup low-fat Monterey jack cheese
1 15-ounce can black beans, drained and rinsed
2 tablespoons chopped fresh cilantro leaves
3/4 cup chopped red onion
3/4 cup chopped tomatoes

Directions:

- **Cooking Instructions**
  For the salsa:
  In a mixing bowl, combine all of the ingredients. (This can be made up to 2 days in advance and stored in the refrigerator.)

- For the quesadillas:
  1. Preheat the oven to 200°F.

- 2. Lay the tortillas out on a work surface and arrange the cheese, beans, cilantro, red onion and tomatoes on half of each tortilla. Fold the tortilla in half to cover the filling.

Directions Continued:

- 3. Heat a large non-stick skillet over medium heat. Carefully cook one quesadilla at a time in the skillet until lightly browned on both sides. Transfer the browned quesadillas to a baking sheet and keep warm in the oven while cooking the rest.

- 4. Slice each quesadilla into 4 wedges and serve with salsa and sour cream.

Nutrition Breakdown:

Diet:
1 Vegetable
2 Protein
1 Starch
1 Fruit
1 Milk

- **Nutrition Facts**
  Serving Size **1 quesadilla**

- **Amount Per Serving**

Calories	**356**
Total Fat	**8 g**
Saturated Fat	**4 g**
Cholesterol	**20 mg**
Sodium	**729 mg**
Total Carbohydrate	**55 g**
Dietary Fiber	**6 g**
Protein 19 g	

Supper: Baby Greens with Grilled Turkey, Cranberries and Roasted Shallot Vinaigrette

- This recipe serves: 4
  Preparation time : 20 minutes
  Cooking time : 20 minutes

Ingredients

For the roasted shallot vinaigrette:
1 shallot
drizzle of olive oil
1/4 teaspoon kosher salt
1 tablespoon Dijon mustard
1 tablespoon extra virgin olive oil
2 tablespoons chicken stock
1 tablespoon red wine vinegar
1/2 tablespoon freshly chopped chives
freshly ground black pepper

Directions:

- **For the grilled turkey:**
  4 turkey cutlets, about 4 ounces each
  2 teaspoons olive oil
  salt and pepper to taste

  For the green salad:
  8 cups fresh baby greens, washed
  1/2 cup dried cranberries

- **Cooking Instructions**
  For the roasted shallot vinaigrette:
  1. Preheat the oven to 350°F.

Directions Continued:

1. With the skin on, cut the shallot in half lengthwise. Spray a baking sheet with non-stick spray. Drizzle the shallot with a bit of the olive oil and place them on the baking sheet cut side down.

2. Roast in the oven until the shallot is very soft, about 20 to 30 minutes.

3. When the shallot is cool enough to handle, remove the skin and the root end. Puree the shallot and salt in a food processor.

Directions Continued:

4. Add the mustard and puree. Add the vinegar by the tablespoon, pureeing after each addition.

5. With the motor running, add the olive oil and stock slowly through the feed tube.

6. Stir in the chives and pepper. Adjust the salt and pepper to taste.

Directions:

7. For the grilled turkey:
   Preheat the grill to medium-high.

8. Brush the cutlets with olive oil and season with salt and pepper.

9. Grill the turkey for about 4 to 6 minutes each side, depending on the thickness until the turkey is cooked through. Remove the turkey from the grill and place on a cutting board to rest. Cut the turkey into strips. (The turkey can be grilled in advance and stored in the refrigerator for up to 2 days.)

Directions Continued:

10. For the green salad:
Place the turkey strips in a mixing bowl, add the cranberries and half of the vinaigrette.

11. Place the lettuce in a separate salad bowl and toss it with the remaining vinaigrette. Arrange the turkey and cranberry mixture on top.

Nutrition Breakdown:

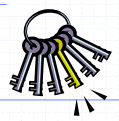
- **Nutrition Facts**
  Serving Size **1turkey cutlet with salad**
- **Amount Per Serving**

Calories	**283**
Total Fat	**7 g**
Saturated Fat	**1 g**
Cholesterol	**98 mg**
Sodium	**317 mg**
Total Carbohydrate	**17 g**
Dietary Fiber	**4 g**
Protein	**36 g**

Diet:
2 Vegetables
2 Protein
1 Starch
1 Milk
1 Fat

Low Carbohydrate Diet

EXTRA MENU



http://www.cdc.gov/
http://www.titanic.kn-bremen.de/allrec.html

Menu

Breakfast: Baked Eggs Surprise
(4 gms carb)

Lunch: Seafood salad
(7gms carb)

Supper:

APPENDIX F

FOLLOW-UP SURVEY

Follow-Up Survey Date_____

Please place your assigned 5-digit identification number here

→_____

In the following section, please circle the answer that <u>BEST</u> fits your situation. Please select only <u>ONE</u> answer for each question.

1. How would you rate your overall diet compliance for the past month?
   A. Very Good
   B. Good
   C. Barely Acceptable
   D. Poor
   E. Very Poor

2. How often at meal or snack times would you say you did not stay on your diet?
   A. Every time
   B. Most time
   C. About half the time
   D. Rarely
   E. Never

3. Which times of day where you more likely to go off your diet?
   A. Morning
   B. Midday
   C. Afternoon
   D. Evening
   E. Night
   F. I did not go off my diet.

4. How would you rate your motivation to follow this diet?
   A. Excellent
   B. Good
   C. Fair
   D. Poor
   E. Very poor

5. Do you eat the same number of meals each day?
   A. Yes
   B. No

6. On average, how many meals (**NOT** including snacks) a day do you eat?
   A. 1
   B. 2
   C. 3
   D. 4
   E. 5
   F. 6
   G. More than 6

7. Do you eat the same number of **SNACKS** each day?
   A. Yes
   B. No

8. On average, how many **SNACKS** (**NOT** including meals) a day do you eat?
   A. 1
   B. 2
   C. 3
   D. 4
   E. More than 4

In this section, please provide a brief answer to the questions in the spaces provided below each question.

9 What was most difficult part of following your assigned diet?_____
_____

10 .In the space provided below, please note the easiest aspect of your assigned diet?

In the following section, please circle the answer that <u>BEST</u> fits your situation. Please select only <u>ONE</u> answer for each question.

11. How would you rate your level of hunger in the **MORNING** (between meals and snacks)?
   A. Very strong
   B. Strong
   C. Moderate
   D. Low
   E. No hunger

12. How would you rate your level of hunger in the **AFTERNOON** (between meals and snacks)?
    A. Very strong
    B. Strong
    C. Moderate
    D. Low
    E. No hunger

13. How would you rate your level of hunger in the **NIGHT** (between meals and snacks)?
    A. Very strong
    B. Strong
    C. Moderate
    D. Low
    E. No hunger

14. How would you rate your feelings of fullness after meals and snacks when you complied with your assigned diet?
    A. Stuffed
    B. Full
    C. Not full or hungry
    D. Hungry
    E. Very Hungry

15. How would you rate your satisfaction with the food choices allowed on your assigned diet
    at meals and snacks?
    A. Very Satisfied
    B. Satisfied
    C. Neither satisfied or dissatisfied
    D. Dissatisfied
    E. Very dissatisfied

16. On average, how often did you exercise this month?
    A. Every day
    B. Six times a week
    C. Five times a week
    D. Four times a week
    E. Three times a week
    F. Two times a week
    G. Once a week
    H. Less than once a week

17. On average, how long do your exercise routines last?
    A. 10 minutes
    B. 15 minutes
    C. 20 minutes
    D. 30 minutes
    E. 45 minutes
    F. 60 minutes
    G. 90 minutes
    H. Longer than 90 minutes

18. What is the level of intensity of your exercise?
    A. Very high
    B. High
    C. Moderate
    D. Low
    E. Very low

For this question, please circle the <u>ANSWER OR ANSWERS</u> that <u>BEST</u> fit your situation.

19 .What type of exercise do you **<u>ROUTINELY</u>** participate in?
    A. Walking
    B. Jogging
    C. Bicycling
    D. Swimming
    E. Tennis
    F. Weight lifting
    G. Golf
    H. Gardening
    I. Other: Please explain_____

20 .If you have diabetes, have you experienced an increased incidence of hypoglycemic episodes (i.e., blood glucose less than 70mg/dl) **<u>IN THE PAST MONTH</u>?**
    (Symptoms of hypoglycemia include: hunger, nervousness, anxiety, weakness, shakiness, lightheadedness, confusion, and dizziness)
    A. Yes
    B. No
    C. I am not sure
    D. I do not have diabetes

21. If you answered **"yes"** to the previous question, what did you do?
    A. Eat something containing carbohydrates to elevate your blood glucose
    B. Contact your healthcare provider
    C. Adjust your diabetic medications based on physician recommendations
    D. Other (Please specify)_____

22. If you have high blood pressure, have you experienced a significant drop in your blood pressure **IN THE PAST MONTH? (**Symptoms of low blood pressure include: weakness, shakiness, lightheadedness upon standing, and dizziness)
    A. Yes
    B. No
    C. I am not sure
    D. I do not have high blood pressure

23. If you answered yes to the previous question, what measure or measures did you take?
    A. Contact your healthcare provider
    B. Adjust your hypertensive medications based on physician recommendations
    C. Other (Please specify)_____

APPENDIX G

FINAL SURVEY

Final Survey

Please place your assigned 5-digit identification number here

→_____

Please assist us in evaluating the quality of the program by answering the following questions. For each question, circle the number that best represents your view: **1 ("No"), 2 ("Somewhat"), and 3 ("Yes, definitely")**.

1. Were the program objectives clear and realistic? 1 2 3

Comments/suggestions:_____
_____

2. Did you learn what you expected to learn? 1 2 3

Comments/suggestions:_____
_____

3. Was the material presented relevant and valuable to you? 1 2 3

Comments/suggestions:_____
_____

4. Was the material presented at an appropriate rate? 1 2 3

Comments/suggestions:_____
_____

5. Was there an adequate amount of time allotted on each topic? 1 2 3

Comments/suggestions:_____
_____

6. Did the instructional techniques and materials

(presentations, handouts, and video displays) assist you in the learning process? 1 2 3

Comments/suggestions:_____
_____

7.If there were opportunities for you to actively participate in the various sessions, was the participation beneficial to you? 1 2 3

Comments/suggestions:_____
_____

8. Was the program well organized and effectively conducted? 1 2 3

Comments/suggestions:_____
_____

9. Were the presenters enthusiastic? 1 2 3

Comments/suggestions:_____
_____

10. Were the presenters well prepared? 1 2 3

Comments/suggestions:_____
_____

11. Did the presenters have expert knowledge and content? 1 2 3

Comments/suggestions:_____
_____

12.Did the presenters make an effort to make you feel comfortable? 1 2 3

Comments/suggestions:_____
_____

13.Did the presenters communicate well with the participants, for example, use language that made you comfortable? 1 2 3

Comments/suggestions:_____
_____

14. Did the presenters hold your interest? 1 2 3

Comments/suggestions:_____
_____

15. Were the sign-in procedures "participant friendly"? 1 2 3

Comments/suggestions:_____
_____

16. Was the program schedule well planned (allowing adequate time for each activity)? 1 2 3

Comments/suggestions:_____
_____

17. Would you recommend that these same facilities be used again? 1 2 3

Comments/suggestions:_____
_____

18. Will you be able to apply what you have learned? 1 2 3

Comments/suggestions:_____
_____

19. Please circle which answer best describes your overall opinion of the program?

A. Very Poor
B. Poor
C. Adequate
D. Good
E. Excellent

20.Please comment on the major strengths of the program and changes you would recommend?

Major strengths:_____

Suggestions for Improvement:_____

Any other observations:_____

APPENDIX H

MEASUREMENT DEVICES UTILIZED FOR GATHERING ANTHROPOMETRIC DATA

(FIGURES A1 – A4)

HEM-712C Automatic Inflation Blood Pressure Monitor

- Automatic inflation with a push of the button
- Preset switch lets user control inflation level
- Stores last reading in memory
- Large, easy to read digital display displays blood pressure and pulse rate
- Operates on 4 "AA" batteries (not included)
- Approximate battery life is 300 usages
- Two year warranty
- Included standard cuff fits arms 9-13"

Figure A1. Description of device used to measure blood pressure in subjects participating in a longitudinal diet comparison study.

HealthOMeter 402-Series Mechanical Beam Medical Scales

- Capacity: 450 lb / 200 KG
- Readability: 1/4 lb / 100 g
- Platform Dimensions: 10-1/2" x 14"
- Product Dimensions: 10-1/2" x 20" x 57-1/4"
- Rotating poise bars for dual reading of pounds and kilograms. Poise bar lock-in for error-free operation
- Permanent, engraved readings on poise bar for long-lasting readability
- Heavy-duty steel base for improved strength and durability
- Professional "Silent Slide" height rod for smooth, quiet operation.
- Dual-read height rod range 24" to 84" (by 1/8 in.), 60cm to 213cm (by 1 mm).
- ABS plastic platform cover for easy cleaning
- Factory calibrated to ensure acccuracy
- Available Accessories: Casters provide easy mobility
- Some assembly required
- 2 Year Limited Warranty

Figure A2. Description of device used to measure weight of subjects participating in a longitudinal diet comparison study.

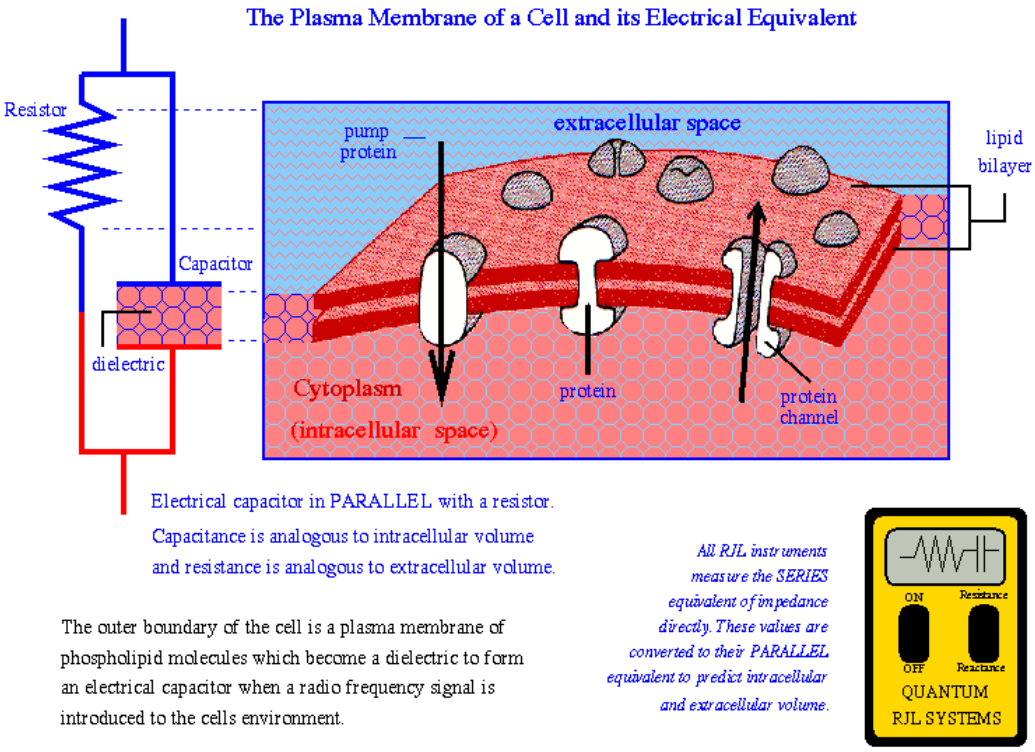
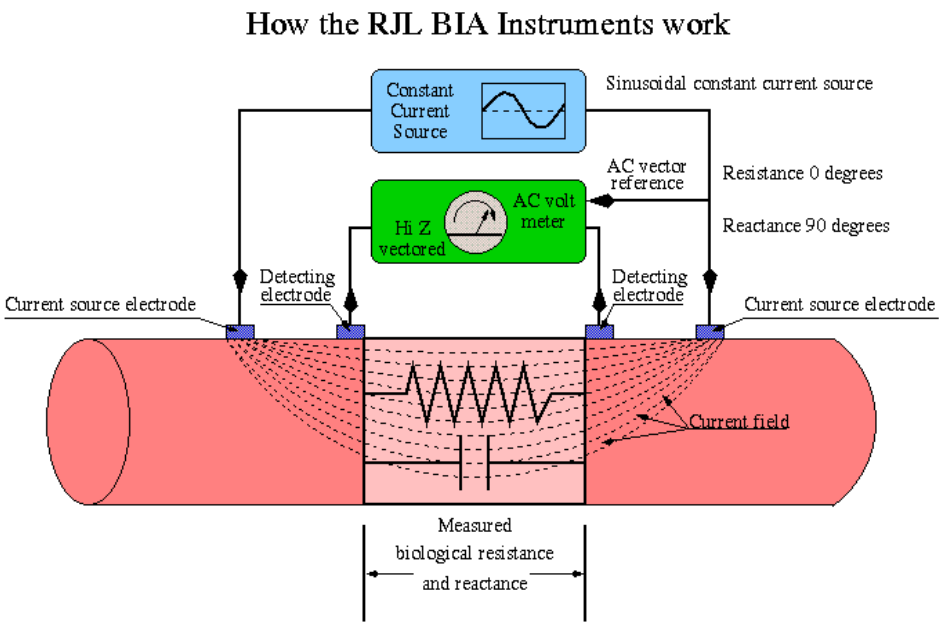


Figure A3. Illustration of scientific principles utilized by bioimpedence measurement of body fat.



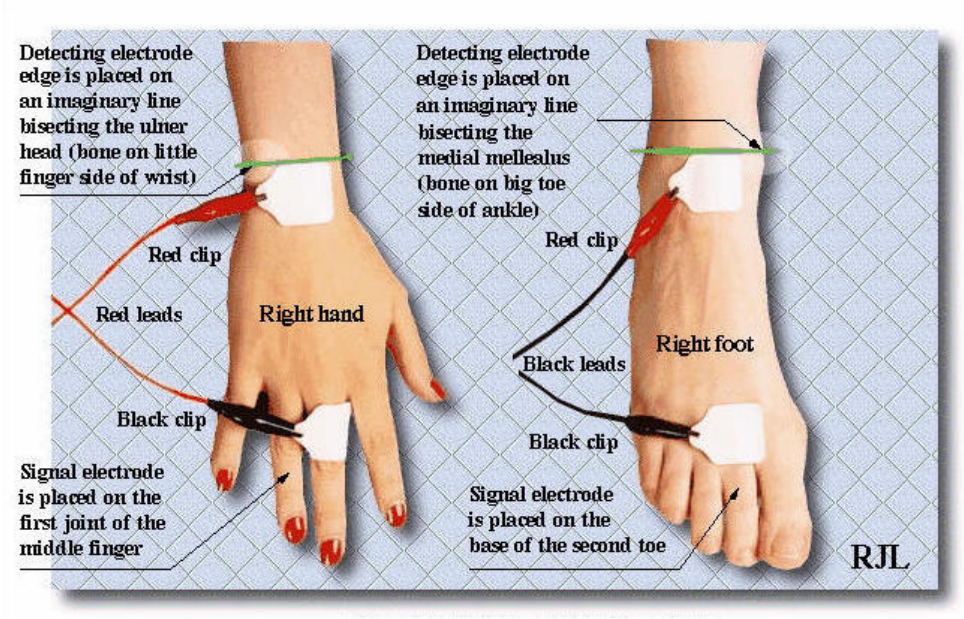


Figure A4. Mechanism for the operation of a bioimpedance instrument used to measure body fat.

APPENDIX I

THE RELATIONSHIP OF DEMOGRAPHICS ON CHANGES IN ANTHROPOMETRIC DATA

(TABLES A10-A14)

Table A10, Mean and Standard Deviation of Changes in Anthropometric Dependant Variables by Marital Status.

Anthropometric Dependant Variables	Marital status	N	Mean	Std. Deviation	Std. Error Mean	Levene's Test for Equality of Variances	
						F	Sig.
Weight Loss	Not married	41	6.1463	25.37574	3.96302	.089	.766
	Married	75	8.1280	16.87956	1.94908		
Body Fat Reduction	Not married	41	.4976	8.50431	1.32815	.011	.916
	Married	74	1.9730	6.28576	.73070		
Systolic Blood Pressure Reduction	Not married	40	3.5750	13.60974	2.15189	.996	.320
	Married	75	4.4133	19.66757	2.27102		
Diastolic Blood Pressure Reduction	Not married	40	5.7250	20.82896	3.29335	.013	.911
	Married	75	9.8133	13.89798	1.60480		

Table A11. *t*-Test for the Equality of Means: Comparing Changes in Anthropometric Dependant Variables by Marital Status with Equal variances Assumed.

	t-test for Equality of Means						
Anthropometric Dependant variables	*t*	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Weight Loss	-.503	114	.616	-1.98166	3.93702	-9.78087	5.81755
Body Fat Reduction	-1.060	113	.291	-1.47541	1.39207	-4.23335	1.28253
Systolic Blood Pressure Reduction	-.240	113	.810	-.83833	3.48724	-7.74718	6.07051
Diastolic Blood Pressure Reduction	-1.256	113	.212	-4.08833	3.25401	-10.53512	2.35845

Table A12. Mean and Standard Deviation of Changes in Anthropometric Dependant Variables by Race.

Anthropometric Dependant Variables	Race	N	Mean	Std. Deviation	Std. Error Mean	Levene's Test for Equality of Variances	
						F	Sig.
Weight Loss	Nonwhite	32	8.6750	13.00955	2.29979	.410	.523
	White	84	6.9524	22.39562	2.44356		
Body Fat Reduction	Nonwhite	32	1.4875	5.73679	1.01413	2.390	.125
	White	83	1.4313	7.66234	.84105		
Systolic Blood Pressure Reduction	Nonwhite	32	3.1563	14.46042	2.55627	.282	.597
	White	83	4.4940	18.91662	2.07637		
Diastolic Blood Pressure Reduction	Nonwhite	32	7.8438	15.18299	2.68400	.499	.481
	White	83	8.6024	17.28170	1.89691		

Table A13. *t*-tests for the Equality of Means: Comparing Changes in Anthropometric Dependant Variables by Race with Equal variances Assumed.

	t-test for Equality of Means						
						95% Confidence	
Anthropometric Dependant variables	*t*	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Interval of the Difference	
						Lower	Upper
Weight Loss	.409	114	.683	1.72262	4.21250	-6.62230	10.06754
Body Fat Reduction	.038	113	.970	.05617	1.49520	-2.90609	3.01844
Systolic Blood Pressure Reduction	-.361	113	.719	-1.33773	3.70500	-8.67800	6.00255
Diastolic Blood Pressure Reduction	-.218	113	.828	-.75866	3.48167	-7.65647	6.13915

Table A14. One-way ANOVA for Comparing Changes in Anthropometric Dependant Variables by Education Level.

Source	df	F	p
Between Groups			
Weight Loss	2	.176	.839
Body Fat Reduction	2	1.588	.209
Reduction in Systolic Blood Pressure	2	.785	.458
Reduction in diastolic Blood Pressure	2	.438	.646
Within Groups			
Weight Loss	112	.176	.839
Body Fat Reduction	111	1.588	.209
Reduction in Systolic Blood Pressure	111	.785	.458
Reduction in diastolic Blood Pressure	111	.438	.646

APPENDIX J

PROGRAM EVALUATION (TABLE A15)

Table A15. Program Evaluation Frequency of Responses Part One (Group A and B Combined).

Questions	Potential Responses	Frequency	Percent
Were the program objectives clear and realistic?	No	1	2.6
	Somewhat	2	5.3
	Yes, definitely	35	92.1
Did you learn what you expected to learn?	No	1	2.6
	Somewhat	7	18.4
	Yes, definitely	30	78.9
Was the material presented relevant and valuable to you?	No	1	2.6
	Somewhat	2	5.3
	Yes, definitely	35	92.1
Was the material presented at an appropriate rate?	0	1	2.6
	No	1	2.6
	Somewhat	4	10.5
	Yes, definitely	32	84.2

Table A15. continued. Program Evaluation Frequency of Responses Part One (Group A and B Combined).			
Was there an adequate amount of time allotted on each topic?	0	1	2.6
	No	1	2.6
	Somewhat	6	15.8
	Yes, definitely	30	78.9
Did the instructional techniques and materials assist you in the learning process?	No	1	2.6
	Somewhat	4	10.5
	Yes, definitely	33	86.8
If there were opportunities for you to actively participate in the various sessions, was the participation beneficial to you?	0	4	10.5
	No	1	2.6
	Somewhat	4	10.5
	Yes, definitely	29	76.3
Was the program well organized and effectively conducted?	No	1	2.6
	Somewhat	2	5.3
	Yes, definitely	35	92.1

Table A15. continued. Program Evaluation Frequency of Responses Part One (Group A and B Combined).			
Were the presenters enthusiastic?	No	1	2.6
	Yes, definitely	37	97.4
Were the presenters well prepared?	No	1	2.6
	Somewhat	5	13.2
	Yes, definitely	32	84.2
Did the presenters have expert knowledge and content?	No	1	2.6
	Yes, definitely	37	97.4
Did the presenters make an effort to make you feel comfortable?	No	1	2.6
	Yes, definitely	37	97.4
Did the presenters communicate well with the participants; for example, use language that made you comfortable?	No	1	2.6
	Somewhat	2	5.3
	Yes, definitely	35	92.1
Did the presenters hold your interest?	No	1	2.6
	Somewhat	4	10.5
	Yes, definitely	33	86.8

Table A15. continued. Program Evaluation Frequency of Responses Part One (Group A and B Combined).			
Were the sign-in procedures "participant friendly"?	No	1	2.6
	Somewhat	2	5.3
	Yes, definitely	35	92.1
Was the program schedule well planned (allowing adequate time for each activity)?	No	1	2.6
	Somewhat	6	15.8
	Yes, definitely	31	81.6
Would you recommend that these same facilities be used again?	No	1	2.6
	Somewhat	2	5.3
	Yes, definitely	35	92.1
Will you be able to apply what you have learned?	No	11	28.9
	Yes	27	71.1